Cigarette Graphic Warnings and the Divided Federal Courts

Introduction

In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). Among the many tobacco control powers delegated to the Food and Drug Administration (FDA) under this law, Congress mandated that the FDA adopt a rule requiring new graphic warnings on cigarette packages and advertisements. Published in June 2011, the FDA’s final rule required that colored graphic warnings cover fifty percent (50%) of the front and back of each cigarette package sold in the U.S and twenty percent (20%) of cigarette advertisements. This regulation is consistent with required warning labels on cigarette packages in a number of other countries, including Canada, Australia, Brazil, and Thailand.

As many in the public health community are aware, following the regulation’s adoption, tobacco companies filed two separate legal challenges to the graphic warning requirements. On August 31, 2009, five tobacco manufacturers and one retailer filed suit in U.S. District Court for the Western District of Kentucky to challenge several provisions of the Tobacco Control Act. This case, *Discount Tobacco City & Lottery, Inc. v. United States (Discount Tobacco)*, upheld Congress’s mandate that the FDA require graphic warning labels. This decision was upheld on appeal to the U.S. Court of Appeals for the Sixth Circuit.

On August 16, 2011, five tobacco manufacturers filed suit in the U.S. District Court for the District of Columbia to challenge the FDA’s final regulation governing graphic warning labels for cigarettes. In this case, *R.J. Reynolds Tobacco Co. v. U.S. Food and Drug Administration (R.J. Reynolds)*, the court found that the graphic warning rule unconstitutionally limited the tobacco companies’ right to freedom of speech. On appeal, the U.S. Court of Appeals for the D.C. Circuit upheld the district court’s finding that the graphic warning requirement was unconstitutional. The federal government decided not to appeal this decision to the U.S. Supreme Court.

This document will provide some clarity about the differences between the two cases and the implications for a potential graphic warning rule in the future.

Statutes vs. Regulations
In examining these two cases, it is important to understand the distinction between the types of laws that were challenged in each case. In *Discount Tobacco*, the plaintiffs challenged the Tobacco Control Act itself, while the plaintiffs in *R.J. Reynolds* challenged a regulation that was promulgated by the FDA under the authority delegated to the agency by the Tobacco Control Act. This distinction has important implications.

The Constitution authorizes Congress to create laws with respect to some subjects, while limiting Congress from creating laws with respect to other subjects. When a bill is passed by both houses of Congress and signed by the President, that bill becomes a law. Permanent laws created by the federal legislative branch are called statutes. These statutes are compiled to form the United States Code, which is a collection of all federal statutes.

Federal executive agencies, such as the FDA, are authorized by statutes to create laws with respect to certain subjects. With the passage of the Tobacco Control Act, Congress delegated specific powers to the FDA to regulate the manufacture, marketing, and distribution of tobacco products. When a federal executive agency promulgates a rule, through a process called rulemaking, that rule becomes law. Rules created by federal executive agencies are compiled to form the Code of Federal Regulations, which is a collection of all rules from all federal executive agencies.

Both statutes and regulations have the “force of law,” meaning that they are binding on all U.S. citizens once they take effect and can be enforced if they are broken. However, the power of a federal executive agency, like the FDA, to make regulations is more limited than the power of Congress to make statutes. The FDA’s statutory authority to regulate tobacco products is derived from the Tobacco Control Act and so it is also limited from taking any actions outside of that delegated authority.

Additionally, the rulemaking power of federal executive agencies is limited by the Administrative Procedures Act (APA), a set of statutes that govern the conduct of all executive agencies. The APA allows the judicial branch to invalidate agency actions that are arbitrary and capricious, in violation of the Constitution, in excess of statutory authority, in breach of required procedure and, in some cases, unsupported by substantial evidence or unwarranted by the facts.

In the context of the graphic warning cases, the most important distinction is that one lawsuit (*Discount Tobacco*) is a challenge to a statute, while the other (*R.J. Reynolds*) is a challenge to a regulation. As a result, there is a difference in what is at stake in these two cases – the FDA’s authority to issue any rule requiring graphic warnings (*Discount Tobacco*), versus the validity of the specific graphic warning rule that the FDA issued in 2011 (*R.J. Reynolds*). In addition, this distinction is likely to influence the willingness of a court to defer to the expertise of the lawmakers (Congress, in *Discount Tobacco*, and the FDA, in *R.J. Reynolds*).

**Current State of the Law**

**Overview of the Cases**

*Discount Tobacco*

In *Discount Tobacco*, the Sixth Circuit upheld the provisions of the Tobacco Control Act that authorized and directed the FDA to issue a rule requiring large, graphic warnings to be placed on
cigarette packages and advertisements. The Act requires color pictorial images showing the health effects of smoking to appear on top half of all cigarette packs, and twenty percent (20%) of the upper portion of cigarette advertisements, along with new textual warnings. The companies argued that these provisions were overly restrictive and infringed upon their free speech rights under the First Amendment.

In January 2010, Judge Joseph H. McKinley, Jr. of the U.S. District Court for the Western District of Kentucky upheld the graphic warning label requirements, along with other key provisions of the Tobacco Control Act. Judge McKinley found that the “content and format” of the warning labels were justified in light of evidence that consumers do not pay attention to current warnings, and ruled that the warnings were not too burdensome because the companies retain half of the space on the cigarette packs and eighty percent (80%) of cigarette advertisements for their own speech. The tobacco companies appealed this ruling to the U.S. Court of Appeals for the Sixth Circuit. In March 2012, a three-judge panel upheld Judge McKinley’s ruling on the graphic warning label requirements. The appeals court ruled that the graphic warnings do not “impose any restrictions on the [tobacco companies’] dissemination of speech, nor do they touch upon plaintiff’s core speech.” The court also held that the textual warnings mandated by the Tobacco Control Act were “reasonably tailored to overcoming the informational deficit regarding tobacco harms.”

While the tobacco companies appealed this decision to the U.S. Supreme Court, the Court declined to hear the case rendering the appeals court’s verdict final.

R.J. Reynolds

In contrast, the U.S. Court of Appeals for the D.C. Circuit found in R.J. Reynolds that the graphic warning rule created by the FDA pursuant to the Tobacco Control Act did violate the tobacco companies’ First Amendment rights.

In June 2011, the FDA issued its final rule mandating graphic warning labels on cigarette packages and advertisements. Nine graphic warning images were selected by the FDA, and the tobacco companies were to be required to display these warnings on a rotating basis. Among these images were a man smoking through a hole in his throat, and a cadaver with chest staples. Two months after the rule was issued, five major tobacco companies filed suit, challenging the FDA’s graphic warning rule, arguing that it forced them to convey the government’s message about smoking and advocate against their own product.

In February 2012, U.S. District Court Judge Richard J. Leon held that the FDA’s graphic warning rule violated the tobacco companies’ First Amendment rights. The court took issue with the size of the mandated warning labels and concluded that the government has other means of discouraging smoking at its disposal. The FDA appealed this decision to the U.S. Court of Appeals for the D.C. Circuit. In a split ruling, the appeals court found that the rule violated the First Amendment. Two members of the panel ruled that the warning labels exceeded the proper scope of government authority to “force the manufacturer of a product to go beyond making purely factual and accurate commercial disclosures and undermine its own economic interest.” The majority also ruled that the FDA failed to prove that the labels would “directly cause” a decrease in smoking rates in the United States.
**Differing Application of First Amendment Reasoning**

To a significant extent, the opposing outcomes of the Sixth Circuit and the D.C. Circuit on the constitutionality of the graphic warning label requirements can be traced to their differing interpretations of the First Amendment in the context of commercial speech.

*Discount Tobacco*

Commercial speech is economic in nature, and relates to communications or advertising for a business or a product. The intent of commercial speech is to encourage individuals to take a specific action, often purchasing a specific product. Commercial speech is protected under the First Amendment but to a lesser degree than political or religious speech. Courts review laws regulating commercial speech under different standards depending on the nature of the regulation, such as whether the law restricts speech or whether it compels a disclosure of factual information.

In *Discount Tobacco*, the Sixth Circuit’s analysis turned on the majority’s characterization of the Act’s graphic warning requirements as a compelled disclosure of factual information, rather than a restriction on commercial speech. The majority recognized that there are “myriad graphic images” that, like textual warnings, would provide “undisputed factual information about the health risks of using tobacco products.” Based on this analysis, the court applied the standard set forth in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*.

The Sixth Circuit Court of Appeals found that under the *Zauderer* standard, disclosure requirements do not violate the First Amendment if they are reasonably related to a government interest in preventing consumer deception. The court determined that the government did establish such a relationship based, first, on the tobacco industry’s extensive, documented history of deception regarding the health risks of smoking, noting that “[t]obacco manufacturers and tobacco-related trade organizations . . . knowingly and actively conspired to deceive the public about the health risks and addictiveness of smoking for decades.” Moreover, the court found that “[tobacco company] advertising promoting smoking deceives consumers if it does not warn consumers about tobacco’s serious health risks.” Based on the body of empirical evidence addressing the public’s understanding of the health risks of smoking, the court found that existing warnings fail to adequately prevent tobacco company advertising from being deceptive:

> Faced with evidence that the current warnings ineffectively convey the risks of tobacco use and that most people do not understand the full risks, the Act’s new warnings are reasonably related to promoting greater public understanding of the risks. A warning that is not noticed, read, or understood by consumers does not serve its function. The new warnings rationally address these problems by being larger and including graphics.

While the court found this reasoning sufficient to support the constitutionality of the Act’s graphic warning requirements, the court also found that “abundant evidence [including evidence from other countries who have implemented graphic warning labels] establishes that larger warnings incorporating graphics promote a greater understanding of tobacco-related health risks and materially affect consumers’ decisions regarding tobacco use.” Thus, the Sixth
Circuit Court of Appeals found that the Tobacco Control Act’s graphic warning requirements were permissible under the First Amendment.

**R.J. Reynolds**

In *R.J. Reynolds*, the D.C. Circuit applied a different standard for analyzing whether the FDA’s graphic warning rule violated the First Amendment. The D.C. Circuit stated that the *Zauderer* standard for misleading speech applies only when the government “affirmatively demonstrates that an advertisement threatens to deceive customers.” The court then looked specifically to the cigarette packages rather than the entire context of the history of cigarette advertising and stated that “in the absence of any congressional findings on the misleading nature of the cigarette packaging itself, there is no justification under *Zauderer* for the graphic warning labels.”

After finding that the *Zauderer* standard should not apply to graphic warnings, the D.C. Circuit found that the FDA’s graphic warning rule should be analyzed under the *Central Hudson* test for regulation of non-misleading commercial speech. “Under *Central Hudson*, the government must show that its asserted interest is ‘substantial.’ If so, the Court 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.’”

The Court of Appeals for the D.C. Circuit ultimately found that the FDA’s graphic warning rule did not pass the *Central Hudson* test and was therefore an unconstitutional limitation on the tobacco company’s commercial speech. According to the court, the only “explicitly asserted interest in either the Proposed or Final Rule is an interest in reducing smoking rates” by discouraging nonsmokers from starting to smoke and encouraging current smokers to quit.

While the FDA asserted that its actual interest in the rule was in “[effectively communicating health information] regarding the negative effect of cigarettes,” the court dismissed this argument by characterizing this interest as “merely a description of the means by which [the FDA] plans to accomplish its goal of reducing smoking rates, and not an independent interest capable of sustaining the Rule.”

Although the majority conceded that the governmental goal of reducing smoking may be “a substantial interest,” the court held that the rule was ultimately unconstitutional because the FDA failed to show that the graphic warning rule would directly advance this interest. The majority concluded that the FDA did not provide “a shred of evidence” that the graphic warnings would actually lower smoking rates. That is, the court found that the FDA did not show “substantial evidence” that the graphic warnings would “directly” reduce smoking rates by a “material degree.” It found that there was “no evidence showing that [graphic] warnings have directly caused a material decrease in smoking rates in any of the countries that now require [large graphic warnings].” Additionally, while “[s]ome Canadian and Australian studies indicated that large graphic warnings might induce individual smokers to reduce consumption, or to help persons who have already quit smoking remain abstinent,” the studies “did not purport to show that the implementation of large graphic warnings has actually led to a reduction in smoking rates.”
Conflicting Attitudes towards Scientific Studies and Deference to the FDA

In its decision to uphold the graphic warning labels under the Tobacco Control Act, the Court of Appeals for the Sixth Circuit afforded a high degree of deference to the government’s factual determinations. This deference is most clearly seen in the way the court relied upon the government’s scientific findings to support the legitimacy of the Act’s graphic warning label requirements. By contrast, in RJ Reynolds, the Court of Appeals for the D.C. Circuit was skeptical of all the evidence set forth by the FDA, and engaged in its own evaluation of the FDA’s research methods.

In Discount Tobacco, the Sixth Circuit underscored the continuing need for effective tobacco regulation, particularly with respect to juvenile tobacco use, by beginning its analysis with a brief history of tobacco legislation. The court preface its analysis of the constitutional issues presented in the case with a restatement of the first four legislative findings made by Congress in establishing the Tobacco Control Act:

(1) the use of tobacco products by the Nation’s children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults; (2) virtually all new users of tobacco products are under the minimum legal age to purchase such products; (3) past efforts to restrict advertising and marketing of tobacco products have failed to adequately curb tobacco use by adolescents and (4) advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth.49

The Sixth Circuit succinctly summarized the effect of the abundant scientific findings provided by the government.

The government, in this case, has filed thousands of pages of medical studies and governmental reports supporting the conclusion that the use of tobacco, especially by juveniles, poses an enormous threat to the nation’s health, and imposes grave costs on the government. The government has supplemented this information with copious documentation of the practices used by the industry oftentimes directly aimed at juveniles and other times seriously effecting them, to maintain and increase tobacco use and dependency.50

More specifically in the context of graphic warnings, the Sixth Circuit recognized that “ample evidence establishes that current warnings do not effectively inform consumers of the health risks of tobacco use and that consumers do not understand these risks” and considered this evidence against the “backdrop” of tobacco’s devastating health effects, including “the undisputed fact that [the tobacco companies’] products literally kill users and, often, members of the families of users.”51

The D.C. Circuit’s attitude towards the FDA’s scientific findings in R.J. Reynolds stands in sharp contrast to that of the Sixth Circuit in Discount Tobacco. While the Sixth Circuit was convinced by the government’s extensive scientific findings on the continuing and pervasive threat posed by tobacco use, the FDA’s studies and statistics failed to convince the D.C. Circuit that graphic warning labels were appropriate.
In the promulgation of the graphic warning rule, the FDA based its selection of the nine images for the graphic warning labels on an 18,000 person internet-based consumer study.\textsuperscript{52} While the FDA relied on this study, as well as substantial research showing the effectiveness of similar health warnings in other countries, the D.C. Circuit was not convinced. Instead, it questioned the FDA’s findings, and pointed to public comments “including comments from cancer researchers, nonprofits, and academics” who criticized the government’s “single exposure study design, noting it prevented the government from assessing the long-term, or actual effects of the proposed warnings.”\textsuperscript{53} While the FDA argued that the “existing scientific literature ‘provides a substantial basis for our conclusion that the required warnings will effectively communicate the health risks of smoking, thereby encouraging smoking cessation and discouraging smoking initiation;’” the court was unconvinced.\textsuperscript{54}

The court went on to question the FDA’s statistical evidence. It relied on the public comments of the tobacco companies who were challenging the regulation for the proposition that there was a “lack of statistical evidence supporting the FDA’s belief that requiring cigarette packages to bear graphic warnings would reduce smoking rates.”\textsuperscript{55} The tobacco companies specifically challenged Canadian smoking rate data. The FDA disagreed with this characterization of its statistical evidence and noted that the data from Canada “showed that the warnings have been ‘effective at providing . . . smokers with health information, making consumers think about the health effects of smoking, and increasing smokers’ motivations to quit smoking.’”\textsuperscript{56}

Despite the FDA’s various studies and statistics, the D.C. Circuit found no evidence to support the graphic warning rule: “FDA has not provided a shred of evidence...showing that the graphic warnings will ‘directly advance’ its interest in reducing the number of Americans who smoke.”\textsuperscript{57} The court was unconvinced by the evidence that was presented, noting that the “FDA’s reliance on this questionable social science is unsurprising when we consider the raw data regarding smoking rates in countries that have enacted graphic warnings. FDA claims that Canadian national survey data suggest that graphic warnings may reduce smoking rates. But the strength of the evidence is underwhelming, making FDA’s claim somewhat misleading.”\textsuperscript{58}

With Two Conflicting Decisions – What Happens Next?

The existence of two conflicting decisions on the graphic warning issue has created confusion in the public health community and delayed FDA’s implementation of a graphic warning label requirement. When a graphic warning rule is implemented depends entirely on the actions of the FDA. In March 2013, the federal government announced its decision not to appeal the ruling in \textit{R.J. Reynolds} to the U.S. Supreme Court.\textsuperscript{59} Instead, the FDA stated that the agency plans to develop and issue a new graphic warning rule, essentially starting the rulemaking process from scratch.

There is no longer any question as to whether The FDA has the authority to promulgate a graphic warning rule, as this issue was decided in \textit{Discount Tobacco}. On April 22, 2013, the Supreme Court announced its decision not to review the ruling of the D.C. Circuit’s decision,\textsuperscript{60} solidifying the constitutionality of the Tobacco Control Act’s requirement of graphic warning labels for cigarette packaging and advertisements.

In addition, the adverse ruling in \textit{R.J. Reynolds} may no longer provide precedence to a potential litigation challenge to another FDA graphic warning rule. On July 29, 2014, the U.S. Court of
Appeals for the D.C. Circuit, sitting en banc (all judges in the circuit, rather than a standard three-judge panel heard the case), explicitly overruled the decision in *R.J. Reynolds* that the *Zauderer* standard can only be applied in cases where the government’s interest is in correcting deception. One of the significant differences in the outcomes of *Discount Tobacco* and *R.J. Reynolds* is a result of the court’s application of the lesser *Zauderer* standard in *Discount Tobacco* and the more stringent *Central Hudson* test in *R.J. Reynolds*. While there is certainly no guarantee that a court would uphold an FDA graphic warning rule under the *Zauderer* standard, the application of this standard would lower the government’s burden in any ensuing litigation.

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**Notes**

1. Family Smoking Prevention and Tobacco Control Act, 21 U.S.C.A. §§ 387–387u (West 2009); Pub. L. No. 111-31, 123 Stat. 1776 (2009); (I keep seeing this in our publications, and I don’t know why we keep citing to these particular regulations when referring to the Tobacco Control Act generally and citing it for the first time.)

2. For the purposes of this document, the terms “rule” and “regulation” are interchangeable. Both terms refer to legislative rulemaking where Congress has specifically delegated to a federal executive agency the authority to create laws regulating a specific subject matter.


6. Discount Tobacco City & Lottery, Inc.; Lorillard Tobacco Company; National Tobacco Company, L.P.; R.J. Reynolds Tobacco Company; Commonwealth Brands, Inc.; and American Snuff Company, LLC.


8. This document will refer to this case as *Discount Tobacco*, the name under which the Court of Appeals heard the case. The district court decision in this case is known as *Commonwealth Brands* and upon any potential review by the Supreme Court, the case will be called *American Snuff*.


10. R.J. Reynolds Tobacco Company; Lorillard Tobacco Company; Commonwealth Brands, Inc.; Liggett Group LLC; and Santa Fe Natural Tobacco Company, Inc.


17 1 U.S.C. § 1 ff.


19 Under the Supremacy Clause of the U.S. Constitution (U.S. CONST. art. VI, cl. 2) statutes enacted by Congress have the force of law: “[t]he laws of the United States are the supreme ‘law of the land’ binding on every citizen and every court and enforceable wherever jurisdiction is adequate for the purpose.” Miles v. Illinois Cent. R. Co., 315 U.S. 698 (1942). Rules/regulations promulgated by a federal executive agency also have the force of law if properly issued; “it seems to be established that ‘regulations’, ‘substantive rules’ or ‘legislative rules’ are those which create law, usually implementary to an existing law.” Gibson Wine Co. v. Snyder, 194 F.2d 329, 331 (D.C. Cir. 1952).


22 Commonwealth Brands, 678 F.Supp.2d at 541.

23 Id. at 530-31.

24 Id. at 531.

25 Discount Tobacco, 674 F.3d at 527.

26 Id. at 530.


29 R.J. Reynolds, 696 F.3d at 1212.

30 Id. at 561.

31 Id.

33 For more information about the Zauderer standard, refer to Tobacco Control Legal Consortium, Regulating Tobacco Marketing: “Commercial Speech” Guidelines for State and Local Governments 6-7 (2010), available at http://publichealthlawcenter.org/sites/default/files/resources/tclc-guidelines-speech-2010.pdf. It should be noted that not all courts have limited Zauderer to apply only to cases involving consumer deception or potential deception. See, e.g., Nat’l Elec. Mfrs. Ass’n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001) (applying Zauderer where interest was “protecting human health and the environment from mercury poisoning”); Pharm. Care Mgmt. Ass’n v. Rowe, 429 F.3d 294, 310 & n.8 (1st Cir. 2005) (applying Zauderer where state’s asserted interest was “ensuring that its citizens receive the best and most cost-effective health care possible,” and noting “we have found no cases limiting Zauderer” to potentially deceptive advertising”).

34 Discount Tobacco, 674 F.3d at 562.

35 Id.

36 Id. at 564.

37 Id. at 564.

38 Id. at 565.

39 R.J. Reynolds, 696 F.3d at 1214.

40 Id. at 1214-15.

41 Id. at 1217.

42 Id. at 1218.

43 Id. at 1221.

44 Id. at 1222.

45 Id. at 1219.

46 Id. at 1220.

47 Id. at 1219.

48 Id.

49 Discount Tobacco, 674 F.3d at 520.

50 Id. at 519.

51 Id. at 569.

52 R.J. Reynolds, 696 F.3d at 1209.

53 Id. at 1210.
54 Id.

55 Id.

56 Id. at 1210-11 (formatting in original).

57 Id. at 1219.

58 Id.

59 Dennis, supra note 13.

60 Am. Snuff Co. 133 S. Ct. at 1996.