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 a brief overview of lawsuits challenging the FDA's deeming rule that attempts to accurately summarize 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.

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, as well as requesting that the court 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 may file a motion for summary judgment[2] by July 8, 2016. The RSF Plaintiffs may file their own motion for summary judgment related to any unique claims by July 25, 2016. The FDA must respond to those motions and file a cross-motion for summary judgment by August 16, 2016. Plaintiffs' consolidated reply is due August 26, 2016. The FDA's reply must be filed by September 9, 2016, and a hearing on the motions is scheduled for October 19, 2016.

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 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;
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, as well as requesting that the court permanently strike down the rule. The FDA must answer this complaint by July 22, 2016. Lost Art Liquids may then file a reply with the court by August 12, 2016.

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 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.

John Middleton Co. LLC v. U.S. Food and Drug Administration

No:16-cv-996 (D.D.C. 2016)

On May 26, 2016, John Middleton Co. LLC, a Pennsylvania company and 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. John Middleton has requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds, as well as requesting that the court permanently strike down the rule. The FDA's answer is due July 26, 2016, and John Middleton may then file a reply by August 16, 2016.

The lawsuit alleges that:

1) the rule indiscriminately prohibits the use of the modified risk descriptor "mild," an action that is "arbitrary and capricious," a violation of the APA;
2) the rule's prohibition on the use of the modified risk descriptor "mild" for cigars and pipe tobacco is not based on reliable evidence, an action that is "arbitrary and capricious," a violation of the APA;
3) the FDA did not explain why it rejected alternatives to prohibiting the use of the modified risk descriptor "mild," an action that is "arbitrary and capricious," a violation of the APA;
4) the FDA failed to respond to comments addressing the prohibition on the use of the modified risk descriptor "mild," an action that is "arbitrary and capricious," a violation of the APA;
5) the rule's prohibition on the use of the modified risk descriptor "mild" is a content-based speech restriction in violation of the First Amendment's protection of free speech; and
6) the rule's prohibition on the use of the modified risk descriptor "mild" amounts to a taking of John Middleton's trade name "Black & Mild," a violation of the Fifth Amendment's protection from unlawful governmental takings.

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. Icaza has requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds, as well as requesting that the court permanently strike down the rule. The FDA must answer this complaint by August 1, 2016. Icaza may then file a reply with the court by August 22, 2016.

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, as well as requesting that the court permanently strike down the rule. The FDA's answer is due August 9, 2016, Faircloth may then file a reply with the court by August 30, 2016.

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.

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.