

# California Proposition 65 Update

## Pharmaceutical EHS Counsel Roundtable

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# Agenda

- **Prop 65 Refresher** – what it is, how it is enforced, and what has changed
- **Prop 65 and the Pharmaceutical Industry** – top scenarios where changes may impact industry
- **Contours of Federal Preemption**
- **Developments to Watch**

# What is Prop 65?

- The warning requirement:
  - “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...”
- Applies to approximately 900 [listed chemicals](#)
- Covers [consumer product exposures](#), [occupational exposures](#), and [environmental exposures](#)
- Key exemptions
  - exposures that are within acceptable risk levels
  - exposures for which federal law governs warning in a manner that preempts state authority

# How is Prop 65 Enforced?

- Can be enforced by California AG, district or city attorneys, and any individual acting in the public interest (i.e., “bounty hunters”)
- Plaintiffs have sufficient basis for claim if they can show any level of exposure (mere detection of a listed chemical is usually enough)
- Burden then shifts to defendant to show that any exposure would be within acceptable risk levels
- Civil penalties of up to \$2,500 per violation per day, plus plaintiffs’ attorney’s fees

# Why is Prop 65 a “hot topic” now?

- Prop 65 enacted in 1986; warning regulations in 1988
- In 2016, warning regulations significantly revised for the first time
- After a 2 year transition period, revised regulations became effective August 30, 2018
- Changes impact how warnings should be provided, not whether warnings are required
- Yet prompted a wave of activity across industry sectors and supply chains that has led to more warnings

# Prop 65 and the Pharmaceutical Industry

- Prescription drugs covered by safe harbor from Prop 65 warning requirements
- New safe harbor warning provisions for dental care exposures
- No safe harbor for over-the-counter medications, medical devices, or other medical products
  - Any warnings for these products should take into account recent regulatory changes for consumer product exposures
  - But potential federal preemption argument if warning would conflict with FDA approved label
- Other regulatory changes may be relevant to California workplaces and research facilities

# Prescription Drugs Safe Harbor

- “For prescription drugs the labeling approved or otherwise provided under federal law and the prescriber’s accepted practice of obtaining a patient’s informed consent complies with this subarticle.”
- Essentially unchanged by recent revisions to regulations

# New Dental Care Exposure Provisions

- “A warning for an exposure that occurs during delivery of dental care, including an exposure from the use of dental appliances, meets the requirements of this subarticle if it complies with the content requirements [below] and is provided using one or both of the following methods...”
  - Signs in dental offices
  - Warning via informed consent form signed by patient
- Warning content
  - **WARNING:** Certain dental procedures performed in this office can expose you to chemicals known to the State of California to cause cancer or birth defects or reproductive harm or both. Those procedures can include sedation with nitrous oxide, root canals, placement or removal of crowns, bridges, and restorations such as mercury-containing fillings and the use of dental appliances. Consult your dental care provider about these exposures and which materials are appropriate for your treatment. Additional information is also available at [www.P65Warnings.ca.gov/dental](http://www.P65Warnings.ca.gov/dental).

# Other Medical Products

- No safe harbor protections specific to over-the-counter drugs, medical devices or other medical products in revised regulations
- Medical devices industry group sought safe harbor similar to prescription drugs but OEHHA (state lead agency) declined
- Consumer product exposure warnings may need to be provided for any of these products that could expose CA individuals to a listed chemical at a level that requires a warning

# Consumer Product Exposures

Revised warning *content*

Short form variations (can use if affixed to product/package)

-  **WARNING:** Cancer - [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).
-  **WARNING:** Reproductive Harm - [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).
-  **WARNING:** Cancer and Reproductive Harm - [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

Long form (example for carcinogen and reproductive toxicant)

-  **WARNING:** This product can expose you to chemicals including lead, which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

# Consumer Product Exposures

## Revised warning *methods*

- Four primary options
  - Point of display warnings (shelf signs, tags in stores)
  - Via any electronic device or process that provides warnings prior to purchase (QR codes, electronic displays)
  - Label using long form warning content
  - Label using short form warning content (if affixed to product or package)
- Additional warnings prior to sale for internet or catalog purchases
- Specific provisions on font size, languages other than English, and limitations on providing other consumer information

# Considerations for California Facilities

- Occupational exposures
- Environmental exposures
- Specific product, chemical and area exposure warnings



Alcoholic Beverages



Passenger and Off-Highway Vehicles



Amusement Parks



Hotels



Diesel Engine Exhaust



Petroleum Products



Dental Offices



Restaurants



Food



Recreational Vessel



Designated Smoking Areas



Service Stations



Furniture Products



Wood Dust



Enclosed Parking Facilities



Vehicle Repair Facilities

# Contours of Federal Preemption

- Federal Food, Drug & Cosmetic Act contains preemption provisions on national uniformity for over-the-counter drugs and cosmetics
  - But provisions contains a [savings clause](#) intended to exempt Prop 65
- Generally has meant that FDA-related preemption evaluated on case-by-case basis
- Successful preemption challenges have turned on conflict preemption
  - *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910 (2004)
  - *Post Foods LLC et al. v. Superior Court* (July 16, 2018, B284057) Cal. App. 2d

# Developments to Watch

- Private enforcement
  - New focus on adequacy of warnings?
  - Metals (lead and cadmium) in nutritional supplements and nutraceuticals?
  - PFOS/PFOA?
- From OEHHA
  - Requests for information from entities on why warnings provided
  - Emergence of additional industry-specific approaches through tailored warnings rulemaking by OEHHA
  - More guidance from OEHHA on obligations of different entities within supply chain



**Questions?**

Thank You!