Assembly ESTM Oversight Hearing on Prop 65

"Toxic Chemical Exposures: Protecting and Informing the Public"

August 22, 2017 – 1:30 PM State Capitol, Chair Dr. Bill Quirk, 20th District

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Good afternoon Chair Quirk and members of the Committee on Environmental Safety & Toxic Materials. Thank you for inviting me to speak at this oversight hearing.

I am a family physician and an Environmental Health Scientist with a particular focus on the population-level health effects of toxic chemicals. As a UCSF primary care physician at San Francisco General Hospital, I took care of families living in some of the city's most polluted neighborhoods. That experience motivated me to pursue an additional post-graduate degree in Environmental Health at UC Berkeley.

While I still practice clinical medicine part-time, my primary work is in the UC Berkeley School of Public Health, where my research and teaching focuses on endocrine disrupting chemicals, including environmental contributors to breast cancer, as well as U.S. and European chemicals policy, and strategies for applying environmental health knowledge to the design and selection of safer chemicals and materials. Since 2009 I've served on Cal/EPA's Green Ribbon Science Panel for implementation of the state's Safer Consumer Products program, and in 2014 I was appointed by Speaker of the Assembly to the Scientific Guidance Panel for California's biomonitoring program, which I now chair. At Cal, I also serve as Associate Director of the interdisciplinary Berkeley Center for Green Chemistry.

Every fall I teach a course that partners teams of graduate students with companies looking to find safer substitutes for hazardous chemicals in their products. One of the things we've noticed is that companies seeking safer alternatives are often motivated to do so by pending or anticipated chemical regulation. For example, a couple of years ago our students worked with a manufacturer of spray polyurethane foam insulation after a key chemical ingredient in the foam was named among the first priority products under our state's new Safer Consumer Product regulations.

It's in this context that I have experienced chemical regulation as a driver of innovation, rather than as a barrier. And there is some historical evidence of Prop 65 serving just that role, with companies reformulating to remove toluene from nail polish, paints, and adhesives; to remove lead from ceramics, faucets and water pumps; and to remove potent chlorinated solvents from spot removers, paint strippers, and typewriter correction fluid (a product that's less relevant than it used to be).[1] Studies have demonstrated that programs like Prop 65 and Massachusett's Toxics Use Reduction Act prompt businesses to conduct audits of the chemicals they use, an action that -in and of itself- often causes them to reduce their use of hazardous chemicals.[2]

Today I'd like to discuss three topics relevant to the role of Prop 65 in protecting public health and in ultimately moving the marketplace as a whole toward safer chemistries. First, I'll describe the statute's focus on known toxic chemicals; I'll then review some of the biomonitoring evidence that links synthetic

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[1] Rechtschaffen C. 1996. Ecology Law Q. 23. http://digitalcommons.law.ggu.edu

[2] O'Rourke D. and Lee E. 2007 J Envt Plan Mgt. 47:2 181-200. And Cal/EPA 1992 survey as described in Rechtschaffen *Ibid*.

chemicals in products, workplaces and the environment with the presence of those same chemicals in the blood and urine of people; and finally, I'll address some common misperceptions about how well Prop 65 reflects the current science on how chemicals contribute to cancer and reproductive harm.

I. Starting with the first topic: In my view, Prop 65 serves an important role as one tool for protecting workers and the public from exposure to *known* toxic chemicals. The Prop 65 list now contains nearly 900 chemicals known to cause cancer or reproductive harm. I want to put this number in context. 85,500 individual chemicals are now registered with US EPA, and while we don't know how prevalent each of those chemicals is in commerce, we do know that approximately 3,000 of them are registered as "high production-volume" chemicals, meaning they're produced or used in the U.S. in volumes over a million pounds per year.[3] Another nearly 5,000 chemicals are produced in over 25,000 lbs/year.[4]

While there is a lot we don't know about the health effects of many of the chemicals on the market, the Prop 65 list of almost 900 compounds is actually a select, well-studied subset. These are chemicals like lead, which is still found in over 16,000 California children yearly at levels that can contribute significantly to decreased IQ and behavioral problems such as ADHD.[5] Diesel exhaust is another Prop 65 compound whose chemical mixture has been deemed the most potent carcinogen of all the common toxic air contaminants[6] and is estimated to contribute approximately *70% of the cancer risk attributable to air pollution*.[7] That is, diesel exhaust likely causes 7 out of every 10 cancers caused by air pollution.

Other Prop 65 chemicals include formaldehyde, a known human carcinogen to which 100s of thousands of workers are still exposed worldwide[8] and that contributed to 11,000 health complaints from the people housed in FEMA trailers following hurricane Katrina.[9] Also on the Prop 65 list: mercury, vinyl chloride, benzene, dioxins. You get the picture. In general, Prop 65 lists a relatively small subset of known toxic chemicals from among the tens of thousands of industrial chemicals in commerce. The list does not go out on a limb; these are what scientists call "well characterized" chemicals, meaning we have a lot of data on them, and the question of whether they are harmful is settled from a scientific perspective.

II. The second topic I wanted to discuss relevant to the role of Prop 65 in protecting public health is that people's exposure to industrial chemicals is not a hypothetical risk. It's a proven fact. The CDC regularly detects hundreds of synthetic chemicals and pollutants in the blood and urine of a representative sample of the U.S. population.[10] This includes not just normal, healthy adults, but also children and pregnant women.

In fact, a closer look at those CDC data done by UCSF showed that pregnant women in the U.S. are exposed to a wide variety of industrial chemicals that are known to be toxic, but particularly that 99-

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[3] According to U.S. EPA 2006 Inventory Update Reporting.
[4] *Ibid.*
[5] According to CDC surveillance data. https://www.cdc.gov/nceh/lead/data/national.htm. Latest available data for California is 2011.
[6] Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA) https://oehha.ca.gov/air/health-effects-diesel-exhaust
[7] Cal/EPA Health Risk Assessment for Diesel Exhaust. 1998. https://www.arb.ca.gov/toxics/dieseltac/part_b.pdf
[8] IARC Monograph 100F http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-29.pdf pp.401-404
[9] Hsu S. Washington Post. July 3 2008. http://www.washingtonpost.com/wp-dyn/content/article/2008/07/02/AR2008070202800.html CDC study on Formaldehyde in trailers https://www.cdc.gov/nceh/ehhe/trailerstudy/pdfs/femafinalreport.pdf
[10] CDC, Fourth National Report on Human Exposure to Environmental Chemicals (2009) and updated tables (2017). Available: https://www.cdc.gov/exposurereport/

100% of them had detectable levels of PCBs, organochlorine pesticides, and phthalates in their blood or urine.[11] Members of each of those classes of chemicals appear on the Prop 65 list because they are known to cause developmental toxicity-- and they're in virtually every pregnant woman in the U.S. While it would be comforting to assume that the levels of these chemicals detected in pregnant women were insignificant, on the contrary, many of them were measured at levels comparable to those associated with developmental effects seen in epidemiological studies.[12]

Many of these same chemicals are also routinely detected in human breast milk,[13] which means that breastfeeding infants are exposed to these developmental toxicants not just prenatally but also in early infancy, because their sole source of food is contaminated.

So where do these exposure levels stand relative to the risk levels OEHHA has established under Prop 65? A couple of studies have made these comparisons. For example, over 80% of children in California childcare facilities are exposed to phthalate levels (in indoor dust and air) that exceed reproductive health benchmarks set under Prop 65.[14] Similarly, a majority of California childcare facilities were recently found to have flame retardant concentrations that exceeded Prop 65's guidelines for carcinogens.[15]

Fortunately, though, we also know that –in general- policy intervention can lower the levels of industrial chemicals measured in people. There are some major public health success stories here, such as the dramatic 78% decline in U.S. blood lead levels that followed the removal of lead from gasoline in the 1970s;[16] or the effect of restricting cigarette smoking in public places, which is credited with causing a 70% drop in average levels of cotinine among *nonsmokers* (cotinine measures tobacco smoke exposure).[17] Likewise, while pregnant women in California once had some of the highest blood levels ever measured worldwide of the flame retardants Penta-BDE and Octa-BDE, those levels dropped by about two thirds over the course of the three years following California's ban of the two chemicals.[18]

So, if listing a chemical under Prop 65 causes industry to reduce its use, even if only to avoid having to warn the public about its presence, we can expect human exposures to decrease and to see that change reflected in biomonitoring data. Biomonitoring data would then confirm that we've reduced Californian's health risks associated with those chemical exposures.

III. Finally, I'd like to address the third topic: some common misperceptions about how well Prop 65 reflects the current science on how chemicals contribute to cancer and reproductive harm.

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[11] Woodruff T. *et al.*, Environ Health Persp. 119:878–885 (2011). DOI: 10.1289/ehp.1002727

[12] *Ibid.*

[13] Lakind J, et al. Toxicology and Applied Pharmacology 198 (2004). DOI: 10.1016

[14] Gaspar, Fraser W., et al. "Phthalate exposure and risk assessment in California child care facilities." Environmental science & technology 48.13 (2014): 7593-7601.

[15] Bradman, Asa, et al. "Flame retardant exposures in California early childhood education environments." Chemosphere 116 (2014): 61-66.

[16] Pirkle, JL et al. (1994). JAMA. **272** (4): 284–291. DOI:10.1001/jama.1994.03520040046039

[17] See Pickett MA ET AL.Tob Control 2006;15:302-7; Pirkle JL et al. Environ Health Perspect 2006;114(6):853-8; and

[18] Zota A, et al. *Environ. Sci. Technol.*, 2013, *47* (20), pp 11776–11784 DOI: 10.1021/es402204y Note that no equivalent decline was detected in PCBs (other persistent organic compounds) tested at the same time, increasing the likelihood that the observed decline in flame retardant levels was attributable to the regulatory action.

A common criticism of the Prop 65 approach is that exposure to a chemical, or its simple presence in a product, is not sufficient proof of harm to justify regulation. Based on this idea, warnings are not warranted simply because a chemical is known to be hazardous (what we call *inherent hazard)*. Instead, warnings should only be required after determining that the *risk of harm* would exceed a certain threshold for a person using one specific product in exactly the intended manner. This is pointing to the tension between a *hazard-based* approach, and a *risk-based* approach.

In fact, Prop 65 threads this needle nicely: the statute's listing aspect is based on *inherent hazard*, while the requirements for warnings are based on estimated *risk* (or likelihood) of harm from the presence of a particular concentration of a Prop 65 chemical in a specific product, workplace, or environment.

I want to say a little more about why this distinction between hazard and risk is important—that for a chemical to be listed under Prop 65 it must only be determined to be hazardous, but its listing isn't *risk* based, that is, listing doesn't depend on how potent the chemical is, or the *likelihood* that it will cause harm from any particular exposure.

This hazard-based listing mechanism is important because:

1. There are *many sources of exposure* to the same hazardous chemical;
2. Some people are *more vulnerable* to the effects of chemical exposure than others—particularly, developing infants and children, or people with underlying disease; and
3. We often *can't predict* how people will use products, or how they will be exposed.

A comparison from my field of medicine can be instructive: Acetaminophen (Tylenol) is an inherently hazardous substance. But it's useful for reducing fever or pain when it's used as intended. The acetaminophen dose in over-the-counter Extra Strength Tylenol may be relatively safe on its own. But if you unintentionally take the wrong dose, or if you take that painkiller, as well as a Tylenol PM to sleep at night, or a dose of cough medicine, you could cause serious liver damage.

If you're someone with underlying liver disease (whether you know it or not), or if you have more than a couple of alcoholic drinks, your threshold for harm from acetaminophen will be much lower, and you could wind up in the hospital after taking an over-the-counter medication. And in fact, unintentional acetaminophen overdose sends tens of thousands of people to the hospital every year in the U.S., and it's the nation's leading cause of acute liver failure.

As a result, the FDA requires that medications containing acetaminophen are labeled with a warning about the possibility of "severe liver damage". Not because a single dose used as intended would be expected to cause harm in the *average* person. But instead, the warning exists because acetaminophen is *inherently hazardous*, people can be *exposed from multiple sources*, some people are *particularly vulnerable* to its effects, and not everyone *uses it as intended*.

These are *precisely the same factors* that inform Prop 65 warnings, and they're sound. For example, children are exposed to lead from multiple sources: from house paint, plumbing, contaminated food, and (before Prop 65 enforcement actions) from ceramic dishes and jewelry. Treating each of these sources of exposure in isolation defies common sense. The way Prop 65 works to reduce children's lead exposure is to list lead based on its inherent hazard, and then to require warnings only for those products (workplaces, or environments) that contain enough lead to contribute meaningfully to exposure. Like acetaminophen, lead is *inherently hazardous*, children can be *exposed from multiple*

sources, their developing brains are *particularly vulnerable* to its effects, and children do things *no one intended* them to do, like eat paint chips and put jewelry in their mouths.

So in my view, Prop 65 takes a very common-sense approach, balancing the need to list chemicals based on their inherent hazard, with the requirement that the concentration of that chemical be high enough to contribute meaningfully to the risk from aggregate exposures before warnings are mandated.

Two more brief points of frequent misunderstanding about Prop 65 to mention before I close:

First, much of the evidence we have for chemical hazards comes from animal testing. While of course there are some subtle differences between species, animal evidence has always been used in medicine when establishing the safety and efficacy of pharmaceuticals because our experience is that hazards seen in animals are predictive of hazards in humans. Likewise in chemical testing, while there are isolated examples of specific toxic effects in animals that may not be relevant in humans (and vice versa) these instances are the exception to the rule that animal data regarding cancer and reproductive hazard generally predict the chemical's likelihood of causing those harms in humans. This has been specifically investigated in research on chemicals that contribute to breast cancer risk and to hormonally driven developmental effects.[19]

A final common misperception is that Prop 65 regulates some risks that are actually trivial, because they involve tiny amounts of a listed chemical, or a very short period of exposure. But in fact, small doses and short exposures can be highly significant. This is particularly true in the case of chemicals that cause birth defects, in which case the *timing* of exposure is at least as important as the dose. We know this not just from emerging evidence of male reproductive birth defects associated with low-level prenatal exposure to phthalates (the class of chemicals made popular by their presence in rubber duckies, but that are also present in many building materials and scented personal care products). This phenomenon is also evident from such well-understood chemicals as thalidomide, methyl mercury, and lead.

In the case of Thalidomide, the anti-nausea medication used in the 1950s that caused birth defects, the type of birth defect produced depended on the precise day during pregnancy when exposure occurred. Upper limb malformations occurred after pregnant women took the drug during the 3rd week after fertilization, while lower limb malformations developed following exposure during the 4th week of pregnancy.[20] This human tragedy taught us that even a single-day exposure to certain toxic chemicals can cause a major, life-altering birth defect.

So to summarize, Prop 65 serves some critical public health functions by focusing on a subset of known toxic chemicals whose presence in consumer products, workplaces and the environment translates into detectable levels of those chemicals in people, including pregnant women and children. The statute strikes a careful balance by relying on inherent hazard for chemical listing, but by establishing sufficient risk estimates before warning requirements apply; in doing so, it reflects current science on how chemicals contribute to cancer and reproductive harm.

The question of whether Prop 65 produces meaningful health protections is worthy of a systematic investigation, and I applaud you for the hearing on this topic. We will be setting out to answer some of these questions with data in a 3-year research project recently funded by the California Breast Cancer

[19] Rudel RA et al. 2011 Environ Health Perspect 119:1053–1061;doi:10.1289/ehp.1002864
[20] Kim JH et al. Toxicological sciences 122(1), 1–6 (2011) doi:10.1093/toxsci/kfr088

Research Program that will launch this fall. Working with Professor Polsky and an interdisciplinary team of public health researchers from across the country, I will be leading the investigation into how Prop 65 has affected Californian's exposures to known breast carcinogens and endocrine disruptors. We'll be investigating how the statute could *better* address these two categories of chemicals that appear to be linked to a significant burden of disease. I'd be happy to come back to this committee in the future to discuss our findings. We're hoping to understand not just how to streamline the statute to keep compliance costs down, but how to continue to tailor it to accomplish critical public health goals.

Thank you for holding this hearing and for giving me the opportunity to discuss these issues with the committee today.