

California's Safer Soap Act (AB 916) stands on solid legal ground against potential Federal Food, Drug, and Cosmetic Act (FDCA) preemption challenges.

## Regulatory Void

The FDA's eight-year delay in finalizing regulations for these antimicrobials creates a regulatory void that states have legitimate authority to fill:

1. **No Federal Determination:** Unlike scenarios where the FDA has made definitive safety and efficacy determinations, the agency has merely deferred action on these ingredients as a result of lobbying from manufacturers and their trade associations.
2. **Public Health Imperative:** AB 916 cites specific concerns including antimicrobial resistance, respiratory issues, and developmental harm, particularly for children. These health concerns provide a compelling state interest in the absence of federal regulation.

## Absence of Direct Conflict

AB 916 doesn't create requirements that conflict with established federal standards:

1. **No Contrary Federal Position:** Since the FDA has not issued a final determination finding these chemicals safe and effective, a state prohibition doesn't contradict established federal policy.
2. **Precedent in *Wyeth v. Levine*:** The Supreme Court landmark decision in *Wyeth v. Levine* established that FDA regulations generally serve as a floor for consumer protection, not a ceiling that precludes additional state safeguards.

## Established State Police Powers

California can draw on traditional state authority to protect public health:

1. **Historical State Authority:** States have traditionally maintained broad authority to regulate matters of public health and safety within their borders. The Supreme Court has consistently affirmed that states retain broad authority to protect public health. In *Hillsborough County v. Automated Medical Laboratories*, the Court established: "Given the presumption that state and local regulation related to matters of health and safety can normally coexist with federal regulations, we will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety".
2. **Minnesota Precedent:** Minnesota's successful implementation of its triclosan ban provides a direct precedent for state action in this regulatory area. See more below.

## Narrow Interpretation of FDCA Preemption

Recent court decisions suggest a trend toward narrower interpretation of FDCA preemption:

1. **Ninth Circuit Precedent:** In *Davidson v. Sprout Foods* (2024), the Ninth Circuit held that California's Sherman Law, which incorporates FDCA requirements, is not impliedly preempted by the FDCA.
2. **Complementary State Action:** Courts have distinguished between state laws that create new requirements versus those that broadly address public health concerns compatible with federal objectives. Importantly, AB 916 does not conflict with FDA positions but actually aligns with concerns the FDA itself has expressed. The bill cites the FDA's own statements that "there isn't evidence to show that over-the-counter antibacterial soaps are better at preventing illness than washing with plain soap and water" and that "some data suggest that antibacterial ingredients could do more harm than good over the long-term."

## Product Ban vs. Additional Requirements

Courts may distinguish between state laws that ban products entirely and those that impose additional requirements on federally regulated products:

1. **Type of State Action:** A complete prohibition on certain ingredients may be viewed differently than attempts to impose additional labeling or warning requirements while keeping products on the market.
2. **No Uniformity Concerns:** Unlike cases where courts found preemption based on "national labeling uniformity" objectives, a product ban doesn't create conflicting state-by-state labeling requirements.

## Express vs. Implied Preemption

Unlike medical device regulation, the FDCA does not contain an express preemption clause for drug products:

1. **No Statutory Preemption for Drugs:** While Section 521 of the FDCA explicitly preempts state regulation of medical devices, "Congress did not expressly preempt state law with respect to drug regulation".
2. **Implied Preemption Standard:** For drug-related state laws, courts instead evaluate "implied preemption under conflict preemption theories", focusing on whether it is impossible to comply with both state and federal requirements.

## The Minnesota Precedent: Successful State-Level Ban of Antimicrobial in Hand Soap

In May 2014, Minnesota became the first state to ban the antibacterial chemical triclosan in consumer soaps and cleaning products, with the prohibition scheduled to take effect on January 1, 2017. The legislation passed with overwhelming bipartisan support, securing a 110-19 vote in the House and a unanimous 58-0 vote in the Senate. This landmark legislation preceded the FDA's nationwide ban on triclosan and 18 other antibacterial ingredients in consumer soaps

by more than two years. Minnesota's triclosan ban avoided federal preemption for several key reasons:

1. **Regulatory Gap:** When Minnesota passed its legislation in 2014, the FDA had not yet issued a final determination on triclosan's safety and efficacy in consumer soaps. This regulatory gap allowed Minnesota to act without directly contradicting established federal policy. This is directly analogous to the gap AB 916 will fill.
2. **Strong Scientific Foundation For Health *and* Environmental Concern:** The law was supported by mounting scientific evidence regarding triclosan's potential environmental impacts, particularly findings from the University of Minnesota showing triclosan degradation products in Minnesota lakes. Note that antimicrobials targeted by AB 916 have been detected in the San Francisco Bay and other water bodies.
3. **Limited Scope:** Like AB 916, the ban specifically targeted consumer personal care products while exempting medical settings, carefully balancing public health concerns without overreaching into areas of clear federal jurisdiction.