



First Amendment Issues in Advertising and Product Packaging

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First Amendment

*Congress shall make no law . . .
abridging the freedom of speech, or of
the press*

United States v. United Foods

533 U.S. 405

“The fact that speech is in aid of a commercial purpose does not deprive respondent of all First Amendment Protection.”

Central Hudson Gas & Electric v. PSC

447 U.S. 557

“For commercial speech to come within [First Amendment protection], it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.”

Central Hudson Gas & Electric v. PSC

447 U.S. 557

- 1) Is speech concerning lawful activity and not misleading?
- 2) Is government interest substantial?
- 3) Does regulation directly advance government interest asserted?
- 4) Is regulation more extensive than necessary to serve government interest?

Rubin v. Coors Brewing Co.

514 U.S. 476

- Government must show regulation advances interest “in a direct and material way”
- Burden “not satisfied by mere speculation or conjecture”
- Government “must demonstrate that harms it recites are real and that its restrictions will alleviate them to a material degree.”

Thompson v. Western States Med. Ctr.

535 U.S. 357

“We have . . . rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.”

Expressions Hair Design v. Schneiderman

137 S.Ct. 1144

“In regulating the communication of prices rather than the prices themselves. [the law] regulates speech.”

FDA Regulation of “Tobacco” Products



FDA Regulation of “Tobacco” Products

- “Modified Risk” claims
- Smoking Cessation Claims

Nicopure Labs v. FDA

(D.D.C. July 2017)

- Ban on distribution of free samples regulates conduct, not speech.
- Prohibition on unapproved, “truthful and misleading” modified-risk claims upheld.

Pearson v. Shalala

164 F.3d 650

“when government chooses a policy of suppression over disclosure-at least where there is no showing that disclosure would not suffice to cure misleadingness-government disregards a ‘far less restrictive’ means.”

FDA Regulation of “Tobacco” Products



Modified-risk tobacco product: represents “explicitly or implicitly” that

- Tobacco product presents a lower-risk of tobacco-related disease or is less harmful than other commercially marketed tobacco products, or
- Contains a reduced level of a substance or presents reduced exposure, or
- The tobacco product or its smoke does not contain or is free of a substance.

21 U.S.C. §387k(b)(2)(A)(i)



Product likely MRTP if producer says:

- “contains less nicotine”
- “healthier alternative to smoking”

82 Fed Reg. 2205



“the inhalation of nicotine (i.e. nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products”

81 Fed. Reg. 28981



“several studies support the notion that the quantity of toxicants [in e-cig vapor] is significantly less than those in tobacco cigarettes and tobacco smoke and similar to those contained in recognized nicotine-replacement therapies”



Drug or Device?

“statements related to quitting smoking generally create a strong suggestion that a product is intended for a therapeutic purpose.”



“there is emerging data that some individual smokers may potentially use ENDS to transition away from combustible tobacco products”

81 Fed. Reg. 29037

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