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Smoking Out Big Tobacco: Can the Family Smoking Prevention and Tobacco Control Act Equip the FDA to Regulate Tobacco Without Infringing on the First Amendment?

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SMOKING OUT BIG TOBACCO: CAN THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT EQUIP THE FDA TO REGULATE TOBACCO WITHOUT INFRINGING ON THE FIRST AMENDMENT?

ABSTRACT

Tobacco use is one of the most catastrophic public health issues facing the world today. The recently passed Family Smoking Prevention and Tobacco Control Act (FSPTCA) gives the United States Food and Drug Administration (FDA) unprecedented power to regulate tobacco products. While Congress has explicitly maintained the legality of tobacco distribution in the United States, the FDA's newfound regulatory authority under the FSPTCA is a necessary step to continue the fight against tobacco use. Among the most significant provisions of the FSPTCA are restrictions aimed at tobacco advertising and promotions. These provisions, however, may unconstitutionally infringe on First Amendment commercial speech under the judicially crafted commercial speech doctrine governed by Central Hudson Gas & Electric Corp. v. Public Service Commission. Indeed, after the FSPTCA's passage, several tobacco companies filed suit, arguing that these advertising restrictions violate the First Amendment.

This Comment examines the constitutionality of the FSPTCA by first explaining the development of the commercial speech doctrine from Central Hudson to Lorillard Tobacco Co. v. Reilly, the Supreme Court's most recent application of the commercial speech doctrine. This Comment further explains the wavering deference afforded the legislature under this doctrine, making Central Hudson's modern application uncertain. It then follows with an analysis of the relevant FSPTCA provisions at issue, examines proposed amendments to make the FSPTCA constitutional, and discusses implications for the FDA's jurisdiction over tobacco.

Ultimately, in light of the probable unconstitutionality of a portion of the FSPTCA, this Comment argues that Congress must amend the provisions by narrowly tailoring them to meet the government's substantial interest in preventing underage tobacco consumption. If these provisions are not modified to fall within the constitutional confines of Central Hudson, the FSPTCA will be nothing more than an impotent piece of legislation, leaving an overworked FDA to pick up the pieces.

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INTRODUCTION: FIGHTING THE WAR AGAINST TEEN SMOKING

*[T]he marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare.*¹

After nearly fifty years of falling smoking rates, tobacco consumption in the United States is increasing.² Today, roughly 20% of adults in the United States are smokers.³ Smoking kills more than 400,000 Americans a year⁴ and more than five million people worldwide.⁵ Death is not the only social ill caused by tobacco products; the Centers for Disease Control and Prevention estimates that tobacco-related illness in the United States costs upward of \$193 billion each year in health care expenditures and lost productivity.⁶ Equally troublesome is the number of young people using tobacco products in the United States. According to the Surgeon General, more than three million American adolescents use smoking products, one million adolescent males use smokeless tobacco products, and 82% of adults who have tried smoking first smoked when they were under the age of eighteen.⁷ In contrast to the striking toll on productivity and millions of deaths around the globe is the enormous profit for the corporations that control the tobacco market.⁸ To protect this

¹ FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 137 (2000) (quoting Agriculture Adjustment Act of 1938, 7 U.S.C. § 1311(a) (2000), *repealed* by American Jobs Creation Act of 2004, Pub. L. No. 108-357, § 611(a), 118 Stat. 1418, 1522) (internal quotation marks omitted).

² Betsy McKay, *Downward Trend in Smoking Rate Stalls*, WALL ST. J., Nov. 13, 2009, at A3 (discussing the Centers for Disease Control and Prevention (CDC) 2008 national survey and reporting that states who have used more aggressive regulatory schemes to curtail smoking have lower smoking rates and that the CDC is hopeful that the FDA's newly implemented regulatory scheme will have a more beneficial impact on the continuing decline in smoking rates).

³ *Id.* (increasing from 19.8% in 2007 to 20.6% in 2008).

⁴ It has been well publicized that smoking has killed more than 400,000 people a year in the United States since the late 1980s. See, e.g., *Cigarette Smoking: Attributable Mortality and Years of Potential Life Lost—United States, 1990*, 42 MORBIDITY & MORTALITY WEEKLY REP. 645, 645 (1993) (434,000 deaths attributable to tobacco use in 1988); *Smoking & Tobacco Use: Fast Facts*, CTRES. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts (last updated Sept. 15, 2010) (443,000 Americans die of tobacco-related causes each year).

⁵ See *Smoking & Tobacco Use: Fast Facts*, *supra* note 4.

⁶ See *id.* (\$97 billion in lost productivity and \$96 billion in health care expenditures).

⁷ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996) (codified as amended at 21 C.F.R. pts. 897, 1140) [hereinafter 1996 Final Rule] (citing U.S. DEP'T OF HEALTH & HUMAN SERVS., PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GENERAL 5, 65 (1994)).

⁸ Compare Duff Wilson, *Philip Morris Meeting Mixes Tobacco Profit and Protests*, N.Y. TIMES, May 6, 2009, at B5 (reporting profits of \$16.3 billion on cigarettes sold outside the United States), with British Am. Tobacco, Big Four Tobacco Profits Summary (Jan. 1, 1992), available at <http://legacy.library.ucsf.edu/tid/>

market share and profitability, tobacco companies spend more than \$6.1 billion a year on advertising.⁹

While headlines in recent decades have publicized strong efforts by the United States Food and Drug Administration (FDA) to curb tobacco use,¹⁰ the government has not always been so assertive in addressing the public health problems created by tobacco products.

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA).¹¹ The FDCA defines the scope of FDA jurisdiction over drugs and medical devices¹² and requires the FDA to ensure that all drugs and devices are safe and effective.¹³ Less than twenty years after the FDCA's passage, the Surgeon General declared that smoking causes lung cancer and other diseases.¹⁴ In response, the House passed a bill amending the FDCA to include FDA oversight of tobacco,¹⁵ but the bill never made it through the Senate.

Following that failure, Congress enacted numerous pieces of legislation designed to regulate the tobacco industry. For instance, in 1965, Congress enacted the Federal Cigarette Labeling and Advertising Act (FCLAA).¹⁶ Since the FCLAA's inception, the Federal Trade Commission (FTC) has exercised regulatory authority over cigarette labels and imposed restrictions on claims, while enforcing mandatory Surgeon General's warnings on packaging.¹⁷ In

uai50a99/pdf (showing that the combined profits of the top four tobacco companies were over \$16.8 billion in 1992, and Phillip Morris's profits were over \$10.9 billion in that same year).

⁹ 1996 Final Rule, *supra* note 7, at 44,475 (discussing 1993 Federal Trade Commission figures).

¹⁰ See, e.g., Winford R. McGowan III, Comment, *Is It Time to Give Congressional Delegation a New Filter?*, 69 TENN. L. REV. 485, 497 (2002) (describing the media and social outcry against abusive tobacco company practices and the subsequent regulatory scheme imposed by the FDA); Barnaby J. Feder, *Tobacco Curbs Face Legal Fight*, N.Y. TIMES, Aug. 24, 1996, at 1.8.

¹¹ Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399 (2006)).

¹² See 21 U.S.C. § 321(g)(1), (h).

¹³ See *id.* §§ 355(d), 360d(a)(2).

¹⁴ PUB. HEALTH SERV., U.S. DEP'T OF HEALTH, EDUC., & WELFARE, PUB. NO. 1103, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE 29 (1964), available at http://profiles.nlm.nih.gov/NN/B/B/M/Q/_/nbbmq.pdf (finding smokers are 70% more likely to die of heart disease, 500% more likely to die from chronic bronchitis or emphysema, and 1000% more likely to die of lung cancer).

¹⁵ H.R. 2248, 89th Cong. (1965).

¹⁶ Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-1341 (2006)).

¹⁷ 15 U.S.C. § 1333(a)(1). There are four warnings required on cigarette packaging, to be implemented on a rotating basis: (1) "Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy"; (2) "Quitting Smoking Now Greatly Reduces Serious Risks to Your Health"; (3) "Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight"; and (4) "Cigarette Smoke Contains Carbon Monoxide." *Id.* Similarly, there are three required warnings for smokeless tobacco

1967 the Federal Communications Commission (FCC) entered the tobacco arena, promulgating regulations governing tobacco advertising on the radio and television.¹⁸ In addition to the FTC and FCC, government agencies like the Internal Revenue Service (IRS), Department of Agriculture, and the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), have authority to regulate various aspects of the tobacco industry.¹⁹

In 1996, the FDA unsuccessfully attempted to regulate tobacco products under the FDCA,²⁰ which prohibits any misbranded food, drug, or device from “introduction into interstate commerce.”²¹ The FDCA denotes a product as misbranded “[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.”²² However, to be regulated as a “drug,” the product must be “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.”²³ After extensively investigating tobacco companies’ practices, the FDA maintained that it had found the requisite intent needed to regulate tobacco products.²⁴ Without imposing an outright ban, the FDA sought to

packaging. *Id.* § 4402(a)(1). See generally Ronald M. Davis et al., *The Rotation of Health Warnings in Cigarette Advertisements: Compliance with the Comprehensive Smoking Education Act of 1984*, 9 J. PUB. HEALTH POL’Y 403 (1988) (describing the increased efficacy of the mandated warning rotation system).

¹⁸ Jennifer Costello, Comment, *The FDA’s Struggle to Regulate Tobacco*, 49 ADMIN. L. REV. 671, 677 & n.32 (1997) (describing the FCC’s initial regulatory role, which required smoking cessation advertising in conjunction with smoking advertising, and how successful lobbying by tobacco manufacturers led to a ban on tobacco radio and television advertising altogether). Two years later Congress passed the Public Health Cigarette Smoking Act of 1969, which banned tobacco advertising on the radio and television. Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331–1340 (2006)).

¹⁹ See Costello, *supra* note 18, at 678 n.42 (explaining the IRS’s role in taxing tobacco sales, the Department of Agriculture’s regulation of tobacco farming, and the ATF’s job fighting illegal tobacco sales and distribution).

²⁰ See 1996 Final Rule, *supra* note 7, at 44,615–18. These regulations are now the basis for certain Family Smoking Prevention and Tobacco Control Act (FSPTCA) provisions at issue. FSPTCA, 21 U.S.C. § 387a–1(a)(2) (Supp. III 2009).

²¹ 21 U.S.C. § 331(a) (2006).

²² *Id.* § 352(j).

²³ *Id.* § 321(g)(1)(B) (emphasis added); see also *id.* § 321(h)(3) (“intent” requirement for medical devices that affect the structure or function of the body).

²⁴ See *id.* § 321(h)(2)–(3) (defining a “device” as having an “intended” effect on the structure or function of the body or an “intended” use in the cure or prevention of disease). This intent requirement has been a difficult hurdle for the FDA in the past. See Costello, *supra* note 18, at 681–83 (discussing the FDA’s struggle to establish jurisdiction through indirect evidence of intent); see also *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (holding that cigarette labels showed the manufacturer’s intent to affect the structure or function of a user’s body).

classify cigarettes as restricted drug-delivery devices in an attempt to reduce the exposure and influence of tobacco on the nation's adolescents.²⁵

Despite the FDA's efforts, the Supreme Court in *FDA v. Brown & Williamson Tobacco Corp.* held that the FDA lacked jurisdiction to regulate the tobacco industry.²⁶ The Court concluded that under the FDCA, tobacco would have to be banned altogether because it would be a "misbranded" product that could not be approved as safe and effective.²⁷ But due to Congress's repeated actions ensuring tobacco's legality and prior FDA acquiescence over tobacco regulation, the FDA had no jurisdiction to regulate, or ban, tobacco products.²⁸

Responding to mounting public pressure following the *Brown & Williamson* decision, President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act (FSPTCA or Act) into law on June 22, 2009.²⁹ The FSPTCA adopts the ill-fated 1996 FDA regulations and gives the FDA exclusive jurisdiction to regulate tobacco,³⁰ but specifically prohibits the FDA from banning tobacco sales or eliminating nicotine from cigarettes.³¹

²⁵ See generally 1996 Final Rule, *supra* note 7, at 44,398 ("[T]he agency has concluded that, while taking cigarettes and smokeless tobacco off the market could prevent some people from becoming addicted and reduce death and disease for others, the record does not establish that such a ban is the appropriate public health response under the act.").

²⁶ 529 U.S. 120, 132–33, 137 (2000) (applying the two-prong statutory interpretation test set out by the Supreme Court in *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984)); see also *Costello*, *supra* note 18, at 673–79 (describing Congress's exclusion of the FDA in the development of tobacco regulation).

²⁷ *Brown & Williamson*, 529 U.S. at 135–37 (relying on 21 U.S.C. § 331(a), which prohibits introduction of misbranded goods into interstate commerce). The Court found that if the FDA evaluated cigarettes as devices, it would have to regulate them as Class III devices subject to premarket approval, and as a result, tobacco products would not survive because of their danger. *Id.* at 136.

²⁸ *Id.* at 137–39 ("Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965.").

²⁹ Pub. L. No. 111-31, 123 Stat. 1776 (2009) (amending FDCA, 21 U.S.C. §§ 301–399 (2006)); see also *Obama Signs Sweeping Anti-Smoking Bill*, MSNBC.COM, June 22, 2009, <http://www.msnbc.msn.com/id/31481823> ("The decades-long effort to protect our children from the harmful effects of smoking has finally emerged victorious . . ." (quoting President Barack Obama) (internal quotation marks omitted)).

³⁰ FSPTCA, 21 U.S.C. § 387a(a) (Supp. III 2009); see also *Regulating Tobacco: Q&A with Lawrence Deyton*, FOOD & DRUG ADMIN., 2 (Sept. 28, 2009), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM183967.pdf> (discussing with the director at the Center for Tobacco Products the FDA's plan to regulate tobacco products in a way that protects the vulnerable youth population from undue influence by tobacco advertising).

³¹ FSPTCA § 387g(d)(3) (noting the "importance of a decision of the Secretary to issue a regulation" yet restricting the Secretary's authority to reduce nicotine yields to zero or ban tobacco products). The FDA aims to strike a balance between protecting the country's youth from smoking and the rights of smokers to engage in legal consumption of cigarettes. See *Regulating Tobacco: Q&A with Lawrence Deyton*, *supra* note 30, at 1;

The Act also includes advertising and promotional restrictions,³² and places an outright ban on the sale of flavored tobacco products.³³

In light of the First Amendment attack on the advertising provisions of the FSPTCA, Part I of this Comment analyzes the development of commercial speech jurisprudence stemming from *Central Hudson Gas & Electric Corp. v. Public Service Commission*, which set the framework for the modern commercial speech doctrine. Part II examines the constitutionality of select provisions of the Act and proposed amendments that may bring the FSPTCA's advertising provisions within the province of the First Amendment. This Part concludes by assessing the efficacy of the FSPTCA as it would stand without its advertising restrictions—arguably the FSPTCA's most significant provisions. It then argues for Congress to amend the Act to accommodate the First Amendment in order to give the FDA a fighting chance against the tobacco industry. Part III reviews alternatives to the First Amendment position adopted here, while posing questions for future thought in the realm of public health regulation. This Comment concludes by summarizing the constitutionality of the FSPTCA and the direction the FDA should take to most benefit public health and safety. Overall, this Comment takes a skeptical look at the constitutionality of the FSPTCA in order to shed light on how this Act can remain viable to further the country's best interests in the area of public health by successfully regulating tobacco products.

I. FIRST AMENDMENT JURISPRUDENCE: BUILDING THE COMMERCIAL SPEECH FRAMEWORK

Among its provisions, the FSPTCA restricts tobacco advertising and product distribution, adopting the FDA's 1996 regulations.³⁴ Because the FSPTCA specifically gives the FDA jurisdiction to regulate tobacco products,

cf. James T. O'Reilly, *FDA Regulation of Tobacco: Blessing or Curse for FDA Professionals?*, 64 *FOOD & DRUG L.J.* 459, 459–61 (2009) (arguing that despite the positive headlines about the FDA's newfound regulation of tobacco, such regulation is really “the sticky remains of a messy bargain, negotiated in a distracted Congress by expensive lawyers with clients who were potent contributors to political action committees”).

³² For example, FSPTCA § 387a–1(a)(2)(G) significantly restricts free sample distribution. *See infra* Part II.C.5.

³³ FSPTCA § 387g(a)(1) (including flavors like cinnamon, chocolate, vanilla, and cherry, yet specifically excluding menthol from the ban).

³⁴ *Id.* § 387a–1(a)(2).

the fight now centers on the First Amendment constitutionality of the proposed advertising and brand name distribution regulations.³⁵

On August 31, 2009, several major cigarette manufacturers filed suit against the United States and the FDA in *Commonwealth Brands, Inc. v. United States*, alleging that the advertising restrictions embodied in the FSPTCA unconstitutionally infringe on the First Amendment.³⁶ These provisions include: restricting advertising to black-and-white text; restricting tobacco companies from advertising “light” cigarettes; prohibiting advertising within 1,000 feet of areas where children congregate; banning event sponsorship by tobacco companies; and prohibiting free sample distribution of cigarettes.³⁷ On January 5, 2010, the U.S. District Court for the Western District of Kentucky issued a summary judgment ruling, partly in favor of the tobacco companies and partly in favor of the government.³⁸ Both sides plan to appeal the decision.³⁹

As a result of the pending appeal, an analysis of First Amendment commercial speech jurisprudence is necessary to give an informed perspective on the implications for the future of FDA tobacco regulation. Thirty years ago, the Supreme Court set the standard for the regulation of commercial speech in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.⁴⁰ Section A analyzes this seminal case and sets the framework for subsequent commercial speech jurisprudence. Section B discusses the emerging

³⁵ See, e.g., Complaint for Declaratory Judgment and Injunctive Relief at 34–42, *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010) (No. 1:09-CV-117-M), 2009 WL 2842131 [hereinafter Complaint]; cf. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (holding that the FDA lacked jurisdiction to regulate tobacco products).

³⁶ Complaint, *supra* note 35, at 34–42. Interestingly, Altria Group, Inc. (owner of Philip Morris USA, Inc.) is the only major manufacturer openly supporting the Act. See Letter from Michael E. Szymanczyk, Chairman & Chief Exec. Officer, Altria, to President Obama (June 12, 2009), available at http://www.us smokeless.com/en/cms/Responsibility/Legislative_Issues/pdfs/MES_Letter_061209.pdf.aspx (explaining that Altria supports curbing youth smoking through H.R. 1256 but questioning the First Amendment constitutionality of some of the Act’s provisions). Not surprisingly, the plaintiffs filed suit in the Western District of Kentucky, an indisputably pro-tobacco state that relies on tobacco as its number one cash crop with an average of more than \$800 million in revenue from 1990 to 1996. WILL SNELL & STEPHAN GOETZ, UNIV. OF KY. COLL. OF AGRIC., OVERVIEW OF KENTUCKY’S TOBACCO ECONOMY 1 (1997), available at <http://www.ca.uky.edu/agc/pubs/aec/aec83/aec83.pdf>.

³⁷ See Complaint, *supra* note 35, at 34–42.

³⁸ *Commonwealth Brands*, 678 F. Supp. 2d at 541.

³⁹ Duff Wilson, *Judge Lifts Some Limits on Tobacco Advertising*, N.Y. TIMES, Jan. 6, 2010, at B3. The FDA filed a notice of appeal on March 8, 2010. See FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA STAFF 4 (2010), available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM210766.pdf>.

⁴⁰ 447 U.S. 557 (1980).

interpretation of *Central Hudson* and the varying standards of deference afforded the government since the test's adoption.

A. *The Standard*—*Central Hudson Gas & Electric Corp. v. Public Service Commission*

After years of unclear commercial speech jurisprudence,⁴¹ the Supreme Court established a four-part test to govern the constitutionality of commercial speech regulations in *Central Hudson Gas & Electric Corp. v. Public Service Commission*:

For commercial speech to come within [First Amendment protection], it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.⁴²

This test established a guiding standard of broad application in the wake of contrary precedent⁴³ and unclear constitutional guidance with regard to government regulation of commercial speech.⁴⁴

In *Central Hudson*, the Court invalidated a New York regulation banning all promotional advertising by electric utility companies.⁴⁵ The New York

⁴¹ Compare *Valentine v. Chrestensen*, 316 U.S. 52, 54 (1942) (holding that the First Amendment protects informational and political speech, not commercial advertising), *overruled by* *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), and *Breard v. Alexandria*, 341 U.S. 622, 642 (1951) (finding a regulation prohibiting door-to-door solicitation constitutional despite the “fact that periodicals are sold does not put them beyond the protection of the First Amendment”), *abrogated by* *Village of Schaumburg v. Citizens for a Better Env't*, 444 U.S. 620 (1980), with *Bigelow v. Virginia*, 421 U.S. 809, 825–26 (1975) (deeming Virginia's statute prohibiting circulation of publications encouraging abortion to be an unconstitutional infringement of free speech even though the speech appeared in commercial form), and *Va. State Bd. of Pharmacy*, 425 U.S. at 773 (finding another Virginia statute unconstitutional where it restricted pharmacists' advertisements of prescription drug prices because a state may not “completely suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of that information's effect upon its disseminators and its recipients”).

⁴² 447 U.S. 557, 566 (1980).

⁴³ Compare *Breard*, 341 U.S. at 642 (finding no First Amendment protection for door-to-door periodical sales), with *Bigelow*, 421 U.S. at 825–26 (including legal pharmaceutical price advertising in First Amendment protection).

⁴⁴ Compare *Valentine*, 316 U.S. at 54 (finding no constitutional protection for commercial speech), with *Bigelow*, 421 U.S. at 825–26 (providing First Amendment constitutional protection for commercial advertising of abortion).

⁴⁵ 447 U.S. at 557.

Public Service Commission first prohibited promotional advertising in the wake of a winter energy shortage.⁴⁶ Three years later, however, the Commission continued to implement the restriction after the energy shortage had passed.⁴⁷

Applying these facts to its new test, the Court dispatched the first two prongs in short order: finding that the promotional advertising was lawful and nonmisleading⁴⁸ and that regulations promoting energy conservation represented a substantial government interest in conserving energy and maintaining equitable rates.⁴⁹

Moving to the third prong, the Court accepted the government's speculative argument that because promotional advertising directly increased demand, restricting such advertising would directly advance the government's interest in energy conservation.⁵⁰

The Court asserted, however, that the Commission failed to establish the fourth prong—that the means used to further its substantial interest were not more extensive than necessary.⁵¹ Despite the government's undoubtedly important interest in conserving energy and maintaining equitable rates, “suppressing information about electric devices or services” was unjustifiable because the regulation reached all promotional advertising regardless of its impact on energy use.⁵² Further, the Commission could not show that a more limited restriction would not serve the state's interests in energy conservation.⁵³

⁴⁶ *Id.* at 558–59.

⁴⁷ *Id.* at 559.

⁴⁸ *Id.* at 566–68 (refuting the New York Court of Appeals' argument that advertising by a monopoly can not improve decision making by consumers and thus is not worthy of First Amendment protection).

⁴⁹ *Id.* at 568–69 (upholding a complex economic argument advanced by the Commission, which argued that promotional advertising would more likely lead to inequitable energy rates and distribution among consumers). The Court utilizes a similar approach in most cases; the first two prongs are rarely at issue, while the Court spends most of its time on the latter two prongs. *See infra* Part II.

⁵⁰ *Central Hudson*, 447 U.S. at 569 (“There is an immediate connection between advertising and demand for electricity. *Central Hudson* would not contest the advertising ban unless it believed that promotion would increase its sales. Thus, we find a direct link between the state interest in conservation and the Commission's order.”).

⁵¹ *Id.* at 569–70.

⁵² *Id.* at 570.

⁵³ *Id.* at 569–71 (considering that the Commission's regulation also prevented *Central Hudson* from advertising energy conservation).

Central Hudson thereby established an intermediate scrutiny standard for the protection of nonmisleading commercial speech, placing the burden of proof on the government to substantiate its regulations on lawful commercial speech.⁵⁴

B. Commercial Speech Jurisprudence Following Central Hudson: Wavering Judicial Scrutiny of Government Regulation

Despite the four clear prongs set forth in *Central Hudson*, the Supreme Court has inconsistently interpreted the standard, leaving lower courts with uncertainty and a flexible range of outcomes depending on the burden of proof and deference afforded the government.⁵⁵ This section first highlights the wavering deference applied by the Court in the thirty years since the *Central Hudson* decision. It then sets the stage for Part II by briefly explaining the background to the most recent Supreme Court commercial speech decision—*Lorillard Tobacco Co. v. Reilly*.⁵⁶

Six years after *Central Hudson*, the Court in *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico* upheld a complete ban on casino advertising to Puerto Rico’s residents through the Games of Chance Act,⁵⁷ which sought to increase Puerto Rico’s tourism revenue, yet prohibited casinos from advertising “or otherwise offer[ing] their facilities to the public of Puerto

⁵⁴ *Id.* at 566–71; *see also* *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 575 (2001) (Thomas, J., concurring in part and concurring in the judgment) (citing his argument in 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 518 (1996) (Thomas, J., concurring in part and concurring in the judgment), that commercial speech should be given the same strict scrutiny protection given to noncommercial speech—similarly supported by Justice Scalia’s aversion to *Central Hudson* intermediate scrutiny); Kerri L. Keller, Note, *Lorillard Tobacco Co. v. Reilly: The Supreme Court Sends First Amendment Guarantees Up in Smoke by Applying the Commercial Speech Doctrine to Content-Based Regulations*, 36 *AKRON L. REV.* 133, 140–42, 172–79 (2002) (arguing content-based speech should be given strict scrutiny protection even if it is “commercial” in nature).

⁵⁵ *Compare* *Posadas de P.R. Assocs. v. Tourism Co. of P.R.*, 478 U.S. 328, 330–31 (1986) (declaring restrictions on the local advertising of gambling to be constitutional while giving deference to legislatures to establish regulations restricting speech), *and* *United States v. Edge Broad. Co.*, 509 U.S. 418 (1993) (upholding regulations restricting broadcasters from advertising lotteries while affording some deference to the legislature), *with* *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 412 (1993) (striking down a ban on commercial publications distributed through freestanding news racks on public property because the regulation barred an entire class of constitutionally protected speech), *and* *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488–91 (1995) (finding the Federal Alcohol Administration Act’s prohibition against displaying alcohol-content percentages on alcohol-product labels failed both the third and fourth prongs of the *Central Hudson* test because the regulatory scheme was irrational and failed to use less intrusive alternatives).

⁵⁶ 533 U.S. 525 (2001).

⁵⁷ P.R. LAWS ANN. tit. 15, § 71 (1972).

Rico.”⁵⁸ For the first time, the Court deferred to the legislature, implementing a standard akin to rational basis scrutiny and departing from the intermediate scrutiny standard established in *Central Hudson*.⁵⁹

Applying the first *Central Hudson* prong, the Court plainly found gambling advertising lawful, giving it protection under the First Amendment.⁶⁰ Conversely, Puerto Rico had a substantial interest in regulating advertising for gambling—an activity that compromises “the health, safety and welfare of [its] citizens.”⁶¹ The Court made an about-face, however, in applying the third prong. Deferring to the legislature’s findings, the Court stated, “The Puerto Rico Legislature obviously believed, when it enacted the advertising restrictions at issue here, that advertising of casino gambling aimed at the residents of Puerto Rico would serve to increase the demand for the product advertised. We think the legislature’s belief is a reasonable one”⁶² Deciding the fourth prong, the Court simply stated that “it is up to the legislature to decide whether [less restrictive alternatives] would be as effective in reducing the demand for casino gambling as a restriction on advertising.”⁶³

The Court in *Rubin v. Coors Brewing Co.*⁶⁴ and *44 Liquormart, Inc. v. Rhode Island*⁶⁵ rebuked the deferential standard applied in *Posadas*.⁶⁶ Adopting similar interpretations of the *Central Hudson* test, the Court vigorously reviewed the government’s evidence and tailoring under the third

⁵⁸ 478 U.S. at 330–32 (quoting P.R. LAWS ANN. tit. 15, § 77 (1972)) (internal quotation mark omitted).

⁵⁹ See generally *supra* note 54 and accompanying text.

⁶⁰ *Posadas*, 478 U.S. at 340–41.

⁶¹ *Id.* at 341 (upholding the government’s argument that gambling by its residents, but not by tourists, leads to an “increase in local crime, the fostering of prostitution, the development of corruption, and the infiltration of organized crime” (quoting Brief for Appellees at 37, *Posadas*, 478 U.S. 328 (No. 84-1903)) (internal quotation mark omitted)).

⁶² *Id.* at 341–42 (“There is an immediate connection between advertising and demand for electricity. *Central Hudson* would not contest the advertising ban unless it believed that promotion would increase its sales.” (quoting *Cent. Hudson, Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 569 (1980)) (internal quotation marks omitted)).

⁶³ *Id.* at 344.

⁶⁴ 514 U.S. 476 (1995).

⁶⁵ 517 U.S. 484 (1996).

⁶⁶ See *id.* at 510–14 (Stevens, J.) (following the reasoning in *Coors* and refuting two of the State’s core arguments adopted from the *Posadas* opinion); *Coors*, 514 U.S. at 487 (reversing the deferential standard espoused in *Posadas* and placing the burden on the government to show “that the challenged regulation advances the Government’s interest ‘in a direct and material way.’”). The conclusory rationale offered in *Posadas*, that the greater power to completely ban casino gambling necessarily includes the lesser power to ban advertising of casino gambling, was also refuted in *Coors*. See *id.* at 482 n.2.

and fourth prongs.⁶⁷ The deferential standard espoused in *Posadas* has been similarly disregarded and chastised by commentators.⁶⁸

The strict analysis requiring strong government evidence and independent judicial review adopted by the Court in *Coors* and *44 Liquormart* may have been relaxed in *Lorillard Tobacco Co. v. Reilly*—the most recent Supreme Court decision on commercial speech and most directly related to the current tobacco litigation under the FSPTCA.⁶⁹ In *Lorillard*, the Massachusetts Attorney General, unhappy with the tobacco restrictions imposed in the Master Settlement Agreement (MSA),⁷⁰ expanded tobacco advertising regulation to “close holes” in the settlement and “to stop Big Tobacco from recruiting new customers among the children of Massachusetts.”⁷¹ The state regulations, which covered cigarettes, smokeless tobacco, and cigars, prohibited outdoor advertising within a 1,000-foot radius of a school or playground.⁷² The regulations also required point-of-sale advertising to be placed five feet or higher in retail operations open to minors and covered by the 1,000-foot rule.⁷³ While the Court ultimately struck down these two advertising restrictions, the

⁶⁷ See *infra* Part II.C.

⁶⁸ Commentators have derided *Posadas* as a poor attempt to apply the *Central Hudson* test in any meaningful way. See, e.g., Terrence Leahy, *A Game of Chance: Commercial Speech After Posadas*, A.B.A. J., Sept. 1, 1988, at 58, 61 (“The concept that a right to restrict speech is merely a lesser included power of the right to regulate conduct . . . is fundamentally at odds with many years of First Amendment jurisprudence.”); Gary Weeks, Case Note, *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico: Promising Precedent for Proponents of Tobacco Advertising Prohibition?*, 40 ARK. L. REV. 877, 889 (1987) (arguing that *Central Hudson*’s restrictions on government regulation of free speech were not applied in *Posadas*).

⁶⁹ *Lorillard*, 533 U.S. 525, 557–59 (2001).

⁷⁰ In 1998, forty-six states and the four largest U.S. tobacco companies entered into the Master Settlement Agreement, restricting tobacco advertisement and promotion while paying the states \$206 billion over twenty-five years in exchange for dismissal of pending litigation against the tobacco companies. Master Settlement Agreement (Nov. 25, 1998), available at <http://www.ag.ca.gov/tobacco/pdf/1msa.pdf>. Under the agreement, tobacco advertisements are banned on billboards, in sports stadiums, shopping malls, and on promotional products like shirts and hats or in movies or television shows. *Id.* § III(c)–(f). Since the advertising and promotional restrictions were self-imposed, the agreement does not infringe on the First Amendment’s commercial speech protections. See generally Lori Ann Luka, Note, *The Tobacco Industry and the First Amendment: An Analysis of the 1998 Master Settlement Agreement*, 14 J.L. & HEALTH 297 (1999–2000) (arguing that tobacco companies that did not enter the MSA cannot be held to its terms without infringing on their First Amendment commercial speech rights).

⁷¹ David S. Modzeleski, Note, *Lorillard Tobacco v. Reilly: Are We Protecting the Integrity of the First Amendment and the Commercial Free Speech Doctrine at the Risk of Harming Our Youth?*, 51 CATH. U. L. REV. 987, 1004 (2002) (quoting *Lorillard*, 533 U.S. at 533) (internal quotation marks omitted) (discussing the MSA’s failure to protect youth from the hazards of smoking and Massachusetts’s subsequent attempt to further restrict tobacco advertising).

⁷² 940 MASS. CODE REGS. § 21.04(5)(a) (LexisNexis 2000).

⁷³ *Id.* § 21.04(5)(b).

tight Court split and differing opinions about the proper constitutional analysis pervaded the Court's opinion.⁷⁴

Whatever its past justifications, the judiciary is now faced with a remarkable dilemma: protecting the country's children from the single most dangerous product in America or defending one of our most cherished constitutional rights and the public's right to be informed.⁷⁵

II. A *CENTRAL HUDSON* ANALYSIS OF SELECTED FSPTCA PROVISIONS AND PROPOSED AMENDMENTS TO BRING THOSE PROVISIONS WITHIN THE PROVINCE OF THE FIRST AMENDMENT

This Part analyzes the merits of the tobacco companies' suit in *Commonwealth Brands* as those facts apply to the four *Central Hudson* prongs. Section A discusses the first prong and whether tobacco advertising is lawful and nonmisleading—concluding that tobacco advertising should be subject to First Amendment protection. Section B follows, proposing that the government has a substantial interest in reducing youth smoking under *Central Hudson*'s second prong.

⁷⁴ The Court rejected the tobacco companies' argument that strict scrutiny should apply to content-based regulations. *Lorillard*, 533 U.S. at 554. However, several Justices had certain qualms with the malleable application of the *Central Hudson* test. *Id.* (pointing to past opinions where Justices Stevens, Scalia, Kennedy, Thomas, and Ginsburg each doubted *Central Hudson*'s application in particular circumstances). These questions about *Central Hudson*'s viability are not new—similar arguments were discussed in *Greater New Orleans Broadcasting Ass'n v. United States*, 527 U.S. 173, 184 (1999) (noting scholars', amici's, and other judges' arguments to abandon *Central Hudson*'s test in favor of a more objective and less malleable test, but ultimately concluding that *Central Hudson* "provides an adequate basis for decision"). See generally Michael Hoefges, *Protecting Tobacco Advertising Under the Commercial Speech Doctrine: The Constitutional Impact of Lorillard Tobacco Co.*, 8 COMM. L. & POL'Y 267 (2003) (discussing the evolution of commercial speech doctrine following *Central Hudson* and leading up to *Lorillard*). Supreme Court Justices are not alone in questioning the suitability of tests like *Central Hudson*'s as an appropriate method for decision making. See generally JEFFREY SEGAL & HAROLD SPAETH, *THE SUPREME COURT AND THE ATTITUDINAL MODEL REVISITED* 52–53 (2003) (noting that the legal model of judicial decision making serves "only to rationalize the Court's decisions and to cloak the reality of the Court's decision-making process").

⁷⁵ The Court has often acknowledged the importance of the First Amendment in relation to the need for regulations that benefit the public. Justice Stevens noted that other Justices

expressed "doubt whether suppression of information concerning the availability and price of a legally offered product is ever a permissible way for the State to 'dampen' the demand for or use of the product." Indeed, Justice Blackmun believed that even "though 'commercial' speech is involved, such a regulation strikes at the heart of the First Amendment."

44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 500 n.10 (1996) (Stevens, J.) (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 574 (1980) (Blackmun, J., concurring in the judgment)).

Considering the variety and number of restrictions in the Act, this Comment analyzes a select group of problematic provisions.⁷⁶ Section C focuses on the third and fourth *Central Hudson* prongs. This section starts by outlining the current standards for each of the prongs. The section follows with an analysis of their application to the selected FSPTCA provisions, as well as proposed amendments that would help the restrictions adhere to the First Amendment standards espoused by *Central Hudson*.

A. *Central Hudson's First Prong: Nonmisleading Commercial Speech*

The tobacco advertising subject to FDA regulation under the FSPTCA easily meets *Central Hudson's* first prong because it is nonmisleading and lawful commercial speech, and thus entitled to First Amendment protection.⁷⁷

Faced with a constitutional challenge to the FSPTCA, the FDA is confronted with a challenge analogous to the one in *Lorillard*. With no analysis, the *Lorillard* Court quickly stated that the first *Central Hudson* prong was easily satisfied.⁷⁸ *Lorillard* is not alone in broadly construing what speech is nonmisleading. For example, in *Pearson v. Shalala*, the U.S. District Court for the District of Columbia held that unsubstantiated claims made on product labels were lawful and nonmisleading and entitled to *Central Hudson* review.⁷⁹ There, dietary-supplement manufacturers made health-related claims about folic acid with no evidence to back their claims.⁸⁰ Applying the first *Central Hudson* prong in that context, the *Pearson* court differentiated “inherently misleading” and “potentially misleading” claims, subjecting the latter to *Central Hudson* analysis.⁸¹ Even though no evidence supported the claims, the court found the labeling only potentially misleading.⁸²

Despite the firm precedent establishing First Amendment protection,⁸³ the FDA argues that tobacco advertisements are misleading because they depict

⁷⁶ See *infra* Part II.C.1–5.

⁷⁷ See, e.g., *Lorillard*, 533 U.S. at 554–55 (majority opinion).

⁷⁸ *Id.* at 555.

⁷⁹ 130 F. Supp. 2d 105, 113 (D.D.C. 2001).

⁸⁰ *Id.* at 108–09.

⁸¹ *Id.* at 113.

⁸² *Id.* (ultimately failing the fourth prong because there were less restrictive alternatives).

⁸³ Though not argued here, it is clear that the government’s long-argued “vice” rationale is no longer viable. See, e.g., 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 513–14 (1996) (Stevens, J.) (rejecting *Posadas's* “vice” rationale); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 482 n.2 (1995) (refuting the government’s argument that *Posadas* created an exception to the *Central Hudson* test because that reasoning

young and healthy smokers in spite of extensive evidence linking tobacco use to death and disease.⁸⁴ This argument is misplaced because the advertisements are not “inherently misleading.” First, tobacco companies are required to put warning labels on all their packaging and advertisements.⁸⁵ Second, though advertisements may depict happy young people—like any product—the advertisement merely tries to stress the product’s positive attributes.⁸⁶

Persisting further, the FDA argues that such advertisements are illegal because they are aimed at minors, whose purchase of tobacco products is an illegal transaction.⁸⁷ This argument, however, goes too far. If the Court were to allow the government to engage in this slippery slope, regulators could ban any advertising of activities that are not legal to certain segments of the population; for instance, driving a car, purchasing a gun, voting, or drinking alcohol.

The Court has always adopted a broad stance on what speech is protected as nonmisleading under the First Amendment, and as held in *Lorillard*, tobacco advertisements are no exception. Like other forms of advertising that showcase a company’s product in a positive light, tobacco advertisements are subject to the same First Amendment protection afforded all other commercial speech. If the Court embraced the FDA’s narrow view, the government would hold virtually unrestricted power in regulating undesirable speech it deems misleading.⁸⁸

was dicta, made after *Central Hudson* was applied). See generally *Lorillard*, 533 U.S. at 554 (rejecting the argument that strict scrutiny should be the appropriate standard for commercial speech).

⁸⁴ See 1996 Final Rule, *supra* note 7, at 44,471.

⁸⁵ See *supra* note 17 and accompanying text (describing the warning label restrictions implemented by the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1333 (2006)).

⁸⁶ But see Charles J. Harder, Comment, *Is It Curtains for Joe Camel? A Critical Analysis of the 1995 FDA Proposed Rule to Restrict Tobacco Advertising, Promotion and Sales to Protect Children and Adolescents*, 16 LOY. L.A. ENT. L.J. 399, 417 (1995).

⁸⁷ But see *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 522 n.3 (W.D. Ky. 2010) (rejecting the government’s argument that advertising reaching minors would be unlawful, failing the first *Central Hudson* prong).

⁸⁸ Cf. *Pearson v. Shalala*, 130 F. Supp. 2d 105, 113 (D.D.C. 2001) (referring to the settled principle that “disclaimers are ‘constitutionally preferable to outright suppression’” in coming to the conclusion that products that are only potentially misleading can be remedied with disclaimers rather than suppression of advertising (quoting *Pearson v. Shalala*, 164 F.3d 650, 657 (D.C. Cir. 1999))); Richard A. Samp, *Courts Are Arriving at a Consensus on Food and Drug Administration Speech Regulation*, 58 FOOD & DRUG L.J. 313, 319–23 (2003) (describing the Court’s position on “inherently misleading” commercial speech and the government’s ability to completely ban such speech).

After the speech at issue passes the first prong, the burden shifts to the government to prove the regulations further a substantial government interest, directly advance the stated substantial interest, and are not more extensive than necessary in furthering that interest.⁸⁹

B. Central Hudson's Second Prong: Substantial Government Interest

The FDA should have no difficulty satisfying the second prong, that furtherance of the FSPTCA promotes a substantial government interest. The Supreme Court decided a strikingly similar issue in *Lorillard*.⁹⁰ The Massachusetts Regulations there were based solely on the 1996 FDA regulations that are the substance of the FSPTCA's advertising restrictions here.⁹¹ Swiftly analyzing the second prong, the *Lorillard* Court noted that no party contested the State's substantial interest in "preventing the use of tobacco products by minors."⁹²

Moreover, the *Lorillard* Court is one among many to promptly accept the government's position on the second prong; several other cases similarly give a remarkable amount of deference to the government's decision to regulate in a given area. For example, in *Rubin v. Coors Brewing Co.*, the Federal Alcohol Administration Act (FAAA) prohibited beer manufacturers from disclosing alcohol content on their labels or advertising.⁹³ The Court found a substantial interest in preventing "strength wars," a term used to describe the theory that consumers may choose a beer solely based on its high potency, leading to "greater alcoholism and its attendant social costs."⁹⁴

Relying on similar reasoning, the district court in *Pearson* accepted the FDA's argument that it had a substantial interest in protecting uninformed consumers from unsubstantiated health claims.⁹⁵ Ironically, it seems that the court was willing to give broad First Amendment protection by finding the

⁸⁹ See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). The Court has disavowed a possible "vice exception" to First Amendment commercial speech protection, an argument the government has used in the past to shift the burden of proof. See *supra* note 83 and accompanying text.

⁹⁰ See *Lorillard v. Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001).

⁹¹ *Id.* at 557.

⁹² *Id.* at 555.

⁹³ See *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 478 (1995) (citing FAAA, 27 U.S.C. §§ 201–211 (1982) (amended 1988)).

⁹⁴ *Id.* at 485–86; see also *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 504 (1996) (Stevens J.) (noting substantial government interest in temperance); 1996 Final Rule, *supra* note 7, at 44,472–74 (articulating the FDA's position regarding *Central Hudson's* second prong).

⁹⁵ *Pearson v. Shalala*, 130 F. Supp. 2d 105, 113 (D.D.C. 2001).

claims nonmisleading, yet utilized the same unsubstantiated health-claims argument to give merit to the FDA's interest in protecting consumers from misinformation.⁹⁶

As described in the FSPTCA,⁹⁷ Congress's purpose in granting FDA jurisdiction to regulate tobacco is to reduce youth tobacco use, making the outcome of this prong relatively straightforward after *Lorillard*.⁹⁸ Moreover, the Act focuses on the ill effects of adult use, general tobacco dependence, and full information regarding "modified risk" tobacco products.⁹⁹ Applying the uninformed-consumer-base problem in *Pearson*, these motivations give the FDA's argument further credence under the second prong. The substantial interest in complete information is additionally persuasive when viewed in light of the fact that the nation's youth continue to become addicted to tobacco even though the dangers of smoking have been known for more than forty years.¹⁰⁰ The government surely has a substantial interest in protecting the public's interest in making informed decisions.

The Supreme Court's decision in *Lorillard* firmly establishes the Court's trend in *Central Hudson* jurisprudence under the second prong.¹⁰¹ As a result, the FDA's substantial interests in preventing consumer misinformation and reducing underage tobacco consumption should pass the second prong.

⁹⁶ Compare to the district court's treatment regarding the first *Central Hudson* prong, *supra* notes 79–80 and accompanying text.

⁹⁷ See *supra* note 25 and accompanying text.

⁹⁸ See FSPTCA, Pub. L. No. 111–31, §§ 2–3, 123 Stat. 1776, 1776–82 (2009) (describing congressional findings and the purposes of the FSPTCA); see also U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 7, at 230 (describing the effects of youth smoking on adult smoking and noting that "well over 80 percent of adolescents who smoked half a pack a day or more as seniors in high school . . . were smoking five to six years later as young adults").

⁹⁹ FSPTCA § 2 (describing Congress's findings regarding the justifications for the FDA's tobacco regulation through the FSPTCA); see also *id.* § 2(37) ("The costs to society of the widespread use of . . . modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.").

¹⁰⁰ But see U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 7, at 135 (finding that "virtually all U.S. adolescents—smokers and nonsmokers alike—are aware of the long-term health effects of smoking" but choose to smoke anyway "because many adolescents feel inherently invulnerable").

¹⁰¹ Potentially realizing this, the plaintiffs devoted one sentence to disputing this issue in their complaint, but provided no support to their argument that the government lacks a substantial interest. Complaint, *supra* note 35, at 30. The district court opinion thus did not address the second prong. See *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010).

C. Central Hudson's *Third and Fourth Prongs and an Analysis of Select FSPTCA Provisions*

The first two *Central Hudson* prongs generally apply to an entire piece of legislation, rather than individual provisions, because the speech being regulated and the substantial interest being served usually apply across the entirety of a statute. The last two prongs are provision specific, however, and this section will thus give a brief overview of the modern application standards for the third and fourth prongs before offering a more detailed analysis of the selected FSPTCA provisions and proposed amendments to each.

Most of the FSPTCA provisions at issue pass the third *Central Hudson* prong because they directly advance the government's substantial interest in reducing underage smoking. For the government to prevail, it must show more than mere "speculation or conjecture"¹⁰² by providing evidence that the regulation will advance its substantial interest "to a material degree."¹⁰³ It is thus imperative for the government to establish a link between tobacco marketing and increased underage consumption¹⁰⁴ because repeated judicial opinions have refused to afford deference to the government's "commonsense" judgments.¹⁰⁵

As supportive evidence, the 1996 regulations adopted by the FSPTCA describe extensive studies showing the effect of advertising on youth consumption of tobacco products.¹⁰⁶ While this evidence correctly departs

¹⁰² *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001) (quoting *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 188 (1999)).

¹⁰³ 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 505 (1996) (Stevens, J.) (quoting *Edenfield v. Fane*, 507 U.S. 761, 771 (1993)) (internal quotation marks omitted) ("[A] commercial speech regulation 'may not be sustained if it provides only ineffective or remote support for the government's purpose.'" (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980))); see also *Lorillard*, 533 U.S. at 557–61 (finding that the Massachusetts regulations adopting the evidence provided in the 1996 FDA regulations were sufficient to fulfill the government's burden under the third *Central Hudson* prong).

¹⁰⁴ See Gerald W. Griffin, Note, *Looking Past a Smoke Screen: A First Amendment Analysis of the Food and Drug Administration's Rule Restricting Tobacco Advertising*, 6 J.L. & POL'Y 363, 371 (1997).

¹⁰⁵ See, e.g., *supra* note 66 and accompanying text. The FDA argued in favor of deference in its 1996 regulations, which are now adopted by the FSPTCA. See 1996 Final Rule, *supra* note 7, at 44,474.

¹⁰⁶ See 1996 Final Rule, *supra* note 7, at 44,474–81 (noting studies establishing a correlative link between anthropomorphic characters like "Joe Camel" and youth smoking, as well as R.J. Reynolds's in-house study to use similar characters to expand its young market (eighteen- to twenty-year-old smokers)). Even highly suggestive Joe Camel advertisements are not without controversy concerning a causal connection to underage consumption. See Griffin, *supra* note 104, at 371 (describing FDA studies admitting that no causal connection between the advertising and underage consumption exists despite the clear intuition behind such an argument).

from the government's early reliance on common sense¹⁰⁷ and tends to show that the advertising restrictions directly advance the government's interest in reducing youth tobacco use,¹⁰⁸ the government still must show that the regulations as a whole are consistent and coherent with regard to the government's substantial interest.¹⁰⁹

The biggest obstacle facing the FSPTCA's advertising provisions is the fourth *Central Hudson* prong, because the scope of the regulations is out of proportion with the interest served in preventing underage tobacco use. The fourth prong asks whether the FSPTCA provisions are more extensive than necessary to further the goal of reducing underage tobacco use.¹¹⁰ This requires a case-by-case inquiry and "a reasonable fit between the means and ends of the regulatory scheme" imposed by the Act.¹¹¹ The fit need not be perfect, but the scope of the regulations must be "'in proportion to the interest served'; that employs not necessarily the least restrictive means but . . . [is] narrowly tailored to achieve the desired objective."¹¹² The restrictions also must be imposed through careful calculation of "the costs and benefits associated with the burden on speech imposed by the regulations."¹¹³

Applied in this context, the Court looks at the extent to which the regulation infringes on the speech rights of both the regulated entities and the

¹⁰⁷ The plaintiffs, and some commentators, disagree with *Lorillard*, arguing that the provided evidence fails to establish a causal link to underage teen smoking. See Complaint, *supra* note 35, at 33 (arguing that the Surgeon General's reports show that almost all U.S. adolescents are aware of the dangers of smoking but choose to smoke anyway because they feel inherently invulnerable); 1996 Final Rule, *supra* note 7, at 44,487 (acknowledging claims that its cited report does not establish a causal relationship between advertising and smoking, and addressing comments from trade associations and tobacco companies, which argue that advertising does not have a material effect on youth decisions to smoke).

¹⁰⁸ See *Lorillard*, 533 U.S. at 566–67 (striking the advertising restrictions under the third and fourth prongs). The FDA, however, does not blindly rely on such studies to prove a causative link between advertising and tobacco use. 1996 Final Rule, *supra* note 7, at 44,476 (arguing the studies provide "useful insight into how advertising affects smoking behavior and when considered with other studies provide sufficient support for the agency's conclusions").

¹⁰⁹ See, e.g., *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173 (1999) (striking down a regulation on private casino advertising that left Native American casinos unaffected, thus not directly advancing the substantial interest in curbing the social ills attributed to gambling).

¹¹⁰ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980).

¹¹¹ E.g., *Lorillard*, 533 U.S. at 561.

¹¹² *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989) (citation omitted) (quoting *In re R. M. J.*, 455 U.S. 191, 203 (1982)); *id.* at 479–80 (discussing cases in which the Court deferred to the legislature's reasonable judgment).

¹¹³ *Lorillard*, 533 U.S. at 561 (quoting *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 (1993)) (internal quotation mark omitted).

public,¹¹⁴ and whether the government could employ less restrictive alternatives that would further its substantial interest.¹¹⁵ The Court is especially wary of absolute advertising bans that completely restrict consumers from lawful product information.¹¹⁶

1. *Black-and-White Text Requirement*

The black-and-white text requirement, which prohibits tobacco advertising or labeling unless the advertisement consists of only black text on a white background, will likely be struck down under the *Central Hudson* test. Though the provision appears to pass muster under *Central Hudson*'s third prong, it is not narrowly tailored to further the government's interest in reducing underage tobacco use under the fourth prong. While the FSPTCA provisions do not allow the FDA to lift the black-and-white requirement,¹¹⁷ there are a number of alternatives Congress can adopt to narrowly tailor the provisions, such as expanding the range of publications excepted from the ban and making a distinction between advertisements aimed at minors and those directed specifically to adults.

Likely satisfying the third prong, the black-and-white restrictions directly advance the government's interest in reducing youth tobacco consumption because color imagery is an important tool for advertisers, and without it, tobacco advertisements may be less effective and have less influence on adolescents.¹¹⁸ Often referred to as tombstone advertising, the FSPTCA prohibits tobacco-product advertising or labeling unless the advertisement consists of "only black text on a white background."¹¹⁹ This restriction applies to all advertisements except those in "an adult publication" or adult-only

¹¹⁴ See, e.g., *id.*

¹¹⁵ See, e.g., *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 490–91 (1995).

¹¹⁶ See, e.g., *Lorillard*, 533 U.S. at 561–63; 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 500 (1996) (Stevens, J.).

¹¹⁷ See FSPTCA, 21 U.S.C. § 387a–1(a)(2) (Supp. III 2009) (adopting the 1996 final rule and precluding any amendment to the 1996 final rule, except as expressly contemplated in the FSPTCA); Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 21 C.F.R. § 1140.32 (2010) [hereinafter 2010 Final Rule].

¹¹⁸ *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 523 (W.D. Ky. 2010) (finding children highly influenced by color and imagery because they are unlikely to inquire further than an advertisement's images and are subject to more social pressure than adults).

¹¹⁹ FSPTCA § 387a–1(a)(2) (adopting 21 C.F.R. § 897 (1997)); 2010 Final Rule, *supra* note 117, § 1140.32.

facility.¹²⁰ Adult publications are defined as having less than 15% youth readership and less than two million total readers under age eighteen.¹²¹ Adult-only facilities can only use color advertisements that are attached to a fixture in the facility and that cannot be seen from outside.¹²²

The *Lorillard* opinion is instructive here because the Massachusetts statute there adopted the same 1996 FDA regulations at issue in the FSPTCA.¹²³ The *Lorillard* Court departed significantly from the rigorous review applied by the Court in *Coors* and *44 Liquormart*, relaxing the extensive government evidence required to satisfy the third prong.¹²⁴ Though the studies cited in the FDA regulations predominantly applied to cigarettes, the Court liberally construed the evidence to apply to cigars and smokeless tobacco.¹²⁵ The Court also recognized an implied relationship between advertising and consumer demand, concluding that “suppressed advertising may have the opposite effect.”¹²⁶

Recent Court decisions lend credence to the government’s argument that restricting color and imagery from advertising will further its substantial interest in reducing underage tobacco use. Without color and graphics,

¹²⁰ FSPTCA § 387a-1(a)(2)(G) (amending 21 C.F.R. § 897.16(d) (1997)); 2010 Final Rule, *supra* note 117, § 1140.32(a)(2).

¹²¹ See sources cited *supra* note 120. Under this definition, magazines like *Sports Illustrated*, *People*, and *ESPN the Magazine* would fail to qualify as adult publications because they have more than two million youth readers, despite having less than 15% youth readership. See Complaint, *supra* note 35, at 13.

¹²² FSPTCA § 387a-1(a)(2).

¹²³ See *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 557–58 (2001). The Court only applied the *Central Hudson* test to cigars and smokeless tobacco because the Massachusetts regulations were preempted as they applied to cigarettes. *Id.* at 541 (“No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.” (quoting 15 U.S.C. § 1334(b) (2006)) (internal quotation marks omitted)).

¹²⁴ See *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 505, 507 (1996) (Stevens, J.); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487–89 (1995).

¹²⁵ *Lorillard*, 533 U.S. at 558–59 (using the FDA’s findings that “considered several studies of tobacco advertising and trends in the use of various tobacco products”).

¹²⁶ *Id.* at 557. Despite the Court’s lenient standard, six Justices agreed that the regulation banning point-of-sale advertisements positioned less than five feet from the floor failed the third prong. *Id.* at 566–67. Justice O’Connor dismissed the regulation’s logic because “[n]ot all children are less than 5 feet tall, and those who are certainly have the ability to look up and take in their surroundings,” showing that the regulations did not logically advance the government’s interest. *Id.* (“Massachusetts may wish to target tobacco advertisements and displays that entice children, much like floor-level candy displays in a convenience store, but the blanket height restriction does not constitute a reasonable fit with that goal.”).

advertisements will likely be less effective, especially to children, who are arguably more susceptible to idealized imagery.¹²⁷

Despite satisfying the third prong, the tombstone provision likely fails the fourth prong because it is broader than necessary to further the government's substantial interest. The FDA achieves its goal of reducing underage smoking only by "camouflaging tobacco advertisements in black-and-white text, in an effort to delegitimize smoking" to all consumers.¹²⁸ In support of its argument, the FDA maintains that "consumers will lose little utility from these particular advertising restrictions" because meaningful information is still allowed to be distributed through nonmisleading printed words.¹²⁹ The FDA further contends that the restrictions will not impose significant burdens on the distribution or receipt of information because it will coordinate with other public health agencies to "disseminat[e] truly important consumer safety information."¹³⁰

The FDA's paternalistic arguments are misplaced given the Supreme Court's extension of First Amendment protection to color and imagery.¹³¹ And while the tombstone requirement is not a complete ban,¹³² the very limited adult publication and facility exceptions make it a short step to an all-encompassing ban, thereby instigating closer review under *Central Hudson*.¹³³ The Court has also repeatedly intimated that the government may not regulate speech by arbitrarily choosing the speech it sees fit for public consumption.¹³⁴

¹²⁷ Tobacco trade associations argue this point in the fourth prong: color and imagery "are prerequisites for disseminating relevant quality information," without which "consumers could not be adequately informed about the merits of new products." 1996 Final Rule, *supra* note 7, at 44,591.

¹²⁸ Griffin, *supra* note 104, at 398.

¹²⁹ 1996 Final Rule, *supra* note 7, at 44,591 (conceding that imagery may be important for tobacco sales).

¹³⁰ *Id.*

¹³¹ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 647–49 (1985) (finding that the government may not forego the difficulty of distinguishing between advertisements aimed at the proposed substantial interest simply because it is more convenient to implement a prophylactic rule).

¹³² The district court in *Commonwealth Brands* focused on this point, noting that the "'blanket ban' on all uses of color and images in tobacco labels and advertising has a 'uniformly broad sweep... [that] demonstrates a lack of tailoring.'" *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 526 (W.D. Ky. 2010) (alterations in original) (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 563 (2001)).

¹³³ See Complaint, *supra* note 35, at 13 (arguing that the adult magazines excepted from the regulation would exclude major adult-focused publications, reducing the exception to a marginal audience); *supra* note 116 and accompanying text. The district court rejected this argument because the plaintiffs did not provide evidence that an alternative definition of *adult publication* would be better tailored. *Commonwealth Brands*, 678 F. Supp. 2d at 525. The burden, however, is on the FDA to show less restrictive alternatives do not exist.

¹³⁴ See, e.g., *Lorillard*, 533 U.S. at 564 (noting that adult consumers have a right to receive information about lawful products); 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 500 (1996) (Stevens, J.) (indicating

The FDA's rationalization that it will decide what consumer information is "truly important" is an insult to the First Amendment.

Congress can amend the black-and-white text provisions by expanding the range of publications and facilities allowed to convey tobacco advertisements containing color and imagery. As they stand now, the restrictions are broader than necessary to limit underage tobacco use because an adult who does not read qualified adult-only magazines or frequent bars and nightclubs will be completely removed from colored advertising promoted by tobacco companies and retailers. An integral first step is to increase or remove the two-million-youth-subscriber element. Another plausible option would be expanding the exceptions to include tobacco-only facilities or allowing retailers to implement "adult-only" barriers like those required for smokeless-tobacco sample distribution.¹³⁵

Congress should also impose more probative requirements on the FDA, thereby properly accounting for lawful consumers and their First Amendment rights while still furthering the substantial interest of protecting the nation's youth from the risks of tobacco addiction and its attendant diseases. To do this, Congress could require the FDA to distinguish advertisements that influence minors from those directed solely toward the adult population on a case-by-case basis. For instance, the FDA could delineate between advertisements showing young, attractive people in a fun atmosphere or anthropomorphic characters like Joe Camel, and advertisements aimed toward older segments of the population. While clearly a burdensome task, the Supreme Court requires the government to expend the resources necessary to protect the First Amendment.¹³⁶ These further alterations would make the restrictions more narrowly tailored to the substantial interest of reducing underage tobacco use and less like a complete ban.

2. *Restriction on Modified Risk Tobacco Product Advertising*

The restrictions on modified risk tobacco products may fail both the third and fourth *Central Hudson* prongs. A more coherent policy would place modified risk tobacco products on at least a level playing field with traditional

that "a ban on speech could screen from public view the underlying governmental policy" aimed at the regulated activity).

¹³⁵ See *infra* Part II.C.5 (describing the regulations for smokeless-tobacco sample distribution).

¹³⁶ See *Zauderer*, 471 U.S. at 646.

cigarettes, giving more credence to the positive health implications of a reduced-tobacco (or nicotine) product.¹³⁷

The FSPTCA defines a modified risk tobacco product as “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.”¹³⁸ Tobacco companies are prohibited from “us[ing] the descriptors ‘light,’ ‘mild,’ or ‘low,’”¹³⁹ or directing statements to the public “that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful” than other tobacco products.¹⁴⁰ Manufacturers may only market modified risk tobacco products with advance FDA approval, which is to be provided only if the Secretary determines the product will “(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) 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.”¹⁴¹

Viewed in light of the FSPTCA as a whole, the modified risk provision may fail the third *Central Hudson* prong due to its inconsistent application. The government persuasively argues that products making unsubstantiated claims can create an insidious problem by persuading consumers to purchase purportedly healthier products, which may actually be just as dangerous as traditional cigarettes.¹⁴² Seen in this light, the FDA’s reasoning is similar to that upheld in *Pearson v. Shalala*, where the court found that government regulation of dietary supplements passed the third *Central Hudson* prong.¹⁴³ Though it deemed that unsubstantiated claims made by supplement distributors were nonmisleading, it held that this same lack of evidence merited the government’s interest in protecting consumers under the second prong.¹⁴⁴ In this context, the government’s restriction on unsubstantiated health claims

¹³⁷ See Joseph A. Page, *Federal Regulation of Tobacco Products and Products That Treat Tobacco Dependence: Are the Playing Fields Level?*, 53 FOOD & DRUG L.J. 11, 41 (1998) (“It would not seem reasonable to permit the playing field to tilt in favor of the more hazardous product. Indeed, the opposite would be more consistent with sound public health policy.”).

¹³⁸ FSPTCA, 21 U.S.C. § 387k(b)(1) (Supp. III 2009).

¹³⁹ *Id.* § 387k(b)(2)(A)(ii) (“or similar descriptors”).

¹⁴⁰ *Id.* § 387k(b)(2)(A)(iii).

¹⁴¹ *Id.* § 387k(g)(1).

¹⁴² See FSPTCA, Pub. L. No. 111-31, § 2(37), 123 Stat. 1776, 1780 (2009); *supra* note 99 and accompanying text (describing the government’s interest in protecting consumers against tobacco products that do not reduce risk as advertised).

¹⁴³ See *Pearson*, 130 F. Supp. 2d 105, 113 (D.D.C. 2001).

¹⁴⁴ See *supra* notes 79–82, 95, and accompanying text.

directly advanced its substantial interest in protecting the veracity of consumer information.¹⁴⁵ An analogous argument can be made here. By eliminating tobacco manufacturers' ability to make claims about the reduced nicotine, tobacco, or carcinogens in its products, consumers cannot make the misinformed assumption that these products are safe or safer than other tobacco products on the market.

Upon further review, however, this provision may be inconsistently applied, as derided by the Supreme Court in *Greater New Orleans Broadcasting Ass'n v. United States*.¹⁴⁶ The Court there struck down a federal regulation banning broadcast advertising for casino gambling in New Orleans, where such gambling was legal.¹⁴⁷ Because the restriction applied to private casino advertising, yet left Indian casinos unaffected, the provision was inconsistently applied and did not directly advance the government's substantial interest in curbing the social ills created by gambling.¹⁴⁸

The FSPTCA is similarly problematic because modified risk tobacco products are strictly regulated, yet cigarettes making no health claims are subject to less stringent FDA review if they qualify under the Act's "substantially equivalent" provision.¹⁴⁹ To qualify for this special standard, a predicate tobacco product must have been on the market on or before February 15, 2007,¹⁵⁰ and the current product must have the same ingredient and design characteristics as the predicate product.¹⁵¹ In this vein, the substantial equivalence provision maintains the tobacco industry's pre-FSPTCA status quo while imposing stringent controls over premarket review for modified risk tobacco products.¹⁵² These FSPTCA provisions are inconsistent and inappropriate to fix the nation's health problems created by tobacco

¹⁴⁵ *Pearson*, 130 F. Supp. 2d at 113.

¹⁴⁶ 527 U.S. 173, 190 (1999).

¹⁴⁷ *Id.* at 176–78. The Court pointed out that "[s]ome form of gambling is legal in nearly every state." *Id.* at 186 n.5. These legislative acts suggest that the government's argument is not as strong when Congress has made it clear that despite harm, some activities have countervailing economic benefits that outweigh their attendant social costs. *See id.* at 186 & n.5.

¹⁴⁸ *Id.* at 190 ("The operation of [the regulation] and its attendant regulatory regime is so pierced by exemptions and inconsistencies that the Government cannot hope to exonerate it.").

¹⁴⁹ FSPTCA, 21 U.S.C. § 387j(a)(3) (Supp. III 2009).

¹⁵⁰ *Id.* § 387j(a)(2)(A)(i)(I).

¹⁵¹ *Id.* § 387j(a)(3)(A)(i), (B). If the product has different characteristics than the predicate product, it may still pass the substantial equivalence standard if the Secretary determines that "it is not appropriate to regulate the product . . . because the product does not raise different questions of public health." *Id.* § 387j(a)(3)(A)(ii).

¹⁵² *See id.* § 387j(a)(2).

consumption.¹⁵³ This regulatory scheme creates “the absurd result that certain tobacco products—like low tar cigarettes or electronic cigarettes—would be exposed to the more onerous regulatory burdens . . . merely because they claim to be healthier alternatives to traditional tobacco products.”¹⁵⁴

The regulations at issue in *Greater New Orleans*, however, are distinguishable. While those regulations were facially inconsistent by applying to one subset of the population but not another, the inconsistencies in the FSPTCA regulations implicated here are not as immediately apparent, and the FDA can at least make the argument that it has tested predicate products, making testing of their substantial equivalents unnecessary. Given this distinction, the outcome under *Central Hudson*’s third prong could go either way. Regardless, it is hard to ignore the fact that modified risk products are more strictly regulated than traditional tobacco cigarettes, yet may be less harmful.

Congress needs to abolish the substantial equivalence provision if it has any intention of rectifying these contradictions. Though Congress could relax the substantial equivalence application standards to include lower risk products, most of these products are new to the market and thus unable to pass such a review in any event. Further, the current problem lies with the FSPTCA’s disincentive for tobacco companies to innovate and create healthier products. In light of these perverse incentives, the better policy alternative would be to remove the substantial equivalence provision and place all tobacco products on a level playing field, starting with universal premarket review.¹⁵⁵

Even if the modified risk provision passes the third *Central Hudson* prong, it fails the fourth prong because it is more extensive than necessary to further the substantial interest in reducing the health risk of tobacco users, let alone underage consumption. At first glance, the provision seems narrowly tailored by initially requiring tobacco companies to seek FDA approval before marketing modified risk tobacco products and instigating case-by-case FDA

¹⁵³ See O’Reilly, *supra* note 31, at 459 (arguing that the FSPTCA was negotiated between Congress and tobacco companies that made large contributions to political action committees); Kevin Gauntt Barker, Comment, *Thank You for Regulating: Why Philip Morris’s Embrace of FDA Regulation Helps the Company but Harms the Agency*, 61 ADMIN. L. REV. 197 (2009) (arguing that an initially rejected version of the FSPTCA, H.R. 1108, 110th Cong. (2007), is good for tobacco industry leaders like Philip Morris and bad for the Food and Drug Administration’s pursuit of tobacco control).

¹⁵⁴ *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 75 (D.D.C.) (enjoining FDA regulation of electronic cigarettes under the FDCA), *aff’d sub nom. Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

¹⁵⁵ See Page, *supra* note 137 and accompanying text.

evaluation.¹⁵⁶ The provision nevertheless falls short by prohibiting the Secretary from granting approval unless the product will “benefit the health of the population as a whole.”¹⁵⁷ This restriction requires the Secretary to take into account nonusers of tobacco, making it virtually impossible for a tobacco manufacturer to market a modified risk tobacco product that will benefit the nonsmoking population unless the product does not emit secondhand smoke.¹⁵⁸ Moreover, this restriction flatly prohibits tobacco companies from making truthful and easily quantifiable statements about the ingredient content of their products relative to other types and brands of tobacco products.¹⁵⁹ It is important to recall that “the Constitution 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.”¹⁶⁰ The government clearly has a substantial interest in protecting consumers from advertising practices that *misinform* them of product attributes.¹⁶¹ But commercial speech related to nonmisleading tobacco advertising remains protected by the First Amendment so long as tobacco products remain lawful to adult consumers.¹⁶² The government thus cannot make overly broad restrictions on the distribution of tobacco product information.

To rectify the tailoring problems inherent in these provisions, Congress must remove the requirement that a modified risk tobacco product be beneficial to the nonusing public. To retain its significance, the regulation should still require the product to reduce harm to tobacco users. This requirement would also narrowly tailor the provision to the users at which the substantial government interest is directed.

¹⁵⁶ See FSPTCA § 387k(g)(1).

¹⁵⁷ *Id.* § 387k(g)(1)(B); see also FSPTCA, Pub. L. No. 111-31, § 2(37), 123 Stat. 1776, 1780 (2009).

¹⁵⁸ This essentially limits possible product exceptions to smokeless tobacco products and electronic cigarettes (tobacco-free cigarettes that vaporize nicotine for smokers to inhale), which the FDA has tried to ban in separate litigation. See *Smoking Everywhere*, 680 F. Supp. 2d 62.

¹⁵⁹ See FSPTCA, 21 U.S.C. § 387k(b)(2)(A)(ii) (Supp. III 2009).

¹⁶⁰ *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 497 (1995) (Stevens, J., concurring in judgment). See generally Howard K. Jeruchimowitz, Note, *Tobacco Advertisements and Commercial Speech Balancing: A Potential Cancer to Truthful, Nonmisleading Advertisements of Lawful Products*, 82 CORNELL L. REV. 432 (1997) (arguing that advertisements lead to better informed consumers).

¹⁶¹ See *Pearson v. Shalala*, 130 F. Supp. 2d 105, 113 (D.D.C. 2001).

¹⁶² The district court in *Commonwealth Brands* did not analyze this provision under a First Amendment analysis because the FDA has up to 360 days to review a modified risk tobacco product before making a decision, and the labeling restraint is not a restriction on free speech but on placing a product into interstate commerce. *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 533 (W.D. Ky. 2010) (refraining from issuing an advisory opinion and thus waiting for the FDA to make a decision until after the FDA’s 360-day time limit has elapsed).

From a public health standpoint it is undeniably important to take issue with the death and disease caused by secondhand smoke. But the government cannot ban “light” or “reduced risk” tobacco smoke while allowing traditional secondhand smoke to continue to harm the public.¹⁶³ The modified risk provision, coupled with the substantial equivalence exemption, ties the hands of new product manufacturers by requiring them to meet “new product” standards and prohibiting them from offering traditional tobacco users a possibly healthier alternative.¹⁶⁴ These requirements amount to a near-complete ban on speech related to reduced-risk products and must be revised to pass constitutional muster.

3. *The 1,000-Foot Outdoor Advertising Ban*

As already dictated by the Supreme Court in *Lorillard*, the 1,000-foot outdoor advertising ban violates *Central Hudson*’s fourth prong because it is more extensive than necessary to further the government’s interest in preventing underage tobacco consumption.¹⁶⁵ Deciding the third prong in favor of the state, the Court concluded that the outdoor advertising ban directly advanced the government interest because the FDA regulations adopted by the state provided ample evidence that tobacco advertising is linked to underage tobacco consumption.¹⁶⁶ Because this issue has largely been decided, this subsection will hereinafter focus on the fourth prong.¹⁶⁷

¹⁶³ Though lacking evidentiary support, it seems intuitive that the large majority of tobacco products meet the substantial equivalence standards while only those with possibly less harmful effects are subject to nonusers benefit standards.

¹⁶⁴ See O’Reilly, *supra* note 31, at 466 (“If a truly healthier cigarette were to be invented, the 2009 Act erects substantial hurdles which disincentivizes the investment needed to reach the market.”). *But cf.* ELINOR DEVLIN ET AL., *LOW TAR PRODUCT CATEGORY 1*, 3–4 (2003) (finding that even though “low tar” products have been unanimously disproved as a “safer alternative” to traditional cigarettes, consumers continue to rely on such products for a healthier alternative to traditional tobacco products). It is, however, important to note that new products like electronic cigarettes still contain nicotine, technically a tobacco product, yet are free from the harmful smoke and tar attributed to traditional cigarettes. See *E-Cigarette Benefits*, E-CIGARETTES CHOICE, <http://www.ecigaretteschoice.com/pages/Benefits.html> (last visited Mar. 6, 2011). Yet, the FDA has sought to ban them; under the FSPTCA, e-cigarettes are considered a modified risk tobacco product, making their availability subject to FDA approval. See Press Release, Food & Drug Admin., FDA and Public Health Experts Warn About Electronic Cigarettes (July 22, 2009), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm>; see also Craig A. Conway, *FDA Takes on Electronic Cigarette Companies*, HEALTH L. PERSP. (Aug. 2009), [http://www.law.uh.edu/healthlaw/perspectives/2009/CC\)ElecCig.pdf](http://www.law.uh.edu/healthlaw/perspectives/2009/CC)ElecCig.pdf).

¹⁶⁵ *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 561 (2001).

¹⁶⁶ *Id.*; see also *supra* notes 123–25 and accompanying text. It is also interesting to note that the Court was closely split, 5–4, on the third *Central Hudson* prong. *Lorillard*, 533 U.S. at 561. While the Court

To pass constitutional muster, the outdoor advertising restrictions must be more specifically tailored to reducing underage tobacco use while providing more adults with exposure to lawful outdoor advertising. The FSPTCA adopts the 1996 federal regulations' ban on outdoor tobacco advertising within 1,000 feet of defined places where children congregate¹⁶⁸—the same one adopted by the Massachusetts legislature¹⁶⁹ and struck down in *Lorillard*.¹⁷⁰ Because Massachusetts adopted the FDA regulations wholesale, without adapting them to the characteristics of the state, the restrictions were not narrowly tailored to further the state's substantial interest in reducing underage use.¹⁷¹ Similarly troubling, the 1,000-foot restriction would result in an almost-complete ban on outdoor advertising in metropolitan areas.¹⁷²

In response to the analysis offered in *Lorillard* and the limited guidance set forth in *Commonwealth Brands*,¹⁷³ the FDA has placed the outdoor advertising restriction on hold and is considering

“several options” for altering the 1996 outdoor advertising provision, including limiting the prohibition . . . to only apply to billboards within 1,000 feet of elementary or secondary schools, or prohibiting signs or collections of advertisements greater than 14 square feet at

composition has changed since 2001 with the addition of Chief Justice Roberts and Justices Alito, Sotomayor, and Kagan, the Court's political ideology is beyond the scope of this Comment.

¹⁶⁷ The district court in *Commonwealth Brands* did not address this issue, however, because it found the issue was not ripe because the Secretary had until March 22, 2010, to issue a final regulation. 678 F. Supp. 2d at 536. Ripeness, however, is outside the scope of this Comment.

¹⁶⁸ See FSPTCA, 21 U.S.C. § 387a-1 (Supp. III 2009) (adopting 1996 Final Rule, *supra* note 7, at 44,617, § 897.30(b) (defining restricted areas as “the perimeter of any public playground[,] . . . elementary school, or secondary school”).

¹⁶⁹ See 940 MASS. CODE REGS. § 21.04(5)(a) (2000).

¹⁷⁰ *Lorillard*, 533 U.S. at 565. The district court in *Commonwealth Brands* noted that because the “ban is indistinguishable from the Massachusetts’ [sic] ban the Supreme Court struck down in *Lorillard*, Plaintiffs are undoubtedly right [that the outdoor advertising ban is unconstitutional].” 678 F. Supp. 2d at 535.

¹⁷¹ *Lorillard*, 533 U.S. at 562-63 (“[A]lthough a State or locality may have common interests and concerns about underage smoking and the effects of tobacco advertisements, the impact of a restriction on speech will undoubtedly vary from place to place.”).

¹⁷² *Id.* at 562. It is also important to note that the advertising ban is not limited to outdoor advertising such as billboards. As noted in *Commonwealth Brands*' complaint, retailers use tobacco advertising on their storefronts to entice customers into their store and hopefully to “trigger spontaneous purchase decisions of non-tobacco products.” Complaint, *supra* note 35, at 24. This is an important distinction, highlighting the fact that retailers advertise price and product with no intent to influence adolescents into making tobacco purchase decisions.

¹⁷³ See *supra* note 167 (noting the issue is not ripe because under this provision the Secretary has yet to issue a final rule comporting with the First Amendment).

retail establishments located in close proximity to any elementary or secondary school.¹⁷⁴

As noted in *Lorillard*, the 1,000-foot restrictions will have very different effects depending on “whether a locale is rural, suburban, or urban.”¹⁷⁵ An adult consumer seeking to receive truthful tobacco information would be hard-pressed to find tobacco billboards in a city, while a similarly situated consumer in a rural area would find such information easily available. Placing the burden on the FDA to apply a more subjective rule depending on population density would reconcile the disparity in teenagers’ abilities to view such advertising¹⁷⁶ and assuage the restriction on adult consumers.

The regulations should also aim to differentiate between manufacturer advertising targeted at influencing new product purchase decisions and advertising by retailers that highlights products within the store.¹⁷⁷ Given that the FDA has failed to establish a link between retailer advertising and underage tobacco consumption, it is necessary to amend the current provisions to allow merchants to price-advertise. Without such changes, it may not be possible to make a meaningful distinction between the FSPTCA and the Massachusetts regulations that failed the fourth *Central Hudson* prong in *Lorillard*.¹⁷⁸

4. *Ban on Event Sponsorship and Promotional Products*

Though the promotional ban will likely pass muster under the third *Central Hudson* prong, it is probably more extensive than necessary to achieve the ascertained goal of reducing underage tobacco use. To meet the requirements of the fourth prong, Congress should implement less restrictive alternatives like expanding the Federal Cigarette Labeling and Advertising Act’s warning requirements to include merchandise, strictly enforcing merchandise purchase age requirements, and distinguishing between adult-only events and those likely to attract underage audiences.

¹⁷⁴ C. STEPHEN REDHEAD & TODD GARVEY, CONG. RESEARCH SERV., R41304, FDA FINAL RULE RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO 14 (2010) (quoting Request for Comment on Implementation of the FSPTCA, 75 Fed. Reg. 13,241, 13,242 (proposed Mar. 19, 2010)) (internal quotation mark omitted).

¹⁷⁵ *Lorillard*, 533 U.S. at 563.

¹⁷⁶ Consider a person’s ability to view a billboard 1,000 feet away in a city surrounded by tall buildings and where a minor might not travel more than a few blocks in a given day. Compare this with a rural teenager who travels a greater distance to schools and has a more unobstructed view of outdoor advertising.

¹⁷⁷ See *supra* note 172.

¹⁷⁸ See *Lorillard*, 533 U.S. at 562–63.

Under the Secretary's final rule, tobacco manufacturers may not "sponsor . . . any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event . . . [with any] indicia of product identification . . . identifiable with[] those used for any brand of cigarettes or smokeless tobacco."¹⁷⁹ The rule also prohibits distribution or marketing of any promotional item with a tobacco product's "logo, symbol, motto, selling message," or pattern.¹⁸⁰ These provisions essentially ban tobacco manufacturers from marketing their brand name outside of magazines.¹⁸¹

The promotional ban appears to directly advance the government's substantial interest of reducing youth tobacco use because the underage population readily consumes tobacco merchandise and event sponsorship.¹⁸² It is conceivable that minors may even increase their tobacco consumption to fulfill the purchase requirements necessary to obtain these promotional products. Also, products like lighters and matches are directly attributable to tobacco use and establish a clear connection between distribution and consumption.¹⁸³ Adding to the government's argument, tobacco merchandise and sponsorship advertising do not contain the health warnings otherwise required on packaging and product advertising, making the risks of tobacco use less recognizable.¹⁸⁴ Considering the extent of event sponsorship through the wide reach of television and other media outlets, a restriction on tobacco promotion will undoubtedly lead to reduced youth tobacco use.

Even though the required connection is likely made under the third prong, these restrictions may be more extensive than necessary because they unnecessarily restrict not only youth advertising and merchandise consumption, but lawful adult distribution as well. While some underage consumers may get their hands on promotional products, these merchandise

¹⁷⁹ 2010 Final Rule, *supra* note 117, § 1140.34(c); *see also* FSPTCA, 21 U.S.C. § 387a-1(a) (Supp. III 2009).

¹⁸⁰ 2010 Final Rule, *supra* note 117, § 1140.34(a).

¹⁸¹ *Id.* There are no exceptions to these restrictions.

¹⁸² Merchandise distribution, however, is directly aimed at adults and often requires proof of purchase or UPC labels. *Compare Age Filtering Software*, CAMEL.COM, <https://camel.tobaccopleasure.com/modules/FooterLinks/AgeFiltering.aspx> (last visited Mar. 6, 2011) (encouraging age filtering software and also screening new users' ages, including a forty-eight-hour waiting period to use the site), with Kurt M. Ribisl et al., *A Content Analysis of Web Sites Promoting Smoking Culture and Lifestyle*, 30 HEALTH EDUC. & BEHAV. 64 (2003) (finding most web sites that promote smoking culture do not require age verification).

¹⁸³ *See* Edward Sepe et al., *Smooth Moves: Bar & Nightclub Tobacco Promotions That Target Young Adults*, 92 AM. J. PUB. HEALTH 414, 415 (2002).

¹⁸⁴ *See* Scott Sullivan, Note, *Tobacco Talk: Why FDA Tobacco Advertising Restrictions Violate the First Amendment*, 23 WM. MITCHELL L. REV. 743, 782 (1997).

programs are directed at adults, where the vast majority of use lies. These programs also require age verification to obtain promotional products.¹⁸⁵ While event sponsorship is generally aimed at all viewers, not just adults, the FSPTCA institutes a complete ban on sponsorship without considering less restrictive alternatives for adult-specific events.¹⁸⁶

In its summary judgment opinion, the district court in *Commonwealth Brands*, however, found the merchandising provisions sufficiently tailored, passing the fourth prong.¹⁸⁷ The court relied on Congress's finding that "[t]here is no way to limit the distribution of these items to adults only" and that the MSA was an ineffective solution to the problem.¹⁸⁸ Agreeing with the FDA, the court deemed that even if such merchandise were not distributed to children, adult wearers would become "walking advertisements" and would be "very effective in creating the sense that tobacco use is widely accepted."¹⁸⁹ Concluding its analysis, the court surmised that even though some advertising is for adult-only events, the advertising itself is distributed to the public and available to minors.¹⁹⁰

The district court's analysis is comprehensive but unconvincing. First, the court unduly deferred to Congress's findings despite the Supreme Court's explicit assertions in *Coors* and *44 Liquormart* repudiating overt legislative deference.¹⁹¹ Further, the MSA's ineffectiveness is not an adequate justification for adopting overbroad restrictions. Second, the court's reasoning that adults become walking tobacco advertisements perpetuating tobacco's societal acceptance discounts the fact that smoking is accepted by Congress itself. Several provisions within the FSPTCA highlight this discontinuity. For instance, the modified risk products provision maintains the status quo for major tobacco manufacturers,¹⁹² and the FSPTCA's limited confidentiality

¹⁸⁵ *Cf. supra* note 182.

¹⁸⁶ For example, Lorillard sponsors a gambling tournament in Las Vegas; participants must be over twenty-one, and minors are not allowed on the premises. *See* Complaint, *supra* note 35, at 25.

¹⁸⁷ *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 527–28 (W.D. Ky. 2010).

¹⁸⁸ *Id.* at 527 (alteration in original) (quoting 1996 Final Rule, *supra* note 7, at 44,526); *id.* at 524–26 (refuting the plaintiff's argument that the Act does not differentiate between adults and children). The court cited two journal articles and a district court case that found tobacco companies increased their sponsorship budgets after signing the MSA. *Id.* at 526–28. Not only is this "proof" unconvincing, the argument that Congress found the MSA insufficient is not a relevant justification for implementing an overbroad restriction on commercial speech.

¹⁸⁹ *Id.* at 527–28 (quoting 1996 Final Rule, *supra* note 7, at 44,526).

¹⁹⁰ *Id.* at 527 n.4.

¹⁹¹ *See supra* note 66 and accompanying text.

¹⁹² *See supra* Part II.B.2.

provision¹⁹³—lauded for providing much needed transparency—is more protective of the tobacco industry than it is restrictive. So long as such provisions continue to contradict the purpose of the FSPTCA, it remains difficult to make a compelling argument that advertising of lawful products explains children’s conception that tobacco use is widely accepted. Third, the court’s argument that sponsorship of adult-only events is still available to minors belies the problem with these provisions. For instance, casinos that advertise an adult-only event sponsored by a tobacco company are unlikely to direct their advertisements to children, and any advertising distributed solely “in-house” would be completely unavailable to minors. In contrast, the assertion that most large sporting and musical events are widely available to the youth population is undoubtedly correct. But commercial speech jurisprudence is also clear in requiring the government to undertake the difficulty of distinguishing between advertisements aimed at the proposed substantial interest and those otherwise caught within a broad prophylactic rule that infringes on the public’s First Amendment rights.¹⁹⁴

With regard to merchandise distribution, the FSPTCA could implement less restrictive alternatives like utilizing stricter age laws and extending the FCLAA’s warning requirements¹⁹⁵ to include tobacco merchandise. Though difficult to employ less restrictive alternatives for sponsorship because of the wide viewership of athletic events and concerts, Congress could narrowly tailor the restrictions to create exceptions for adult-only advertising venues like gambling or fighting events. While such exceptions may be difficult to administer, it is up to Congress and the FDA to make such distinctions in order to uphold the First Amendment rights of tobacco manufacturers, retailers, and lawful consumers.

5. *Prohibition on Free Sample Product Distribution*

The restrictions on free sample distribution may not pass the third *Central Hudson* prong because they are applied inconsistently between cigarettes and

¹⁹³ FSPTCA, 21 U.S.C. § 387f(c) (Supp. III 2009). Despite this provision, tobacco companies are actually protected by the Freedom of Information Act, prescribing that manufacturers’ product information “shall not be disclosed” if their commercial interests are affected. See O’Reilly, *supra* note 31, at 461–62 & n.18 (quoting 21 U.S.C. § 387f(c)) (arguing that the language in § 387f(c) “is an effort to trigger blanket secrecy under [Freedom of Information Act] exemption 3”). For example, this issue would be implicated under the product testing provision of the FSPTCA. FSPTCA § 387o(b)(1).

¹⁹⁴ See *supra* note 131 and accompanying text.

¹⁹⁵ 15 U.S.C. § 1333 (2006).

smokeless tobacco products. Similarly problematic under the fourth prong, these provisions give no justification for banning cigarette samples, yet provide a narrowly tailored alternative for smokeless tobacco products. A simple solution to both problems is to bring cigarettes within the province of the exception provided for smokeless tobacco products.

Section 387a–1(a)(2)(G) prohibits free sample distribution of “cigarettes, smokeless tobacco, or other tobacco products,” with certain limited exceptions.¹⁹⁶ Free sample distribution is only permitted for smokeless tobacco products in a “qualified adult-only facility.”¹⁹⁷ To qualify as an adult-only facility, a retailer cannot sell alcohol or be located across from a space used for youth activities, must contain an enclosed barrier for free sample distribution out of public view, and have a security guard to check the authenticity of consumers’ age identification.¹⁹⁸

The FDA has not provided a coherent justification for allowing a smokeless product exception under § 387a–1(a)(2)(G), yet placing an outright ban on cigarette and other smoking tobacco sample distribution. One could imagine the argument that cigarettes are more dangerous to the public than smokeless tobacco products, which do not produce secondhand smoke and are only dangerous to the user. The substantial government interest offered by the government, however, works to curb youth consumption. Aiming to protect the public from secondhand smoke is a much broader interest and at odds with the rest of the Act, which allows for continued distribution of traditional smoking products. For example, a strikingly disingenuous provision allows for distribution and continued use of menthol cigarettes while banning cloves and flavored cigarettes.¹⁹⁹ Though only 2%–3% of teenagers use flavored cigarettes and cloves,²⁰⁰ 25%–30% of the cigarettes sold in the United States

¹⁹⁶ FSPTCA § 387a–1(a)(2)(G); 2010 Final Rule, *supra* note 117, § 1140.16(d)(1).

¹⁹⁷ FSPTCA § 387a–1(a)(2)(G); 2010 Final Rule, *supra* note 117, § 1140.16(d)(2). The *Commonwealth Brands* court held that free samples do not fall within the realm of First Amendment protection because they entail “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.” *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 538 (W.D. Ky. 2010). Congress, however, did not restrain the distribution of tobacco products, as it is still lawful to sell and distribute them. It is not clear that Congress sought to create a price restriction on free tobacco.

¹⁹⁸ FSPTCA § 387a–1(a)(2)(G); 2010 Final Rule, *supra* note 117, § 1140.16(d)(2).

¹⁹⁹ FSPTCA § 387g(a)(1)(A).

²⁰⁰ See *Teen Smoking Statistics*, TEEN SMOKING, <http://www.teensmoking.us/content/teen-smoking-statistics.html> (last visited Mar. 6, 2011).

are of a menthol variety.²⁰¹ If the substantial interest sought by the FSPTCA were to protect the general public health, it is inconceivable that tobacco product distribution would still be a lawful activity.²⁰² Though the advertising restrictions in *Greater New Orleans* more flagrantly disregarded the substantial government interest at hand,²⁰³ the arbitrary distinction between free samples of smokeless tobacco and cigarettes is problematic because it creates an incoherent gap between the product classes and thus calls into question § 387a-1(a)(2)(G)'s viability under the third prong.

The complete ban on tobacco sample distribution, save smokeless tobacco, is also more extensive than necessary to accomplish the government's interest in reducing teen smoking. In addition to the Court's misgivings concerning complete bans,²⁰⁴ the disconnect between smoking and smokeless tobacco products underscores the problem with this provision.²⁰⁵ Completely restricting one class of products is clearly more rigorous than the qualified adult-only facilities exception created for smokeless tobacco products. This juxtaposition begs the question: Are the requirements for smokeless-tobacco sample distributions not rigorous enough or are the regulations on all other tobacco products more extensive than necessary?

A possible answer to this question may be drawn through analogy. It has been shown that raising cigarette taxes will inhibit youth smoking by making it cost prohibitive.²⁰⁶ Free sample distribution to underage smokers could circumvent teenagers' inability to fund their smoking habits. Preventing free

²⁰¹ See Daniel R. Brooks et al., *Menthol Cigarettes and Risk of Lung Cancer*, 158 AM. J. EPIDEMIOLOGY 609, 609-10 (2003).

²⁰² See generally *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 138-39 (2000) (finding Congress's repeated legislation enabling continued distribution of tobacco products precluded the FDA from regulating tobacco products).

²⁰³ *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173 (1999) (finding that the statute aimed to protect the public from the social ills of gambling, yet failed to regulate Native American casinos); see also *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488-89 (1995) (finding that the statute failed the third *Central Hudson* prong due to incoherent and contradictory regulatory provisions).

²⁰⁴ See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 561-63 (2001); *44 Liquormart v. Rhode Island*, 517 U.S. 484, 501 (1996) (Stevens, J.).

²⁰⁵ Compare FSPTCA, 21 U.S.C. § 387a-1(a)(2)(G) (Supp. III 2009) (amending 21 C.F.R. § 897.16(d)(2)(A)-(B) (1997)), with *id.* (amending 21 C.F.R. § 897.16(d)(2)(C) (1997)).

²⁰⁶ See Sherry Emery et al., *Does Cigarette Price Influence Adolescent Experimentation?*, 20 J. HEALTH ECON. 261, 268-69 (2001) (finding that excise taxes are only a deterrent to advanced teen smokers, not lightly using experimenters). For an economist's viewpoint, see Steven M. Suranovic, *An Economic Model of Youth Smoking: Welfare and Tax Effects* 27 (Oct. 2005) (unpublished manuscript, available at <http://129.3.20.41/eps/hew/papers/0511/0511003.pdf> ("[T]he results show that much higher cigarette taxes . . . could reduce or eliminate teen smoking but the levels of taxes may need to be quite high.")).

sample distribution to underage consumers clearly extends from such an intuitive argument. It is less certain, however, that underage consumers in search of cheap cigarettes would roam different locations in search of free samples. It is even less clear that minors would skirt the qualified adult-only facilities provision by producing false identification to a police officer or security guard.²⁰⁷ Moreover, policy initiatives that include retailers in the fight against underage consumption and point-of-sale purchase have been successful where efforts to educate and promote legal tobacco distribution are long-term, community wide, and coupled with strict enforcement.²⁰⁸ The qualified adult-only facility exception not only requires police officers to verify age identification, but also involves retailers by restricting where and how sample distribution displays must be erected. It thus provides at least an initial step toward the retailer involvement that is necessary for a successful campaign against illegal tobacco sales.

Without further justification, a blanket restriction on free sample distribution of cigarettes is more extensive than necessary to reduce teen smoking, and a qualified adult-only exception may be more properly tailored to the substantial interest at hand. The safest amendment to § 387a-1(a)(2) would be to treat all smoking and smokeless tobacco products the same, curing the incoherent distinction between the two. Adapting the current qualified adult-only facility exception to include smoking products also lifts the complete ban on free sample distribution and rectifies the provision's current failure to comply with the fourth *Central Hudson* prong.

6. *Consequences of Unconstitutional Advertising Restrictions and the Remnants of the FSPTCA*

If the FSPTCA's advertising restrictions unconstitutionally violate the First Amendment, then the rest of the Act will lose the ability to fulfill its stated purpose of reducing underage smoking—and ultimately the FDA's capacity to improve public health.²⁰⁹ The FSPTCA's most pertinent remaining provisions

²⁰⁷ Compare Emery et al., *supra* note 206 (finding new smokers get cigarettes from friends, ask others to buy cigarettes for them, or both), with U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 7, at 10 ("Illegal sales of tobacco products are common. Active enforcement of age-at-sale policies by public officials and community members appears necessary to prevent minors' access to tobacco.").

²⁰⁸ See Jean L. Forster & Mark Wolfson, *Youth Access to Tobacco: Policies and Politics*, 19 ANN. REV. PUB. HEALTH 203, 225-27 (1998); Jeruchimowitz, *supra* note 160, at 439-40 (arguing for stricter enforcement of age restrictions and retailer enforcement laws).

²⁰⁹ See FSPTCA, Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1781-82 (2009); see also 2010 Final Rule, *supra* note 117, § 1140.2.

would be the restrictions on new tobacco products,²¹⁰ the prohibition on flavored tobacco products,²¹¹ inspection of tobacco manufacturer facilities,²¹² and limited confidentiality of product ingredients.²¹³ These provisions are universally impotent and contain considerable exceptions, notably consistent in maintaining the tobacco industry's status quo.²¹⁴ Considering the FDA's substantial limitations on regulating existing tobacco products, losing the advertising provisions would be a catastrophic blow to the efficacy of the FSPTCA. As evidence of such, the FDA is restricted from recalling cigarettes from the market,²¹⁵ increasing the age limitation on tobacco purchase,²¹⁶ or banning tobacco products entirely.²¹⁷ The FDA is thus hobbled by the inability to truly reduce the harmful effects of tobacco products by directly restraining their supply.

Tobacco use still contributes to at least 400,000 deaths in the United States each year.²¹⁸ To combat this public health crisis without banning tobacco distribution entirely, the FDA must direct its efforts at consumer demand by regulating tobacco advertising that has ostensibly targeted the youth population for years.²¹⁹ It is thus imperative that Congress amend the advertising provisions to comply with the First Amendment through *Central Hudson*.

Several of the amendments proposed earlier in this Part argue for more narrowly tailored provisions that emphasize a regulatory scheme specifically aimed at combating underage tobacco consumption. While such distinctions are difficult to make, a prophylactic rule banning all such communication creates an unwarranted and overly broad restriction on lawful communication between tobacco companies and consumers.²²⁰ This lawful communication is

²¹⁰ FSPTCA, 21 U.S.C. § 387j(a)(1) (Supp. III 2009).

²¹¹ *Id.* § 387g(a)(1).

²¹² *Id.* § 387e(g).

²¹³ *Id.* § 387f(c).

²¹⁴ *See supra* Part II.C.1–5.

²¹⁵ FSPTCA § 387h(c) (requiring a “reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market,” meaning tar, nicotine, carcinogens, and the risk of death and disease are not adequate reasons to recall a tobacco product).

²¹⁶ *Id.* § 387f(d)(3)(A)(ii).

²¹⁷ *Id.* § 387g(d)(3) (stating that “[b]ecause of the importance of a decision of the Secretary to issue a regulation” the FDA may not ban cigarettes or smokeless tobacco from the market nor reduce their nicotine content to zero).

²¹⁸ *See supra* note 4 and accompanying text.

²¹⁹ *See* FSPTCA, Pub. L. No. 111-31, § 2(15)–(21), 123 Stat. 1776, 1777–78 (2009). It is similarly questionable that the world's largest purveyor of tobacco products, Philip Morris, is absent from this litigation and supported the FSPTCA's adoption. *See* Letter, *supra* note 36 (showing Altria's support of the FSPTCA).

²²⁰ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985).

so valuable to the public welfare that regulators must bear the burden of “distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful.”²²¹ For the FDA to withstand the First Amendment challenges made in *Commonwealth Brands*, it must be prepared to take on the advertising issue in a case-by-case manner, abandoning the inhibitory measures that call the FSPTCA’s constitutionality into question.

In addition to the specific proposals made earlier, there are several alternatives passed on by the FSPTCA that aim at the heart of reducing underage tobacco consumption and apply to all the Act’s restrictions, such as: implementing smoking cessation and tobacco education programs for children; increasing tobacco excise taxes; prosecuting underage use, possession, and sale to minors; and government-sponsored public service announcements aimed at reducing smoking.²²² All of these alternatives have proven somewhat successful in reducing smoking.²²³ For example, government-sponsored advertisements aimed at informing the public of tobacco’s harmful effects were so successful in the 1960s that the tobacco industry agreed to take tobacco advertisements off the radio in exchange for in-kind removal of public service announcements.²²⁴

²²¹ *Id.*; see also Luka, *supra* note 70, at 318 (“The First Amendment interests threatened by the regulation of tobacco advertising are considerably more substantial than many have recognized.”).

²²² See Complaint, *supra* note 35, at 31; see also 1996 Final Rule, *supra* note 7, at 44,491–92 (recognizing the need to implement some alternative programs in addition to the tobacco advertising and access restrictions). This is not to say that regulatory authorities have paid no heed to the efficacy of additional restrictions. These controls, however, are generally only being considered in addition to the advertising restrictions considered in this Comment. For example, the FDA and the U.S. Department of Health and Human Services have issued draft guidance for proposed regulations instituting civil money penalties and “No-Tobacco-Sale Orders” against retailers who fail to comply with the FSPTCA. See CTR. FOR TOBACCO PRODUCTS, U.S. DEP’T OF HEALTH & HUMAN SERVS., DRAFT GUIDANCE FOR FDA AND TOBACCO RETAILERS: CIVIL PENALTIES AND NO-TOBACCO-SALE ORDERS FOR TOBACCO RETAILERS 5–11 (2010), available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM224464.pdf>.

²²³ For example, a study promoted by the National Cancer Institute argues that smoking cessation advertising restrictions should be less rigorous in light of the success of direct-to-consumer advertising and smoking cessation products’ ability to help smokers quit. Rosemary Avery et al., *Regulating Advertisements: The Case of Smoking Cessation Products*, 31 J. REG. ECON. 185, 203–04 (2007). The FDA cited other countries’ restrictions on tobacco advertising and the positive youth impact they have had. See 1996 Final Rule, *supra* note 7, at 44,491–92. Yet those countries included the alternatives discussed above in conjunction with the advertising restrictions to achieve such progress. *Id.*; see also Sullivan, *supra* note 184, at 774–75.

²²⁴ See *Capital Broad. Co. v. Mitchell*, 333 F. Supp. 582, 588–89 (D.D.C. 1971) (Wright, J., dissenting) (arguing that tobacco companies agreed to be taken off the airwaves in exchange for removal of public service announcements, which led to later increases in tobacco consumption), *aff’d sub nom.* *Capital Broad. Co. v. Kleindienst*, 405 U.S. 1000 (1972), and *aff’d sub nom.* *Nat’l Ass’n of Broadcasters v. Kleindienst*, 405 U.S. 1000 (1972).

In *Commonwealth Brands*, the district court generally disagreed that less restrictive alternatives are worthwhile.²²⁵ After listing several things the government has done that did not reduce underage consumption, the court found the alternatives “notable for the extent to which they would impose substantial new costs on state and local governments and private persons . . . to counter the impact that [Plaintiffs’] billions of dollars of advertising has on youth.”²²⁶ This argument simply ignores the Court’s requirement imposed in *Zauderer*, that the government must expend the resources necessary to protect the First Amendment.²²⁷ In addition to the evidence showing alternatives that reduce underage use, the district court disregarded the most blatant statistic indicating that these alternatives do work: smoking rates have continually decreased over the past fifty years.²²⁸ The fact that teens continue to take up smoking does not provide carte blanche for the government to impose sweeping commercial speech restrictions. Ultimately, the First Amendment gives consumers a right to be informed about the products they are consuming and the public is better off for it.²²⁹ As long as tobacco is legally sold and distributed in the United States, the public has a right to the information applicable to the tobacco products they consume. Indeed, Congress must be willing to give up some ground to the tobacco industry to maintain the usefulness of an Act touted as a victorious finale to “[t]he decades-long effort to protect our children from the harmful effects of smoking.”²³⁰

III. RELEVANT CONSIDERATIONS EXTERNAL TO A MODERN COMMERCIAL SPEECH ANALYSIS UNDER *CENTRAL HUDSON*

This Comment examines the FSPTCA through the lens of the First Amendment’s commercial speech doctrine in order to take a prospective look at the implications of the current dispute in *Commonwealth Brands*. This analysis is only one of many possible angles amenable to closer inspection. In response, this Part briefly looks at a few important issues looming over the

²²⁵ *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 536–38 (W.D. Ky. 2010).

²²⁶ *Id.* at 537 (alterations in original) (quoting Response of United States at 36 (No. 1:09:CV:00117)) (internal quotation mark omitted).

²²⁷ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985).

²²⁸ See McKay, *supra* note 2, and accompanying text.

²²⁹ See Rosemary J. Avery et al., *Health Disparities and Direct-to-Consumer Advertising of Pharmaceutical Products*, in *BEYOND HEALTH INSURANCE: PUBLIC POLICY TO IMPROVE HEALTH* 71 (Advances in Health Econ. & Health Servs. Research, Vol. 19, Lorens Helmchen et al. eds., 2008) (“Consumers who are better-informed about smoking, diet, and physical activity make healthier choices outside the health care sector.”).

²³⁰ See *Obama Signs Sweeping Anti-Smoking Bill*, *supra* note 29 (internal quotation mark omitted).

future of tobacco regulation in an effort to acknowledge the possible counterarguments to the perspective adopted by this Comment. Section A steps outside the Act's provisions and asks whether the FDA is even capable of regulating the tobacco industry when considered in light of its already extensive obligations. Section B serves as a reminder that commercial speech analysis under *Central Hudson* is anything but settled and the legitimacy of the FSPTCA rests squarely on the shoulders of the Supreme Court.

A. *Can the FDA Regulate Big Tobacco?*

The tobacco industry is faced with unprecedented regulation of its products through the FSPTCA. For decades, the FDA shied away from regulating tobacco products.²³¹ Congress similarly took a backseat approach to tobacco legislation, delegating minimal regulatory authority to a variety of agencies for the better part of fifty years.²³² This regulatory hesitance may have been for good reason. It remains to be seen whether the FDA can actually handle the overwhelming burden imposed by the tobacco industry. As described in many of the proposed amendments in Part II, passing constitutional muster under the fourth *Central Hudson* prong commands an enormous burden on the FDA and its employees to screen advertisements and employ more subjective rules on a case-by-case basis.²³³ If the FDA's other areas of expertise are any indication, the agency is already overwhelmed.²³⁴ Though Congress handed the FDA²³⁵ a toothless provision, ill-equipped to protect the public health, the FDA's "tenacious drive to maximize its regulatory power has resulted in its advocacy of an interpretation of the relevant law that . . . [is] unreasonable"²³⁶ and may be untenable.

²³¹ See *supra* note 28 and accompanying text.

²³² See *supra* notes 16–19.

²³³ See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 566 (2001); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985).

²³⁴ See Craig A. Conway, *FDA Gains Regulatory Authority over Tobacco*, HEALTH L. PERSP. (July 2009), [http://www.law.uh.edu/healthlaw/perspectives/2009/\(CC\)Tobacco.pdf](http://www.law.uh.edu/healthlaw/perspectives/2009/(CC)Tobacco.pdf) (noting that the FDA may only inspect 8% of foreign drug manufacturers subject to inspection each year and has had to divert resources to address major health issues related to tainted food products in the past few years, including peanut butter, cookie dough, pistachios, and peppers).

²³⁵ While the modern nondelegation doctrine seems to support Congress's delegation of tobacco jurisdiction to the FDA, it is by no means uncontroversial. See McGowan, *supra* note 10 (arguing that the Supreme Court should reformulate the nondelegation doctrine to take some power away from regulatory agencies).

²³⁶ *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 78 (D.D.C. 2010) (finding the FDA lacks jurisdiction to regulate e-cigarettes under the FDCA), *aff'd sub nom. Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

With the growing demands placed on the FDA, it is also important to consider the source of its funding and whether regulators have enough support to reasonably meet the FDA's obligations.²³⁷ The Government Accountability Office reported that "the demands on the agency have soared in recent years for a variety of reasons," and the "FDA's resources ha[ve] not increased in proportion to the growing demands placed on it, putting public health at risk."²³⁸ The FSPTCA does include a "User Fees" provision that allows the FDA to collect quarterly fees from tobacco manufacturers.²³⁹ Where these fees will go and whether they will help the FDA meet its public health obligations is yet to be seen. But given the FSPTCA's inconsistent provisions, Philip Morris's support of the Act, and the relatively ineffective regulation left in place, it is hard not to view the user fees provision as the product of a deal between tobacco lobbyists and congressional committees meagerly trying to appease their constituencies while leaving the tobacco industry remarkably unscathed. With the feasibility of FDA regulation clearly unsettled, the proposals made in this Comment should be taken, assuming (1) the FDA is a suitable administrative agency for tobacco regulation, and (2) the tobacco industry is capable of being adequately regulated.

Whether the FDA can handle the enormous task of regulating the tobacco industry is better left for a separate article. It is important nonetheless to recognize that there is a cogent argument that the FDA may not be the agency that should be regulating tobacco. That argument sharply diverges from the proposals adopted in Part II that argue for amendments to the FSPTCA in order to give the FDA a more sensible regulatory scheme. From either perspective, it is relevant to point out the hurdles facing Congress, regulators, and public health officials when contemplating tobacco regulation.

B. Stepping Outside the Modern Central Hudson Framework

The analysis adopted in this Comment arguably lacks consequence when considered in light of the Court's failure to adopt a consistent standard of interpretation. Looming over the entire First Amendment issue is the level of scrutiny the Court will apply. As described in Part II, the Court has wavered dramatically over the past thirty years in its application of deference to the

²³⁷ See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-271, HIGH RISK SERIES: AN UPDATE 16 (2009).

²³⁸ *Id.*

²³⁹ FSPTCA, 21 U.S.C. § 387s (Supp. III 2009) (allowing fees of \$85 million in 2009 and up to \$712 million for fiscal year 2019).

legislature. From *Central Hudson*'s initial intermediate scrutiny, *Posadas* and rational basis, *Coors*'s and *44 Liquormart*'s attempts to abolish legislative deference, and the recent Court compromise in *Lorillard*, the future of *Central Hudson* is anything but certain.²⁴⁰ The *Lorillard* decision is a prime example of the Court's failure to settle on an application standard. Rife with debate and marked by four concurrences and two dissents,²⁴¹ the opinion lends weight to the conclusion that the Court has yet to find its commercial speech equilibrium. Should the Court revert to legislative deference or adopt a vice exception to commercial speech protection, the analysis in Part II would be largely for naught because the FSPTCA should stand unscathed, easily passing a rational basis challenge. Conversely, if the Court breaks new ground and adopts a strict scrutiny standard, Congress would have to meet even stricter constitutional standards. This would require even more government resources and amendments that further chip away at the already-compromised advertising provisions.

Either of these scenarios, however, is unlikely. Though some Supreme Court Justices and commentators appear willing to adopt a strict scrutiny standard, this outcome is improbable given the makeup of the Court.²⁴² Reverting to the standard espoused by *Posadas* seems even more dubious considering no Justice has positively cited the opinion since it was refuted in

²⁴⁰ However controversial, if congressional and, indirectly, public opinion are any indicators of the Court's decision making, then the future of commercial speech may be in the hands of a reactive Court. See generally Tom S. Clark, *The Separation of Powers, Court Curbing, and Judicial Legitimacy*, 53 AM. J. POL. SCI. 971, 984–96 (2009) (arguing that the Court responds to public opinion and congressional threats through Court-curbing legislation). It is similarly instructive to note the parallel progression of the Court, presidential administrations, and wavering judicial ideologies applied to the commercial speech doctrine since the *Central Hudson* decision in 1980. See BARRY FRIEDMAN, *THE WILL OF THE PEOPLE* 293–322 (2009) (tracking presidential nominations of Supreme Court Justices and their corresponding judicial philosophies and stances on constitutional interpretation). It is imperative to note that the Court took its most liberal regulatory stance in *Posadas* when the Court was filled with Burger-era Justices, a notably liberal Court. *Id.* at 283. The Court's regulatory turn in *Coors* and *44 Liquormart* was instituted in the aftermath of Ronald Reagan's FDR-reminiscent, court-packing strategy. *Id.* at 313–14. After public backlash from the *Bush v. Gore*, 531 U.S. 98 (2000), the Court set forth "a shockingly progressive set of decisions from a supposedly conservative court," FRIEDMAN, *supra*, at 339 (quoting Dahlia Lithwick, *The Ghost of the Warren Court Past*, SLATE (June 26, 2003, 2:03 PM), <http://www.slate.com/id/2084657/entry/2084901>) (internal quotation marks omitted); *id.* at 337–43. Given Congress's current posture and the Obama Administration's marked interest in tobacco regulation, adopting a more conservative approach to commercial speech jurisprudence seems unlikely.

²⁴¹ See *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001).

²⁴² See *supra* note 166. Though outside the scope of this Comment, Judge Posner and William Landes offer an enlightening look at the historical trend in Supreme Court Justice ideology through statistical regression and political science methodology. William M. Landes & Richard A. Posner, *Rational Judicial Behavior: A Statistical Study*, 1 J. LEGAL ANALYSIS 775 (2009).

Coors almost fifteen years ago.²⁴³ Though some political scientists argue that ad hoc decisional analyses like the one adopted in *Central Hudson* provide no systematic guidance and promote subjective, ideological decision making,²⁴⁴ these commentators provide no workable alternative. The *Central Hudson* test may be unavoidable for commercial speech cases where the Court must necessarily balance two important interests—the First Amendment and the public interest. Accurately predicting the ultimate outcome may be an impossible endeavor, but the implications flowing from the FSPTCA are all too clear—the future of tobacco regulation, public health, and the right to First Amendment protection hang in the balance of this impending commercial speech decision.

CONCLUSION

On its face, the FSPTCA is an unprecedented regulation seeking to rein in the tobacco industry's nefarious efforts at addicting a new generation of smokers. Nevertheless, the First Amendment protects not only consumers and public information, but also unpopular speech directed at influencing consumer vices. The Supreme Court has repeatedly rejected paternalistic government intervention aimed at circumventing consumer choice by continually reinforcing *Central Hudson's* core principles and challenging past deference to the government.

Beyond optimistic headlines, the Act's advertising and promotional restrictions are overly broad and poorly aligned with the Act's overall purpose in preventing underage tobacco consumption and protecting the adult public's right to truthful information. By ignoring less restrictive alternatives and implementing Congress's contradictory deal making, the Act's advertising provisions are an unconstitutional affront to the commercial speech doctrine.

Given its unconstitutional speech provisions, the FSPTCA is stripped of its ability to effectively control the public health consequences of tobacco by leaving a gutted piece of legislation effective only at reining in possibly healthier alternatives to traditional smoking products. Instead of restricting traditional tobacco distribution, the Act bans cloves and flavored cigarettes, a miniscule tobacco niche, while illogically exempting menthol-flavored tobacco, a product that makes up more than a quarter of all tobacco sales.

²⁴³ See generally *supra* Part I.

²⁴⁴ See SEGAL & SPAETH, *supra* note 74.

Amidst the myriad of inconsistencies buried in the FSPTCA, it is no wonder that Philip Morris supported its passage.

The FSPTCA's advertising provisions are the most important piece of this legislation. Without these restrictions, the Act is incapable of effectively regulating the enormous tobacco industry and effectuating the laudable goals it prescribes. Congress must be willing to put forth the resources necessary to amend the provisions as required by *Central Hudson* and provide the FDA with the tools needed to actively control the tobacco industry. It is important to note that Congress's refusal to ban tobacco distribution is precisely what leaves the door open for First Amendment protection. Though clearly making the FDA's job more difficult with cumbersome—yet constitutional—advertising restrictions, the FDA can take the necessary steps to mitigate tobacco's overwhelming effect on public health.

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