CHAPTER 5

COMMONWEALTH BRANDS, INC., ET AL. v. UNITED STATES ET AL.

MICHAEL H. HINCKLE AND
CAROLINA M. HEAVNER

I. Why It Made the List

Commonwealth Brands, Inc. v. United States[1] is included in this edition primarily because of its place in history as the opening salvo in what is certain to be a lengthy and hard-fought legal battle over the Food and Drug Administration's (FDA's) regulation of tobacco products and the interpretation of the Family Smoking Prevention and Tobacco Control Act[2] (the Tobacco Act). The legal significance of the District Court decision discussed in this chapter is likely to be overshadowed by the appellate court opinions that are probable to occur in the coming months and years. Nevertheless, the District Court's holding in ***Commonwealth Brands*** is significant in that it raises constitutional issues that have not been seriously considered by food and drug attorneys for decades. The Tobacco Act also provides a new vehicle for litigation over old issues created by the enactment of the Federal Food, Drug, and Cosmetic Act (FDCA), including the regulation of articles based on intended use and the extent to which the government may prohibit truthful and non-misleading speech. How the courts resolve the issues surrounding the new Tobacco Act will likely have far-reaching implications for other products subject to regulation under the FDCA. For that reason alone, the ***Commonwealth Brands*** case deserves the careful consideration of all members of the Food and Drug Bar.

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1 No. 1:09-CV-117-M, 2010 WL 65013 (W.D. Ky. Jan. 5, 2010).

2 Pub. L. No. 111-31, 123 Stat. 1776 (2009).

II. Facts of Case

On August 31, 2009, just two months after the enactment of the Tobacco Act, five tobacco product manufacturers (Commonwealth Brands, Inc., Conwood Company, LLC, Lorillard Tobacco Company, National Tobacco Company, L.P. and R.J. Reynolds Tobacco Company) and a retailer of tobacco products (Discount Tobacco City and Lottery, Inc.) (hereafter referred to as plaintiffs) filed a complaint against FDA alleging that the labeling and advertising provisions of the Tobacco Act violated their rights under the U.S. Constitution. Specifically, the plaintiffs alleged that the law infringed on their First Amendment right to engage in commercial speech, their Fifth Amendment due process rights, and effected an unconstitutional taking of their property under the Fifth Amendment.

The Tobacco Act, which granted FDA the power to regulate tobacco products, was signed into law by President Barack Obama on June 22, 2009. Included within FDA's new broad scope of regulatory authority and responsibility with respect to tobacco products was the authority to develop and enforce stringent labeling requirements, ingredient disclosure, and advertising limitations.

The Tobacco Act's labeling requirements compel tobacco product packaging to prominently display one of several warnings describing the adverse health effects caused by using such products.[3] Such warnings must be located in the upper portion of the front and rear panels of the cigarette package and must comprise the top 50 percent of the front and rear panels.[4] For smokeless tobacco products, the warnings must be located on the two principal display panels of the package and must comprise at least 30 percent of each display panel.[5] In addition, the law requires that, before June 22, 2011, FDA issue regulations that "require color graphics depicting the negative health consequences of smoking" to accompany the required textual warnings on cigarette packages.[6] The Tobacco Act does not require that the textual warnings on packages of smokeless tobacco products be accompanied by color graphic images, but it empowers FDA to issue regulations requiring such images.[7]

The Tobacco Act also further restricts advertising activities for tobacco products. First, FDA must issue a final rule requiring that any labeling or advertising for cigarettes or smokeless tobacco by any manufacturer, distributor or retailer be restricted to black text on a white background, with certain exceptions for adult facilities and publications.[8] This ban on color or graphic images does not apply to adult publications that are read by fewer than 2 million

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3 *See* Pub. L. No. 111-31, § 201(a) (amending Section 4 of 15 U.S.C. § 1333).
4 *Id.*
5 *Id.* at § 204(a) (amending Section 3 of 15 U.S.C. § 4402).
6 *Id.* at § 201(a).
7 *Id.* at § 205(a).
8 *Id.* at § 102(a)(2) (adopting 21 C.F.R. § 897.32(a)).

persons younger than 18 years of age and whose readers younger than 18 years of age constitute 15 percent or less of the total readership.[9]

Second, the Tobacco Act requires FDA to issue regulations that a) prohibit the sponsorship of athletic, musical, artistic or other social or cultural events in the brand name or other indicia of tobacco product identification; b) prohibit the marketing, licensing, distribution or sale of any item or service which bears the brand name or other indicia of tobacco product identification; and c) prohibit the offer of any gift in consideration for the purchase of a tobacco product.[10] Third, FDA must issue regulations prohibiting any outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters or placards, placed within 1,000 feet of the perimeter of any public playground, elementary school or secondary school, subject to any modifications deemed appropriate in light of governing First Amendment case law,[11] including the decision of the U.S. Supreme Court in *Lorillard Tobacco Company v. Reilly*.[12]

Fourth, the Tobacco Act prohibits any express or implied statement or representation conveying that a tobacco product is approved by FDA, that FDA deems the product to be safe for use by consumers or that the product is endorsed by FDA for use by consumers, or that the product is safe or less harmful by virtue of its regulation or inspection by FDA, or its compliance with any regulatory requirements set by FDA.[13] With respect to modified risk tobacco products, the Tobacco Act prohibits the labeling or advertising of a tobacco product from explicitly or implicitly stating that the product is less harmful than other commercially marketed products, contains a reduced level of a substance or presents a reduced exposure to a substance, or that the tobacco product or its smoke does not contain or is free of a substance, without prior FDA approval of the product as a "modified risk" tobacco product.[14]

Finally, the Tobacco Act allows for the enactment of more stringent regulations pertaining to the marketing and sale of tobacco products by federal agencies, state and local governments, and Indian tribes.[15]

III. Court Ruling

On January 5, 2010, acting on crossmotions for summary judgment, the U.S. District Court for the Western District of Kentucky struck down as unconstitutional the Tobacco Act's ban on color and graphics in labels and advertising and the ban on claims implying that a

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[9] *Id.*

[10] *Id.* (adopting 21 C.F.R. § 897.34).

[11] *Id.* (adopting 21 C.F.R. § 897.30(b)).

[12] 533 U.S. 525 (2001).

[13] *Id.* at § 103(b)(13).

[14] *Id.* at § 101(b) (amending the FDCA (21 U.S.C. §§ 301 *et seq.*) to add § 911(b)(2)(A)).

[15] *Id.* at §101(b) (amending the FDCA to add 21 U.S.C. § 916), and § 203 (amending the Federal Cigarette Labeling and Advertising Act to add 15 U.S.C. § 1334(c)).

tobacco product is safer because of its regulation by FDA.[16] While the District Court struck down these provisions as unconstitutional, it upheld several other provisions of the Tobacco Act. The authors discuss these other provisions below.

IV. Rationale for Decision

A. District Court's Rationale for Finding the Ban on Color and Graphics and the Ban on Claims That Imply FDA Approval Unconstitutional

1. Ban on Color and Graphics

The plaintiffs in *Commonwealth Brands* alleged that the Tobacco Act creates a "blanket" prohibition against the use of color and imagery in the labeling and advertising of tobacco products, thus violating their right to freedom of speech under the First Amendment.[17]

In defending the validity of this provision, FDA argued that the ban was "carefully tailored" to address the particular advertising and promotion practices, such as imagery and color, which appeal to youth.[18] The plaintiffs countered by emphasizing the power of images, brand symbols and color to communicate important commercial information about their products.[19]

Where a statute regulates commercial speech it must satisfy the requirements set forth in *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York*.[20] In commercial speech cases, courts apply a four-part analysis.[21] First, the court determines whether the expression is protected by the First Amendment by assessing whether the speech concerns lawful activity and is not misleading.[22] Commercial speech that is not accurately informing the public about lawful activity is not protected by the First Amendment.

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[16] *See Commonwealth Brands*, No. 1:09-CV-119-M, 2010 WL 65013 (W.D. Ky. Jan. 5, 2010).

[17] As previously noted, the Tobacco Act directs FDA to issue a final rule requiring that any labeling or advertising for tobacco products be restricted to black text on a white background, with certain exceptions for adult-only facilities and magazine advertising if less than 15 percent of the magazine's readership is under the age of 18 and if the magazine is read by fewer than 2 million persons 18 years or younger. *See* Pub. L. No. 111-31 at § 102(a)(2) (adopting 21 C.F.R. § 897.32(a)).

[18] *See* Defendant's Motion for Summary Judgment at 39 (hereafter referred to as Government's Brief), No. 1:09-CV-119-M (W.D. Ky. Nov. 30, 2009) (citing Bates v. State Bar of Arizona, 433 U.S. 350, 364 (1977) and Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 563 (2001)).

[19] *See* Memorandum in Opposition to Defendant's Motion for Summary Judgment at 13 (hereafter referred to as Plaintiff's Brief), No. 1:09-CV-119-M (W.D. Ky. Dec. 14, 2009); *see also Commonwealth Brands*, 2010 WL 65013 at *6.

[20] 447 U.S. 557 (1980).

[21] *Id.* at 566.

[22] *Id.*

Second, the court determines whether the asserted governmental interest is substantial.[23] If both inquiries yield positive answers, the court then determines "whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest."[24]

In applying this four-part test to the facts of *Commonwealth Brands*, the District Court quickly disposed of the first three parts of the test. Because tobacco products remain lawful for adult users, tobacco advertising and labeling aimed at adults is lawful activity that meets the first prong of *Central Hudson*. Likewise, the court quickly determined that the Tobacco Act's stated objective of preventing the use of tobacco products by minors was a "substantial government interest" and that the law's restrictions directly advance that interest—thus fulfilling the second and third parts of the test. As a result, the District Court's First Amendment analysis focused on whether the Tobacco Act's speech restrictions were "more extensive than is necessary to serve that interest."

Upon considering the facts, the District Court held that the Tobacco Act's ban on all uses of color and imagery was not sufficiently tailored to serve the government's interest of preventing youth tobacco use.[25] Although the District Court acknowledged the government's evidence that colors and graphics may have a special appeal to young people and may lead such people to experiment with tobacco, the court ultimately held that the Tobacco Act's "blanket ban" on all uses of color and images in the labeling and advertising of tobacco products has a "uniformly broad sweep … [that] demonstrates a lack of tailoring."[26] Further, the District Court stated with particularity that "Congress could have exempted large categories of innocuous images and colors—e.g., images that merely identify products and producers, and colors that communicate information about the nature of a product, at least where such colors and images have no special appeal to youth."[27]

2. Ban on Claims Implying FDA Approval

Plaintiffs challenged the Tobacco Act's provision that bans[28] the mentioning of FDA's regulation of tobacco products as unconstitutional.[29] In particular, plaintiffs challenged the part of the provision that prohibits any statements directed to consumers that a tobacco product is

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[23] *Id.*

[24] *Id.*

[25] *See Commonwealth Brands,* 2010 WL 65013 at *7.

[26] *See id.* (quoting *Lorillard*, 533 U.S. at 563).

[27] *Id.*

[28] The provision prohibits "any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing that (1) the product is approved by [FDA]; (2) the [FDA] deems the product to be safe for use by consumers; (3) the product is endorsed by the [FDA] for use by consumers, or (4) the product is safe or less harmful by virtue of — (A) its regulation or inspection by the [FDA] or (B) its compliance with regulatory requirements set by" the FDA. *See* 21 U.S.C. § 331(tt).

[29] *See Commonwealth Brands,* 2010 WL 65013 at *16.

"safe" or less "harmful" by virtue of FDA regulation, inspection or by the product's compliance with any regulatory standards set by FDA.[30] Plaintiffs argued that "almost any public comment on these 'product standards,' other than perhaps a comment denigrating them, could be construed as an 'implied claim' statement that they made plaintiffs' products 'less harmful,' since that is, after all, their express purpose."[31] The District Court agreed.

The District Court rejected the government's contention that the ban would not extend to news organizations and politicians based on its "assumption that those categories of speakers would not need to make statements through the media 'directed to consumers with respect to a tobacco product.'"[32] The District Court stated how groups such as doctors, scientists, politicians, journalists and many others "could have an interest in and are capable of making statements about the effect of FDA's regulation that are 'directed to consumers with respect to a tobacco product.'"[33] Thus, the District Court concluded that the ban applied to "more than just commercial speech" and as such "must satisfy strict scrutiny."[34] In finding that this provision was "facially unconstitutional," the District Court noted it seemed clear that the ban could not be justified under such a standard of review.[35]

B. Tobacco Act Provisions Surviving Constitutional Challenge

While the District Court found two aspects of the Tobacco Act to be unconstitutional, there were several provisions that were upheld by the Court. In particular, the District Court disagreed with the plaintiff's challenge of 1) the Tobacco Act's restrictions on brand-name sponsorship and branded merchandise; 2) the Tobacco Act's authorization for "further Restrictions"; 3) the required tobacco product warnings; 4) the provision on modified risk tobacco products; 5) the regulation of outdoor advertising; 6) non-speech restriction alternatives; and 7) the restrictions on product samples, gifts with purchase, and the marketing of tobacco products in combination with non-tobacco products.

1. Brand-Name Event Sponsorship and Merchandise/Branded Merchandise

The Tobacco Act directs FDA to issue regulations prohibiting the sponsorship of athletic, musical, artistic or other social or cultural events in the brand name or other indicia of tobacco product identification.[36] The plaintiffs argued that the ban on brand-name sponsorship

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[30] *Id.*

[31] *See* Plaintiff's Brief at 34; *see also Commonwealth Brands*, 2010 WL 65013 at *16.

[32] *Id.* (citing Government's Response at 23).

[33] *Id.*

[34] *Id.* (citing United States v. Playboy Entm't Group Inc., 529 U.S. 803, 813 (2000), Bd. of Trs. of SUNY v. Fox, 492 U.S. 469, 481-482 (1989)).

[35] *Id.*

[36] *See* Pub. L. No. 111-31, § 102(a)(2) (adopting 21 C.F.R. § 897.34(c)).

is unduly broad because it is not specifically targeted toward events directed at youth.[37] In essence, the plaintiffs argued that the ban failed to meet both the third and fourth prongs of the *Central Hudson* test because it was not sufficiently targeted at youth and therefore more extensive than necessary to achieve the government's interest. The District Court disagreed, holding that the prohibition of brand-name sponsorship is a reasonable fit with the interests of the government.[38]

The District Court cited with approval sources finding that event sponsorship is a means of associating tobacco use with exciting and glamorous events, which is an associative technique particularly effective with youth.[39] Further, Congress found that the exposure of young people, including via television broadcasts, to sponsored events is "substantial" and that such televised events reach large numbers of youth "in settings that facilitate sampling and promotions and to associate the brands with the allure of racing and rodeo heroes."[40] The District Court sided with the government, discussing findings which indicate that restricting event sponsorship to events directed at (or restricted to) adults would not be effective in shielding youth from the effects of such sponsorship.[41]

With regard to branded merchandise,[42] plaintiffs contended that the ban is broader than necessary to achieve the government's interest because it prohibits the placement of a brand name on any promotional item, including those given solely to adults in adult venues.[43] The District Court disagreed and found the ban sufficiently tailored to serve the government's "substantial interest in reducing youth tobacco use by reducing youth possession of and exposure to branded merchandise."[44]

In support of its holding, the District Court cited congressional findings that there is no way to limit distribution of branded merchandise to adults only and that, even if distributed solely to adults, such adult-only distribution could nonetheless result in recipients becoming in effect walking advertisements for tobacco use, thus creating the sense that tobacco use is widely accepted and the norm.[45]

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[37] *Commonwealth Brands,* 2010 WL 65013 at *8 (citing Plaintiff's Brief at 32).

[38] *Id.*

[39] *Id.* at *7 (citing 61 Fed. Reg. 44,527 and 44,521).

[40] *Id.* (quoting 61 Fed. Reg. 44,529 and 2009 National Cancer Institute Report at 158).

[41] *See id.* at *8 (discussing the perceived inadequacy of the November 1998 Master Settlement Agreement (MSA) between certain tobacco companies and certain state Attorneys General).

[42] The Tobacco Act requires FDA to issue regulations prohibiting a manufacturer of tobacco products from marketing, licensing, distributing or selling any item or service which bears the brand name or other indicia of tobacco product identification. *See* Pub. L. No. 111-31, § 102(a)(2) (adopting 21 C.F.R. § 897.34(a)).

[43] *Commonwealth Brands,* 2010 WL 65013 at *8 (citing Plaintiff's Brief at 12).

[44] *Id.* at *9.

[45] *Id.* (citing 61 Fed. Reg. 44,526).

2. Authorization of "Further Restrictions"

Plaintiffs argued that the Tobacco Act is an unconstitutional delegation of legislative power because it authorizes federal, state, local and tribal governments to enact even more stringent regulations.[46] The District Court disagreed, holding that the Tobacco Act is not an unconstitutional delegation of legislative power because it does not "authorize" more stringent regulations; it merely "does not limit" the authority of federal, state, local and tribal governments from adopting, promulgating or enforcing any other measure with respect to tobacco products which is in addition to or more stringent than provisions of the Tobacco Act or FDA regulations.[47]

3. Tobacco Product Warnings

Plaintiffs alleged that the Tobacco Act warning requirement is unconstitutional "because it 'unjustifiably and unduly burden[s] Plaintiffs commercial speech … and unconstitutionally compel[s] Plaintiffs to disseminate the Government's anti-tobacco message."[48] Further, the plaintiffs argued that the warnings were not justified because the "Government cannot 'point to any harm that is potentially real' … that these 'warnings' are needed to remedy."[49] Plaintiffs noted that the "only conceivable harm is consumer ignorance about the health risks of smoking … [and] the record demonstrates that the public—both adults and youth—is not only fully aware of those risks, but, in fact, substantially overestimates them."[50] Plaintiffs also argued that the warnings were "too large and too prominent," and that the warning requirement must "satisfy strict scrutiny (and that it does not) because this is not a case mandating publication of 'purely factual and uncontroversial information' … ."[51]

Lastly, plaintiffs argued that the warnings constituted an unconstitutional "taking" because the warnings deprive them of "their trademarks, trade dress, packaging, and advertising without just compensation," and as such, it is "no different than if the Government confiscated half of every billboard for a message on any other issue of public policy."[52]

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[46] *Id.* (citing Tobacco Act §§ 101(b)(3) and 203).

[47] *Id.*

[48] *Id.* at *10 (citing Plaintiff's Brief at 44).The Tobacco Act requires updated warnings for cigarette packages that occupy 50 percent of the front and rear panels of the package, and include "color graphics depicting the negative health consequences of smoking to accompany the label statements." *See* 21 U.S.C. § 201(a), (d). Similar warnings are required for smokeless tobacco products. The warnings must be located on the two principal display panels of smokeless tobacco products and must comprise at least 30 percent of each display panel. *See* 21 U.S.C. § 205(a).

[49] *Id.* (citing to Plaintiffs' Brief at 45).

[50] *Id.* at *11.

[51] *Id.* at *12 (citing Plaintiffs' Brief at 50).

[52] *See* Plaintiffs' Amended Complaint for Declaratory Judgment and Injunctive Relief against all defendants at ¶¶ 66, 119, No. 1:09-CV-117-M (W.D. Ky. Sept. 21, 2009); *see also*, Plaintiffs' Brief at 52 (citing Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency, 535 U.S. 302, 324 (2002)), *Commonwealth Brands,* 2010 WL 65013 at *20.

The District Court disagreed with plaintiff's argument noting that it "rest[ed] on the idea that, since the public already appreciates the health risks associated with using tobacco products, the government's goal must be to browbeat potential tobacco consumers, including youths, over the head with its anti-tobacco message at the manufacturer's expense."[53] The District Court found that the government's goal was "not to stigmatize the use of tobacco products on the industry's dime; [but] … to ensure that the health risk message is actually ***seen*** by the consumers in the first instance."[54]

In finding that Congress's decision to revise the content and format of the tobacco warnings was justified, the District Court pointed to the 1994 report by the Surgeon General showing that empirical studies have demonstrated that the "Surgeon General's Warnings are given little attention or consideration by viewers."[55] In addition, the court noted that in 2007, the Institute of Medicine (IOM) declared that the "basic problems with the U.S. warnings are that they are unnoticed and stale, and they fail to convey relevant information in an effective way."[56] The IOM Report also noted that a study of warnings in magazine advertisements found that more than 40 percent of subjects did not even view the warning and that another 20 percent failed to read it.[57]

The District Court found plaintiffs' argument that the warnings were "too large" and "too prominent" unpersuasive. The District Court noted that Congress had "provided reasons for the particular features of the warning requirement."[58] For example, Congress had relied on the consensus achieved by the World Health Organization's Framework Convention on Tobacco Control, and the "nearly identical warning requirement in Canada."[59] Thus, the District Court rejected plaintiffs' argument that the warning provision should be subject to strict scrutiny. The District Court found that the government's message in this case was "objective and has not been controversial for many decades."[60] Therefore, the District Court concluded that "the warning requirement is sufficiently tailored to advance the government's substantial interest under *Central Hudson*."[61]

Finally, the District Court found that it lacked jurisdiction to address the merits of plaintiffs' "taking" claim.[62] Plaintiffs raised an interesting Fifth Amendment argument based on the Tobacco Act's requirement that government-mandated warning and graphic images must

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[53] *Id.* at *11.
[54] *Id.* at 12.
[55] *Id.* (citing Surgeon General's Report at 168).
[56] *Id.* (citing IOM Report at 291).
[57] *Id.*
[58] *Id.* at *12.
[59] *Id.*
[60] *Id.*
[61] *Id.* at *13.
[62] *Id.* at *20.

constitute the top 50 percent of both sides of cigarette package labels and 30 percent of both principal display panels for smokeless tobacco. According to plaintiffs, space on product labels is the "property" of the tobacco product manufacturers and that "property" cannot be taken by the government and used to convey an anti-tobacco message without providing the manufacturers with just compensation. The government countered with a jurisdictional argument claiming that "takings" claims under the Fifth Amendment must be brought in the U.S. Court of Federal Claims under the Tucker Act.[63] Plaintiffs responded by asserting that "takings" claims seeking injunctive relief instead of monetary damages may be heard in the U.S. District Court.[64] The District Court acknowledged that there was a split in the federal courts concerning the District Court's jurisdiction over a Tucker Act claim seeking solely injunctive relief, but determined that the Sixth Circuit Court of Appeals had taken the position that such jurisdiction did not exist.[65]

The District Court then turned to plaintiffs' argument that, based on the holding in *E. Enters. v. Apfel*, the District Court had jurisdiction over a takings case where the taking resulted from a direct transfer of funds to the government. Plaintiffs argued that the user fees required under the Tobacco Act were "direct transfers" of funds to the government and therefore the court had jurisdiction to hear the case. The District Court disagreed, holding that the alleged taking did not relate to the user fees and the value of the alleged taking was separate and distinct from the value of the user fees transferred to the government. Therefore, the District Court concluded that jurisdiction did not lie with the court under the "direct transfer" theory and the government's motion for summary judgment on the "takings" claim was granted on jurisdictional grounds without addressing the merits of the claim.

4. Modified Risk Tobacco Products

Plaintiffs challenged the Tobacco Act's provision on modified risk tobacco products (MRTPs) "as applied" and as constituting a "prior restraint" on their First Amendment right to free speech.[66] The plaintiffs argued that they were challenging the constitutionality of the provision as applied to television interviews and various other statements including those made on Internet websites.[67] In rejecting this argument, the District Court noted that

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[63] The Tucker Act states that "[t]he United States Court of Federal Claims shall have jurisdiction to render judgment upon any claim against the United States founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort." 28 U.S.C. § 1491.

[64] *See* Plaintiff's Response at 34 (citing E. Enters. v. Apfel, 524 U.S. 498, 521 (1998)).

[65] *Commonwealth Brands*, 2010 WL 65013 at *20 (citing Coalition for Government Procurement v. Federal Prison Indus., Inc., 365 F.3d 435, 479 (6th Cir. 2004)).

[66] The District Court noted that to the extent that plaintiffs argued that the MRTP provision violates their due process rights, plaintiffs failed to pursue any such arguments in their memoranda to the court. Thus, the District Court concluded that summary judgment in favor of the government was warranted. *See Commonwealth Brands*, 2010 WL 65013 at *13.

[67] *Commonwealth Brands*, 2010 WL 65013 at *14.

"[b]ecause what the MRTP provision bans is the 'introduc[tion] or deliver[y] for introduction into interstate commerce' of a MRTP without FDA approval, and because a manufacturer's speech is only used to determine whether a product is sold 'for [such] use', … that provision does not implicate the First Amendment outside of the context of the proposed advertising and labels submitted as part of an MRTP application."[68]

With regard to plaintiffs' argument that the provision constitutes a "prior restraint" on speech, the District Court held that the MRTP provision is not a "viewpoint-based restriction on speech."[69] The Court found that the government was not "proscribing a viewpoint … it [was] requiring tobacco manufacturers to go through a process of having their regulated product approved for sale as 'modified risk' before making untested claims about the relative health benefits of that product."[70] The District Court went on to say how non-manufacturers were "free to express the ostensibly-suppressed viewpoint, and even manufacturers may do so after their product is approved for the purposes for which it is intended to be marketed."[71]

5. Ban On Outdoor Advertising

Plaintiffs argued that the Tobacco Act's nationwide ban on outdoor advertising within 1,000 feet of a school is unconstitutional. While the District Court acknowledged that the provision, as written, is indistinguishable from the Massachusetts' ban that was struck down by the Supreme Court in ***Lorillard***, the District Court concluded that the challenge on the ban was not ripe because, "before the provision takes effect, Congress has instructed the Secretary to 'include such modifications [to the outdoor advertising ban], if any, that the Secretary determines are appropriate in light of governing First Amendment law."[72] The Tobacco Act requires that FDA issue a "final" regulation on March 22, 2010, which will become effective on June 22, 2010.[73] Thus, the District Court concluded that, until FDA issues regulations implementing this provision, the plaintiffs' constitutional challenge is not ripe for review.[74]

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[68] *Id.* (citing 21 U.S C. § 387k(b)(1), (b)(2)(A)); *see also* Order Denying Plaintiffs' Motion for Preliminary Injunction at 4-5.

[69] *Id.* at *15.

[70] *Id.*

[71] *Id.*

[72] *Id.* at *16 (citing Pub. L. No. 111-31, § 102(a)(2(E)).

[73] *Id.*

[74] The District Court also rejected plaintiffs' argument that the outdoor advertising ban violates their due process rights. The Court found that a due process hearing was not required in this case because "Plaintiffs have already been heard on this issue at various times throughout the lengthy history of this regulation-now-turned legislation, and because the only task before the Secretary is to conform the earlier ban to existing case law." *Commonwealth Brands*, 2010 WL 65013 at *17.

6. Non-Speech Restrictive Alternatives

Plaintiffs contended that the speech-restrictive provisions of the Tobacco Act "individually and collectively" violate their First Amendment right to free speech because "there are numerous and obvious less burdensome alternatives to the restriction of commercial speech."[75] Plaintiffs argued that Congress could have taken other measures, rather than restricting speech (e.g., preventing the unlawful sale of tobacco products to youth; requiring states to use Centers for Disease Control and Prevention (CDC)-recommended levels of tobacco revenues for tobacco control programs, etc.).[76] The District Court disagreed with plaintiffs' contention finding that Congress did not simply go "straight to [their] speech," but that after "decades of implementing various measures that did not affect Plaintiff's speech, [Congress] decided to add label and advertising restrictions to its comprehensive regulation of the tobacco industry."[77] The District Court found these restrictions to be "reasonable," "since every other tool in the government's arsenal is made less effective and more costly by Plaintiffs' use of advertising to stimulate underage demand."[78] Therefore, the District Court concluded that the fact that there may be other non-speech restrictive alternatives does not make the Tobacco Act's "speech restriction unconstitutional for lack of tailoring."[79]

7. Samples, Gifts with Purchase, and Combination Marketing

Plaintiffs also alleged that the Tobacco Act's restrictions on product samples, gifts with the purchase of tobacco products, and their ability to market their products with non-tobacco products violated their First Amendment rights. The District Court disagreed stating that it "does not believe any of these provisions implicate, let alone violate, plaintiffs' free speech rights."[80] First, the District Court noted that the Tobacco Act's ban on free samples "clearly regulates the distribution of a product, not speech—and, even if thought of as a speech restriction, it would seem fully permissible as a restriction on price, i.e., tobacco products cannot be free."[81] Second, the District Court held that plaintiffs do not have a First Amendment right to reward purchasers of their tobacco products with prizes.[82] Finally, the District Court noted that any impact that the "co-marketing" provision of the Tobacco Act would have on speech is "incidental and outside the scope of the First Amendment" because the

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[75] *See* Plaintiffs' Brief at 16; *see also Commonwealth Brands*, 2010 WL 65013 at *17.
[76] *Id.* (citing Plaintiff's Brief at 19-23).
[77] *Id.* at *41 (citing to Plaintiffs' Brief, p.19).
[78] *Id.* (citing to Government's Response, p. 40).
[79] *Id.*
[80] *Id.*
[81] *Id.* (citing to 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 507 (1996)).
[82] *Id.*

prohibition addressed conduct without a "significant expressive element."[83] In reaching its conclusion concerning the co-marketing prohibition, the court relied heavily on an FDA guidance document, published during the pendency of the case that purported to define the limits of the prohibition.[84]

V. Impact of Decision

It is difficult to predict the long-range impact of the *Commonwealth Brands* District Court decision. Both the plaintiffs and the government are likely to file appeals to the U.S. Court of Appeals and perhaps even to the U.S. Supreme Court.[85] As a result, the District Court's holding could be significantly modified. Nevertheless, the authors have undertaken an analysis of the potential impact of the decision, should it be upheld by the appellate courts in its current form.

A. Impact on FDA and Its Ability to Regulate Tobacco Products

Although the District Court upheld the majority of the Tobacco Act's provisions, two key aspects of the law were struck down: 1) the prohibition on color and graphics in labeling/advertising; and 2) the prohibition on claims of implied safety by virtue of FDA regulation or compliance with tobacco standards.

The loss of the Tobacco Act's ban on colors and graphics in tobacco product labeling and advertising is arguably the greater setback to FDA and its ability to achieve the goals of the Tobacco Act. The requirement for black-and-white "tombstone" labeling and advertising was an important part of the Tobacco Act's regulatory scheme. By stripping tobacco advertising of all colors and graphics, Congress sought to eliminate implied messages that tobacco products enhance one's lifestyle or are otherwise socially acceptable. Anti-tobacco advocates and public health organizations have long alleged that the use of colorful images contributes to the allure of tobacco for minors.

From a practical perspective, even one unskilled in the finer arts of marketing is compelled to conclude that plain black-and-white text advertising is not an effective means of attracting new consumers—especially young people who are saturated by the current culture's constant barrage of eye-pleasing images. The tombstone advertising requirement can only

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[83] *Id.* (citing Philip Morris USA Inc. v. City & County of San Francisco, No. 08-17649, 2009 WL 2873765, at *1 (9th Cir. Sept. 9, 2009) (explaining that "[s]elling cigarettes isn't [protected activity] because it doesn't involve conduct with a 'significant expressive element.'") (quoting Arcara v. Cloud Books, Inc., 478 U.S. 697, 701-02, 706 (1986)).

[84] *See FDA Draft Guidance for Industry and FDA Staff: The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act, Section II.A* (Sept. 30, 2009).

[85] As of February 8, 2010, neither party had appealed the District Court's decision.

be explained as an attempt by Congress to completely eliminate any meaningful tobacco product advertising. Therefore, the District Court's finding that the provision is unconstitutional was significant in that it ensured that the tobacco industry will be permitted to continue to conduct effective advertising campaigns that could entice minors to experiment with tobacco. Thus, one would have to conclude that the loss of this key component to the advertising regulatory scheme has the potential to reduce the effectiveness of the Tobacco Act to prevent tobacco use by minors.

The District Court's decision, however, left open the possibility of Congress enacting a more targeted color and graphics ban that would pass constitutional muster. The District Court's decision to strike down the ban was based on its overly broad reach. The District Court did not find that the ban on colors and graphics was not directed to a substantial government interest—in fact it implied that a properly tailored prohibition that provided exceptions for innocuous colors and images would be permitted under the First Amendment. Given the importance of this advertising restriction in the overall Tobacco Act's regulatory scheme, it is likely that Congress will take up new legislation attempting to enact a color/graphics ban that complies with the court's interpretation of the First Amendment.

Losing the prohibition on claims implying safety by virtue of FDA regulation is unlikely to have as great an impact on the effectiveness of the Tobacco Act as the loss of the color/graphics ban. The District Court's decision, however, may result in a significant erosion of the public's confidence in FDA. While it is true that some consumers may mistakenly believe that cigarettes are safer because of FDA regulation, it is just as likely that the public may think less of FDA as a public health agency because it has failed to make cigarettes safer. In many ways, the primary value of the Tobacco Act's prohibition on claims implying safety by virtue of FDA regulation was that it protected FDA's image. The Tobacco Act gave FDA an impossible task. Congress told FDA to regulate tobacco, and thereby presumably make it safer, but withheld the authority to ban tobacco or the nicotine contained in tobacco products. FDA was left in the untenable position of being responsible for ensuring the safety of a product that cannot be safely consumed. The Tobacco Act's ban on implied claims by virtue of FDA regulation was broadly worded and effectively prevented any mention of FDA regulation of a tobacco product, thus shielding FDA from direct accountability to the public for any perceived failure to "fix" the problem of tobacco-related deaths. With the striking down of the ban, manufacturers will be permitted to state that their products comply with the applicable FDA standard and the public may reasonably conclude either that such compliance renders tobacco products safer, which is unlikely to be true, or that the standards provide no meaningful benefit to the public health. In either case, FDA's image as a defender of the public health will likely be tarnished.

Despite its significant losses, FDA won three key issues in the ***Commonwealth Brands*** case. First, the District Court's decision to uphold the prohibition on sponsorship is significant

in that it forecloses an advertising venue that has given tobacco companies access to young viewers for many years. Second, the upholding of the label warning requirements ensures that a key element of the Tobacco Act's educational program will be implemented. The government presented compelling evidence that the current tobacco product warnings had become stale and were essentially ineffective in transmitting the desired risk information. The new warnings and the required placement in the top half of cigarette pack labels will ensure that the risk information will be "seen" by consumers. Third, the District Court's decision to uphold the Tobacco Act's MRTP pre-approval requirement was a major win for the government because a loss in this area would have had significant impact on other FDA-regulated products. The concept of regulation based on the "intended use" of an article is the foundation of the FDCA's pre-approval requirements for drugs, devices and certain food additives. Had the plaintiffs prevailed in their MRTP arguments, it could have raised questions about the ability of FDA to use a regulated party's statements as evidence that a drug, device or food additive is "unapproved" and therefore in violation of the FDCA.

B. Impact on the Tobacco Industry

The District Court's holding presents significant challenges for the regulated industry. The plaintiffs prevailed on two counts in their original complaint and only one of those victories, the striking down of the color/graphics advertising ban, has a significant impact on the industry's practices. By retaining the right to use color and graphics, the tobacco industry won the ability to continue meaningful advertising campaigns. This is especially important for smaller manufacturers that are seeking to compete with well-established brands in the marketplace. The conventional wisdom surrounding the Tobacco Act is that the virtual elimination of tobacco advertising, which would have been the effect of the tombstone labeling/advertising requirements, would work to the advantage of those companies that currently have large market shares, such as Philip Morris's Marlboro® brand cigarettes. If one holds to this view, the striking down of the color/graphics ban should ensure a more competitive tobacco products marketplace and maintain an incentive for new companies to enter the market.

In contrast, the plaintiffs' hard-fought victory allowing them to make claims related to FDA regulation of their products is unlikely to provide any meaningful benefit to tobacco manufacturers. While there may be some commercial benefit derived from claiming that a product is "FDA regulated" or complies with FDA's standard for cigarettes, any such benefit would seem to be minimal at best. Nevertheless, any regulated industry benefits from enhanced certainty in the regulations to which it must comply. In that sense, the District Court's decision provides some certainty that tobacco manufacturers will not be subjected to FDA enforcement actions as a result of claims related to compliance with FDA standards. Perhaps this allows the plaintiffs to claim some small measure of victory.

In general, the plaintiffs lost more than they gained, and the losses suffered were significant. As previously noted, the District Court upheld the vast majority of FDA's new-found authority under the Tobacco Act. Importantly, FDA retained the power to regulate MRTPs based on the intended use of such products, as evidenced by oral and written statements concerning the products; and the Tobacco Act's requirement that 50 percent of tobacco product labels and 20 percent of product advertising be set aside for government-mandated graphic warnings.

The loss of product label space could have a significant impact on smaller companies that are seeking to gain a market share because consumers will not be as familiar with their brands. The law relegates company logos and information to the bottom half of labels. But, cigarette display cases in stores often obscure the bottom half of the product package. Thus, smaller companies and manufacturers of discount products that do not have access to point-of-sale advertising may lose their only means of exposing potential buyers to their distinguishing marks and/or logos. As such, manufacturers of new products may find it difficult to get consumers to ask store clerks for their products when only the government warnings, and no product-specific information, is visible to the potential buyer.

Furthermore, the tobacco industry suffered a major setback with regard to its ability to sponsor events. Sponsorship by tobacco companies was significantly curtailed under the 1998 Master Settlement Agreement (MSA). The Tobacco Act, however, eliminates what little was left in the way of sponsorship activities. Perhaps the one positive in the outcome, at least for tobacco companies that were signatories to the MSA, is that the Tobacco Act has leveled the playing field in terms of sponsorship for both MSA and non-MSA tobacco companies.

C. Impact on the Public

The public, particularly tobacco consumers, will feel the impact of the *Commonwealth Brands* decision. The new warning labels are certain to be noticed by smokers and users of smokeless tobacco, as it will be more difficult for those consumers to select their preferred brand of tobacco products in a sea of government warnings. Among smokers, the large government warnings may provoke negative sentiments of a "nanny state" government that may actually be counterproductive to the Tobacco Act's goal of informing consumers of the risks associated with tobacco use. Nevertheless, the retention of colors and graphics in labeling and advertising will likely be viewed as a positive outcome for tobacco users who would have been subjected to much less aesthetically pleasing black-and-white advertising under the Tobacco Act.

The actual impact of the decision on the public health will be more difficult to quantify. As discussed above, the continued ability of tobacco manufacturers to use color and graphics in their labeling advertising may result in thousands of new young smokers. The actual number of young people enticed to smoke by fanciful colors and graphics, however, is impossible to calculate with any meaningful degree of accuracy. Thus, the true impact in terms of lives

lost may never be known. The *Commonwealth Brands* decision will also affect public health by the removal of FDA's insulation from accountability under the Tobacco Act. Consumers may now be informed of FDA's regulation of tobacco in a more direct way. People who lose loved ones may reasonably ask why FDA has not done a "better job" of making tobacco safer. Many may question why FDA has not banned tobacco without realizing that Congress has forbidden such regulatory action. Finally, FDA's resulting loss of credibility will have a detrimental impact on the overall public health as consumers lose faith in FDA's ability to protect them from harmful products.

VI. Conclusion

The *Commonwealth Brands* decision represents neither final victory nor fatal defeat for either side. The District Court recognized that preventing tobacco use by children was a legitimate and substantial government interest that, if properly tailored, could support restrictions on commercial speech. Thus, the basic concept of FDA regulation of tobacco under the Tobacco Act remains intact. The court also concluded that the vast majority of the Tobacco Act provisions were sufficiently directed to this governmental interest and therefore do not run afoul of the First Amendment under the *Central Hudson* test. Yet, a key provision of the Tobacco Act pertaining to the use of colors and graphics in tobacco labeling and advertising was struck down by the District Court on the grounds that the ban was not sufficiently tailored to the specific governmental interest of protecting minors. Similarly, the District Court struck down the Tobacco Law's prohibition on implied safety claims by virtue of FDA regulation due to the overly broad language of the ban. As such, the District Court's decision is likely to be appealed by both the government and the plaintiffs. Thus, *Commonwealth Brands* will not be the last battle in the legal war of the Tobacco Act, but it will always be significant by virtue of it being the first shot fired.