



From Pharma to Produce: California's Evolving Tort Terrain

Presented by Steven J. Boranian and Sarah B. Johansen

ReedSmith

Today's speakers



Steven Boranian
Partner



Sarah Johansen
Counsel

ReedSmith

ReedSmith

ReedSmith



Before we dive in:

Housekeeping items

- Views expressed are our own, and not those of Reed Smith.
- Participation here does not establish an attorney-client relationship and information communicated should not be recognized as legal advice.



What We'll Cover

California Prop 65	1
Sherman Law	2
Learned Intermediary Doctrine	3
Personal Jurisdiction	4
Gilead Life Sciences v. Superior Court	5

California Prop 65

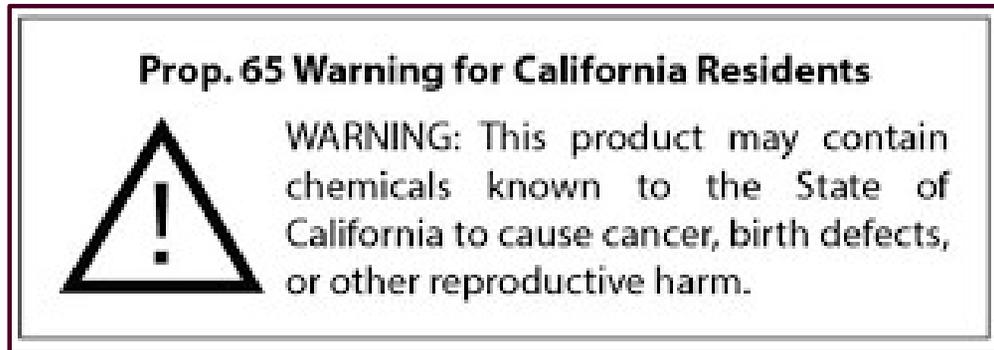


Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65

- Prop 65 requires businesses to provide “clear and reasonable” warnings re presence of chemicals that the state has determined cause cancer or reproductive toxicity
- State maintains the list, more than 1,000 chemicals
- Enforcement by Attorney General, district attorneys, certain city attorneys, and private parties
- Civil penalties of up to \$2,500 per day per violation and the potential for recovery of fees and costs
- Cal. Health & Safety Code §25249.5 et seq.



Required warning



Note: More detailed warnings required starting in 2028

Implied preemption

Center for Env't. Health v. Perrigo Co., 89 Cal. App. 5th 1 (2023)

- “Private enforcer” sued over nitrosamines allegedly present in generic OTC drugs, claiming failure to provide a Prop 65 warning
- Trial court dismissed case on implied preemption, no method by which the generic drug manufacturer could provide a Prop 65 warning while still complying with federal labeling requirements
- Held: Affirmed
 - No express preemption because FDCA’s express preemption provision for OTC drugs exempts Prop 65.
 - Implied preemption applied because FDA has not approved drug warnings like those required by Prop 65

First Amendment

Nat'l Ass'n of Wheat Growers v. Bonta, 85 F.4th 1263 (9th Cir. 2023)

- Agricultural producers sued to enjoin Prop 65 warnings that glyphosate was “listed” or “classified” as causing cancer
- **Held:** The warning requirement violated First Amendment right to be free from compelled speech
- No scientific consensus, and evidence overwhelmingly shows that glyphosate does not pose a risk of cancer
- Intermediate scrutiny applies to compelled commercial speech unless it is “purely factual and uncontroversial.”
 - The Prop 65 cancer warning (“known carcinogen”) was scientifically complex (i.e., not purely factual) and obviously controversial
 - Intermediate scrutiny applied

First Amendment (cont.)

***California Chamber of Commerce v. Bonta*, 781 F. Supp. 3d 1071 (E.D. Cal. 2025)**

- California Chamber of Commerce sued to enjoin Prop 65 cancer warning re dietary acrylamide in coffee
 - Studies re cancer risk are inconclusive.
 - Ninth Circuit affirmed preliminary injunction, holding that unsupported Prop 65 cancer warning violated the First Amendment

On remand, California promulgated a new regulation specifically requiring a Prop 65 cancer warning for dietary acrylamide.

- **Held:** Permanent injunction granted
- Prop 65 warnings were “neither uncontroversial nor purely factual as the warnings espouse a one-sided view that dietary acrylamide poses a human cancer risk despite a lack of scientific consensus.”

First Amendment (cont.)

Personal Care Prods. Council v. Bonta, No. 2:23-cv-01006 (E.D. Cal. Aug. 12, 2025)

- Business association sued to enjoin Prop 65 cancer warning re titanium dioxide used as whitening agent in various personal care products.
- **Held:** Permanent injunction granted
- No scientific consensus that titanium dioxide poses a risk of cancer in humans
- Prop 65 warning failed two speech analyses (*Zauderer, Central Hudson*), titanium dioxide warning was improper because the Prop. 65 warning was neither purely factual nor uncontroversial.
- State interest is not served by compelling a warning if a potential risk has not been confirmed by a regulatory body, could use alternative methods to inform the public.

Sherman Law





Overview: California Sherman Food, Drug, and Cosmetic Law



State statute that mirrors the federal Food, Drug, and Cosmetic Act (FDCA) and regulates the manufacturing, distribution, labeling, and sale of food, drugs, devices, and cosmetics – enforced by the Cal. Dept. of Public Health

The FDCA and 21 U.S.C. 337 states that actions to enforce the FDCA must be brought by the federal government – and not private parties

California's Sherman Law incorporates by reference the FDCA, making violations of the FDCA also violative of state law

Background - Food

***Davidson v. Sprout Foods, Inc.*, 106 F.4th 842 (9th Cir. 2024), cert denied 145 S. Ct. 1922**

- Plaintiffs (putative class action) alleged that Sprouts violated the Sherman Law and California's UCL by mislabeling nutritional information on baby foods. They alleged this constituted a violation of the Sherman Law, which parallels the FDCA.

Held: Although the court acknowledged that food-labeling requirements imposed by Sherman Law are requirements established by the FDCA, it held section 337 did not preempt private suits to enforce those requirements because "plaintiffs are claiming violations of California law, the Sherman Law, not the federal FDCA."

- Private enforcement of the Sherman Law did not conflict with federal enforcement of federal law.

Application

Bubak v. Golo, LLC, 2025 U.S. App. LEXIS 26524 (9th Cir. 2025)

- Plaintiff (putative class action) alleged a claim under California's UCL (which permits suit by private parties) for marketing and distribution of a dietary supplement. Plaintiff asserted violations of the FDCA "as incorporated into California law" via the Sherman law.
- Plaintiff alleges that she can sue under the UCL because the FDCA is "incorporated into" the Sherman Law, and defendant violated the FDCA by representing that its supplement can mitigate or prevent disease.
- **Held:** The court explained that her UCL claim "necessarily requires litigating 'the alleged underlying FDCA violation,'" which implicates implied preemption.
- The concurring opinion agreed with the result, but disagreed with the court's attempt to reconcile the case with prior rulings, and "to suggest that in the appropriate case we should overruled *Davidson's* limitation on the FDCA's prohibition of private actions to enforce the FDCA."

Learned intermediary doctrine





Overview: The learned intermediary doctrine



The learned intermediary doctrine is a legal principle that releases a prescription drug or medical device manufacturer from the duty to warn patients directly about a product's risks.

Instead, the manufacturer's duty is to provide adequate warnings to the prescribing physician, who acts as the "learned intermediary."

Legal impact: Whether an allegedly inadequate drug or medical device warning caused the plaintiff's alleged injury depends on whether a stronger warning would have altered a physician's decision to prescribe the product.



California's adjusted standard

Himes v. Somatics, LLC, 549 P.3d 916 (Cal. 2024)

- Alleged failure to warn that electroconvulsive therapy device could cause various injuries
- Treating physician said stronger warning would not have mattered, summary judgment granted under learned intermediary rule
- Ninth Circuit certified warnings causation question to California Supreme Court

Held: "A plaintiff is not required to show that a stronger warning would have altered the physician's decision to prescribe the product to establish causation. Instead, a plaintiff may establish causation by showing that the physician would have communicated the stronger warning to the patient and an objectively prudent person in the patient's position would have thereafter declined the treatment."



The good news

The learned intermediary rule is still the law of California

- Complicated and confused the warnings causation burden
- BUT:
 - Affirmed learned intermediary rule, rejected duty to warn patients
 - Prescription products \neq consumer goods
 - Applied learned intermediary rule to medical devices
 - Learned intermediary rule is not a defense
 - Rejected argument that rule ceases with allegations of inadequate warning
 - Objective standard applies

The fallout from *Himes* (so far)

***Nazzal v. Wyeth*, No. CV 23-10102, 2024 WL 3914878 (C.D. Cal. July 16, 2024)**

Motion to dismiss denied where plaintiff alleged that “no reasonable physician would have prescribed” the product and “eight out of nine doctors would not have prescribed [the drug] if it contained a black box warning.”

***Canty v. DePuy Orthopaedics Inc.*, No. 14-cv-05407, 2024 WL 4149954 (N.D. Cal. Sept. 10, 2024)**

Summary judgment granted because prescribing surgeon did not rely on manufacturer’s written materials

***Riera v. Mecta Corp.*, No. 2:17-cv-06686, 2024 WL 4800073 (C.D. Cal. Oct. 24, 2024)**

On remand from *Himes*, summary judgment denied because (1) physician would have included more information in informed consent and (2) “alternative, unexplored treatments...were available” to the plaintiff

The fallout from *Himes* (so far) (cont.)

***Robi v. Merck & Co.*, No. BC628589, 2024 Cal. Super. LEXIS 60549 (Cal. Super. Ct. Dec. 20, 2024)**

Summary judgment denied where defendant presented no evidence that the prescribing physicians would not have communicated a stronger warning to the patient had they received more risk information from the manufacturer.

Plaintiff stated that had she been “correctly” warned, she would not have consented.

***In re BioZorb Device Prods. Liab. Litig.*, No. 23-cv-10260, 2025 WL 276628 (D. Mass. Jan. 3, 2025)**

Summary judgment denied under Pennsylvania law, in part because “a reasonable person” in the patient’s position would not have consented if apprised of risks (citing *Himes*)

Personal jurisdiction





Overview

California personal jurisdiction

- Determination regarding whether a court can exercise its jurisdiction over a defendant based on its connection to California
- Cal. Civ. Proc. Code section 410.10 (Cal. long arm statute) provides for personal jurisdiction to the maximum extent allowed by 14th Amendment due process
- For personal jurisdiction to exist over a nonresident defendant, the defendant must have “certain minimum contacts” with California “such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice”

Two types of personal jurisdiction

- General: the defendant’s “affiliations with the state are so ‘continuous and systematic’ as to render them essentially at home in the forum state” [*Goodyear*]
- Specific: (1) purposeful direction or purposeful availment; (2) the claim arises out of or relates to the forum-related activities; (3) jurisdiction must be reasonable [*Schwarzenegger*]



Expanded California standard – specific jurisdiction

Briskin v. Shopify, Inc., 135 F.4th 739 (9th Cir. 2025)

- Plaintiff alleged privacy-related torts against Shopify, an e-commerce platform, for installing “cookies” on his device without his consent to collect data regarding his online shopping activity - including targeting of Cal. consumers
- Shopify argues it is “agnostic” as to California because it operates nationwide
 - “Something more” than “mere passive nationwide accessibility” is required
- **Held:** Shopify knew about its Cal. consumer base, conducts regular business, contacts Cal. residents, interacts with them as an intermediary for merchants, and installs software on their devices. Accordingly, “Shopify expressly aimed its conduct at California”
 - Overruled cases imposing requirement of “differential treatment” or “express aiming” of the allegedly tortious conduct

Concurrence and dissent

Two concurring opinions

- Where the conduct is “purely automated” as it was here (e.g., “by the operation of software that, when it conducts transactions with Californians in California, does so, by design, in a way that allegedly violates California law”), that “automated tort” is the relevant conduct and is sufficient to support specific personal jurisdiction.
- Disagrees that “something more” is required than a “passive” website.

One dissent

- Disagrees with the majority’s reliance on Shopify’s knowledge of plaintiff’s location in California when they installed software/cookies on his phone.
- The majority’s rule “creates a traveling cookie that ultimately crumbles when held up against Supreme Court precedent because it detaches the jurisdictional inquiry from the contacts that the ‘defendant *himself*’ creates with the State.”

Application

***Thomas v. Papa John's Int'l, Inc.*, 2025 U.S. App. LEXIS 15039 (9th Cir. 2025)**

- Plaintiff alleged that she was browsing and using defendant's website to place orders for food, but it embedded a Session Replay Code without her consent. Defendant argued it merely operated a nationally accessible website.

Held: "Papa John's (1) operates an interactive "website with national viewership and scope" that "appeals to, and profits from, an audience in" California, and (2) it used its website to intentionally collect information invading the privacy of its users, and expressly aimed its conduct at California (citing *Briskin*).

Gilead Sciences v. Superior Court
- “Duty to Innovate”





Overview

***Gilead Sciences, Inc. v. Superior Court*, 98 Cal. App. 5th 911, 917 (2024)**

- Patients taking Truvada and other TDF-based medicines have sued Gilead, alleging mainly kidney injuries and bone-density issues
- Plaintiffs abandoned all claims of defect re TDF medicines after years of discovery
- Plaintiffs allege instead that Gilead should have developed and marketed a **different antiretroviral medicine** (TAF) sooner and faster than it actually did, i.e., breached a duty to innovate

Held: Summary judgment on negligence denied, California Court of Appeal affirmed

- Pharmaceuticals manufacturer, having invented what it knows is a safer, and at least equally effective, alternative to a prescription drug that it is currently selling and that is not shown to be defective, has a duty of reasonable care to users of the current drug when making decisions about the commercialization of the alternative drug



What does that mean?

If a product user is allegedly injured by a product that is not itself defective, the product manufacturer can *still* be liable for that user's injuries if the manufacturer unreasonably failed to bring another, allegedly safer and equally as effective product to market sooner.



What does that mean?

“[W]e conclude that the legal duty of a manufacturer to exercise reasonable care can, in the appropriate circumstances, extend beyond the duty not to market a defective product.”

Gilead Sciences, Inc. v. Superior Court,
98 Cal. App. 5th 911, 917 (2024)



What does that mean?

“In context, then, the duty question we must address is whether a drug manufacturer, having invented what it knows is a safer, and at least equally effective, alternative to a prescription drug that it is currently selling and that is not shown to be defective, has a duty of reasonable care to users of the current drug when making decisions about the commercialization of the *alternative drug*.”

Gilead Sciences, Inc. v. Superior Court,
98 Cal. App. 5th 911, 917 (2024)



The Court of Appeal's caveats

- The plaintiff has to allege harm by a product **currently on the market**.
- The **same manufacturer** developed both the **current drug** and **alleged alternative**.
- The duty “does not apply generally to ‘improved’ products, but only to products that the manufacturer knows will avoid significant side effects of a manufacturer’s existing product.”
- “[T]he duty does not require manufacturers to **perfect** their drugs, but simply to act with **reasonable care** for the users of the existing drug when the manufacturer has developed an alternative that it knows is safer and at least equally efficacious.”

THE WALL STREET JOURNAL.

OPINION REVIEW & OUTLOOK [Follow](#)

California Invents a Crazy New Tort

Golden State judges rule that Gilead can be sued for taking too long to develop an HIV drug.

By The Editorial Board [Follow](#)

Jan. 14, 2024 12:06 pm ET



Gilead Sciences Inc pharmaceutical company in Oceanside, Calif. PHOTO: MIKE BLAKE/REUTERS

Businesses are often sued for selling allegedly faulty products that aren't actually defective. Last week a California appeals court ruled that businesses can also be sued for *failing* to develop a product. Behold California's new tort standard: You should have built that.

Some 24,000 patients have sued Gilead Sciences in California state court for failing to introduce an allegedly safer version of an HIV drug. The Food and Drug Administration in 2001 approved a life-saving HIV medication by Gilead. The plaintiffs don't argue that the drug is defective or lacked adequate warnings.

"The appellate court said its ruling doesn't create a 'duty to innovate' or 'pursue ever-better new products.' But once a company starts tinkering with a new and potentially improved product, it could be legally obligated to bring it to market, no matter the commercial or technological barriers."

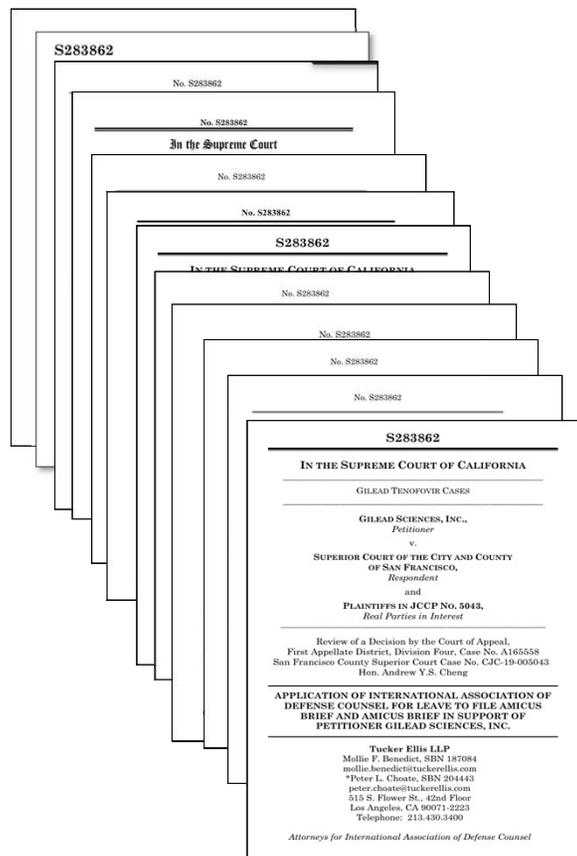
"This will create a disincentive to innovate."

Petition for Review with The California Supreme Court

GRANTED



74 Amici In Support of Petitioner Gilead in California TDF Product Liability Litigation



13 Amicus Briefs In Support of Gilead Industry and Civil Justice

- Alliance for Automotive Innovation
- American Chemistry Council
- American Coatings Assoc.
- American Tort Reform Assoc.
- Assoc. Of Defense Counsel (No. Cal, So. Cal, Nevada)
- Atlantic Legal Foundation
- BioCom
- Biotech Innovation Organization
- Bay Area Council
- Cal. Business Roundtable
- California Life Sciences
- Cal. Chamber of Commerce
- Cal. Manufacturers & Tech. Assoc.
- Center of Law and Public Policy
- Consumer Technology Association
- Defense Research Institute
- Intern'l Assoc. of Defense Counsel
- Medical Device Manufacturers Assoc.
- National Assoc. of Manufacturers
- PhRMA
- US Chamber of Commerce
- Washington Legal Foundation

Individual Companies

- Archer Aviation
- Bayer
- Becton Dickinson
- Biogen
- Bristol Myers Squibb
- Cytokinetics, Inc.
- Dow
- DuPont
- Eli Lilly
- GE Healthcare
- Genentech
- General Motors
- Glaukos
- GSK
- Hamilton Beach Brands
- Hyundai
- Incyte
- J&J
- Kenvue
- Kia
- Lyft
- Medtronic
- Merck
- Organon
- Pfizer
- Regeneron
- Roche
- Sanofi
- Sonoma Biotherapeutics
- STORM Therapeutics
- Takeda
- Textron
- Toyota
- Uber
- Vertex
- Viasat
- Vizio
- Volkswagen
- Zimmer Biomet

Academia/Think Tank

- Pacific Research Institute
- Prof. Richard Epstein
- International Center for Law & Economics
- Prof. Jeremy Kidd
- Atlantic Legal Foundation

Patient Advocacy

- Community Education Group
- C. Virginia Fields, Pres. & CEO of the National Black Leadership Commission on AIDS, Inc.
- Liver Coalition of San Diego
- Global Coalition on Aging
- Dr. Eugene McCray, Former Dir. of CDC's Division of HIV/AIDS Prevention
- HIV+HEP Policy Institute
- Partnership to Fight Chronic Disease
- National Minority Quality Forum
- Phill Wilson, Founder and Former President and CEO of the Black AIDS Institute

Law Firms

- Gilead Orrick, Goldman Ismael, Proskauer, Shook Hardy,
- Bowman and Brooke
- Calvin House
- Covington
- DLA Piper
- Gibson Dunn
- O'Melveny
- Paul Weiss
- Quinn Emanuel
- Reed Smith

Questions?





Where we are: Our global view

Reed Smith is a dynamic international law firm, dedicated to helping clients move their businesses forward.

Our global offices

Abu Dhabi	New York
Astana	Orange County
Athens	Paris
Austin	Philadelphia
Brussels	Pittsburgh
Century City	Princeton
Chicago	Richmond
Dallas	Riyadh
Dubai	San Francisco
Frankfurt	Shanghai
Hong Kong	Silicon Valley
Houston	Singapore
London	Tysons
Los Angeles	Washington, D.C
Miami	Wilmington
Munich	



Our offices



Our regional business teams