ACS CAN & Federal Tobacco Litigation - An Overview

The tobacco industry has a history of using litigation to avoid and delay laws and regulations enacted to safeguard the public. The American Cancer Society Cancer Action Network (ACS CAN), with our tobacco control partners, has also relied on the courts to hold Big Tobacco accountable and to ensure the federal government is effectively implementing the Tobacco Control Act. Through ACS CAN's Judicial Advocacy Initiative, we have worked to ensure public health interests are effectively represented by filing our own cases against the Food and Drug Administration (FDA), weighing into other important court disputes by filing *amicus curiae* or "friend of the court" briefs, and intervening in a major lawsuit. This fact sheet briefly summarizes major active tobacco control cases at the federal level.

DOJ/RICO Case

ACS continues as an intervenor in this decades-long case brought by the U.S. Department of Justice in which Big Tobacco was convicted of fraud and conspiracy in violation of the Racketeer Influenced and Corrupt Organizations (RICO) Act for misleading the public about the dangers of tobacco and manipulation of the products to make them more addictive. As a result of *US v Philip Morris et al*, Big Tobacco has been required to post rotating "corrective statements" on television, in newspapers, on their websites, on product package "onserts,"and in retail stores. The statements are posted at over 220,000 tobacco retailers across the nation until June 30, 2025. Big Tobacco was recently required to pay $3.5 million in civil fines to the U.S. Treasury because 16% of retailers were not in compliance with the requirements. Learn more here.

Graphic Warnings

ACS CAN and other tobacco control partners celebrated in March of 2024 when the U.S. Court of Appeals for the Fifth Circuit upheld the FDA's final rule requiring graphic warnings on cigarette packages and advertisements in its entirety in *RJ Reynolds Tobacco et al v. FDA*. The Fifth Circuit *en banc* refused to hear an appeal of the case, and Big Tobacco has now petitioned to the Supreme Court of the U.S. (SCOTUS). ACS CAN and partners have supported the FDA as *amicus* at every level of the case. While ACS CAN has been supporting the FDA for years in legal challenges brought by the tobacco industry by filing *amicus curiae* briefs in federal lawsuits, tobacco control partners also sued the FDA in 2016 claiming the FDA had unreasonably delayed putting out a new rule and shirked its duties under the Tobacco Control Act. In 2018, a judge agreed and ordered the agency to issue the rule by March of 2020, which the agency did. ACS CAN is now helping defend that rule. Learn more here.

"Premium" Cigars

In 2016, FDA issued a final Deeming Rule that placed all existing and future tobacco products under its authority. The tobacco industry sued the FDA to exempt certain products from FDA oversight. The D.C. Circuit ruled in 2022 that the FDA acted arbitrarily and capriciously in its decision not to exempt "premium" cigars from the final Deeming Rule in *Cigar Assn of America v FDA*. The court noted that the FDA ignored an evidence base including data on how "premium" cigars were consumed. This decision also invalidated required warning labels on premium cigars. Other issues related to "premium" cigars are still being litigated at the district court level. ACS CAN and partners have filed *amicus* briefs supporting FDA in every phase of this case.

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Pre-Market Tobacco Applications (PMTA)

ACS CAN and other public health partners sued the FDA in 2018 for failing to require tobacco manufacturers to submit PMTAs as required by the Tobacco Control Act in *American Academy of Pediatrics et al v FDA*. We won the lawsuit in 2019, and that victory directly resulted in a concrete timeline for product manufacturers to submit applications for FDA's review. Further action in the lawsuit forced the FDA to publicly disclose how many of the applications it has issued decisions on. The agency sought to end its reporting obligations; ACS CAN and partners opposed the request, but unfortunately the district court recently ruled in FDA's favor. Learn more here.

In addition, two significant lawsuits related to FDA's premarket review of tobacco products, include whether the FDA has jurisdiction to regulate flavored cigars and upholding the FDA's issuance of marketing denial orders for various flavored e-cigarette premarket applications.

Flavored Cigars

The Tobacco Control Act and the Deeming Rule require that most cigar manufacturers obtain an FDA "substantial equivalence" order before the company may continue to market and sell flavored cigars in the U.S. after February 15, 2007. A major manufacturer of flavored cigars sued FDA to prevent it from enforcing the premarket review/substantial equivalence sections of the Tobacco Control Act in *Swisher International v FDA*. The district court recently ruled in favor of the government on all counts. ACS CAN and partners have been submitting *amicus* briefs in support of FDA throughout the many years of this litigation.

Flavored E-cigarettes

ACS CAN worked with tobacco control partners in filing numerous amicus briefs supporting the FDA in cases in which the agency had issued marketing denial orders (MDOs) for flavored e-cigarette products as part of the premarket review process. With our help, the FDA has won the majority of these challenges. Eight different circuit courts have upheld MDOs while only two circuits have vacated them. SCOTUS announced in July that it will hear one of these cases: *FDA v. Wages and White Lion Investments dba Triton Distribution.* In this case the Fifth Circuit vacated MDOs for these flavored e-cigarette products and the FDA appealed. ACS CAN has filed dozens of amicus briefs supporting FDA in these cases since late 2021, including most recently at SCOTUS in September of 2024. Learn more here.

Menthol Cigarettes

The Tobacco Control Act prohibited all flavors in cigarettes, except for menthol. For menthol flavoring, the law required the FDA's Tobacco Product Scientific Advisory Committee to study the issue of menthol cigarettes and granted FDA the authority to prohibit menthol in products. ACS CAN joined a citizen's petition in 2013 urging the agency to prohibit menthol in cigarettes. In 2020, with no action from FDA, several public health groups sued the FDA to issue a rule to prohibit menthol in cigarettes (*African American Tobacco Leadership Council et al v FDA)*. ACS CAN filed as *amicus* in support of those plaintiff public health groups. The lawsuit directly resulted in FDA issuing a draft rule that has yet to be finalized. Plaintiffs re-filed their lawsuit in 2024. ACS CAN plans to support the new lawsuit as an *amicus*. Learn more here.