



# ADVERTISING, THE FDA, AND THE TOBACCO SETTLEMENT: AS HOPES FOR SETTLEMENT DIM, CHALLENGES OF FDA AUTHORITY AND FIRST AMENDMENT CONCERNS ARE REKINDLED

## Citation

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SETTLEMENT:  
AS HOPES FOR SETTLEMENT DIM, CHALLENGES OF FDA  
AUTHORITY  
AND FIRST AMENDMENT CONCERNS ARE REKINDLED

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The headline in January 26th's U.S. News and World Report read: Tobacco Fighters Find Another Smoking Gun. New Documents Dim Settlement Hopes.<sup>1</sup> A few days earlier, Representative Henry Waxman, a leading tobacco opponent, released internal R.J. Reynolds Tobacco Company documents produced between 1973 and 1990, many marked secret or confidential, which apparently describe the company's efforts to attract new young smokers to R.J. Reynolds brands such as Camel.<sup>2</sup> The documents included such recommendations as If our company is to survive and prosper, over the long term we must get our share of the youth market, and The brand must increase its share penetration among the 14-to-24 age group.<sup>3</sup>

As indicated by the headline, the release of the documents, with their implications of intentional attempts by the tobacco industry to target minors, hurt the industry's chances for congressional approval of the sweeping settlement of state lawsuits seeking to recoup health care costs,<sup>4</sup> a settlement that includes a host of advertising and promotion restrictions intended to prevent just such a targeting of minors. Among such tobacco advertising restrictions are a ban on the use of human images and cartoon characters in all advertising, a ban on all billboard and

<sup>1</sup>Marianne Lavelle, Tobacco Fighters Find Another Smoking Gun. New Documents Dim Settlement Hopes, *US. News & World Report*, January 26, 1998.

<sup>2</sup>See Id.

<sup>3</sup>See Id. RJR claims that the memos are taken out of context and that some mentions of underage smokers are the result of typographical errors. See Id.

See Id. Among those skeptical of the settlement is Senate Majority Leader Trent Lott, who recently expressed doubts that the package would pass Congress. See Id.

outdoor advertising, and a restriction of print advertising to black text on a white background (except for advertising in adult-only facilities and publications).<sup>5</sup> These advertising restrictions essentially reflect expanded versions of regulations that the Food and Drug Administration (FDA) proposed in August 1995 and issued on August 28, 1996,<sup>6</sup> which the tobacco, advertising, and convenience store industries have been fighting in court since the release of the proposed rule on the grounds that 1.) the FDA does not have the authority under the Food, Drug and Cosmetic Act (FDCA) to regulate tobacco products (including their advertising and promotion) and 2.) that the restrictions are an unconstitutional restraint of free speech in violation of the First Amendment.<sup>7</sup> With the settlement, these important questions and challenges were somewhat put to rest, for under the terms of the settlement, the tobacco companies effectively agree to accept the authority and constitutionality of the advertising restrictions by dropping their case against the FDA's regulations.<sup>8</sup>

However, the issues of FDA authority to regulate tobacco advertising and the constitutionality of the restrictions will not remain dormant. The damaging R.J. Reynolds documents are the latest indications that the once heralded tobacco settlement may fail to receive the Presidential and Congressional approval necessary for it to take effect. If this occurs, the lawsuit against the regulations will continue, and questions of authority and constitutionality of

<sup>5</sup>See Douglas J. Wood, Will Bans on Tobacco Ads Pass Muster? *The National Law Journal*, July 7, 1997, at B9.

621 C.F.R. 801 et seq. and 61 Fed. Reg. 44,396 et seq.

<sup>7</sup>*Coyne Beahm Inc. v. FDA*, 966 F.Supp. 1374 (M.D.N.C. 1997)

<sup>8</sup>See Wood, *supra* note 5, at B9.

tobacco advertising will rise to the forefront. Additionally, even if the settlement is approved by federal legislation, other factors may result in such issues being raised irrespective of the settlement's approval. This discussion will attempt to explore the controversy and dynamics of FDA authority over tobacco advertising and the constitutionality of the existing (although unapproved) restrictions on tobacco advertising, the two major obstacles to the firm establishment of government limitations on the tobacco industry's commercial speech.

#### I. BACKGROUND

The restrictions on advertising contained within the landmark tobacco settlement began as FDA proposals to regulate tobacco products. In February of 1994, responding to a petition asking it to regulate low-tar and low-nicotine cigarettes, the FDA began to seriously consider the question of whether it had jurisdiction over nicotine-containing tobacco products.<sup>9</sup> Throughout the following year, testimony is heard before various committees in Congress concerning the addictive properties of nicotine and its relation to the conduct of tobacco companies, culminating in an announcement by President Clinton of the proposed FDA rule to reduce the access and appeal of tobacco products to children in August 1995.<sup>10</sup> Public comment periods were open and closed, and finally, on August 23, 1996, President Clinton announced the publication of the final FDA rule as part of a program to prevent children and adolescents from smoking cigarettes or using smokeless tobacco.<sup>11</sup>

The FDA's final regulations are based upon studies and data that the agency gathered

<sup>9</sup>FDA Press Release, August 23, 1996.

<sup>10</sup>See Id.

<sup>11</sup>See Id.

concerning the addictive properties of nicotine and the use of tobacco products by children.<sup>2</sup> Based on this information, the FDA claims to assert jurisdiction over tobacco products as combination products under the FDCA consisting of both a drug component (nicotine) and a device component (tobacco, ventilation system, filter, etc.) that delivers the drug.<sup>3</sup> Rather than an outright ban of tobacco products, the FDA determined that the best way to regulate tobacco to protect the public health is to focus on preventing children and adolescents from becoming addicted.<sup>4</sup> This goal is to be achieved by limiting access to tobacco products and reducing the appeal of tobacco advertising.<sup>5</sup> Restrictions on access to children and adolescents include federal minimum age requirements, bans on vending machines, self-service displays, free-samples, and packages with less than 20 cigarettes.<sup>6</sup> The specific advertising provisions limit the appeal of tobacco products to children by:

1. Prohibiting billboards within 1,000 feet of schools and playgrounds.
2. Permitting only black text on a white background for print media with significant youth readership (15% or more than 2 million readers under 18).
3. Prohibiting sale or giveaways of non-tobacco products (like caps, gym bags, Tshirts, etc.) or services that carry tobacco product brand names or logos.
4. Prohibiting brand-name, logo, or color sponsorship of any sporting, cultural, or other event but permitting sponsorship by corporate name.

In September of 1995, shortly after the publication of the proposed rules, the tobacco, advertising, and retail industries collectively filed suit challenging the FDA's authority to

<sup>2</sup>See Executive Summary, Final Rule (1996) <sup>3</sup>See 61 Fed. Reg. 44,396 at 33,397 (1996) <sup>4</sup>See Executive Summary, Final Rule <sup>5</sup>See Id.

<sup>6</sup>See Id.

regulate tobacco products and the constitutionality of the regulations.<sup>77</sup> District Court judge Osteen decided on April 25, 1997, two months before the tobacco settlement was finalized, that the FDA did have authority to regulate tobacco products but not their advertising or marketing under the FDCA.<sup>78</sup> Given its finding that the FDA lacked authority under the FDCA to restrict the promotion and advertising of tobacco products, the court in Coyne Beahm declined to determine whether the promotion and advertising restrictions violate the First Amendment. Both the FDA and the tobacco companies appealed the decision in to the Fourth Circuit Court of Appeals, which is still considering the case, leaving the FDA authority and constitutionality issues open for the time being.

Two months later, a potential solution to the authority and constitutionality problems came in the form of what is probably the largest settlement in the history of litigation. While part of the tobacco industry was litigating the Coyne Beahm case in the district court, other tobacco industry representatives, along with private lawyers and attorney generals representing 40 states, were negotiating the settlement of the state and private class-action lawsuits against the major tobacco companies seeking recovery for state Medicaid funds and health problems from smoking. The settlement, announced on June 20, 1997, would dismiss the existing state and private class-action suits against tobacco companies and provide immunity from future suits in exchange for payment of \$368.5 billion over 25 years, preservation and acceptance of FDA

<sup>77</sup>See Covne Beahm Inc. v. FDA. 966 F.Supp. 1374 (M.D.N.C. 1997)

<sup>78</sup>See Id. Judge Osteen's decision was on plaintiffs motion for summary judgment. Osteen certified the case for interlocutory appeal, since the case involves controlling questions of law as to which there is substantial ground for difference of opinion. Id. at 1400.

<sup>79</sup>See Id. at 1400, n33.

authority over tobacco products as drugs and devices by withdrawal of the Coyne Beahm appeal and its challenge to agency regulations, and submission to a number of restrictions regarding youth access to tobacco products and tobacco advertising.<sup>20</sup> Although advertising restrictions embodied in the settlement basically reflect the FDA's Final Rule, there are some amended and additional limitations that significantly increase the burden on speech.<sup>21</sup> The settlement would:

1. Restrict print advertising to black text on a white background (no color or images), except for advertising in adult-only facilities and publications.
2. Ban all non-tobacco merchandise bearing the name, logo or selling message of a tobacco brand.
3. Ban sponsorship of events in the name, logo, or selling message of tobacco products.
4. Ban offers of non-tobacco gifts based on proof of purchase of tobacco products.
5. Ban the use of human images and cartoon characters in all tobacco advertising or on packages.
6. Ban all outdoor and billboard advertising of tobacco products, including stadium posters and point of sale ads (window signs, etc.)
7. Ban Internet tobacco advertising in the United States.
8. Prohibit direct or indirect payments for tobacco product placements in movies, television programs, or video games.<sup>22</sup>

## II. THE TOBACCO SETTLEMENT, FDA AUTHORITY OVER TOBACCO ADVERTISING, AND THE FIRST AMENDMENT.

This settlement, if approved by Congress and the President, would alleviate some of the tensions over FDA authority to regulate advertising and the constitutionality of advertising restrictions. First of all, by dropping its appeal in the Coyne Beahm case, the tobacco companies

<sup>20</sup>Henry Weinstein, \$368 Billion Tobacco Accord Deal With States Would Restrict Marketing, *Los Angeles Times*, June 21, 1997, at A1.

<sup>21</sup>See *Id.*; and Wood, *supra* note 5.

<sup>22</sup>Restrictions 1 through 3 are essentially the same as the FDA's regulations, but 4 through

8 represent new or modified restrictions.



are implicitly accepting the FDA regulations issued in 1996, essentially allowing the FDA to have unchallenged authority to regulate tobacco advertising (as well as tobacco products in general).<sup>23</sup> Moreover, without the tobacco industry's legal challenge through the Coyne Beahm appeal, the constitutionality of the regulations may also go unchecked.<sup>2</sup>

However, this acceptance of FDA authority and advertising restrictions is dependent upon the passage of federal legislation which, at least for now, seems remote.<sup>25</sup> The smoking gun documents from R.J. Reynolds are only the latest in a series of events that cast doubt upon the prospects for congressional and presidential approval. From the day the settlement was announced, a number of critics have voiced concerns about the leniency of the settlement and how cigarette companies will emerge better off from the deal than they would if no settlement was reached, since business will remain highly profitable.<sup>26</sup> The Federal Trade Commission helped to confirm such critics' fears when it released a report saying that cigarette makers could realize substantial profits by raising cigarette prices above levels needed to finance the \$368.5

<sup>23</sup>Critics have indicated that although tobacco companies agree to nicotine regulation, the legal burden established in the settlement to justify reduction in nicotine levels (substantial evidence) is so high that no reductions will occur. Nonetheless, FDA authority under Coyne Beahm will stand, and the FDA will have its authority to regulate tobacco products as drugs and devices.

<sup>2</sup>Although the District Court in Coyne Beahm declined to examine the constitutionality of the FDA rules, if the tobacco industry continues in its appeal, the issue would likely be addressed by the 4th Circuit or the Supreme Court.

<sup>25</sup>Felix H. Kent, Reviewing 1997: Tobacco Settlement, *New York Law Journal*, December 19, 1997, at 3.

<sup>26</sup>Myron Levin, Tobacco Foes Scour Pact for Smoke and Mirrors Settlement, *Los Angeles Times*, June 22, 1997, at A1.

billion in payments under the settlement.<sup>27</sup>

Among such critics were former Surgeon General C. Everett Koop and former FDA Commissioner David A. Kessler, who were concerned that the settlement placed too heavy a legal burden on the FDA to justify control over nicotine content, since it was written in such a way that makes it virtually impossible for the FDA to regulate nicotine.<sup>28</sup> Koop and Kessler soon urged lawmakers in congressional hearings on the settlement to reject the plan and instead implement an aggressive tobacco control program which includes granting the FDA explicit authority to regulate nicotine, but their proposals were met with skepticism.<sup>29</sup> President Clinton also shares some of Koop and Kessler's concerns as well, for he refused to embrace the settlement and stated that he sought to build on it, suggesting five key elements that must be part of any national tobacco legislation.<sup>30</sup> Clinton only strengthened his position with the recent release of the R.J. Reynolds documents.<sup>31</sup>

Other factors have also complicated efforts to finalize the tobacco settlement. With the delay in Congress and White House approval of the settlement, a number of states in the

<sup>27</sup>Brett D. Fromson, Tobacco's Quiet counteroffensive; PR Effort Seeks to Blunt Criticism That Settlement Wouldn't Hurt Them, *The Washington Post*, October 10, 1997, at A02.

<sup>28</sup>See Levin, supra note 26. Comments by David A. Kessler.

<sup>29</sup>John Schwartz, To Anti-Tobacco Advocates, Issue is Anything But Settled; Koop, Kessler propose Control Plan; Senate Skeptical, *The Washington Post*, July 30, 1997, at G01.

<sup>30</sup>Myron Levin, Clinton Ups the Anti-Tobacco Ante, *Los Angeles Times*, September 18, 1997, at A1.

<sup>31</sup>From Associated Press, Clinton Urges Congress to Join Anti-Tobacco Battle, *Los Angeles Times*, January 18, 1998, at A20.

settlement are likely to face pressures to separately settle with the tobacco companies, thus weakening the settlement as a whole. These pressures are only increased with the release of the R.J. Reynolds documents and the beginning of a Minnesota lawsuit, which promises to make public more damaging industry documents.<sup>32</sup> Additionally, conflicts over the source of lawyers' fees<sup>33</sup> and whether federal Medicaid costs (in addition to state Medicaid) should be reimbursed from the settlement<sup>3</sup> have further dimmed the hopes for an approved settlement.

Clearly, if the tobacco settlement deal collapses, the questions of FDA authority over advertising and First Amendment violations will surface, as tobacco companies deny the legal basis and constitutionality of any governmental advertising limitations and the Covne Beahm appeal continues. It is equally important to address these issues even if the settlement is likely to be approved, however, for their emergence may be inevitable, as parties outside the settlement have incentives to challenge FDA authority over advertising and the constitutionality of any restrictions.

A foreign tobacco company not a party to the settlement or a nonparticipating company to the settlement may assert that the deal also unconstitutionally restricts its speech. Although nonparticipating companies are not technically held to the restrictions of the settlement but rather grouped into a separate regime, that separate regime apparently amounts to substantial payments

<sup>32</sup>See Lavelle, *supra* note 1.

<sup>33</sup>Saundra Torry, Billions of Dollars in Lawyers' Fees Become Hot Issue in Tobacco Settlement, *The Washington Post*, January 17, 1998, at A09.

<sup>3</sup>Attorneys General Tell President They Want All of Tobacco Settlement, 11 No. 6 *Mealey's Litigation Reports: Tobacco*, November 20, 1997.

in lieu of speech restrictions, thereby establishing a price for free speech.<sup>35</sup> Such payments may be viewed as direct burdens on speech and would likely prompt a First Amendment challenge.

Additionally, nonparticipating competitors of the industry-leading companies in the tobacco settlement may recognize possible benefits to the few largest companies involved in the settlement and may themselves challenge the advertising restrictions. Indeed, the restrictions would make it hard to introduce new brands or sell less popular brands, brands which may depend upon the more flashy, colorful, stylish advertising and different venues (billboards, outdoor, etc.) to attract and retain new customers.<sup>36</sup> While limiting the prospects for smaller tobacco firms, the restrictions in the settlement would simultaneously allow well-established tobacco brands to reduce costs on advertising and promotion without much fear of reducing consumer loyalty or appeal, for the barring and limiting of venues will forcefully reduce promotional costs for all companies yet keep all advertisements at roughly the same limited, competitive level.

### III. FDA AUTHORITY TO REGULATE TOBACCO AND TOBACCO ADVERTISING

The FDA's alleged authority to regulate tobacco advertising begins with its assertion that

nicotine in cigarettes and smokeless tobacco is a drug, and cigarettes and tobacco products are nicotine delivery devices under the FDCA.<sup>37</sup> Essentially, the FDA claims that cigarettes and smokeless tobacco are intended to affect the structure or function of the body, within the meaning

<sup>35</sup>See Wood, *supra* note 5.

<sup>36</sup>Denise Gellene, *The Tobacco Settlement: A New Frontier Is Opening Up for Cigarette Ads*, *Los Angeles Times*, June 21, 1997, at D1.

<sup>37</sup>See 61 Fed. Reg. 44,396 at 44,397 (1996).

of the FDCA's definitions of drug and device. The nicotine in cigarettes and smokeless tobacco is a 'drug' which produces significant pharmacological effects in consumers, including satisfaction of addiction, stimulation, sedation, and weight control. Cigarettes and smokeless tobacco are combination products consisting of the drug nicotine and device components (tobacco, filters, etc.) intended to deliver nicotine to the body.<sup>38</sup> Given their combination product status, cigarettes and smokeless tobacco could be regulated as a drug or a device, and the FDA chose to regulate under the FDCA's device authorities.<sup>39</sup> More specifically, the FDA draws its advertising restrictions from the restricted medical device provisions.<sup>0</sup> Since the FDA's authority to regulate tobacco advertising is predicated upon an initial finding of jurisdiction over nicotine and tobacco products, it would prove fruitful to examine some of the issues concerning FDA authority over tobacco in general before addressing the regulation of advertising in particular.

Review of the FDA's construction of the FDCA generally follows the analysis set forth in Chevron. U.S.A.. Inc. v. Natural Resources Defense Council. Inc., which sets out a two step process.<sup>7</sup> One must begin by determining whether Congress has directly spoken to the precise question at issue or expressed a clear intent to allow or withhold jurisdiction, for [i]f the intent of Congress is clear, that is the end of the matter.<sup>2</sup> If the statute is silent or ambiguous with

<sup>38</sup>Id.

<sup>39</sup>Id. at 44,399.

<sup>0</sup>Id. at 44,399.

<sup>7</sup>467 U.S. 837 (1984).

<sup>2</sup>Id at 842.

respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.<sup>3</sup> These guidelines translate into two basic questions concerning tobacco product regulation. First, has Congress expressed a clear intent to either permit or deny the FDA jurisdiction over tobacco products? If there is no congressional intent, then is the FDA's reading of the FDCA, such that nicotine and tobacco products are together a drug delivery device and combination product, a permissible interpretation of the statute?

A. CONGRESSIONAL INTENT

The FDCA does not contain any specific reference to authority over tobacco, so both opponents and proponents of FDA authority look elsewhere. Proponents argue that the FDA has been granted broad authority by Congress commensurate with its vital mandate to protect the public health and safety. Congress obviously knew in 1938 that it could not foresee future developments, and that it must proceed primarily by establishing general principles, permitting implementation within broad parameters, if regulation in this important area was to be effective. In this respect, the Act must be regarded as a constitution. It establishes a set of fundamental objectives...The mission of the Food and Drug Administration is to implement those objectives through the most effective and efficient controls that can be devised.<sup>5</sup>

While opponents may grant that, in general, the FDCA does have a constitution-like quality to it, they would point to a number of indications that Congress has intended to withhold

<sup>3</sup>Id. at 843.

James T. O'Reilly, *Tobacco and the Regulatory Earthquake: Why the FDA Will Prevail After the Smoke Clears*, 24 *N Ky. L. Rev.* 509, 514 (1997).

<sup>5</sup>Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food Drug & Cosmetic Act*, 28 *Food Drug Cosm. L. J* 177, 178-79 (1973).

from the FDA the power to regulate tobacco. The history of failed attempts within Congress to enact legislation to place tobacco products within the reach of the FDA serves as the first major indication that Congress does not intend to grant the FDA authority.<sup>6</sup> The Covne Beahm court responded, on the other hand, that unenacted bills generally provide rather unpersuasive evidence of congressional intent.

Critics of FDA authority also indicate that Congress, through the enactment of legislation that granted certain authority to regulate tobacco products to other agencies (especially the FTC in regards to tobacco product advertisement), has intentionally reserved the authority to regulate tobacco products.<sup>8</sup> Opponents typically cite such laws as the Federal Cigarette Labeling and Advertising Act, the Comprehensive Smokeless Tobacco Education Act, and the Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992 as examples.<sup>9</sup> While such laws do indicate congressional intent in each particular instance, the FDA and proponents would argue that each law is limited to its own structure, history, and specific provisions such that Congress, in enacting and later amending the three statutes, adopted narrow preemption language, evidencing its intent not to prohibit other agency action in the area.<sup>50</sup>

Finally, opponents of regulation are quick to point out that since 1914, the FDA's

<sup>6</sup>John E. Jevicky, Esq., FDA's Regulation of Tobacco Products: A Flagrant Disregard of Congressional Intent, *24 N Ky. L. Rev.* 535, 53 7-40 (1997).

<sup>7</sup>966 F.Supp. at 1382.

<sup>8</sup>See Jevicky, *supra* note 46, at 541.

<sup>9</sup>966 F.Supp. at 13 84-88.

<sup>50</sup>966 F.Supp. at 1388.

historical interpretation of the FDCA has been that it lacks any authority to regulate tobacco products.<sup>51</sup> Indeed, there is evidence not only that FDA previously asserted that it lacked jurisdiction to regulate tobacco products as customarily marketed, but also that some members of Congress agreed with FDA and introduced legislation to expressly grant FDA jurisdiction, legislation which failed to be enacted.<sup>52</sup> Conceivably, this not only indicates that the FDA's present position is contradictory and inconsistent, but that Congress has accepted the FDA's previous assertions that it lacks authority, and its intent to is to remain faithful to those claims.

The FDA and its proponents offer equally valid arguments, though. In particular, they assert that the change results not from a new interpretation of the FDCA, but from application of its longstanding interpretation to new evidence, information and understanding about tobacco and nicotine addiction which now justify FDA authority over tobacco products.<sup>53</sup> It seems reasonable that an agency should be able to adapt its policies and not be frozen in a time warp according to the knowledge of 1906 or 1938, until and unless special legislation added each new drug to the agency's list of regulable entities.<sup>5</sup> Additionally, the Covne Beahm court indicated that congressional acquiescence to or ratification of agency policy would not necessarily connote approval or disapproval of the agency's later alteration of that policy...[Since] [e]ven if Congress acquiesced to FDA's assertion of lack of jurisdiction, such acquiescence would not

<sup>51</sup>See Jevicky, supra note 46, at 543-4

52966 F.Supp. at 1382.

~966 F.Supp. at 1384.

<sup>5</sup>See O'Reilly, supra note 44, at 526.



necessarily connote Congress' opposition to FDA's [present] assertion of jurisdiction.<sup>55</sup>

B. FDA'S ASSERTION OF JURISDICTION UNDER THE FDCA  
DRUG AND DEVICE DEFINITIONS

The FDCA defines a drug, in relevant part, as articles (other than food) intended to

affect the structure or any function of the body.<sup>56</sup> Similarly, the Act defines a device, in

relevant part, as an instrument...or other similar or related article...which is intended to affect the structure or any function of the body.<sup>57</sup> The FDA argues that, based upon evidence of the

addictive and pharmacological effects of nicotine, nicotine can be regulated as a drug, and, thus, tobacco products can be regulated as a combination product or drug delivery device.<sup>58</sup>

The major issues here, given the mounting evidence over the years of nicotine's effects

on the body,<sup>59</sup> have not involved whether nicotine may have an effect on the structure or function of the body, but whether tobacco products are *intended* to have an effect on the body.<sup>60</sup> At the

966 F.Supp. at 13 83-84.

5621 U.S.C.A. §321(g)(1)(c) (1996).

21 U.S.C.A. §321(h)(3) (1996).<sup>58</sup> See 61 Fed. Reg. at 44,399.

<sup>59</sup> See, e.g., 61 Fed. Reg. at 44,854-912.

<sup>60</sup> There is another subtle and less discussed, but significant issue: Whether the device

component of tobacco products are technically devices. Opponents have claimed that tobacco products are not devices because they do not themselves affect the structure or function of the

body, and even if they do affect the body, they fall within the FDCA exception for products that achieve their primary purposes through chemical action within the body. See 966 F.Supp. at

1394-95. Covne Beahm recently ruled that each of the products in a combination device does not have to be capable of being separately regulated, and that a combination product, as opposed to

device, can achieve its primary purpose by chemical action within the body. See 966 F.Supp. at

1395.

heart of the controversy is a disagreement over the proper means to measure a manufacturer or vendor's intent.

Tobacco companies and opponents to regulation indicate that the requisite intent to affect the body exists only if the manufacturers or vendors make health claims about their products or it may be inferred from the labeling, promotional material, advertising, and any other relevant source.<sup>61</sup> Indeed, in the past, the FDA has asserted jurisdiction over tobacco products only when they were accompanied by therapeutic claims.<sup>62</sup> Given such an interpretation, regulation opponents would indicate that there is no evidence that tobacco companies promote, market, or intend tobacco products to affect the structure or function of the body. Rather, tobacco products are intended for smoking pleasure, and there is no evidence from the labels, advertisements, and promotional materials to suggest otherwise.<sup>63</sup> Moreover, evidence suggests that teenagers do not use tobacco to affect the structure or function of the body but rather for psychosocial reasons.<sup>64</sup> For teenagers, smoking may be as a social smoker, to enhance image, or to experiment with the taboo, not to affect the body.<sup>65</sup>

<sup>61</sup>See Action on Smoking and Health v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980) (where the court concluded that the FDA's decision to refrain from asserting jurisdiction was warranted since there was no evidence that cigarette manufacturers or vendors represent to consumers that cigarettes are intended to affect the structure or function of the body).

<sup>62</sup>See Lars Noah and Barbara A. Noah, *Nicotine Withdrawal: Assessing the FDA's Effort to Regulate Tobacco Products*, 48 *Ala. L. Rev.* 1, 10 n34 (1996).

<sup>63</sup>See Jevicky, *supra* note 46, at 548.

<sup>64</sup>See Philip Rohde Costello, *Put This In Your Pipe and Smoke It: FDA Regulation of Tobacco Products*, 4] *N XL. Sch. L. Rev.* 703, 714 (1997).

<sup>65</sup>See *Id.*

The FDA measures intent quite differently. It suggests that intent may be satisfied by

evidence of a consumer's actual use and the manufacturer's knowledge of that use, regardless of whether the manufacturer made any health claims,<sup>66</sup> a suggestion which the Coyne Beahm court accepted.<sup>67</sup> Under such an expansive interpretation, intent could be inferred if there is evidence of consumers' use to affect the structure and function of the body (including addiction and other pharmacological effects) and the manufacturer's knowledge of such use. Proponents readily

have such evidence at hand, with studies of nicotine addiction and some evidence that manufacturers have been aware of nicotine's affects on the body.<sup>68</sup>

Nonetheless, basing the regulation of products on actual consumer use and manufacturer knowledge may prove too much of a stretch of the jurisdictional definitions. Under the FDA's construction of the Act, if a manufacturer of wool coats becomes aware that a consumer wears its wool coat, not because it keeps him warm, but because he likes the smell and feel of the coat and that it makes him feel good to wear it, all of which affect his senses and thereby his

psychological well-being, i.e., functions of the body, it could be regulated as a drug.<sup>69</sup>

#### C. RESTRICTED MEDICAL DEVICES AND ADVERTISING RESTRICTIONS

The specific advertising restrictions are promulgated under the FDA's authority to

regulate restricted medical devices.<sup>70</sup> The FDA wishes to regulate tobacco products as medical

<sup>66</sup>See 61 Fed. Reg. at 45,203

67966 F.Supp. at 1389.

<sup>68</sup>See 61 Fed. Reg. at 45,203 and 41,483.

<sup>69</sup>See Jevicky, supra note 46, at 550.

<sup>70</sup>61 Fed. Reg. at 44,399.

devices, and restricted medical devices in particular, because it can potentially assert authority over the advertising, sale, and other aspects of the cigarette market without having to impose an complete ban, as might be expected under regulation as a drug.<sup>71</sup> The restricted devices provision allows the FDA to:

.require that a device be restricted to sale, distribution, or use –

(A.) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B.) upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.<sup>72</sup>

The first question raised by the FDA's attempt to use the restricted devices provision to restrict advertising and promotion would naturally address whether the FDA's restriction to sale, distribution, or use includes advertising or promotion. The FDA asserts that advertising is an offer for sale, and thus is part of the sale of a product, for the sale is linked inextricably to the advertising that promotes the sale.<sup>73</sup> If the law were otherwise, advertising could attract children in such a way as to undermine all of the other conditions on sale and distribution.<sup>7</sup>

The court in Coyne Beahm disagreed, however, and stated that the ordinary definition of sale did not encompass advertising.<sup>75</sup> Additionally, Judge Osteen reiterated the arguments of the tobacco company plaintiffs by noting that although Congress expressly used the words 'offer

<sup>71</sup>See Costello, supra note 64, at 723.

<sup>72</sup>21 U.S.C.A. §360j(e) (1996).

<sup>73</sup>See 61 Fed. Reg. at 44406.

<sup>7</sup>See Defendant's Opposition Brief. Coyne Beahm, Inc. v. FDA.

<sup>75</sup>See 966 F.Supp. at 1398.

for sale' and 'advertising' or 'advertisements' elsewhere in the FDCA, it chose not to use such a language in § 360j(e).<sup>76</sup>

Even if the phrase sale, distribution, or use allowed restriction of advertising as part of an offer for sale, can the other conditions as the Secretary may prescribe, which must be met by manufacturers or vendors in order for the FDA to permit such limited sale, distribution, or use, be read to include conditions on advertising? In other words, even if the FDA had the authority to require certain other conditions as prerequisites to permitting tobacco advertising, can such other conditions include restrictions on advertising and promotion? (For example, compare the FDA requiring a certain nicotine content before allowing advertising, with a regulation that will only allow advertising if it is black and white text. If this still sounds a bit confusing, it is likely due to the FDA's attempt to restrict speech in a context not originally designed for such restrictions, as we shall see)

Both the FDA and its opponents engaged in a study of the legislative history and related provisions to determine the answer to this question.<sup>77</sup> The FDA's opponents argued that the restricted devices provision should be read in context with other provisions, the first being §353(b), which limits certain drugs (as opposed to devices) to prescription sale, indicating the medical context of § 320j(e). Moreover, a look at the legislative history indicated an even stronger medical context in which § 320j (e) was to be interpreted, for the other suggested limits, in addition to prescription status, included use only in hospitals or clinics and

<sup>76</sup>Id

See Defendant's Opposition Brief& 966 F.Supp at 1399.

<sup>78</sup>See 966 F.Supp. at 1399.

authorization of certain devices by nurses and technicians.<sup>79</sup> Tobacco companies also indicated that other provisions existed which directly addressed the regulation of advertising of restricted devices, thus denying such a broad reading of § 360j(e).<sup>80</sup> The FDA's position simply states that § 360j (e) can and should be interpreted separately from the other sections to yield a more expansive reading, and that the other claimed advertising provisions cannot be used to regulate the advertising of restricted devices.<sup>81</sup>

#### IV. CONSTITUTIONALITY OF ADVERTISING REGULATIONS (FDA Rules and Settlement Provisions)

Although the United States has a long history of extending First Amendment protections, the Supreme Court did not recognize First Amendment protection for commercial speech until 1975.<sup>82</sup> In 1980, the Court finally delineated a means to determine whether the First Amendment had been violated in relation to commercial speech. In Central Hudson Gas v. Public Service Commission,<sup>83</sup> the Court established a four-part test that continues to be the standard today:

1.) Is the speech protected by the First Amendment? For commercial speech to receive

<sup>79</sup>See 966 F.Supp. at 1399, fn 27.

<sup>80</sup>See 966 F.Supp. at 1399, & fn 28. These regulations included § 352(q) and § 352(r).

<sup>81</sup>See Defendant's Opposition Brief.

<sup>82</sup>Bigelow v. Virginia, 421 U.S. 809 (1975).

<sup>83</sup>See Scott Joachim, Seeing Beyond the Smoke and Mirrors: A Proposal for the Abandonment of the Commercial Speech Doctrine and an Analysis of Recent Tobacco Advertising Regulations, 19 *Hastings Comm/Ent LJ* 517 (1997) for a discussion of the illusory commercial/noncommercial speech distinction.

<sup>84</sup>447 U.S. 557 (1980).

protection, it must concern lawful activity and not be misleading. 2.) Is the government interest in regulation substantial? 3.) Does the regulation directly and materially advance the governmental interest asserted? 4.) Is the regulation narrowly tailored such that it is not more extensive than is necessary to serve that interest?<sup>85</sup>

A. Lawful and Nonmisleading

With the current release of documents concerning the targeting of minors by tobacco

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companies, proponents of speech restrictions are likely to claim that tobacco advertisements are

both unlawful and misleading. The advertisements may be unlawful in the sense that they relate to and encourage the illegal purchase of tobacco products by minors.<sup>87</sup> However, a court is unlikely to find them unlawful, for without good proof (which remains to be seen) that the tobacco industry targets children, the speech may be seen as relating to the lawful activity of adult tobacco purchase and consumption.<sup>88</sup> The possibility of misleading speech is also rather rare, for mere puffery would not suffice as misleading, **89** and claims in advertisements are difficult to classify as simply true or false.<sup>90</sup> Indeed, if intended targets such as Joe Camel and the Marlboro Man are found misleading under this standard, virtually every modern

**85447** U.S. at 566

<sup>86</sup>See Lavallo, *supra* note 1,

<sup>87</sup>See Defendant's Opposition Brief.

<sup>88</sup>See Kathleen J. Lester, *Cowboys, Camels, and Commercial Speech: Is the Tobacco Industry's Commodification of Childhood Protected by the First Amendment?* 24 *N Ky. L. Rev.* 615, 649 (1997).

<sup>89</sup>Oklahoma Telecasters Ass'n v. Crisp, 699 F.2d 490 (10th Cir. 1983).

<sup>90</sup>See Lester, *supra* note 87, at 650.

advertisement would be misleading as well.<sup>91</sup>

B. Substantial Government Interest

The FDA regulations (and additional settlement limitations) aim to decrease young people's use of tobacco products by ensuring that the restrictions on access are not undermined by the product appeal that advertising for these products creates for young people.<sup>92</sup> Certainly, it is difficult to imagine how this laudable interest, or any, asserted government interest can be found insubstantial. Deference is almost always given to the asserted state interest. The state's interest or motive can rarely be contradicted, since it is what the state says it is. The real concern occurs with the means chosen to achieve this interest. Thus, for our purposes we can safely assume that a substantial interest would be found.

C. Directly and Materially Advances Asserted Interest

Although courts grant deference to the finding of a substantial interest, they do require that the regulations further this interest in a direct and material way.<sup>93</sup> The burden is not satisfied by mere speculation and conjecture; rather a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.<sup>94</sup>

In endeavoring to meet this burden, the FDA presented a wealth of evidence and studies

<sup>91</sup>See Joachim, *supra* note 83, at 551.

9261 Fed. Reg. at 44,465.

<sup>93</sup>Edenfield v. Fane, 507 U.S. 761, 767 (1993).

<sup>94</sup>*Id.* at 770-71.



regarding the importance of advertising as a factor in tobacco use by minors.<sup>95</sup> While the FDA suggests that this evidence indicates a relationship between advertising and use of tobacco products by children,<sup>96</sup> others suggest that the studies only indicate a correlation and not a direct causal link.<sup>97</sup> Certainly, it is conceivable that the link between advertising and use by children is strong enough that the regulations would decrease underage smoking by some amount, thus suggesting a somewhat direct link.

However, that begs the question of whether the restrictions would advance the government interest to a material degree. If one considers the host of regulations and restrictions as a whole, material advance of the state interest is likely. However, such an aggregate approach to the requirement of material advancement seems inappropriate, for individually immaterial burdens on speech may be able to pass muster collectively, thus doing what they could not do individually. Moreover, it is necessary under this third prong that the government to establish this amount, be it big or small, for it must prove advancement to a material degree. It is unclear whether the FDA has met this burden of production.

#### D. Narrowly Tailored

Assuming that the regulations and restrictions directly and materially advance the government interest, the final inquiry under the Central Hudson test determines whether the regulations are narrowly tailored so that they are not more extensive than necessary to serve [the

<sup>95</sup>See 61 Fed. Reg. 44,488.

<sup>96</sup>See *Id.*

<sup>97</sup>Gregory D. Bassuk, Advertising Rights and Industry Fights: A Constitutional Analysis of Tobacco Advertising Restrictions in a Federal Legislative Settlement of Tobacco Industry Litigation, *85 Geo. L.J.* 715, 730 (1997)

governmental] interest.<sup>98</sup> [I]f the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.<sup>99</sup> Aside from such basic guidelines, there appears to be much room for interpretation. On one end of the spectrum, the Court has stated that [t]his requirement is less than the least restrictive 'a On the other end, it recently abandoned the reasonable fit standard.<sup>101</sup> Thus, it would seem that

the standard review for this prong ranges from a least restrictive means test to a reasonable

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fit inquiry, w nsensus on what modified version of the Central Hudson test will be

applied in future decisions.<sup>103</sup> Additionally, the fourth prong may be the most difficult to evaluate in this situation because of the need to ascertain the relationship between tobacco advertising and use by children, a problem encountered earlier with direct and material advancement of governmental interests.

With such uncertainty, it would be difficult to evaluate any of the FDA Rules' or tobacco settlement's advertising restrictions with any surety as to validity. However, a brief analysis would serve to indicate whether each of the restrictions are more or less likely to pass constitutional muster. Of the original FDA Rule restrictions and the settlement, only the black

98447 U.S. at 566.

<sup>99</sup>Id. at 564.

<sup>100</sup>Fox v. University of New York, 492 U.S. 469, 480 (1989).

See 44 Liquormart v. Inc. v. Rhode Island, 517 U.S. 484 (1996) and Rubin v. Coors Brewing Co., 115 S.Ct. 1585 (1995).

<sup>102</sup>See Bassuk, supra note 97, at 733.

<sup>103</sup>See Lester, supra note 87, at 646.

text on white background restriction would seem relatively certain to survive constitutional scrutiny. It does allow relevant informational speech and freedom from restrictions in adult only publications. The other restrictions seem to approach the bounds of constitutionality if not cross them. Banning the non-tobacco merchandise, sponsorship of events, use of human and cartoon images, all outdoor and billboard advertising<sup>10</sup> Internet advertising in the U.S., and product placements in movies or television all seem too encompassing of acceptable speech and make no real attempt to find less restrictive versions of the limitations.

#### CONCLUSION

The landmark tobacco settlement promised a great deal when it first appeared last summer, seeking to settle lawsuits and finally place some restrictions on the tobacco industry. At the time, issues of FDA authority and constitutionality of advertising restrictions seemed to be put to rest in the afterglow of the settlement. However, as time passes, a settlement seems less and less likely, necessitating a look at these issues of authority and constitutionality, issues that may occupy the nation's attention in the coming months.

<sup>10</sup>Although, the original FDA Rules which had a within 1000 feet of schools clause may be narrowly tailored.