UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
BOWLING GREEN DIVISION

COMMONWEALTH BRANDS, INC.; CONWOOD COMPANY, LLC; DISCOUNT TOBACCO CITY & LOTTERY, INC.; LORILLARD TOBACCO COMPANY; NATIONAL TOBACCO COMPANY, L.P.; and R.J. REYNOLDS TOBACCO COMPANY,	*	
Plaintiffs,	*	CIVIL ACTION NO. _____
v.	*	(Electronically Filed)
UNITED STATES OF AMERICA; UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration; and KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,	*	
Defendants.	*	

COMPLAINT FOR DECLARATORY JUDGMENT
AND INJUNCTIVE RELIEF

INTRODUCTION

1. "[S]o long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001). On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (the "Act"), which does not outlaw tobacco products, but which imposes unprecedented restrictions on Plaintiffs' First

Amendment rights by limiting their ability to disseminate truthful information about tobacco products to adult consumers. Plaintiffs do not challenge portions of the Act that materially and directly address tobacco sales to minors.[1] However, Plaintiffs do challenge a number of restrictions that circumscribe their rights to communicate truthful information to adult consumers who have an interest in receiving such information. Prior to the passage of the Act, existing federal and state laws already severely restricted Plaintiffs' ability to speak truthfully and freely to adult tobacco consumers—the Act now adds layer upon layer of additional restrictions, thereby virtually eliminating the remaining few avenues for protected speech.

2. The Supreme Court has explained that limitations on commercial speech, at a minimum, must directly advance an asserted substantial government interest and must not be more extensive than necessary to serve the government's interest. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). The Government "bears the burden of showing not merely that its regulation will advance its interest, but also that it will do so 'to a *material degree*,'" and "'speculation or conjecture' . . . is an unacceptable means of demonstrating that a restriction on commercial speech directly advances the [Government]'s asserted interest." *44 Liquormart, Inc. v. R.I.*, 517 U.S. 484, 505, 507 (1996) (plurality op.) (emphasis added) (citations omitted). The Act cannot pass muster under this standard.

3. While the Act is purportedly intended to reduce youth tobacco use, a number of its provisions broadly restrict all speech by Plaintiffs about tobacco products, including truthful speech intended for and received by adults. For example, the Act *prohibits* Plaintiffs from conveying any speech through the use of color lettering, trademarks, logos, or any other imagery

[1] For example, the Act contains provisions that restrict sales of tobacco products to minors and make retailers responsible for complying with the requirements, Pub. L. No. 111-31, § 102(a), 123 Stat. at 1830 (adopting 61 Fed. Reg. 44,616, § 897.14(a) (Aug. 28, 1996)), and restrict vending machines to adult-only facilities, *id.* (adopting 61 Fed. Reg. 44,617, § 897.16(c)(2)(iii) (Aug. 28, 1996)).

in most advertisements, including virtually all point-of-sale and direct-mail advertisements. Another restriction renders completely ineffective the one place where such color imagery can be used: Plaintiffs' packaging. The top half of the front and back of all cigarette packaging is appropriated by a Government-drafted anti-tobacco message, including shocking, color graphic images and other mandated information, leaving Plaintiffs with just a small portion of the bottom half of their cigarette packages to communicate with adult consumers. The obvious purpose of this is to force Plaintiffs to stigmatize their own products through their own packaging. Given that consumers in many retail establishments generally must view tobacco products from across a counter-top, the only thing adult consumers are likely to see is the Government-drafted message; the bottom half of the cigarette packaging, to which Plaintiffs' branding is relegated, will be difficult, if not impossible, to see. Together, these restrictions leave Plaintiffs with virtually no means of effectively communicating with many adult tobacco consumers through advertisements, and the Act substantially impairs the value of their trademarked logos on packaging. These speech restrictions are particularly egregious as the population has, for decades, been well informed of the harms of tobacco use and the Government cannot demonstrate that the restrictions will further increase consumer awareness or reduce youth tobacco use.

4. The Act goes so far as to prohibit Plaintiffs from making truthful statements about their products in scientific, public policy, and political debates—speech that receives the highest level of protection and is subject to strict scrutiny review. For example, one key provision of the Act prohibits Plaintiffs from making truthful statements about the relative health risks of tobacco products to "individual tobacco users," if the FDA determines that such truthful statements would not "benefit the health of the population as a whole." Pub. L. No. 111-31, sec. 101(b), §

911(g)(1), 123 Stat. at 1784, 1814 (amending the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., to insert 21 U.S.C. § 387k(g)(1)). This restriction, moreover, is not limited to advertising, promotion, and other traditional forms of commercial speech, but rather, applies to "*any* action directed to consumers through the media *or otherwise*." *Id*., sec. 101(b), § 911(b)(2)(A)(iii), 123 Stat. at 1812-13 (amending the FDCA to insert § 387k(b)(2)(A)(iii)) (emphases added). Plaintiffs would be barred from disseminating this truthful information if, in the FDA's view, it would not "benefit the health of the population as a whole" because it may offer current tobacco users a level of reassurance that might encourage them to consume less harmful tobacco products rather than to quit altogether. Pub. L. No. 111-31, sec. 101(b), § 911(g)(1), 123 Stat. at 1784, 1814 (amending the FDCA to insert 21 U.S.C. § 387k(g)(1)). Yet the law provides absolutely no criteria by which such judgments shall be made, and thus relegates Plaintiffs' truthful, non-misleading speech to vagaries of subjective, standardless assessments by Government officials.

5. These are but a few of the Act's many flaws and they do not pass muster under either intermediate or strict scrutiny review. Congress, having repeatedly chosen not to ban tobacco products altogether, cannot now prohibit Plaintiffs from truthfully speaking about their lawful products to adult consumers. *See, e.g., Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 192-93 (1999). As the Supreme Court has emphasized, "regardless of the strength of the Government's interest in protecting children, [t]he level of discourse reaching a mailbox simply cannot be limited to that which would be suitable for a sandbox." *Reno v. ACLU*, 521 U.S. 844, 875 (1997) (internal quotation marks and citation omitted).

6. In short, while each of these provisions individually violates the Constitution, collectively, the Act's provisions cut off nearly every currently-available avenue of tobacco

advertising and marketing. In so doing, they run afoul of Plaintiffs' rights to free speech and due process, and effectuate an unconstitutional taking of private property, in violation of the First and Fifth Amendments by, among other things, chilling Plaintiffs' right to participate in scientific and political debates surrounding their products, unduly restricting Plaintiffs' right to engage in commercial speech, and confiscating Plaintiffs' packaging, advertising, and intellectual property for an anti-tobacco message drafted by the Government. Plaintiffs therefore respectfully request that this Court declare the challenged provisions of the Act in violation of the First and/or Fifth Amendments to the United States Constitution and enjoin the Government from enforcing these unconstitutional provisions.

PARTIES

7. Plaintiff Commonwealth Brands, Inc. ("Commonwealth") is a Kentucky corporation with its corporate offices located in Bowling Green, Warren County, Kentucky, and its manufacturing operations in North Carolina. Commonwealth is the fourth-largest tobacco manufacturer in the United States, selling a variety of tobacco products, including cigarettes, roll-your-own tobacco, and tobacco-related products. Its cigarette brands are sold under the brand names USA Gold, Davidoff, and Sonoma, among others. Commonwealth's brands are advertised, distributed, and sold nationwide, including in this district. Commonwealth is a signatory to the 1998 Master Settlement Agreement ("MSA"), as a Subsequent Participating Manufacturer ("SPM"), under the terms of the MSA.

8. Plaintiff Conwood Company, LLC ("Conwood") is a Delaware limited liability company with its corporate offices located in Memphis, Tennessee, and its manufacturing operations in Bowling Green, Warren County, Kentucky (through its Scott Tobacco division), and in North Carolina and Tennessee. Conwood is the second-largest manufacturer of smokeless tobacco products in the United States. Its smokeless brands are sold under the brand names

Kodiak, Grizzly, and Levi Garrett, among others. Conwood's brands are advertised, distributed, and sold nationwide, including in this district. Conwood is not a signatory to the MSA.

9. Plaintiff Discount Tobacco City & Lottery, Inc. ("Discount Tobacco City") is a Kentucky corporation with its corporate offices located in Murray, Kentucky, and tobacco specialty stores located in Benton, Hazel, Mayfield, and Murray, Kentucky. Discount Tobacco City sells primarily tobacco products, including numerous cigarette and smokeless tobacco brands, including brands manufactured by Commonwealth, Conwood, Lorillard, National, and Reynolds, among others, consistent with the requirements of Kentucky law.

10. Plaintiff Lorillard Tobacco Company ("Lorillard") is a Delaware corporation with its corporate offices and manufacturing operations located in Greensboro, North Carolina. Lorillard is the third-largest tobacco manufacturer in the United States, selling a variety of cigarette brands. Its cigarette brands are sold under the brand names Newport, Maverick, True, and Old Gold, among others. Lorillard's brands are advertised, distributed, and sold nationwide, including in this district. Lorillard is a signatory to the MSA as an Original Participating Manufacturer ("OPM"), under the terms of the MSA.

11. Plaintiff National Tobacco Company, L.P. ("National") is a Delaware limited partnership with its principal place of business located in Louisville, Kentucky, and its manufacturing operations in Kentucky and Tennessee. National manufactures smokeless tobacco products, cigarettes, roll-your-own tobacco, and pipe tobacco. Its brands are sold under the brand names Beech-Nut, Durango, Havana, Blossom, and Trophy, among others. National also distributes cigarettes, cigarette papers, smoking tobacco, and other roll-your-own tobacco products, including under the Zig-Zag brand. National's brands are advertised, distributed, and sold nationwide, including in this district. National is not a signatory to the MSA.

12. Plaintiff R.J. Reynolds Tobacco Company ("Reynolds") is a North Carolina corporation with its corporate offices and manufacturing operations located in Winston-Salem, North Carolina. Reynolds is the second-largest tobacco manufacturer in the United States, selling a variety of tobacco products, including cigarettes and smokeless tobacco products. Its cigarette brands are sold under the brand names Camel, Winston, Kool, and Pall Mall, among others. Reynolds' brands are advertised, distributed, and sold nationwide, including in this district. Reynolds is a signatory to the MSA as an OPM, under the terms of the MSA.

13. Defendant the United States Food and Drug Administration ("FDA") is a federal agency of the United States, within the United States Department of Health and Human Services ("HHS"). The FDA is responsible for approving or disapproving and otherwise regulating drugs, devices, and food, as defined by the FDCA, marketed in the United States. The FDA's headquarters are located in Silver Spring, Maryland. The agency's powers and responsibilities under the Act are delegated to the FDA through HHS Secretary Kathleen Sebelius.

14. Defendant Dr. Margaret Hamburg is the Commissioner of the FDA. The Act amends the FDCA to give the FDA new power to regulate tobacco products. Commissioner Hamburg is directly responsible for the day-to-day implementation and enforcement of the Act.

15. Defendant Kathleen Sebelius is the Secretary of HHS, the parent agency of the FDA. Secretary Sebelius ("Secretary") oversees the FDA's activities and is directly responsible for the implementation and enforcement of the Act.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331. Declaratory relief is authorized by 28 U.S.C. §§ 2201 and 2202.

17. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e).

18. An actual controversy presently exists between the parties concerning the constitutionality of various provisions of the Act. That controversy is justiciable in character, and speedy relief is necessary to preserve Plaintiffs' rights.

19. A declaratory judgment will terminate the uncertainty and controversy between the parties.

20. A preliminary injunction, enjoining Defendants from taking any action to enforce the challenged provisions of the Act already in effect, will protect Plaintiffs' rights while these proceedings are pending.

21. A permanent injunction, enjoining Defendants from enforcing the challenged provisions of the Act, will protect Plaintiffs' rights after the final resolution of these proceedings.

FACTUAL ALLEGATIONS

22. On June 22, 2009, President Obama signed the Act into law. The Act imposes sweeping and unprecedented restrictions on Plaintiffs' ability to communicate with adult tobacco consumers. For example, it severely restricts Plaintiffs' ability to communicate with adult consumers through advertising in magazines, on packaging, through direct mail, and at retail points of sale throughout the country. It also restricts almost every other remaining thoroughfare of speech, such as brand name sponsorship of artistic events in adult-only venues. Indeed, the Act even compels Plaintiffs to carry anti-tobacco messages drafted by the Government by appropriating a large portion of their packaging, simultaneously violating the Plaintiff-manufacturers' First Amendment rights and taking their property rights. And many of the Act's provisions are not even limited to commercial speech, but go so far as to prohibit Plaintiffs from participating in core scientific and policy debates regarding their lawful products.

23. Even prior to the Act, Plaintiffs had few avenues of communication for speaking to their adult consumers, e.g., the ban on advertising on television and radio. The Act imposes sweeping and unprecedented restrictions that effectively foreclose those avenues of communication that remain.

24. Plaintiffs' ability to use these remaining avenues to speak to adult tobacco consumers about their legal tobacco products and about their businesses generally is essential to Plaintiffs' businesses.

25. Plaintiffs' speech is fundamentally aimed at both protecting and increasing Plaintiffs' market share among adult tobacco consumers. In the tobacco industry, the success of Plaintiffs' businesses depends on their ability to build brand equity and to reinforce brand loyalty among current adult users of their products and to convince adult consumers currently choosing a competitor's brand to switch.

26. In order to place their brand and product information directly into the hands of the adult tobacco consumers who desire it, Plaintiff-manufacturers depend on advertising, product descriptions included on packaging, point-of-sale displays, targeted direct mailings, and other methods of communication. These types of communication are especially important to Plaintiff-manufacturers because in many cases they must compete against entrenched market leaders.

27. Plaintiff Discount Tobacco City similarly depends on advertising of tobacco products to generate sales, not only of tobacco products but also of other items on sale. Whether through point-of-sale displays, on-site advertising, or other methods of communication, retailers' ability to communicate to adult consumers that they can purchase popular brands of tobacco inside their stores is essential to their viability.

28. Finally, Plaintiffs' executives and scientists participate in scientific, political, and public policy debates regarding the use and regulation of tobacco products because they are vitally interested in the merits of these issues and the success of their businesses depends on the regulatory and public policy environment, which, in turn, is informed by such research and debate.

29. As explained in detail below, the Act undermines Plaintiffs' ability to engage in all of these commercial and non-commercial communications.

30. The Act thus violates Plaintiffs' free speech rights under the First Amendment, due process rights under the Fifth Amendment, and effects an unconstitutional taking.

Pre-existing Limits on Plaintiffs' Marketing and Sale of Tobacco Products

31. Federal law already prohibits Plaintiffs from advertising tobacco products in television and radio advertisements, *see* 15 U.S.C. §§ 1335, 4402, the media best suited to reaching the greatest numbers of consumers.

32. Pre-existing federal law also imposed a "comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health," the express purpose of which was to ensure that the public was "adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes." 15 U.S.C. § 1331. Government-mandated warnings have appeared on all packages of cigarettes for more than four decades and all packages of smokeless tobacco products for more than two decades. *See id.* § 1333 (cigarettes) and § 4402 (smokeless tobacco). The same warnings have also been included in tobacco product advertising for decades as well.

33. In addition, federal law imposes numerous non-speech restrictions on the marketing and sale of tobacco products. For example, federal funding law requires states to prohibit the sale of tobacco products to anyone under the age of 18, *see* 42 U.S.C. § 300x-26, and imposes taxes on tobacco products designed to deter tobacco use, *see, e.g.,* 27 C.F.R. § 40.1 *et seq.*

34. State and local governments across the country have also enacted a number of conduct-based restrictions on tobacco use. Such conduct-based restrictions include prohibitions on smoking in workplaces; increased enforcement of laws prohibiting sale of tobacco products to minors; and regulations limiting where and how tobacco products may be sold, who may sell tobacco products, who may use tobacco products, and where tobacco products may be used. Many states prohibit smoking in private workplaces, government buildings, restaurants, and/or bars. In addition, all told, more than 2,216 municipalities in the United States currently restrict the use of tobacco products. Of those, 461 provide for a total ban on smoking in private workplaces, government buildings, restaurants, and/or bars. Hundreds of localities across the country have adopted restrictions on the sale of cigarettes through vending machines. More than 100 localities have limited the distribution of tobacco product samples. Federal law also restricts smoking in or around federal buildings. *See* Protecting Federal Employees and the Public from Exposure to Tobacco Smoke in the Federal Workplace, 73 Fed. Reg. 78,360 (Dec. 22, 2008).

35. In addition, in November 1998, numerous tobacco manufacturers, including Plaintiffs Commonwealth, Lorillard, and Reynolds, entered into the MSA with numerous state Attorneys General. The MSA imposes a variety of restrictions and limitations on the marketing and promotion of tobacco products that, but for the voluntary waiver by the signatories of their constitutional rights, would be unconstitutional. *See* MSA § XV.

36. The Act imposes restrictions on Plaintiffs' advertising and promotion of tobacco products that go, in many instances, well beyond the restrictions imposed by the MSA.

37. As noted above, not all Plaintiffs are signatories to the MSA.

38. The Act leaves Plaintiffs—whether they are signatories to the MSA or not—with few remaining avenues through which they may effectively communicate truthfully with adult tobacco consumers about Plaintiffs' lawful tobacco products.

The Act Further Limits Plaintiffs' Marketing and Sale of Tobacco Products

39. The Act's additional restrictions virtually eliminate the few avenues that Plaintiffs still have for communicating truthfully to adult tobacco consumers about Plaintiffs' tobacco products. And these restrictions are not limited to commercial speech; they extend to Plaintiffs' participation in scientific, public policy, and political debates regarding the use and regulation of tobacco products. The Act also undermines Plaintiffs' ability to communicate effectively through direct mail, point-of-sale, print media, and outdoor advertising, while, at the same time, forcing Plaintiffs to disseminate a Government-drafted anti-tobacco message on their packaging and in their advertising. The net result is that Plaintiffs' packaging and advertisements are transformed into a Government-mandated message discouraging adult consumers from using Plaintiffs' lawful products—a message that overwhelms Plaintiffs' ability to communicate with adult tobacco consumers in direct contravention of Plaintiffs' commercial interests, and effectively confiscates Plaintiffs' property rights in their packaging and trademarks.

40. The most egregious provisions of the Act include the following:

(1) Ban on Color and Graphics in Most Advertising

41. The Act prohibits Plaintiffs from communicating to adult consumers through the use of any color or imagery in almost all advertising.

42. Under the Act, the Secretary is required to promulgate a regulation that "shall be identical in its provisions to part 897 of the regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615-44618)." Pub. L. No. 111-31, § 102(a)(2), 123 Stat. at 1830. Section 897.32(a) of those regulations prohibits every "manufacturer, distributor, and retailer" of tobacco products from "advertising, . . . disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco" unless such labeling or advertising consists of "only black text on a white background." 61 Fed. Reg. 44,617, § 897.32(a) (Aug. 28, 1996). This black-and-white-text-only requirement is referred to by the Government as "tombstone" advertising.

43. There are only two narrow exceptions to the Act's broad prohibition. First, while the black-and-white text provision purports to be inapplicable to advertisements in "an adult publication," it narrowly defines "an adult publication" to be limited to print publications that have: (1) 15 percent or less readership under the age of 18, *and* (2) fewer than 2 million total readers under the age of 18. 61 Fed. Reg. 44,617, § 897.32(a) (Aug. 28, 1996). Thus, if 95 percent of a publication's readership is over the age of 18, Plaintiffs still cannot advertise in it if more than 2 million readers are 17 years old. Under this standard, publications that are geared toward adult readers will frequently fail to qualify as "adult publications." For example, *ESPN the Magazine*, *People* (with less than eight percent readership under 18), and *Sports Illustrated* (with less than twelve percent readership under 18), among others, would not qualify as "adult publications" under this overly restrictive standard, even though those publications overwhelmingly and predominantly appeal to adults; accordingly, they are subject to the black-and-white text mandates. *See* MRI, Twelve Plus (2008).

44. Second, the black-and-white text provision contains an exception for "adult-only establishments," but only if "the advertising is not visible from outside the facility" *and* "is affixed to a wall or fixture in the facility." 61 Fed. Reg. 44,617, § 897.32(a) (Aug. 28, 1996). Thus, under the Act, a windowless adult-only tavern that strictly prohibits minors from entering the premises cannot set a color tobacco advertisement display atop its bar. Likewise, an adult-only tavern with windows cannot display a color poster advertising tobacco products.

45. The black-and-white text provision applies equally to tobacconist retail establishments "for which the predominant business is the sale of tobacco products," which must "comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18." Pub. L. No. 111-31, sec. 101(b), § 913, 123 Stat. at 1820 (amending the FDCA to insert 21 U.S.C. § 387m). Thus, a tobacco retail establishment that does not even permit minors to enter the premises is still subject to the black-and-white text requirements for its advertising. This underscores that the Act is not directed at preventing youth tobacco use, but at preventing Plaintiffs from communicating with all consumers, including adult consumers.

46. Similarly, the black-and-white text provision bans the use of color and imagery in point-of-sale coupons, applying even to coupons sent by direct mail to age-verified adult tobacco consumers or distributed in adult-only facilities.

47. For example, Plaintiff Lorillard sends coupons for Newport cigarettes via direct mail to its customers that contain color pictures of adult smokers, pictures of Newport cigarette packages, and the Newport logo. Lorillard sends these types of direct mailings only to adult smokers who have agreed to be on Lorillard's mailing list and are 21 years or older. The Act

would prohibit such truthful advertising, notwithstanding Lorillard's extensive efforts to ensure that its direct marketing communications reach only adult smokers over the age of 21.

48. In addition, by prohibiting the use of color and imagery in point-of-sale and direct-mail coupons, the black-and-white text provision also undermines certain Plaintiffs' existing practice of using colored marks or holograms to prevent counterfeit coupons—security measures that both protect Plaintiffs from fraud and help prevent underage use of tobacco products.

49. The black-and-white text provision also bans Plaintiffs from using established trademarked logos in advertising and labeling. Plaintiff-manufacturers each use trademarks and packaging for their respective brands consisting of color, words, designs, and/or graphics—including, for example, Lorillard's "spinnaker," Reynolds' "Camel Beast," Commonwealth's "Eagle," and Conwood's "Grizzly" bear and picture of Levi Garrett's 18th century factory in Philadelphia. The Act substantially impairs the value of such trademarks because it severely restricts use of color and graphics in most advertising and labeling, and thus prevents companies from displaying their trademarks and brand packaging in messages for the purpose of identifying their brand and having its consumers distinguish such brand from those of competitors in the marketplace.

50. Consequently, Plaintiffs' ability to communicate an effective marketing message to adult consumers through advertising is undermined by the Act.

(2) Mandated Warnings

51. Because the Act virtually eliminates Plaintiffs' ability to communicate to adult consumers through advertising, the only remaining vehicle for such communication is product packaging. But the Act destroys this as well, seizing a substantial portion of Plaintiffs' packaging for a Government-drafted anti-tobacco message—including, for cigarette packaging

and advertising, the use of shocking, graphic color imagery—as well as other mandated information. Pub. L. No. 111-31, sec. 201(a), (b), § 4(a), (d), 123 Stat. at 1842-43, 1845 (amending the Federal Cigarette Labeling and Advertising Act ("FCLAA"), to insert new 15 U.S.C. § 1333(a), (d) (to take effect after mandatory issuance of regulations by the Secretary)); Pub. L. No. 111-31, § 103(q)(5), 123 Stat. at 1840-41; Pub. L. No. 111-31, sec. 301, § 920, 123 Stat. at 1850-51 (amending the FDCA to insert 21 U.S.C. § 387t). Since consumers are already well aware of the risks of smoking, the clear purpose of this "warning" is to force Plaintiffs to stigmatize their own product on their own packaging. As a result, a consumer attempting to view tobacco products from the opposite side of the check-out counter in a retail establishment would likely notice only the Government-drafted anti-tobacco message. Similarly, the warnings overwhelm Plaintiffs' advertisements, in which Plaintiffs' speech is largely limited to black-and-white text.

52. In particular, under the Act, "the top 50 percent of the front and rear panels of" a package of cigarettes must contain one of nine specified "WARNINGS." These warnings, which are to be rotated on packaging under a plan approved by the FDA, must appear "in conspicuous and legible 17-point type . . . . in a manner that contrasts, by typography, layout, or color, with all other printed material on the package." Pub. L. No. 111-31, sec. 201(a), § 4(a), 123 Stat. at 1842-43 (amending the FCLAA to insert new 15 U.S.C. § 1333(a)).

53. These warnings, moreover, must include "color graphics depicting the negative health consequences of smoking to accompany the label statements." Pub. L. No. 111-31, sec. 201(a), § 4(d), 123 Stat. at 1845 (amending the FCLAA to insert new 15 U.S.C. § 1333(d)). Thus, the top half of cigarette packages must include shocking color graphics, plainly intended to deliver a visually striking, attention-grabbing anti-smoking message.

54. The Act also requires cigarette packaging to include other detailed information, in addition to the top 50 percent of the front and back of the packaging taken up by the warnings and color graphics. All cigarette packaging, for example, must bear the statement "Sale only allowed in the United States." Pub. L. No. 111-31, sec. 301, § 920(a)(1), 123 Stat. at 1850 (amending the FDCA to insert 21 U.S.C. § 387t(a)(1)). In addition, package labels must contain: (1) the name and address of the manufacturer, packer, or distributor; (2) a net quantity statement; and (3) the percentage of tobacco that is foreign versus domestic. *Id*. sec. 101(b), § 903, 123 Stat. at 1788 (amending the FDCA to insert new 21 U.S.C. § 387c).

55. As a result of these restrictions, any trademarks or other imagery used by manufacturer Plaintiffs on cigarette packaging must be dramatically reduced in size and relegated to the bottom half of the packaging. Other information about the brand contained on the package will similarly have to be reduced in size and/or content.

56. Consequently, only a small portion of the least visible part of Plaintiffs' packaging is available to Plaintiffs to communicate truthful information to adult consumers. This is particularly harmful to Plaintiffs' interests given the manner in which tobacco products are sold. The Act and state laws generally require tobacco products to be kept behind the check-out counter and thus are not immediately accessible to adult consumers. These consumers therefore must view the tobacco products from a distance, across the check-out counter. Because of the diminished size of Plaintiffs' imagery and the relegation of that imagery to the bottom half of cigarette packaging, it is difficult, if not impossible, for an adult consumer to identify any product brand from that distance. This greatly reduces the likelihood that an adult tobacco consumer will choose a brand other than his or her preferred brand, or that a consumer will ever even become aware of the existence of a new brand or a competitive brand.

57. The Act imposes severe warning requirements on cigarette advertising. The top 20 percent of each press and poster advertisement must display the warnings "in a conspicuous and prominent format," including color, graphic anti-tobacco images. Pub. L. No. 111-31, sec. 201(a), § 4(b), 123 Stat. at 1843-44 (amending the FCLAA to insert new 15 U.S.C. § 1333(b) (to take effect after mandatory issuance of regulations by the Secretary)).

58. Similar requirements apply to smokeless tobacco packaging and advertisements. One of four specified "WARNINGS" must be displayed on "at least 30 percent of" "the 2 principal display panels of the package" of a smokeless tobacco product, "in a manner that contrasts by typography, layout, or color, with all other printed material on the package." Pub. L. No. 111-31, sec. 204(a), (b), § 3(a), 123 Stat. at 1846-47 (amending the Comprehensive Smokeless Tobacco Health Education Act of 1986 ("CSTHEA") to insert new 15 U.S.C. § 4402(a) (effective June 22, 2010)). In addition, smokeless product packaging must also state: (1) "sale only allowed in the United States," Pub. L. No. 111-31, sec. 301, § 920(a)(1), 123 Stat. at 1850 (amending the FDCA to add new 21 U.S.C. § 387t(a)(1)); (2) the name and address of the manufacturer, packer, or distributor; (3) a net quantity statement; and (4) the percentage of tobacco that is foreign versus domestic, *id*. sec. 101(b), § 903, 123 Stat. at 1788 (amending the FDCA to insert new 21 U.S.C. § 387c)).

59. At least 20 percent of press and poster advertisements for smokeless tobacco products must display the mandated warnings, in addition to being subject to the black-and-white text provision for advertisements. *Id*. sec. 204(a), § 3(b), 123 Stat. at 1846, 1847 (amending the CSTHEA to insert new 15 U.S.C. § 4402(b)).

60. These warnings impose substantial burdens on Plaintiffs' ability to use their own packaging and advertising to communicate information to adults. For example, moist snuff

smokeless tobacco packages typically have three surfaces: a top, a bottom, and a circular side. The Act requires that at least thirty percent of each of the "2 principal display panels" be given over to the Government-drafted and mandated warnings.

61. Since the Act limits almost all advertisements for tobacco products to black-and-white-only text, Plaintiffs' advertisements effectively will be dominated by the mandated warnings—including, in the case of cigarette advertisements, the shocking color graphics. As a result, the only message consumers are likely to receive from Plaintiffs' advertisements is the Government-drafted anti-tobacco message.

62. Certain Plaintiffs advertise their cigarette and smokeless tobacco products together. Plaintiff Reynolds, for example, regularly advertises its cigarette and smokeless tobacco products together and otherwise would do so increasingly in the future. In these cases, the combined Government-mandated warnings, including, for cigarettes, the color graphic images, will result in an absurdity: at least 40 percent of the advertisements will be taken up by Government-drafted warnings and color imagery, with the remaining space, in virtually all cases, allowed for black-and-white text only from the Plaintiffs.

63. These restrictions undermine Plaintiffs' ability to compete against other tobacco product manufacturers. By virtually eliminating Plaintiffs' ability to communicate their truthful commercial messages to adult tobacco consumers, the Act undermines Plaintiffs' ability to convince adult consumers currently choosing a competitor's brand to switch.

64. Plaintiffs also have commercially valuable property rights to the packaging of their products, including the design of the packaging and the trademarked logos displayed on those packages. Plaintiffs have made substantial investments in their packaging design and in the trademarked logos displayed on their packaging. Plaintiffs have also made substantial

investment in marketing their products such that their brands can be identified by their packaging, including the design, color, and logos on the packaging.

65. Plaintiffs invested in their packaging and related marketing and intellectual property with the reasonable expectation that the Government would not attempt to so dominate the packaging as to preclude Plaintiffs from meaningfully using the package to display their own brand-identifying design and logos.

66. By appropriating Plaintiffs' packaging and advertisements for a Government-drafted anti-tobacco message (including, for cigarettes, shocking, graphic imagery) while, at the same time, denying Plaintiffs the right to use any color or imagery in most advertisements and relegating such imagery to the bottom of any packaging, the Act goes far beyond what is necessary to inform consumers about the health risks of tobacco use—a purpose that, for decades, has been fully met under existing law. *See* 15 U.S.C. §§ 1331, 1333 (cigarette warnings), and 4402 (smokeless tobacco warnings). Instead, it confiscates Plaintiffs' packaging and advertising to carry a clear and unequivocal Government-dictated message that is in direct conflict with Plaintiffs' commercial interests. It likewise deprives Plaintiffs of their trademarks, trade dress, packaging, and advertising without just compensation.

(3) Ban on Truthful Statements regarding Modified Risk Tobacco Products

67. The Act prohibits Plaintiffs from truthfully describing the relative health risks of different types of tobacco products. Pub. L. No. 111-31, sec. 101(b), § 911, 123 Stat. at 1784, 1812-19 (amending the FDCA to insert 21 U.S.C. § 387k).

68. Under the Modified Risk Tobacco Products provision, the Act prohibits the sale of "modified risk tobacco products" without advance approval by the FDA. The Act, however, defines "modified risk tobacco product" solely on the basis of how those products are described. Consequently, Plaintiffs cannot: (1) make any representation in a tobacco product's "label,

labeling or advertising" that "explicitly or implicitly" represents that the product is less harmful than other tobacco products or contains a reduced level (or is free) of harmful substances, or (2) take "any action directed to consumers through the media or otherwise . . . respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may" be less harmful than other tobacco products or presents a reduced exposure to (or is free of) harmful substances, unless (3) the FDA provides advance approval of such speech. *Id.* § 911(a), (b), 123 Stat. at 1812-13 (amending the FDCA to insert 21 U.S.C. § 387k(a)(1), (b)(1)). The Act thus allows the sale of reduced-risk tobacco products but prohibits truthful description of them as such absent prior Government approval.

69. Moreover, the FDA may not grant such advance approval to truthful, non-misleading statements unless the tobacco product at issue will: (1) "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users," and (2) "benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." *Id.* § 911(g)(1), 123 Stat. at 1814 (amending the FDCA to insert new 21 U.S.C. § 387k(g)(1)). Additionally, there is currently no time limit on the FDA's determination, and the Secretary may take up to two years before issuing regulations that "establish a reasonable timetable . . . to review an application." *Id.* § 911(l), 123 Stat. at 1818 (amending the FDCA to insert new 21 U.S.C. § 387k(l)).

70. The Act thus severely restricts truthful statements about the relative health risks of tobacco products. For example, even if a particular tobacco product would—to a reasonable scientific certainty—"significantly reduce harm and the risk of tobacco-related disease to individual tobacco users," Plaintiffs are flatly prohibited from informing consumers of this truthful information if the FDA determines that it would not "benefit the health of the population

as a whole." Under this vague and sweeping provision, if a particular type of tobacco product reduces risk "to individual tobacco users," the FDA can ban Plaintiffs from disseminating truthful information about the health risks of those products, if, in the FDA's view, dissemination of that truthful information may offer a level of reassurance that may encourage some tobacco users to consume those tobacco products rather than quitting altogether. "[T]he Constitution," however, "is most skeptical of supposed state interests that seek to keep the people in the dark for what the government believes to be their own good." *Rubin v. Coors Brewing Co*., 514 U.S. 476, 497 (1995) (Stevens, J., concurring) (citation omitted).

71. The irrationality of this provision is underscored by the Tobacco Product Standards provision of the Act. *See* Pub. L. No. 111-31, sec. 101(b), § 907, 123 Stat. at 1799-1804 (amending the FDCA to insert 21 U.S.C. § 387g). Under this provision, the FDA is authorized to restrict the "nicotine yields" or otherwise require "the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product," if the Secretary finds "that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful." *Id.* Under the Modified Risk Tobacco Products provision, Plaintiffs may not accurately describe the FDA's product standards without risking criminal punishment.

72. Nor is the Modified Risk Tobacco Products provision limited to commercial speech. To the contrary, it broadly restricts "any action directed to consumers through the media or otherwise," provided only that such action could "be reasonably expected" to result in "consumers believing" that the product "may" have some relative health benefit. For example,

Plaintiffs' scientists may wish to publish papers and participate in scientific debates regarding the relative health benefits of different tobacco products. Likewise, Plaintiffs' executives may engage in similar political and public policy debates about the use and regulation of these products. The Act's vague and sweeping Modified Risk Tobacco Products provision chills Plaintiffs' scientists and executives from participating in these public debates because they can easily be accused of directing their comments to consumers merely by participating in the public scientific debates. This type of restriction on core First Amendment speech is subject to strict scrutiny review and cannot pass muster under such review.

(4) Ban on Outdoor Advertising

73. The Act also resurrects a ban on outdoor advertising similar to the one invalidated by the U.S. Supreme Court in *Lorillard*, 533 U.S. 525.

74. In particular, the Act compels the FDA to either: (1) promulgate an outdoor advertising ban that prohibits all "outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, . . . within 1,000 feet of the perimeter of any public playground or playground area in a public park . . . , elementary school, or secondary school," or (2) promulgate a modified version of this provision by approximately March 22, 2010, which, without regard to the requirements of the Administrative Procedure Act, shall become effective on June 22, 2010. Pub. L. No. 111-31, § 102(a), 123 Stat. at 1830 (adopting 61 Fed. Reg. 44,617, § 897.30(b) (Aug. 28, 1996)); *id.* §§ 6(c)(1), 102(a)(2)(E), 123 Stat. at 1783, 1831.

75. In *Lorillard*, the Supreme Court invalidated under the First Amendment a Massachusetts prohibition almost identical to the first option. As the Supreme Court explained, the prohibition amounts to "nearly a complete ban on the communication of truthful information about [tobacco products] to adult consumers" in major metropolitan areas. *Lorillard*, 533 U.S. at 562.

76. Under the second option, the Act fails to provide any meaningful procedural protections. The Secretary has unfettered discretion to issue a modified "final" regulation without any process and without any opportunity for Plaintiffs to be heard about the specifics of the proposed regulation. This lack of any prior notice of the "final" regulation severely prejudices Plaintiffs, who must plan advertising expenditures well in advance and will not have time to adjust their behavior to comply with the regulation. Moreover, without advance notice of the specifics of a "final" regulation, Plaintiffs cannot comment meaningfully on the proposal.

77. This prohibition is particularly burdensome to Plaintiff Discount Tobacco City and other retailers of tobacco products. On-site advertising of tobacco products constitutes an important means by which convenience stores, gas stations, and other small retail stores that sell tobacco products generate sales, not only of tobacco products, but also of non-tobacco items. To stimulate traffic in such stores, retailers advertise on the outside of their stores that popular brands of tobacco are available inside the store. Once inside the store to purchase tobacco products, consumers often purchase non-tobacco products as well. Therefore, outdoor advertisements for tobacco products often trigger spontaneous purchase decisions of non-tobacco products. The Act, however, places severe restrictions on these retailers from engaging in this type of outdoor advertising.

(5) Ban on Brand Name Sponsorship of Events

78. The Act prohibits any "manufacturer, distributor, or retailer" of tobacco products from "sponsor[ing] or caus[ing] to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name . . . , logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco." Pub. L. No. 111-31, § 102(a), 123 Stat. at 1830 (adopting 61 Fed. Reg.

44,618, § 897.34(c) (Aug. 28, 1996)). The Act thus imposes a complete ban on Plaintiffs' sponsorship of any sporting, cultural, or social event, if they do so in conjunction with a tobacco product brand.

79. This absolute ban contains no exceptions. It applies to all events, including the broad and amorphous category "other social or cultural event[s]." *Id.* It likewise applies to all facilities, including adult-only facilities such as bars and nightclubs.

80. For example, Plaintiff Lorillard sponsors a blackjack tournament in Las Vegas that it calls the Newport Blackjack Tournament. Participants in the tournament must be 21 or older and proof of age is required to participate. The event is private and is held at a casino that does not permit minors to enter the event locale. Notwithstanding the adult-only nature of this event, it is prohibited under the Act, assertedly to protect children from tobacco advertising.

(6) Ban on Brand Name Merchandise

81. The Act prohibits any manufacturer of tobacco products from marketing, distributing, or selling any promotional item (such as hats and t-shirts) bearing the "brand name . . . , logo, symbol, motto, selling message, [or] recognizable color or pattern of colors" of any tobacco product brand. Pub. L. No. 111-31, § 102(a), 123 Stat. at 1830 (adopting 61 Fed. Reg. 44,617, § 897.34(a) (Aug. 28, 1996)).

82. Like the sponsorship ban, this absolute ban on brand name merchandise contains no exceptions. It thus applies to merchandise that is given or sold solely to adult consumers or to employees of Plaintiffs, and regardless of whether such merchandise is suitable for use by youth.

(7) Ban on References to FDA

83. The Act prohibits Plaintiffs from making "any express or implied statement or representation directed to consumers" "through the media or advertising" that "conveys, or misleads or would mislead consumers into believing, that – (1) the product is approved by the

[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 [either] (A) its regulation or inspection by the [FDA]; or (B) its compliance with regulatory requirements set by the [FDA]." Pub. L. No. 111-31, sec. 103(b), § 301(tt), 123 Stat. at 1834-35 (amending the FDCA to add insert 21 U.S.C. § 331(tt)).

84. This ban contains no exceptions. It is not limited to statements made by tobacco product manufacturers in the course of proposing a sale. It applies instead to any speaker in any medium, including, for example, statements or representations made in the course of a scientific, political, or public policy debate over the costs and benefits of FDA regulation of tobacco products.

85. The ban is also extremely vague. It thus arguably prohibits Plaintiffs from making any reference "through the media" to the truthful fact that the FDA regulates tobacco products, because such reference could be construed as an "implied . . . representation" that the product is "approved," "deem[ed] . . . safe," or "endorsed" by the FDA, or "less harmful by virtue of" regulation by the FDA. At a minimum, the Act chills Plaintiffs from engaging in such truthful speech, including truthful non-commercial speech.

86. The irrationality of this provision is underscored by the Tobacco Product Standards provision of the Act, which, as noted, authorizes the FDA to "require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product" if it determines that such reduction or elimination "is appropriate for the protection of public health." Pub. L. No. 111-31, sec. 101(b), § 907, 123 Stat. at 1799-1804 (amending the FDCA to insert 21 U.S.C. § 387g). Thus, the Act explicitly authorizes the FDA to

decide what products lawfully may be sold, but prohibits anyone from truthfully describing the consequences of the FDA's regulations.

(8) Ban on Distributing Product Samples

87. The Act prohibits any "manufacturer, distributor, or retailer" of "cigarettes, smokeless tobacco, or other tobacco products" from "distribut[ing] or caus[ing] to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products." Pub. L. No. 111-31, § 102(a)(1), (a)(2)(G), 123 Stat. at 1830-33 (adopting and amending paragraph (d) of § 897.16 of 61 Fed. Reg. 44,616-17 (Aug. 28, 1996)). A free sample promotion is one method by which manufacturers speak to, and communicate information regarding their products with, adult tobacco consumers.

88. This ban is absolute with respect to cigarettes. Thus, Plaintiffs are prohibited from giving free samples to anyone, anywhere. They can neither give such free samples to adult tobacco consumers nor distribute such free samples in adult-only facilities or at adult-only events.

89. The Act contains a limited exception for smokeless tobacco products. Unlike a cigarette manufacturer, a manufacturer or seller of smokeless products may distribute free samples of smokeless tobacco in "a qualified adult-only facility." Pub. L. No. 111-31, § 102(a)(2)(G), 123 Stat. at 1831 (adding subparagraph (d)(2)(A) to § 897.16 of 61 Fed. Reg. 44,616-17 (Aug. 28, 1996)).

90. This exception, however, does not apply in any facility that "sell[s], serve[s], or distribute[s] alcohol," *id.* (adding subparagraph (d)(2)(C)(ii) to § 897.16). Barring samples of smokeless tobacco products from facilities where alcohol is sold, served, or distributed, makes no sense in light of the Act's purported aim of reducing youth tobacco use. It is of course illegal

to sell alcohol to minors, and many facilities that serve alcohol—e.g., bars and nightclubs—generally do not allow entry by minors.

(9) Ban on Joint Product Marketing

91. The Act prohibits Plaintiffs from marketing a tobacco product "in combination with any other article or product regulated" by the FDA. Pub. L. No. 111-31, sec. 101(a), § 321(rr)(4), 123 Stat. at 1783-84 (amending the FDCA to insert new 21 U.S.C. § 321(rr)(4)).

92. This ban is absolute. Thus, Plaintiffs cannot market tobacco products in conjunction with other products regardless of whether such other products are intended for adult users, and regardless of whether such joint marketing would be directed solely at adults and/or solely distributed in adult-only facilities. For example, Reynolds operates a national program with more than one hundred retailers in which it sends a mailing to certain age-verified, adult tobacco consumers on its direct-marketing database in conjunction with a promotion being offered by a participating local retailer of its brands. The mailing contains content created by Reynolds regarding one or more of its brands, and content created by the local retailer. At times in the past, local retailers have chosen to communicate about promotions involving discounts on food or beverages. The provision also would ban a manufacturer from marketing any quit-smoking product or method that combines a smoking cessation drug (even if FDA-approved), with step-down tobacco content products, even if such a step-down method were proven to be the most effective way for most adult smokers to quit.

(10) Ban on Promotions Offering Gifts in Consideration of the Purchase of Cigarettes or Smokeless Tobacco

93. The Act prohibits Plaintiffs from engaging in promotions that offer gifts or other items in consideration of the purchase of cigarettes or smokeless tobacco or "to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a

purchase." Pub. L. No. 111-31, § 102(a), 123 Stat. at 1830 (adopting 61 Fed. Reg. 44,617-18, § 897.34(b) (Aug. 28, 1996)). Such promotions are methods by which manufacturers speak to, and communicate information regarding their products with, adult tobacco consumers.

94. The Act's ban is absolute. It applies even when such promotions are offered exclusively to adults who already smoke, and even when extraordinary measures are taken to ensure that minors do not participate in such promotional programs.

95. For example, Plaintiff Lorillard engages in a promotional program called Newport Pleasure Goods, which permits adult smokers to mail in Universal Product Code or "UPC" labels from Newport cigarettes in exchange for various prizes, such as MP3 players, digital cameras, and prepaid gift cards from the Discover Network. The promotion is open only to smokers who can affirmatively demonstrate that they are 21 years or older. The Act would prohibit this promotional program, notwithstanding Lorillard's extensive efforts to ensure that it is limited to adult smokers over the age of 21.

(11) Authorization of Further Restrictions

96. Finally, the Act delegates to federal agencies, state and local governments, and Indian tribes the authority to adopt additional laws. The Act provides that federal agencies, states or subdivisions, or Indian tribes may "enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than" those of the Act, including with respect to "advertising and promotion." Pub. L. No. 111-31, sec. 101(b), § 916, 123 Stat. at 1823-24 (amending the FDCA to insert 21 U.S.C. § 387p). Likewise, states or localities may enact statutes and promulgate regulations that impose "specific bans or restrictions on the time, place, and manner, but not content," of cigarette advertising and promotion. Pub. L. No. 111-31, § 203, 123 Stat. at 1846 (amending the FCLAA to insert 15 U.S.C. § 1334(c)). These provisions contain unconstitutional grants of legislative

authority, and the Act fails to impose any intelligible principle limiting the delegated authority. Instead, the Act expressly invites the enactment of laws that are "more stringent" than the already unconstitutional proscriptions of the Act.

There Is No Adequate Justification for These Limits on Plaintiffs' Marketing and Sale of Tobacco Products

97. It is well established that Congress may not impose limitations on truthful commercial speech unless the Government proves that: (1) the restrictions are intended to further a substantial government interest, (2) the restrictions directly advance the asserted government interest, and (3) the restrictions are narrowly tailored such that they are "not more extensive than is necessary" to advance the asserted substantial government interest. *Central Hudson*, 447 U.S. at 566. In this regard, "the existence of 'numerous and obvious less-burdensome alternatives to the restriction on commercial speech … is certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable.'" *Fla. Bar v. Went For It*, 515 U.S. 618, 632 (1995) (citation omitted).

98. It is similarly well established that for truthful non-commercial speech (if not for commercial speech as well), Congress may not impose limitations unless the Government proves that the restriction is "narrowly tailored to promote a compelling Government interest. If a less restrictive alternative would serve the Government's purpose, the legislature must use that alternative. To do otherwise would be to restrict speech without an adequate justification." *United States v. Playboy Entm't Group*, 529 U.S. 803, 813 (2000) (citation omitted).

99. Here, the Act imposes numerous limitations without exceptions on commercial and non-commercial speech. The Government, however, cannot establish a substantial (much less compelling) interest in restricting Plaintiffs' speech, that "the 'fit' between ends and means is reasonable," or that these limitations are "narrowly tailored."

100. The Government's primary purported justification for the Act is to reduce youth tobacco use. Pub. L. No. 111-31, § 2, 123 Stat. at 1776-81. Yet the Act's challenged provisions are not even remotely directed at that asserted goal. Instead, the Act broadly and indiscriminately restricts speech regardless of whether it is directed at adults or at youth or advances the Act's asserted goal of reducing youth tobacco use.

101. To the extent the Act also is secondarily predicated on preventing the health consequences of adult tobacco use, it is well established that there is no "vice" exception to the First Amendment, and "a 'vice' label that is unaccompanied by a corresponding prohibition against the commercial behavior at issue fails to provide a principled justification for the regulation of commercial speech about that activity." *44 Liquormart*, 517 U.S. at 514 (plurality op.). Indeed, the Supreme Court has repeatedly rejected governmental attempts to equate less information with better decision-making. Congress, having repeatedly decided not to ban tobacco products, cannot prohibit Plaintiffs from speaking about their lawful products.

102. Thus, not only are these purported governmental interests pretextual, they are not directly advanced by the Act's numerous speech restrictions.

103. The Act, moreover, ignores numerous (and obvious) conduct-based restrictions that could have advanced the Government's asserted interests. For example, Congress could have increased enforcement of existing state laws prohibiting the sale of tobacco products to minors, criminalized possession of tobacco products by underage users, increased funding for anti-smoking educational campaigns, increased funding for smoking cessation programs, initiated legal action against manufacturers who market products in a false or misleading way, or imposed federal restrictions on possessing or selling cigarettes. Instead, the Act opts for unprecedented restrictions on commercial and non-commercial speech.

104. The legislative history of the Act confirms Congress's indiscriminate and untailored approach.

105. In 1996, the FDA asserted (without congressional authorization) to assume jurisdiction over, and initiated comprehensive regulation of, tobacco products under the medical device provisions of the FDCA. The regulations the FDA promulgated in 1996, which are almost identical to the regulations that Congress directs the FDA to implement following the passage of the Act, placed strict limits on tobacco manufacturers' advertising and promotional practices, in the name of preventing youth tobacco use. Those regulations never took effect, however, because the Supreme Court found that the FDA did not have jurisdiction to regulate tobacco products. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

106. Similarly, in 1999, the Massachusetts Attorney General promulgated regulations limiting the advertising and promotion of tobacco products within that state. By way of example, one of those regulations purported to ban tobacco advertising located within one thousand feet of a public playground, playground area of a public park, or elementary or secondary school. The Supreme Court struck down these restrictions because they violated the First Amendment. *Lorillard*, 533 U.S. 525.

107. The world has changed dramatically in the 13 years since the FDA first attempted to regulate tobacco in 1996. Nearly all indicators show significant decreases in both youth and overall smoking rates. The Centers for Disease Control and Prevention ("CDC") reported this year that adult cigarette use decreased from 24.7 percent in 1995 to 19.8 percent in 2007. The CDC also reported that the prevalence of daily smoking among 12th grade high school students decreased from 21.6% to 11.4% over that same period. All of these significant decreases occurred without the unprecedented speech restrictions contained in the Act.

108. Congress, however, did not consider the numerous alternatives discussed above or the recent dramatic decreases in youth tobacco use reported by the CDC. Congress instead chose a blunderbuss, rather than a scalpel, in re-enacting regulations that the FDA adopted in 1996 and that Massachusetts adopted in 1999, including provisions virtually identical to those the Supreme Court has already declared unconstitutional. This regurgitation of the 1996 proposed regulations failed to consider the numerous available and effective alternatives adopted throughout the country—and that have proven successful.

109. Moreover, fifteen years ago, the Surgeon General reported that "virtually all U.S. adolescents—smokers and nonsmokers alike—are aware of the long-term health effects of smoking." United States Dep't of Health & Human Servs., *Report of the Surgeon General: Preventing Tobacco Use Among Young People* 135 (1994). The Surgeon General noted that this knowledge does not prevent the onset of tobacco use by young people because "many adolescents feel inherently invulnerable in their characteristically short-term view." *Id.* The Government cannot demonstrate that the Act's restrictions will further increase consumer awareness or reduce youth tobacco use.

The Act Is Already Harming Plaintiffs

110. Because Plaintiffs' products and advertisements do not currently conform to the new standards imposed by the Act and because Plaintiffs need to conform to the requirements of the Act in the immediate future, Plaintiffs' speech is already being chilled. Some of the Act's provisions have taken effect and are currently constraining Plaintiffs' speech. And even the provisions that are set to take effect at a definite time in the future are adversely affecting Plaintiffs' businesses and rights.

111. To conform to the Act's requirements, Plaintiffs already have been forced to commence efforts to modify their product packaging and advertising, and to develop new business and marketing practices.

112. Likewise, certain Plaintiffs' scientists and executives who have in the past participated in scientific, public policy, and political debates regarding the use and regulation of tobacco products, have had their speech chilled with respect to current and future participation in such debates.

113. Plaintiffs fear that if they do not conform their behavior to the requirements of the Act, their products will be seized by the FDA. The FDA has not disavowed an intention to enforce the new law.

114. The Act's speech restrictions have had and will continue to have a direct and materially adverse effect on Plaintiffs' businesses. The Act is targeted directly at Plaintiffs and their business practices.

115. The Act has caused substantial hardship to Plaintiffs.

116. Plaintiffs' allegations in this Complaint are justiciable.

FIRST COUNT

Declaratory Judgment That the Act's Black-and-White Text Requirement Is Unconstitutional

117. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-116 of this Complaint, as though fully set forth herein.

118. The Act's black-and-white text requirement that bans the use of colors and graphics in labeling and advertising, Pub. L. No. 111-31, § 102(a)(2), 123 Stat. at 1830 (adopting § 897.32(a) of 61 Fed. Reg. 44,617 (Aug. 28, 1996)), and *id*. sec. 101(b), § 913, 123 Stat. at 1820 (amending the FDCA to insert 21 U.S.C. § 387m), is an unconstitutional infringement of

Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

119. The Act's black-and-white text requirement also effects an unconstitutional taking in violation of the Fifth Amendment to the United States Constitution.

120. Plaintiffs have no adequate remedy at law.

121. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's provision known as the black-and-white text requirement.

SECOND COUNT

Declaratory Judgment That the Act's Warning Label Provisions Are Unconstitutional

122. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-121 of this Complaint, as though fully set forth herein.

123. The Act's warning label provisions that require tobacco product labels and advertisements to contain one of several specified, pre-approved warnings that occupy large portions of advertising and of the two principal display panels of packaging, including graphic, color images on cigarette advertising and packaging, Pub. L. No. 111-31, sec. 201(a), (b), § 4(a), (b), (d), 123 Stat. at 1842-43, 1845 (amending the FCLAA to insert new 15 U.S.C. § 1333(a), (b), (d)); and *id*. sec. 204(a), (b), § 3(a), (b), 123 Stat. at 1846-47 (amending the CSTHEA to insert new 15 U.S.C. § 4402(a), (b)); and that also mandate extensive other information to be included on packaging, *id*. sec. 101(b), § 903, 123 Stat. at 1788 (amending the FDCA to insert new 21 U.S.C. § 387c); *id*. § 103(q)(5), 123 Stat. at 1840-41; and *id*. sec. 301, § 920, 123 Stat. at 1850-51 (amending the FDCA to insert 21 U.S.C. § 387t), are an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

124. The Act's warning label provisions also effect an unconstitutional taking in violation of the Fifth Amendment to the United States Constitution.

125. Plaintiffs have no adequate remedy at law.

126. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's warning label provisions.

THIRD COUNT

Declaratory Judgment That the Act's Ban on Truthful Statements regarding Modified Risk Tobacco Products Are Unconstitutional

127. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-126 of this Complaint, as though fully set forth herein.

128. The Act's Modified Risk Tobacco Products provision, which allows for the sale of reduced-risk tobacco products but prohibits Plaintiffs from accurately describing such products, Pub. L. No. 111-31, sec. 101(b), § 911, 123 Stat. at 1812-19 (amending the FDCA to insert 21 U.S.C. § 387k), is an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

129. The broad and vaguely worded provisions of the Act's Modified Risk Tobacco Products provision likewise are an unconstitutional infringement of Plaintiffs' due process rights as guaranteed by the Fifth Amendment to the Constitution.

130. Plaintiffs have no adequate remedy at law.

131. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's Modified Risk Tobacco Products requirement.

FOURTH COUNT

Declaratory Judgment That the Act's Outdoor Advertising Ban Is Unconstitutional

132. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-131 of this Complaint, as though fully set forth herein.

133. The Act's provision banning outdoor advertising within one thousand feet of designated locations, Pub. L. No. 111-31, § 102(a), 123 Stat. at 1830 (adopting 61 Fed. Reg. 44,617, § 897.30(b) (Aug. 28, 1996)), or requiring publication of an altered final rule without appropriate notice and opportunity for comment, *id*. § 102(a)(2)(E), 123 Stat. at 1831, *id*. § 102(a)(1), 123 Stat. at 1830, as modified by § 6(c)(1), 123 Stat. 1783, and *id*. § 102(a)(2)(F), 123 Stat. 1831, is an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

134. This provision also violations Plaintiffs' due process rights as guaranteed by the Fifth Amendment to the United States Constitution.

135. Plaintiffs have no adequate remedy at law.

136. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's provision banning outdoor advertising within one thousand feet of designated locations.

FIFTH COUNT

Declaratory Judgment That the Act's Ban on Brand Name Sponsorship of Events Is Unconstitutional

137. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-136 of this Complaint, as though fully set forth herein.

138. The Act's provision that bans brand name sponsorship of sporting, cultural, and other events, Pub. L. No. 111-31, § 102(a), 123 Stat. at 1830 (adopting 61 Fed. Reg. 44,618, §

897.34(c) (Aug. 28, 1996)), is an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

139. Plaintiffs have no adequate remedy at law.

140. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's provision that bans brand name sponsorship of sporting, cultural, and other events.

SIXTH COUNT

Declaratory Judgment That the Act's Ban on Branded Promotional Items Is Unconstitutional

141. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-140 of this Complaint, as though fully set forth herein.

142. The Act's provision that bans the use and distribution of promotional items that contain the brand name, logo, symbol, motto, selling message, or recognizable color or pattern of any brand of cigarettes or smokeless tobacco, Pub. L. No. 111-31, § 102(a), 123 Stat. at 1830 (adopting 61 Fed. Reg. 44,617, § 897.34(a) (Aug. 28, 1996)), is an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

143. Plaintiffs have no adequate remedy at law.

144. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's provision that bans the use and distribution of promotional items that contain the brand name, logo, symbol, motto, selling message, or recognizable color or pattern of any brand of cigarettes or smokeless tobacco.

SEVENTH COUNT

Declaratory Judgment That the Act's Ban on Truthful Statements regarding FDA Regulation, Approval, or Compliance Is Unconstitutional

145. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-144 of this Complaint, as though fully set forth herein.

146. The Act's provision banning truthful statements that a tobacco product is regulated or approved by the FDA or in compliance with FDA regulations, Pub. L. No. 111-31 sec. 103(b), § 301(tt), 123 Stat. at 1834-35 (amending the FDCA to insert 21 U.S.C. § 331(tt)), is an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

147. Plaintiffs have no adequate remedy at law.

148. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's provision banning truthful statements that a tobacco product is regulated or approved by the FDA or in compliance with FDA regulations.

EIGHTH COUNT

Declaratory Judgment That the Act's Ban on the Distribution of Cigarette Samples and Effective Ban on the Distribution of Smokeless Tobacco Samples Are Unconstitutional

149. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-148 of this Complaint, as though fully set forth herein.

150. The Act's provision that bans the distribution of cigarette samples and effectively bans the distribution of smokeless tobacco samples, Pub. L. No. 111-31, § 102(a)(1), (a)(2)(G), 123 Stat. at 1830-33 (adopting and amending paragraph (d) of § 897.16 of 61 Fed. Reg. 44,616-17 (Aug. 28, 1996)), is an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

151. Plaintiffs have no adequate remedy at law.

152. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's provision that bans the distribution of cigarette samples and effectively bans the distribution of smokeless tobacco samples.

NINTH COUNT

Declaratory Judgment That the Act's Ban on Joint Product Marketing Is Unconstitutional

153. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-152 of this Complaint, as though fully set forth herein.

154. The Act's provision that bans joint product marketing, Pub. L. No. 111-31, sec. 101(a), § 321(rr)(4), 123 Stat. at 1783-84 (amending the FDCA by inserting 21 U.S.C. § 321(rr)(4)), is an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

155. Plaintiffs have no adequate remedy at law.

156. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's provision banning joint product marketing.

TENTH COUNT

Declaratory Judgment That the Act's Ban on Promotions Offering Gifts in Consideration of the Purchase of Cigarettes or Smokeless Tobacco Is Unconstitutional

157. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-156 of this Complaint, as though fully set forth herein.

158. The Act's provision that bans promotions that offer gifts or items in consideration of the purchase of cigarettes or smokeless tobacco or "to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase," Pub. L. No. 111-31, § 102(a), 123 Stat. at 1830 (adopting 61 Fed. Reg. 44,617-18, § 897.34(b) (Aug.

28, 1996)), is an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

159. Plaintiffs have no adequate remedy at law.

160. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's provision that bans promotions that offer gifts or items in consideration of the purchase of cigarettes or smokeless tobacco or "to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase."

ELEVENTH COUNT

Declaratory Judgment That the Act's Authorization of Further Restrictions Is Unconstitutional

161. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-160 of this Complaint, as though fully set forth herein.

162. The Act's provisions that authorize federal agencies, states or subdivisions, or Indian tribes to "enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than" those of the Act, including with respect to "advertising and promotion," Pub. L. No. 111-31, sec. 101(b), § 916, 123 Stat. at 1823-24 (amending the FDCA to insert 21 U.S.C. § 387p), and to enact statutes and promulgate regulations that impose "specific bans or restrictions on the time, place, and manner, but not content," of cigarette advertising and promotion, Pub. L. No. 111-31, § 203, 123 Stat. at 1846 (amending the FCLAA to insert 15 U.S.C. § 1334(c)), is an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

163. These provisions also unconstitutionally delegate legislative power to an entity outside the Legislative Branch.

164. Plaintiffs have no adequate remedy at law.

165. Plaintiffs thus seek the entry of a judgment declaring unconstitutional the Act's provisions authorizing further restrictions on Plaintiffs' speech rights.

TWELFTH COUNT

Declaratory Judgment That the Act Violates Plaintiffs' First and Fifth Amendment Rights

166. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-165 of this Complaint, as though fully set forth herein.

167. The Act's provisions, including the provisions cited as examples in paragraphs 1, 3-4, 6, 22-23, 29-30, 36, 38-63, 67-96, 100-04, 110-23, and 126-76 of this Complaint, are an unconstitutional infringement of Plaintiffs' free speech rights as guaranteed by the First Amendment to the United States Constitution.

168. The Act's provisions, including the provisions cited as examples in paragraphs 1, 3, 6, 22-26, 30, 39-66, 111, and 117-26 of this Complaint, are an unconstitutional taking of Plaintiffs' private property without just compensation, in violation of the Fifth Amendment to the United States Constitution.

169. The Act's provisions, including the provisions cited as examples in paragraphs 1, 3-4, 6, 22-23, 29-30, 36, 38-63, 67-96, 100-04, 110-23, and 126-76 of this Complaint, are facially invalid in that they are substantially overbroad.

170. The Act's provisions, including the provisions cited as examples in paragraphs 1, 3-4, 6, 22-23, 29-30, 36, 38-63, 67-96, 100-04, 110-23, and 126-76 of this Complaint, are invalid as applied to Plaintiffs in that they violate Plaintiffs' free speech rights under the First Amendment by imposing prior restraints upon, suppressing, chilling, compelling, and otherwise restricting Plaintiffs' protected speech.

171. Moreover, the Act's restrictions on protected speech collectively cut off virtually all means available to Plaintiffs to communicate truthfully with the adult consumers of Plaintiffs' legal products.

172. Plaintiffs have no adequate remedy at law.

173. Plaintiffs thus seek the entry of a judgment declaring the Act's speech restrictions, both individually and collectively, to be an unconstitutional abridgement of Plaintiffs' rights under the First and Fifth Amendments to the United States Constitution.

THIRTEENTH COUNT

Request for a Preliminary Injunction

174. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-173 of this Complaint as though fully set forth herein.

175. Some of the Plaintiffs have no adequate remedy at law.

176. Those Plaintiffs thus seek the entry of a preliminary injunction, enjoining Defendants from taking any action to enforce those challenged provisions of the Act that are already in effect (Counts Three and Nine), to protect those Plaintiffs' rights while these proceedings are pending.

FOURTEENTH COUNT

Request for a Permanent Injunction

177. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-176 of this Complaint as though fully set forth herein.

178. Plaintiffs have no adequate remedy at law.

179. Plaintiffs thus seek the entry of a permanent injunction, enjoining Defendants from enforcing the Act's restrictions herein challenged, to protect Plaintiffs' rights after the final resolution of these proceedings.

PRAYER FOR RELIEF

Actual controversies have arisen between the parties entitling Plaintiffs to a declaration and injunctive relief.

WHEREFORE, Plaintiffs pray that this Court:

(A) enter a judgment declaring the Act's speech restrictions, both individually and collectively, to be an unconstitutional abridgement of Plaintiffs' free speech rights under the First Amendment to the United States Constitution;

(B) enter a judgment declaring that the Act's warning label and black-and-white text provisions, individually and collectively, effect an unconstitutional taking in violation of the Fifth Amendment to the United States Constitution;

(C) enter a judgment declaring that the Modified Risk Tobacco Products provision violates Plaintiffs' due process rights under the Fifth Amendment to the United States Constitution;

(D) enter a judgment declaring that the provision allowing modification by the Secretary of the outdoor advertising ban violates Plaintiffs' due process rights under the Fifth Amendment to the United States Constitution;

(E) enter a judgment declaring that the Act's restrictions herein challenged collectively effect an unconstitutional taking in violation of the Fifth Amendment to the United States Constitution;

(F) enter a judgment declaring that the Act's provisions allowing the enactment of additional or more stringent laws is an unconstitutional infringement of Plaintiffs' free speech rights and an unconstitutional delegation of legislative power to entities outside the Legislative Branch;

(G) enter, after hearing, a preliminary injunction, pending final resolution of this action, enjoining Defendants from taking any action to enforce the Act;

(H) enter a permanent injunction enjoining Defendants from enforcing the Act's restrictions herein challenged; and

(I) grant Plaintiffs such additional or different relief as it deems just and proper, including an award of reasonable attorneys' fees and the costs of this action.

Dated: August 31, 2009

ENGLISH, LUCAS, PRIEST & OWSLEY, LLP
P.O. Box 770
1101 College Street
Bowling Green, KY 42102-0770
Telephone: (270) 781-6500
Facsimile: (270) 782-7782
E-mail: kames@elpolaw.com
ATTORNEYS FOR PLAINTIFFS

/s/ Charles E. English
Charles E. English
Charles E. English, Jr.
D. Gaines Penn
E. Kenly Ames

OF COUNSEL:

Philip J. Perry
Scott J. Ballenger
LATHAM & WATKINS LLP
555 11th Street, NW, Suite 1000
Washington DC 20004-1304
Telephone: (202) 637-2200

ATTORNEYS FOR PLAINTIFF
COMMONWEALTH BRANDS, INC.

Floyd Abrams
Joel Kurtzberg
CAHILL GORDON & REINDEL LLP
80 Pine Street
New York, NY 10005-1702
Telephone: (212) 701-3000

ATTORNEYS FOR PLAINTIFF
LORILLARD TOBACCO CO.

Robert F. McDermott, Jr.
Donald B. Ayer
Geoffrey K. Beach
Noel J. Francisco
JONES DAY
51 Louisiana Avenue, NW
Washington, D.C. 20001-2113
Telephone: (202) 879-3939

- and -

Leon F. DeJulius, Jr.
JONES DAY
500 Grant St., Suite 4500
Pittsburgh, PA 15219
Telephone: (412) 391-3939

ATTORNEYS FOR PLAINTIFFS
CONWOOD COMPANY, LLC AND R.J.
REYNOLDS TOBACCO COMPANY

853094