



Lawsuits Challenging the FDA's Deeming Rule

On May 10, 2016, the U.S. Food and Drug Administration published its final deeming rule, extending the agency's regulatory jurisdiction over tobacco products to e-cigarettes, cigars, hookah, and other products that had not yet been regulated by the FDA. For more information about the FDA's action, see the Consortium's other [deeming rule resources](#). For information on other lawsuits related to FDA tobacco regulation, see our other [litigation resources](#).

Below is an overview of lawsuits challenging the FDA's deeming rule that briefly summarizes the plaintiff's arguments. The FDA's actions are governed by the Administrative Procedure Act (APA)¹ and the Regulatory Flexibility Act (RFA) and so a reviewing court can overturn an agency action if it violates one of these laws.

After the change in administration in January 2017, the government sought extensions of deadlines "to allow new leadership personnel at the Department of Health and Human Services to more fully consider the issues raised" in the lawsuits. In addition, on May 1, 2017, the FDA extended all future enforcement deadlines for portions of the deeming rule that have not yet been enforced.

Nicopure Labs, LLC et al. v. U.S. Food and Drug Administration

No. 1:16-cv-878 (D.D.C. 2016)

On May 10, 2016, Nicopure Labs, a Florida manufacturer of e-cigarette devices and liquid nicotine, filed suit in the District Court of the District of Columbia, requesting that the court permanently strike down the rule and in the meantime, enjoin enforcement of the rule while the litigation proceeds. Six weeks later, on June 20, 2016, eleven e-cigarette trade groups, Right To Be Smoke-Free (RSF), American E-Liquid Manufacturing Standards Association, American Vaping Association, Electronic Vaping Coalition of America, Georgia Smoke Free Association, Kentucky Vaping Retailers Association, Inc., Louisiana Vaping Association, Maryland Vape Professionals, LLC, New Jersey Vapor Retailers Coalition, Ohio Vapor Trade Association, and Tennessee Smoke Free Association (collectively the RSF Plaintiffs), also filed suit in the District Court of the District of Columbia, requesting that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule.

In an effort by the court to streamline proceedings, these two lawsuits have been consolidated because they are based on the same agency action, have the same defendant, and raise some of the same claims. Nicopure filed a motion for summary judgment² on July 8, 2016. The RSF

Plaintiffs filed their own motion for summary judgment related to unique claims on July 25, 2016. The FDA filed a cross-motion for summary judgment on August 17, 2016. The plaintiffs' consolidated reply was filed on August 26, 2016. The FDA's reply was filed on September 9, 2016, and a hearing on the motions was held on October 11, 2016. The case is yet to be decided.

Nicopure's complaint alleges that:

- 1) the FDA's interpretation of the term, "tobacco product" is "not in accordance with the law" and "in excess of statutory jurisdiction," a violation of the APA;
- 2) the enforcement of premarket review against e-cigarette companies will be costly and stifle innovation, rendering the FDA's action "arbitrary and capricious," a violation of the APA;
- 3) the FDA's cost-benefit analysis for the rule overstates the benefits and understates the costs, an action that is "without observance of procedure required by law," a violation of the APA; and
- 4) e-cigarette manufacturers will be prohibited from making truthful and non-misleading statements and other forms of protected expression, an action that is "contrary to [the] constitutional right" to free speech protected by the First Amendment, a violation of the APA.

RSF Plaintiffs' complaint alleges that:

- 1) the FDA's refusal to select a new grandfather date, later than February 15, 2007 for e-cigarettes renders the Substantial Equivalence premarket review pathway inaccessible, an action that is "arbitrary and capricious," a violation of the APA;
- 2) the FDA's imposition of the rigorous Premarket Tobacco Product Application process is too expensive and difficult, an action that is a violation of the APA;³
- 3) the FDA's treatment of e-cigarettes in a way that is similar to combustible cigarettes violates the equal protection clause of the Fourteenth Amendment by way of the due process clause in the Fifth Amendment.
- 4) the FDA has prohibited the distribution of free samples, an action that is "contrary to [the] constitutional right" to free speech protected by the First Amendment, a violation of the APA.
- 5) e-cigarette manufacturers will be prohibited from making truthful and non-misleading statements, an action that is "contrary to [the] constitutional right" to free speech protected by the First Amendment, a violation of the APA.
- 6) the FDA's interpretation of the term, "tobacco product" is "unreasonable and unlawful under the APA,"⁴
- 7) the FDA's Final Regulatory Flexibility Analysis did not properly quantify the costs of the rule or identify significantly less costly alternatives to the rule, a violation of the RFA;
- 8) the FDA's cost-benefit analysis for the rule overstates the benefits and understates the costs, an action that is a violation of the APA.⁵

Lost Art Liquids, LLC v. U.S. Food and Drug Administration

No. 2:16-cv-3468 (C.D. Cal. 2016)

On May 19, 2016, Lost Art Liquids, a California manufacturer of e-cigarette devices and liquid nicotine, filed suit in the District Court of the Central District of California. Lost Art Liquids has

requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. The FDA answered the complaint on November 14, 2016.⁶ The court has established the following briefing schedule: the plaintiffs must file a motion for summary judgment by August 15, 2017; the FDA must file its opposition to the plaintiff's motion and its own motion for summary judgment by September 15, 2017; the plaintiffs must file any reply by October 16, 2017; and the FDA must file any reply by November 16, 2017. Oral arguments have not yet been scheduled.

The lawsuit alleges that:

- 1) the FDA's Final Regulatory Flexibility Analysis did not properly quantify the costs of the rule or identify significantly less costly alternatives to the rule, a violation of the RFA;
- 2) the FDA's cost-benefit analysis for the rule overstates the benefits and understates the costs, an action that is "without observance of procedure required by law," a violation of the APA;
- 3) the rule's prohibition on using modified risk descriptors and the requirement that products bear warning labels violate the First Amendment's protection of free speech and the Fifth Amendment's protection from unlawful governmental takings; and
- 4) the FDA's enforcement of premarket review against e-cigarette companies will be costly, an "abuse of discretion," in violation of the APA.

Enrique Fernando Sanchez Icaza and Global Premium Cigars, LLC v. U.S. Food and Drug Administration

No. 1:16-cv-21967 (S.D. Fla. 2016)

On June 1, 2016, Global Premium Cigars, LLC, a Florida manufacturer of cigars, and its proprietor Enrique Fernando Sanchez Icaza, filed suit in the District Court of the Southern District of Florida. The plaintiffs have requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. The FDA filed its answer on October 3, 2016.⁷ The court has established the following briefing schedule: the plaintiffs must file a motion for summary judgment by August 30, 2017; the FDA must file its opposition to the plaintiff's motion and its own motion for summary judgment by October 30, 2017; the plaintiffs must file any reply by December 7, 2017; and the FDA must file any reply by January 19, 2018. Oral arguments have not yet been scheduled.

The lawsuit alleges that:

- 1) the FDA's Initial Regulatory Flexibility Analysis did not properly quantify the costs of the rule or identify significantly less costly alternatives to the rule, a violation of the RFA;
- 2) the enforcement of premarket review against cigar companies will be costly and there is no evidence to support the requirement that cigar boxes carry a warning label covering 30% of the principal display panel, actions that are "arbitrary and capricious," violations of the APA;
- 3) the FDA's cost-benefit analysis for the rule overstates the benefits and understates the costs, an action that is "without observance of procedure required by law," a violation of the APA;

- 4) the required warning labels and the enforcement of premarket review with respect to labeling violate the First Amendment's protection of free speech;
- 5) the implementation of required warning labels on cigar boxes amounts to a taking, a violation of the Fifth Amendment's protection from unlawful governmental takings; and
- 6) the enforcement of premarket review with respect to all products marketed after February 15, 2007, violates the due process clause of the Fifth Amendment.

Larry W. Faircloth v. U.S. Food and Drug Administration

No. 2:16-cv-5267 (S.D. W.V. 2016)

On June 10, 2016, Larry W. Faircloth, a user of e-cigarette devices and liquid nicotine, filed suit in the District Court of the Southern District of West Virginia. Faircloth has requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. In lieu of answering the complaint, the FDA filed a motion to dismiss the case on October 28, 2016.⁸ Faircloth filed a response to this motion on November 30, 2016 and the FDA filed a reply to plaintiff's response on December 12, 2016. The court has not yet ruled on this motion.

The lawsuit alleges that:

- 1) the FDA's interpretation of the term, "tobacco product" is "not in accordance with the law" and "in excess of statutory jurisdiction," a violation of the APA;
- 2) the enforcement of premarket review against e-cigarette will drive up the costs for devices and liquids for consumers and push consumers toward cigarettes, rendering the FDA's action "arbitrary and capricious," a violation of the APA;
- 3) the FDA's cost-benefit analysis for the rule overstates the benefits and understates the costs, an action that is "without observance of procedure required by law," a violation of the APA;
- 4) the rule will prevent consumers from receiving truthful and non-misleading statements and other forms of protected expression, such as free samples of products, an action that is "contrary to [the] constitutional right," of free speech protected by the First Amendment, in violation of the APA; and
- 5) by removing many e-cigarettes from the market, the FDA has prevented the state of West Virginia from reducing its Medicaid costs by promoting e-cigarettes over combustible tobacco products to reduce healthcare costs, depriving the state of its sovereignty, in violation of the Tenth Amendment's protection of federalism.

Cyclops Vapor 2, et al. v. U.S. Food and Drug Administration

No. 2:16-cv-556 (M.D. Ala. 2016)

On July 8, 2016, Cyclops Vapor 2, LLC, Tiger Vapor, LLC, and Karma S Clouds, LLC, Alabama-based manufacturers and distributors of e-cigarette devices and liquid nicotine, filed suit in the Middle District of Alabama. The plaintiffs have requested that the court permanently strike down the rule. The FDA filed its answer on November 28, 2016.⁹ The plaintiffs filed a motion for summary judgment on February 1, 2017. The FDA must file its opposition to the plaintiff's motion and its own motion for summary judgment by August 2, 2017. The plaintiffs

must file any reply by September 5, 2017 and the FDA must file any reply by October 5, 2017. Oral arguments have not yet been scheduled.

The lawsuit alleges that:

- 1) the FDA's interpretation of the term, "tobacco product" is "in excess of statutory jurisdiction," a violation of the APA;
- 2) the enforcement of premarket review against e-cigarette companies will be costly, stifle innovation, and does not account for the possibility that e-cigarettes are less harmful than combustible cigarettes, rendering the FDA's action "arbitrary and capricious," a violation of the APA;
- 3) the FDA's cost-benefit analysis for the rule overstates the benefits and understates the costs, a violation of the APA¹⁰ and the RFA; and
- 4) e-cigarette manufacturers will be prohibited from making truthful and non-misleading statements and other forms of protected expression, including distributing free samples, an action that is "contrary to [the] constitutional right" to free speech protected by the First Amendment, a violation of the APA.

Cigar Association of America et al. v. U.S. Food and Drug Administration No. 1:16-cv-1460 (D.D.C.)

On July 15, 2016, the Cigar Association of America, the International Premium Cigar and Pipe Retailers Association, and Cigar Rights of American, non-profit trade associations for retailers and manufacturers, filed suit in the District Court of the District of Columbia. The plaintiffs requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. The FDA filed its answer on October 26, 2016.¹¹ The plaintiffs filed a motion for summary judgment on February 13, 2017. The FDA must file its opposition to the plaintiff's motion and its own motion for summary judgment by August 1, 2017. The plaintiffs must file any reply by September 14, 2017 and the FDA must file any reply by October 16, 2017. Oral arguments are scheduled for December 8, 2017.

The lawsuit alleges that:

- 1) the enforcement of premarket review will be costly, rendering the FDA's action "arbitrary and capricious" in violation of the APA;
- 2) the imposition of user fees is an illegal tax, an action that is in excess of statutory authority and therefore a violation of the APA;
- 3) the imposition of user fees on cigar manufacturers but not e-cigarette manufacturers is "contrary to [the] constitutional right" to due process protected by the Fifth Amendment, a violation of the APA;
- 4) the FDA's Final Regulatory Flexibility Analysis did not properly quantify the costs of the rule or identify significantly less costly alternatives to the rule, a violation of the RFA;
- 5) the FDA's decision to regulate all cigars rather than exempting premium cigars is an action that is "arbitrary and capricious" in violation of the APA;
- 6) the FDA's imposition of particularly sized warning labels without adequately explaining why it decided on the size and format is "arbitrary and capricious" in violation of the APA;

- 7) the required warning labels impermissibly restrict speech, a violation the First Amendment;
- 8) the FDA's decision to treat retailers who blend or repack pipe tobacco or cigars as manufacturers is "arbitrary and capricious" in violation of the APA;
- 9) the FDA's decision to regulate pipes as components or parts of a tobacco product is "arbitrary and capricious" in violation of the APA.

In addition to these cases, John Middleton Co. LLC, a subsidiary of Altria Group, Inc. (formerly Philip Morris Companies) that manufactures cigars and pipe tobacco, filed suit in the District Court of the District of Columbia, challenging the enforcement of the prohibition on the use of modified risk descriptors against its brand, Black & Mild. On July 15, 2016 in light of the FDA's position that it did not intend to enforce that prohibition against Black & Mild, John Middleton voluntarily dismissed its lawsuit, without prejudice, allowing the company to refile its lawsuit in the future.

Other Resources

For more information on the FDA's regulation of tobacco products, visit our [FDA Tobacco Action Center](#).

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¹ The APA provides a list of causes of action that allow a reviewing court to set aside an agency action. Plaintiffs often list the relevant section entirely or multiple sections as the causes of action have a degree of overlap. There are four causes of action relevant to FDA tobacco regulation. A court may overturn a rule if it finds that it is: 1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law; 2) contrary to constitutional right, power, privilege, or immunity; 3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or 4) without observance of procedure required by law.

² A motion for summary judgment asks a court to decide a case on the law when there are no facts in dispute.

³ The complaint fails to identify a particular section of the APA that has been violated and thus there is no reference to statutory language.

⁴ "Unreasonable and unlawful" is not a cause of action under the APA. The complaint does not reference APA statutory language.

⁵ The complaint fails to identify a particular section of the APA that has been violated and thus there is no reference to statutory language.

⁶ The significant delay between the filing of the complaint and the due date for the government's answer is due to the fact that the government was not properly served with the lawsuit until September 15, 2016.

⁷ The significant delay between the filing of the complaint and the filing of the government's answer is due to the fact that the government was not properly served with the lawsuit until August 4, 2016.

⁸ Raising a defense such as a lack of standing to challenge the regulation, as the FDA as done here, must be done by motion before an answer is filed. Fed.R.Civ.P. 12(b). If the court denies this motion, the FDA has 14 days to answer the complaint. Fed.R.Civ.P. 12(a)(4).

⁹ The significant delay between the filing of the complaint and the due date for the government's answer is due to the fact that the government was not properly served with the lawsuit until September 29, 2016.

¹⁰ The complaint fails to identify a particular section of the APA that has been violated and thus there is no reference to statutory language.

¹¹ The significant delay between the filing of the complaint and the due date for the government's answer is due to the fact that the government was not properly served with the lawsuit until August 29, 2016.