

The Legal Authority of the United States Food and Drug Administration to Regulate Tobacco: Calling on Congress

Roseann B. Termini

Follow this and additional works at: <https://scholarship.law.stjohns.edu/lawreview>

Recommended Citation

Termini, Roseann B. (2000) "The Legal Authority of the United States Food and Drug Administration to Regulate Tobacco: Calling on Congress," *St. John's Law Review*: Vol. 74 : No. 1 , Article 2.

Available at: <https://scholarship.law.stjohns.edu/lawreview/vol74/iss1/2>

This Article is brought to you for free and open access by the Journals at St. John's Law Scholarship Repository. It has been accepted for inclusion in St. John's Law Review by an authorized editor of St. John's Law Scholarship Repository. For more information, please contact lasalar@stjohns.edu.

THE LEGAL AUTHORITY OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO REGULATE TOBACCO: CALLING ON CONGRESS

ROSEANN B. TERMINI*

Smoking has plagued America for generations, but the issue has never received more scrutiny than in the past decade. The rise of teen smoking¹ and the long-term deleterious effects of nicotine addiction² prompted a national outcry for change.³ As a

* Roseann B. Termini is currently teaching Legal Writing and Appellate Advocacy at Villanova University School of Law and courses in Food and Pharmacy Law at Temple University School of Pharmacy Graduate Program and St. Joseph's University. She has also taught these courses at Widener University Law School and The Dickinson School of Law, Pennsylvania State University. Formerly, she served as a Senior Deputy Attorney General, Commonwealth of Pennsylvania, Office of Attorney General, where she handled trial and appellate cases and plain language drafting. B.S., *magna cum laude*, Drexel University; M.Ed., *Fellow*, Temple University; J.D., Temple University School of Law.

The author dedicates this article to her parents for instilling in her, at an early age, the qualities of persistence and determination. She wishes to thank her children, who, even at their young ages, understood her need to write this article. Finally, the author gives special thanks to her dependable research assistant, Jill Petrunak, J.D., 2000.

¹ "[A]pproximately 3 million American adolescents . . . smoke . . . [cigarettes, while] an additional 1 million adolescent males use smokeless tobacco [products]." Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (1996) (footnote omitted) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, and 897). "Eighty-two percent of adults who . . . smoked . . . their first cigarette [did so] before the age of 18, and more than half . . . became regular smokers by that age." *Id.* (footnote omitted). Additionally, of those adolescent smokers between the ages of 12 and 17, "70 percent already regret their decision to smoke, and 66 percent say that they want to quit." *Id.* (footnote omitted).

² For example, "[m]ore than 400,000 people die each year from tobacco related illnesses." *Id.* This means that "[t]obacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined." *Id.* (footnote omitted).

³ President Clinton announced an initiative to reduce youth smoking which contemplated the FDA's regulation of tobacco products under the Food Drug and Cosmetic Act. See Remarks Announcing the Final Rule to Protect Youth from

result, the United States Federal Food and Drug Administration (FDA) has asserted jurisdiction over the regulation of tobacco products.⁴

The FDA, as one of the chief health regulatory agencies of the United States, is determined to take action to curb the nation's leading preventable killer.⁵ Due to the large number of adults addicted to cigarettes, however, an outright ban on tobacco would be both impractical and unrealistic.⁶ Therefore, acting on the findings of several major health organizations, the FDA determined the best way to curb the United States' addiction to nicotine was to stop it before it began.⁷ The resulting tobacco initiative included the regulation of the sale of tobacco products to minors, advertisement, and teen education cataloging the dangers of tobacco addiction.⁸

The FDA's controversial regulatory scheme has prompted more public comment than any other agency-proposed regulation.⁹ Specific legislation granting the FDA authority to regulate tobacco products, however, has not occurred.¹⁰ Thus,

Tobacco, PUB. PAPERS 1332, 1333-34 (Aug. 23, 1996).

⁴ See Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619, 44,628 (1996) [hereinafter Nicotine: Jurisdictional Determination].

⁵ See *id.*; see also David A. Kessler et al., *The Food and Drug Administration's Regulation of Tobacco Products*, 335 NEW ENG. J. MED. 988, 991-93 (1996) (discussing the FDA's regulation restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents).

⁶ See Kessler, *supra* note 5, at 991. Health organizations estimate that "50 million Americans currently smoke cigarettes and another 6 million use smokeless tobacco [products]." Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,398 (footnote omitted).

⁷ See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,398-99 (1996) [hereinafter Regulations Restricting the Sale of Tobacco]. The FDA posed an all out war on teenage smoking through regulations enacted to curb the sale of tobacco to minors. See *id.* at 44,399-400.

⁸ See Kessler, *supra* note 5, at 991-93; see *infra* text accompanying note 39.

⁹ See *id.* at 988. More than 700,000 comments were received regarding the proposed rules regulating tobacco products. See *id.*; Regulations Restricting the Sale of Tobacco, *supra* note 7, at 44,557. The initial comment period for the FDA's proposed regulation of tobacco products lasted 144 days. See *id.*

¹⁰ See *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 167 (4th Cir. 1998) (concluding that the FDA has no authority to regulate tobacco under the Federal Food, Drug, and Cosmetic Act), *aff'd* *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291 (2000).

the final words regarding the regulation of tobacco will now emanate from Congress.¹¹

The FDA based its jurisdiction over tobacco products on the Federal Drug and Cosmetic Act's (FDCA) definitions of "drug"¹² and "device."¹³ This article explores the ramifications of the FDA's assertion of jurisdiction. First, it reviews why the FDA has asserted jurisdiction over such products in the past and the judicial decisions reviewing its action. Second, it provides an in-depth analysis as to the Middle District of North Carolina's opinion in *Coyne Beam, Inc. v. FDA*,¹⁴ which allowed FDA jurisdiction, and the subsequent reversal by the Fourth Circuit in *Brown & Williamson Tobacco Corp. v. FDA*, which the United States Supreme Court has recently affirmed.¹⁵ It focuses on the different approaches taken by each court in interpreting whether tobacco products are a "drug" or "device" under the FDCA. This timely analysis is crucial as the case was recently decided by the United States Supreme Court.

¹¹ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1300, *affg* 153 F.3d at 176 (holding that the FDA does not have jurisdiction to regulate tobacco products).

¹² See 21 U.S.C. § 321(g)(1) (1994). The term "drug" in part means: "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals." *Id.* §§ 321(g)(1)(B), (C).

¹³ See *id.* § 321(h). The term "device" is defined in part as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Id. §§ (h)(2), (3).

¹⁴ 966 F. Supp. 1374 (M.D.N.C. 1997), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000).

¹⁵ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1316, *affg* 153 F.3d 155.

I. BACKGROUND ON FDA TOBACCO REGULATION: THE WAFFLE EFFECT AND THE FOOD AND DRUG ADMINISTRATION'S CHANGE IN POLICY ASSERTING JURISDICTION

An indication that tobacco products posed a serious threat to human health surfaced in 1964,¹⁶ when the Surgeon General reported that smoking caused cancer in men and could also affect women in the same way.¹⁷ Congress acted swiftly in response to the report by passing the Federal Cigarette Labeling and Advertising Act in 1965, requiring warning labels on all cigarette packages.¹⁸ Soon thereafter, Congress banned cigarette advertising on television and radio.¹⁹

The Surgeon General then began issuing new, more detailed warnings,²⁰ which prompted the Federal Trade Commission to refine their labeling criteria to specifically reflect warnings about health consequences.²¹ The war on smoking evolved into a full-scale attack when several states enacted indoor clean air laws,²²

¹⁶ See OFFICE ON SMOKING AND HEALTH, U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE, *SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE* (1964).

¹⁷ See *id.* at 31.

¹⁸ The Federal Cigarette Labeling and Advertising Act of 1965 required all cigarette packages to warn, "Caution: Cigarette Smoking May Be Hazardous to Your Health." 15 U.S.C. § 1333 (1964 & Supp. V 1970).

¹⁹ See Public Health Cigarette Smoking Act of 1969, 15 U.S.C. § 1335 (1970).

²⁰ Since 1964, the Surgeon General has issued 24 reports detailing the adverse effects of smoking. One such report outlined the adverse affects of smoking in young people. See U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GENERAL 6-7* (1994).

²¹ See 15 U.S.C. § 1333(a)(1) (1988). Packages of cigarettes are required to bear one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

Id.

²² See LA. REV. STAT. ANN. §§ 1300.21-.26 (West 1992 & Supp. 1999) (regulating smoking in office workplaces); MO. REV. STAT. §§ 191.765-.777 (1999) (prohibiting smoking in public places and meetings); NEV. REV. STAT. §§ 202.2485-.2491 (2000) (prohibiting smoking in public elevators, buildings, waiting rooms, stores, hotels and buses); N.Y. PUB. HEALTH LAW §§ 1399-n to -o (McKinney 1990 & Supp. 1999) (placing smoking restrictions on auditoriums, elevators, gymnasiums, classrooms, and public transportation).

such as Pennsylvania's Clean Indoor Air Act,²³ to combat secondhand smoking's adverse effects.

The findings concerning the dangers of smoking were so alarming that major health organizations declared war on cigarette smoking.²⁴ The FDA entered the battle several times by asserting jurisdiction over tobacco products that promised increased health benefits associated with their use.²⁵ For example, in *United States v. 354 Bulk Cartons*,²⁶ the FDA asserted jurisdiction over cigarettes that promised appetite reduction and subsequent weight loss.²⁷ The district court found that jurisdiction had been properly asserted where the manufacturer's promises were based upon such weight reduction.²⁸ The manufacturer intended the cigarettes to be used for therapeutic purposes. The court held that this satisfied the requisite intent of a drug under the FDCA as a product intended to affect the structure and function of the human body.²⁹

The FDA also asserted jurisdiction in *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*,³⁰ when the manufacturer claimed through advertising leaflets that cigarettes were effective in preventing respiratory infections, circulatory disease, and other physical ailments.³¹ This advertisement was sufficient to bring the cigarettes under the second statutory meaning of a "drug," which is a product intended to mitigate or prevent diseases.³²

²³ PA. STAT. ANN. tit. 35, § 1230.1(a) (West 1993). Pennsylvania's Clean Indoor Air Act regulates smoking in public settings and certain workplaces. *See id.*

²⁴ *See* Nicotine: Jurisdictional Determination, *supra* note 4, at 44,634 (discussing how all major public health organizations recognize the addiction caused by nicotine delivered through cigarettes and smokeless tobacco).

²⁵ *See e.g.*, *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) (noting that "the FDA has asserted jurisdiction over cigarettes only when health claims were made by the vendors or manufacturers").

²⁶ 178 F. Supp. 847 (D.N.J. 1959).

²⁷ *See id.* at 850 (promising that a user can "[s]afely lose up to twenty pounds or double your money back") (citation omitted).

²⁸ *See id.* at 851.

²⁹ *See id.*; 21 U.S.C. § 321(g)(1)(C) (1994); *see also supra* note 12.

³⁰ 113 F. Supp. 336 (D.N.J. 1953).

³¹ *See id.* at 337.

³² The advertisement implied that smokers would be less inclined to contract viral infections, like the common cold. *See id.* at 339 (determining that manufacturers could not "reap" the rewards of therapeutic claims without bearing responsibility for them); 21 U.S.C. § 321 (g)(1)(B); *see also supra* note 12 (defining "drug").

The fact that the FDA only asserted jurisdiction when cigarette manufacturers promised increased health benefits, prompted heated argument from a citizen's group called Action on Smoking and Health (ASH). This group filed suit pushing for the FDA's active assertion of jurisdiction over all tobacco products.³³ The 1980 litigation resulted in the determination that the FDA lacked general jurisdiction over tobacco products.³⁴ The court found no manifestation of the cigarette manufacturer's intent " 'to affect the structure or any function of the body of man.' " ³⁵ The FDA agreed that it lacked general jurisdiction over tobacco products because ASH had presented no evidence proving this requisite intent.³⁶ The court interpreted the FDA's position against general regulation of tobacco, not as an indefinitely binding decision, but rather one reserved for a time when the proper showing of manufacturer intent could be established.³⁷ Thus, this decision should be viewed as an indication of how times have changed, rather than as one that bars the FDA from asserting jurisdiction.

The FDA asserted general jurisdiction over tobacco products only after the majority of health organizations acted in concert to declare nicotine's harmful effects.³⁸ In 1996, the FDA issued regulations to control teen smoking, including the prohibition of the sale of cigarettes to persons under age eighteen and the

³³ See *Action on Smoking & Health v. Harris*, 655 F.2d 236, 237 (D.C. Cir. 1980) (explaining that ASH, along with 13 other organizations and individuals, filed a citizen petition requesting that the agency assert jurisdiction over all cigarettes containing nicotine).

³⁴ See *id.* at 243.

³⁵ *Id.* at 239 (quoting 21 U.S.C. § 321(g)(1)(C)(1998)). The agency originally rejected ASH's request based on this lack of intent. See *id.* at 240. The district court agreed and denied the ASH petition. See *id.* at 243.

³⁶ See *id.* at 239; see also *id.* at 240 (finding that ASH could not sustain the high burden of establishing the vendor's intent "to affect the structure or any function of the body of man" by consumer use). According to the court, ASH could meet this burden with "subjective vendor claims or objective evidence such as labeling, promotional material, and advertising," but not merely with consumer use. *Id.* at 239.

³⁷ See *id.* at 239.

³⁸ See *Nicotine: Jurisdictional Determination*, *supra* note 4, at 44,634. Several organizations recognized the addictive nature of nicotine in tobacco products. See *id.* The American Psychiatric Association began the movement in 1980. See *id.* Since 1981, the U.S. Surgeon General, the World Health Organization, and the American Medical Association, among others, submitted information to the FDA regarding the addictive properties of nicotine. See *id.*

regulation of advertisement geared toward minors.³⁹ As the FDA has based its jurisdiction on the FDCA's definitions of "drug" and "device," a clear understanding of the problem requires a close examination of these definitions.⁴⁰

The FDA has met with litigation over the validity of its assertion of jurisdiction over nicotine products.⁴¹ In *Coyne Beahm, Inc. v. Food & Drug Administration*,⁴² the district court determined, based on judicial history, legislative intent, and product use, that the FDA properly asserted jurisdiction over tobacco products.⁴³ The *Coyne* court discussed the meaning of "drug" and "device" under the FDCA and applied evidence of foreseeable use, actual use, and manufacturer representations to determine that tobacco products are intended to affect the structure or function of the body.⁴⁴ The court also found that congressional intent reinforced their findings, based on Congress' acquiescence to agency interpretation.⁴⁵ Manufacturers appealed this ruling, maintaining that nicotine-containing products do not fall under the definition of "drug" or "device" and thus, should escape regulation by the FDA.⁴⁶

Agreeing with the Fourth Circuit in *Brown & Williamson Tobacco Corp. v. Food & Drug Administration*,⁴⁷ the United States Supreme Court held that the FDA lacked jurisdiction over tobacco products, because the measure lacked the requisite congressional intent required to execute the regulatory

³⁹ See Regulations Restricting the Sale of Tobacco, *supra* note 7, at 44,396 (1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, and 897 (1999)).

⁴⁰ See *supra* notes 29, 35-37 and accompanying text (discussing the manufacturer's requisite intent to affect the structure or function of the body, which is found in the FDCA's definition of device).

⁴¹ See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1379 (M.D.N.C. 1997), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000); *Beatty v. FDA*, 12 F. Supp.2d 1339, 1341-42 (S.D. Ga. 1997).

⁴² 966 F. Supp. 1374 (M.D.N.C. 1997), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000).

⁴³ See *id.* at 1379-88.

⁴⁴ See *id.* at 1388-91, *see also supra* notes 29, 35-37 and accompanying text.

⁴⁵ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1391 (finding that "[t]he plain language and the legislative history of the drug and device definitions do not reveal that Congress clearly intended for FDA to rely only upon evidence of manufacturer representations to establish intended use").

⁴⁶ See *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000).

⁴⁷ *Id.*

framework.⁴⁸ Both the United States Supreme Court and the Fourth Circuit denied the FDA jurisdiction over tobacco products due to "fundamental conflicts"⁴⁹ and several "internal inconsistencies"⁵⁰ in the FDA's regulatory scheme. Thus, the judiciary has determined that the FDA lacks jurisdiction over tobacco products, despite its strong showing of compatible, existing regulatory provisions and convincing evidence of the danger of nicotine addiction.⁵¹

Examination of the FDA's asserted jurisdiction of tobacco regulation requires an analysis similar to that in *Coyne*. This analysis considers tobacco's foreseeable use, actual consumer use of the product, and the content of internal manufacturer memoranda.⁵² The serious health risks associated with tobacco products and the unique hold tobacco has on Americans, warrant a detailed examination of multiple factors, not simply congressional intent. The district court properly considered many factors in its determination, including the plain language of the statute, the effect of tobacco on users, as well as, congressional intent.⁵³

The regulation of tobacco products poses a problem because tobacco is a profitable business for the economy. The tobacco industry generates fifty-four billion dollars in annual revenue.⁵⁴ This wealth allows the industry to create tremendous political

⁴⁸ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1300-01.

⁴⁹ *Id.* at 1302 (noting that because the FDA also claimed tobacco was unsafe, it was impossible for it to implement regulations that would provide "reasonable assurance[s] of safety"), *aff'g* 153 F.3d 155, 164 (4th Cir. 1998).

⁵⁰ *Id.* at 1299 (discussing the FDA's vacillation in classifying tobacco both as a "drug" or "device" depending on which classification suited their purposes at the time), *aff'g* *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 164-67 (4th Cir. 1998).

⁵¹ See *id.* at 1299, *aff'g* *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 167 (4th Cir. 1998).

⁵² See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1391-92 (M.D.N.C. 1997), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000).

⁵³ See *id.* at 1391 (declaring that "foreseeability, actual consumer use, and internal manufacturer memoranda" must be examined in addition to legislative history and judicial construction).

⁵⁴ See Peter S. Arno et. al., *Tobacco Industry Strategies to Oppose Federal Regulation*, 275 JAMA 1258, 1260 (1996). This income, in turn, pays \$12 billion in taxes. See *id.*

pressure,⁵⁵ in the form of lobbying, delays, and filibusters, thereby forcing the failure of much tobacco legislation.⁵⁶

It still appears that the FDA is the obvious choice to regulate the tobacco industry, as the FDCA's broad regulatory authority already grants the FDA the power to assert jurisdiction over "drugs" and "devices."⁵⁷ In fact, the FDA already regulates almost every object placed into or around the human body.⁵⁸ The FDA maintains that cigarettes fall within the "drug" and "device" classifications of the FDCA because nicotine is intended to affect the structure or function of the body.⁵⁹

Tobacco manufacturers objected to this assertion of authority and claimed tobacco products simply did not fit under the statutory definitions.⁶⁰ Despite previous court rulings, including the recent landmark United States Supreme Court decision,

⁵⁵ The tobacco industry also maintains a powerful agricultural impact and plays a dominant role as large subsidiaries of other manufacturing companies. *See id.* It also finances campaigns to influence the political process. *See id.* at 1261.

⁵⁶ On May 18, 1998, Congress introduced the National Tobacco Policy and Youth Smoking Reduction Act. *See* 144 CONG. REC. S5001 (daily ed. May 18, 1998). This act was meant to "reform" and "restructure" tobacco production and marketing processes in an effort to prevent the underage use of tobacco products. *See id.* The bill subsequently failed on June 17, 1998, as a result of 40 million dollars spent by the tobacco industry in lobbying to "hijack the process." 144 CONG. REC. S6485 (daily ed. June 17, 1998) (statement of Sen. Murray).

⁵⁷ *See* 21 U.S.C. §§ 321(g)(1), (h) (1994) (defining "drug" and "device" within the Federal Food, Drug, and Cosmetic Act); *see also supra* notes 12-13.

⁵⁸ The FDA regulates products that are "ingested, inhaled, implanted, or otherwise used in close contact with the human body." Nicotine: Jurisdictional Determination, *supra* note 4, at 44,628. This includes products such as "foods, drugs, medical devices, and cosmetics." *See id.*; *see also* 21 U.S.C. §§ 321(f), (g)(1), (h) and (i) (1994) (defining "food," "drug," "device," and "cosmetic" within the Federal Food, Drug, and Cosmetic Act respectively). The U.S. Department of Agriculture also retains regulatory authority over some specific foods such as meat and dairy products. *See* 7 U.S.C. §§ 1-5106 (1994).

⁵⁹ *See* Nicotine: Jurisdictional Determination, *supra* note 4, at 44,629.

⁶⁰ *See* George Johnson, *With Tobacco, It's Time to Trust Congress to Do the Right Thing*, ST. LOUIS POST-DISPATCH, June 6, 1996, at B3 (noting that "[t]he tobacco industry argues . . . that the FDA does not have the legal authority to regulate cigarettes, as Congress has not specifically given the FDA the authority to regulate nicotine as a drug"), available in 1999 WL 3027246; Robert S. Greenberger & Suein L. Hwang, *Court to Rule on FDA Role Over Tobacco*, WALL ST. J., Apr. 27, 1999, at A3 (providing the legislative intent argument of tobacco manufacturers). Although the district court in *Coyne* rejected this argument, the court of appeals agreed with tobacco companies and concluded that the "FDA [was] attempting to stretch the Act beyond the scope intended by Congress." *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 167 (4th Cir. 1998), *aff'd* *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291 (2000).

which held that the FDA did not have jurisdiction to regulate tobacco,⁶¹ new evidence of manufacturer representations and the addictive qualities of cigarettes could now provide a basis for Congress to accept the FDA's contention.⁶² The agency's new findings and liberal interpretation of the FDCA make the FDA's classification of tobacco as a "drug" or "device" proper and timely. Further, the overall intent of the FDCA is premised on public protection. As the United States Supreme Court in *Kordel v. United States*⁶³ enunciated, "[t]he high purpose of the Act [is] to protect consumers who under present conditions are largely unable to protect themselves."⁶⁴ Nevertheless, the complexity of the FDA assertion of jurisdiction over tobacco continues to spurn argument and controversy.

The FDA determined that it had jurisdiction over tobacco as a combination drug and device, as it considered nicotine a drug, and cigarettes and smokeless tobacco products as drug delivery devices.⁶⁵ The analysis of whether the FDA can validly assert jurisdiction over tobacco products must be examined on two levels. Despite the United States Supreme Court's ruling, the

⁶¹ See e.g., *Action on Smoking & Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

⁶² See Jan Crawford Greenburg & Peter Gorner, *Tackling Tobacco: The Supreme Court Agrees to Decide One of the Most Contentious Health Issues in America—Whether the Government Has the Authority to Regulate Tobacco*, CHICAGO TRIB., Apr. 27, 1999, at 1 (discussing the Supreme Court decision to grant certiorari amid the recent scientific findings), available in 1999 WL 2867370; see also Laurie Asseo, *Court to Rule on Smoking Dispute: Government, Cigarette Industry to Spar Over Whether FDA Can Regulate Tobacco*, FORT WORTH STAR-TELEGRAM, April 27, 1999, at 3 (noting that "[t]he government says . . . [there is] new evidence that the tobacco industry intends its products to feed consumers' nicotine habits"), available in 1999 WL 6231880.

⁶³ 335 U.S. 345 (1948).

⁶⁴ *Id.* at 349 (citation omitted). Other United States Supreme Court decisions have recognized the importance of consumer protection. For example, in *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969), the Supreme Court stated:

[W]e are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health.

Similarly, in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 158 (1958), the Court declared: "We granted certiorari to determine . . . construction of this important statute designed for the protection of the public health." The circuit courts have also recognized the importance of protection. In *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988), *cert. den.* 488 U.S. 924 (1988), the Eleventh Circuit concluded that "[t]he general scheme of the Act and its legislative history indicate that the overriding congressional purpose was consumer protection."

⁶⁵ See *Nicotine: Jurisdictional Determination*, *supra* note 4, at 44,629.

initial inquiry still concerns whether the FDA should even have jurisdiction to regulate tobacco products. A starting point for this issue is to examine the statutory definitions of "drug" or "device," and determine whether nicotine-containing products meet these criteria. Congress's impact on administrative regulatory schemes also plays a vital role in determining whether the FDA possesses the power to regulate tobacco.

The focal point of FDA regulation centers on nicotine, the addictive ingredient in cigarettes and smokeless tobacco.⁶⁶ The FDA maintains that tobacco products meet the "drug" or "device" criteria because they are intended to affect the structure or function of the body.⁶⁷ The FDA issued these findings based on information discovered from industry records and a consensus of health organizations that have joined forces in asserting the addictive properties of nicotine.⁶⁸ The FDA further argued that tobacco products meet the "drug" and "device" criteria due to the manufacturer's intent for consumers to use their products as a combination device.⁶⁹

Although the *Coyne* court agreed with the FDA's assessment in determining that tobacco products fall under the FDA's jurisdiction,⁷⁰ the Fourth Circuit and the United States Supreme Court rejected this argument.⁷¹ The Supreme Court and the court of appeals used very different approaches in analyzing the problem of the FDA's assertion of jurisdiction over tobacco than

⁶⁶ See *id.* at 44,629.

⁶⁷ See *id.* The American Medical Association (AMA) urged the FDA to regulate tobacco products and help reduce nicotine's addictive potential. See Jim Ritter, *AMA Wants Nicotine Curbs, Goal: Less-Addictive Cigarettes*, CHI. SUN TIMES, June 19, 1998, at 18, available in 1998 WL 5585925. The AMA noted that 70% to 80% of smokers want to quit, but cannot because they are "hooked" on nicotine. See *id.*

⁶⁸ See *supra* note 38 and accompanying text; see also Nicotine: Jurisdictional Determination, *supra* note 4, at 44,629 (finding that there has been an "emergence of a scientific consensus that cigarettes and smokeless tobacco cause addiction to nicotine").

⁶⁹ See Nicotine: Jurisdictional Determination, *supra* section III (discussing consumer use as a factor in assessing FDA jurisdiction over tobacco products).

⁷⁰ See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1395-97 (M.D.N.C. 1997), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000).

⁷¹ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1299, 1301, *aff'g* 153 F.3d 155, 175-76 (4th Cir. 1998). The court of appeals did not discuss the manufacturer's intent. See *id.* at 163 (noting only that the FDA did not assert that the manufacturers intended their products to affect the structure and function of the body).

did the district court. Both courts determined that statutory interpretation was the threshold of the analysis, and if the legislative history did not encourage regulation, the product should not be regulated.⁷² The district court found that the FDA's theories of regulation comported with elements such as foreseeable use and actual consumer use, which could not be ignored.⁷³ The *Coyne* court accepted the FDA's position that relied on foreseeable use, actual consumer use, and manufacturer representations to establish intended use.⁷⁴ Furthermore, agency interpretation and judicial decisions do not prohibit the FDA from considering other evidence to prove intended use.⁷⁵ According to the district court, the legislative history and the definitions of "drug" and "device" do not indicate that Congress meant for the FDA to rely solely on evidence of manufacturer representations to establish intended use.⁷⁶

The Supreme Court and the Fourth Circuit, however, rejected this analysis and narrowed the scope of inquiry to the historical role and actions of the FDA in relation to tobacco regulation and prior congressional actions.⁷⁷ The courts ultimately decided that the FDA lacked jurisdiction over tobacco based on legislative intent,⁷⁸ choosing to ignore the vital factors of consumer use, foreseeable use and manufacturer memoranda, and information from newly emergent scientific findings concerning tobacco and its effect on the American public.

⁷² See *id.* at 1299-1300, *aff'g* *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 163 (4th Cir. 1998).

⁷³ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1391-92.

⁷⁴ See *id.* at 1391.

⁷⁵ See *id.* at 1391-92.

⁷⁶ See *id.*; see also *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 845 (1984) (noting that "[o]nce [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], . . . the question before it [is] . . . whether the [agency's] view . . . is a reasonable one").

⁷⁷ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1294-95, *aff'g* 153 F.3d 155, 160-70 (4th Cir. 1998). Since 1914, the FDA had continually asserted that tobacco products were outside the scope of its jurisdiction unless marketed with health claims. See *e.g.*, *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980); *Federal Trade Comm'n v. Liggett & Myers Tobacco Corp.*, 108 F. Supp. 573, 575 (S.D.N.Y. 1952), *aff'd*, 203 F.2d 955 (2d Cir. 1953).

⁷⁸ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1297, *aff'g* 153 F.3d 155, 175-76 (4th Cir. 1998).

II. THE ROLE OF CONGRESSIONAL INTENT OR CONGRESSIONAL INACTION IN AFFORDING EXPLICIT AUTHORITY TO REGULATE BY THE FOOD AND DRUG ADMINISTRATION

Brown & Williamson rejected the lower court's analysis in *Coyne*, as well as the FDA's contention that Congress' lack of explicit delegation of authority to regulate tobacco did not negate its jurisdictional authority.⁷⁹ The Fourth Circuit stated that both the FDA and the district court used only a "mechanical reading" approach to interpret the definition of "drug" and "device" under the FDCA.⁸⁰ The United States Supreme Court and the court of appeals recognized that the FDA was charged with protecting the public health from harmful drugs and devices, but ultimately rejected the FDA's chosen method of regulation.⁸¹ The court determined that the FDA should weigh the risks and benefits of the use of a particular product and not balance the effects of removing that product from the market.⁸² The Supreme Court and the Fourth Circuit disagreed with the FDA's interpretation of why tobacco falls within its regulatory authority, and also determined that the FDA lacked the power to make this "major policy decision."⁸³ Both courts concluded that the FDA went beyond the authority granted to it by Congress.⁸⁴

The determination of the FDA's jurisdiction over tobacco products focuses on an analysis of congressional intent. Despite these judicial determinations, it seems that the nature of the FDA's timely control, coupled with the broad powers of the FDCA, indicate that the FDA's assertion of jurisdiction still coincides with legislative intent.⁸⁵ The Supreme Court in

⁷⁹ See *id.* at 1298-99, *aff'g* 153 F.3d 155, 175-76 (4th Cir. 1998).

⁸⁰ See *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 163 (4th Cir. 1998).

⁸¹ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1298-99, *aff'g* 153 F.3d 155, 163-64 (4th Cir. 1998).

⁸² See *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d at 164 (4th Cir. 1998) (noting that "[b]y statute, the FDA's authority is limited to the balancing of health benefits and risks"); see also 21 U.S.C. § 360c(a)(2)(C) (1994) (expressing that the "weighing [of] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use" determines the suitability of devices on the market).

⁸³ *Brown & Williamson Tobacco Corp.*, 153 F.3d at 176.

⁸⁴ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1313-14, *aff'g* 153 F.3d 155 (4th Cir. 1998).

⁸⁵ See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1392 (M.D.N.C. 1991), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir.

Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.,⁸⁶ set forth criteria for determining whether an agency's statutory construction conflicts with congressional intent.⁸⁷

The two-prong test established by *Chevron* for analyzing congressional intent begins with a determination as to whether Congress has spoken clearly on the issue at hand.⁸⁸ If so, "that is the end of the matter."⁸⁹ If, however, Congress left a gap in the statutory interpretation, or if the intent of Congress is ambiguous, then the agency responsible for issuing regulations may fill this void.⁹⁰ Deference to the agency's regulations is permissible unless the construction is "arbitrary, capricious, or manifestly contrary to the statute."⁹¹ Thus, a court may not substitute its own statutory interpretation for that of the agency if the agency's construction is reasonable.⁹²

Applying the *Chevron* analysis to tobacco regulation begins with a determination as to whether Congress has clearly spoken regarding the FDA's jurisdiction over tobacco products. The United States Supreme Court agreed with the tobacco manufacturers' contention that Congress never authorized nor intended for the FDA to assert jurisdiction over tobacco products.⁹³ The Court further agreed with the contention by tobacco manufacturers that if Congress intended the FDA to regulate tobacco, then acquiescence to the FDA's jurisdiction over tobacco would have been included in either the Cigarette Labeling and Advertising Act,⁹⁴ the Comprehensive Smokeless

1998), *aff'd* 120 S. Ct. at 1313.

⁸⁶ 467 U.S. 837 (1984).

⁸⁷ *See id.* at 842-44. *Chevron* challenged the Environmental Protection Agency's Clean Air Act and the stringent conditions on air quality as well as the use of equipment to nullify pollution emitting devices. *See id.* at 840.

⁸⁸ *See id.* at 842.

⁸⁹ *Id.*

⁹⁰ *See id.* at 843-44.

⁹¹ *Id.* at 844.

⁹² *See id.*

⁹³ *See generally* *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1384 (M.D.N.C. 1997), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000) (noting the manufacturer's contention that "Congress' tobacco-specific legislation supports [the] argument that Congress clearly reserved to itself the authority to regulate tobacco products"). There are several examples of Congress enacting tobacco legislation, without explicit grant of the authority to regulate tobacco. *See generally* 15 U.S.C. §§ 1331-40 (1994); 15 U.S.C. §§ 4401-08 (1994); 42 U.S.C. § 300x-26 (1994).

⁹⁴ *See* *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1298-99; 15

Tobacco Health Education Act,⁹⁵ or the Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992 (the "Acts").⁹⁶ The *Coyne* court found that the FDA's tobacco regulations did not conflict with the text of the Acts.⁹⁷ Additionally, the Acts did not evidence congressional intent to withhold jurisdiction from the FDA to regulate tobacco products.⁹⁸

Second, the tobacco companies argued that because the legislation failed to grant jurisdictional authority to the FDA, Congress explicitly did not intend the FDA to have jurisdiction over tobacco products.⁹⁹ Despite evidence that Congress has repeatedly failed to pass legislation granting such jurisdiction to the FDA, the *Coyne* court rejected this argument,¹⁰⁰ explaining that unenacted legislation did not indicate congressional intent.¹⁰¹ The United States Supreme Court and the Fourth Circuit both disagreed with the *Coyne* court.

The lack of clear congressional intent forced the district court in *Coyne* to move to the second prong of the *Chevron* test.¹⁰² The *Coyne* court examined the FDA's reasoning behind its assertion of jurisdiction over tobacco as a "drug" and "device."¹⁰³ Unlike the United States Supreme Court and the Fourth Circuit, the *Coyne* court accepted the FDA's argument that evidence of actual use and foreseeable use constituted an independent basis for "intended use" under the FDCA.¹⁰⁴ The district court also found that though the FDA had changed its position regarding its authority to regulate tobacco products since the 1980 *ASH*

U.S.C. §§ 1331-40 (1994).

⁹⁵ See *id.*; 15 U.S.C. §§ 4401-08 (1994).

⁹⁶ See *id.*; 42 U.S.C. § 300x-26 (1994).

⁹⁷ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1384-89.

⁹⁸ See *id.* at 1388; see also *supra* note 76.

⁹⁹ See *supra* notes 46-51 and accompanying text. The power of the tobacco industry can be seen in Congress' inaction. This inaction, however, does not mean that Congress does not believe the FDA has the power to regulate tobacco. See generally *Brecht v. Abrahamson*, 507 U.S. 619, 632 (1993) (warning against drawing inferences from congressional inaction).

¹⁰⁰ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1382.

¹⁰¹ See *id.* (citing *Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 187 (1994)).

¹⁰² See *id.* at 1388 (engaging in statutory interpretation in the face of a lack of clear congressional intent).

¹⁰³ See *id.* at 1392.

¹⁰⁴ See *id.* at 1384.

decision,¹⁰⁵ this change was not arbitrary or capricious¹⁰⁶—the Supreme Court determined otherwise.

The district court in *Coyne* relied on *Chevron's* reasoning in noting that "[a]n initial agency interpretation is not instantly carved in stone."¹⁰⁷ Rather, "[an] agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis."¹⁰⁸ The FDA waited to assert general jurisdiction until new findings of nicotine addiction indicated scant scientific doubt regarding the adverse effects of nicotine in tobacco products on the structure or function of the body.¹⁰⁹

It appears that the *Coyne* district court's decision, unlike the United States Supreme Court and the court of appeals in *Brown & Williamson*, is consistent with previous rulings regarding the jurisdictional determination of tobacco regulation,¹¹⁰ which have looked at jurisdictional determination within the context of congressional intent.¹¹¹ As previously mentioned, "[a]n

¹⁰⁵ See *Action on Smoking & Health v. Harris*, 655 F.2d 236, 237 (D.C. Cir. 1980) (discussing the FDA's refusal to assert jurisdiction over nicotine under section 201(g)(1)(C) of the FDCA).

¹⁰⁶ *Coyne Beahm, Inc.*, 966 F. Supp. at 1384 (describing the change in position as "reasonable"); see also *Nicotine: Jurisdictional Determination*: *supra* note 4 at 44,619, 45,219 (including new medical findings of nicotine's addictive properties which helped to develop a new attitude toward the regulation of tobacco products by the FDA). The Supreme Court in *Chevron* also articulated that an agency is entitled to change its policies. See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863–64 (1984).

¹⁰⁷ *Coyne Beahm, Inc.*, 966 F. Supp. at 1384 (quoting *Chevron*, 467 U.S. at 863–64).

¹⁰⁸ *Id.*

¹⁰⁹ See *Nicotine: Jurisdictional Determination*, *supra* note 4, at 45,219–22.

¹¹⁰ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1384; *Action on Smoking & Health*, 655 F.2d at 242 (recognizing the appropriateness of judicial deference to the FDA's changing opinion). Further, *Brown & Williamson* gave little deference to *Chevron*, and gave greater weight to the FDA's original refusal to assert jurisdiction. See *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 169–70 (4th Cir. 1998), *aff'd* No. 99-1152, 2000 WL 289576 (U.S.N.C. Mar. 21, 2000).

¹¹¹ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1384. The court discussed several decisions, which examined drug and device regulation. See *id.* at 1388–92. One such case was *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 330 (2d Cir. 1977), which examined vitamins to determine whether they should be regulated under the FDCA's definition of a drug. The *Mathews* court found that in determining whether a drug is intended for use as a drug, the FDA is not bound by manufacturer's subjective claims but may also rely on objective evidence. See *id.* at 334. The use of a drug for exclusively therapeutic purposes is sufficient to show intent for use in the treatment of disease. See *id.* at 1335. Ultimately, the appellate court found that the FDA could assert jurisdiction over high dosage vitamins. See *id.*

administrative agency is clearly free to revise its interpretations."¹¹² The *ASH* court noted, "[n]othing in this opinion should suggest that [the FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch."¹¹³ Although the FDA declined jurisdiction over nicotine containing products in 1980, it had the ability to alter its position if and when evidence appeared that made the FDA's assertion of jurisdiction timely and proper.¹¹⁴

The *Coyne* court buttressed the FDA's statutory interpretation by clarifying that the FDCA was intended to broaden former food and drug laws.¹¹⁵ The intent of Congress to broaden the statutory definition of a drug is illustrated in *United States v. Bacto-Unidisk*.¹¹⁶ The Supreme Court noted, after examining the product at hand and medical definitions of "drug," that "Congress intended to define 'drug' far more broadly than does the medical profession."¹¹⁷ *Bacto-Unidisk* laid the foundation for *Coyne*'s reasoning that if Congress intended a strictly medical usage for the term "drug," it would have explicitly stated so in the FDCA.¹¹⁸

at 338. The Dietary Supplement and Health Education Act is an example of legislation that was enacted in part due to health concerns and new scientific evidence. See Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. § 321n (1994)). See Stephen H. McNamara, *Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation*, 50 FOOD & DRUG L.J. 341, 341 (1995) (describing congressional intent to restrict the FDA's regulatory authority over dietary supplements).

¹¹² *Coyne Beahm, Inc.*, 966 F. Supp. at 1384 (quoting *Action on Smoking & Health*, 655 F.2d at 242).

¹¹³ *Action on Smoking & Health*, 655 F.2d at 242 n.10.

¹¹⁴ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1384; see also *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (recognizing the need for agencies to adapt their rules and policies to changing circumstances); *Rust v. Sullivan*, 500 U.S. 173, 186-87 (1991) (noting that an agency may revise its earlier statutory interpretation).

¹¹⁵ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1381; see also H.R. REP. NO. 75-2139, at 2 (1938).

¹¹⁶ 394 U.S. 784 (1969). The Supreme Court examined whether or not antibiotic sensitivity disks, used to determine the proper antibiotic to administer to patients would be considered a "drug" under the FDCA. See *id.* at 787-88. The product never touched the body, but was used in connection with the patient's specimen. See *id.* at 787.

¹¹⁷ *Id.* at 793. The Supreme Court went on to add that the addition of a "device" definition that almost paralleled the "drug" definition helped the Court reach this conclusion. See *id.*

¹¹⁸ See *id.* at 793-94.

The *Coyne* court noted that another purpose of the FDCA was to protect the public from problematic devices.¹¹⁹ Clearly, the FDCA is an act aimed at public protection.¹²⁰ The appearance of internal manufacturer memoranda listing the dangers of cigarettes and smokeless tobacco¹²¹ bolsters the public protection basis of the FDCA, thus qualifying nicotine as a regulated product. The district court in *Coyne* correctly found the FDA's statutory interpretation acceptable.¹²²

Finding that the FDA had proper jurisdiction is consistent with the legislative history. The hurdle of regulation still lingers, leaving both proponents and adversaries of the FDA's tobacco regulation wondering what comes next.

III. CONSUMER USE AS A FACTOR IN THE DETERMINATION OF WHETHER THE FOOD AND DRUG ADMINISTRATION HAS THE LEGAL AUTHORITY TO REGULATE TOBACCO

Tobacco companies assert that the FDA cannot consider consumer use in determining whether tobacco products meet the "drug" or "device" criteria.¹²³ The district court in *Coyne* disagreed, finding that actual consumer use was a vital factor in analyzing whether the FDA has jurisdiction over tobacco products.¹²⁴ The *Brown & Williamson* courts agreed with the manufacturers and did not analyze the role of actual consumer use in determining the FDA's jurisdiction over tobacco products.¹²⁵ The discrepancy between the appellate and district courts on the issue of actual consumer use plays a major role in the determination of which court has the most persuasive, and

¹¹⁹ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1392-93.

¹²⁰ See *supra* note 58 and accompanying text.

¹²¹ See Nicotine: Jurisdictional Determination, *supra* note 4, at 44,847-915 (discussing statements and research of each of the major cigarette companies and the Council for Tobacco Research, which shows that cigarette manufacturers know of the dangers of tobacco use, and that they intend their products to have pharmacological effects on the bodies of the consumers); see also *id.* at 45,098-150 (discussing evidence from smokeless tobacco producers on intentional "graduation" of nicotine levels to promote tolerance and addiction).

¹²² See *Coyne Beahm, Inc.*, 966 F. Supp. at 1393.

¹²³ See *id.* at 1391; see also Nicotine: Jurisdictional Determination, *supra* note 4, at 45,160-61.

¹²⁴ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1391-92 (stating that the cases relied upon by the tobacco companies are not on point).

¹²⁵ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1299, *aff'g* 153 F.3d 155, 160 (4th Cir. 1998).

perhaps, most politically correct analysis. The determination of the proper analysis of the FDA's jurisdiction over tobacco products now lies with Congress.

Previous courts have found that actual consumer use plays an important role in determining FDA jurisdiction.¹²⁶ For example, the court in *United States v. 22 Devices "The Ster-O-Lizer MD-200"*¹²⁷ addressed whether a product used to sterilize surgical equipment could be regulated by the FDA as a device.¹²⁸ The district court noted, "[t]he objective intent referred to in the regulation¹²⁹ may be shown not only by a product's labeling claims, advertising or written statements relating to the circumstances of a product's distribution, . . . but also by a product's actual use."¹³⁰ The *Ster-O-Lizer* case illustrated that objective intent looks further than a product's label, into the heart of its purpose.¹³¹

The *ASH* court noted that statutory intent could be inferred when consumers use a product exclusively and with a specific purpose.¹³² A finding that consumers use cigarettes as a drug corroborates the FDA's claims of actual use. The FDA found that 77% to 92% of smokers and 75% of smokeless tobacco users are addicted to nicotine.¹³³ According to the FDA, one third to one half of young smokers use smoking for weight control, and 50% of

¹²⁶ See, e.g., *United States v. 22 Rectangular or Cylindrical Finished Devices, More or Less, "The Ster-O-Lizer MD-200,"* Halogenic Products Co., 714 F. Supp. 1159, 1165 (D. Utah 1989) [hereinafter *Ster-O-Lizer*] (holding that the test to see if a product is a device, and, thus, subject to FDA jurisdiction, is based "solely on the product's intended use"); see also *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 703-04 (2d Cir. 1975) (holding that near exclusive consumer use is evidence of intended use).

¹²⁷ 714 F. Supp. 1159 (D. Utah 1989).

¹²⁸ See *id.* at 1161.

¹²⁹ See 21 C.F.R. § 801.4 (1998) (stating that the objective intent of the manufacturer can be determined by examining the manufacturer's expressions, the way in which they distribute the product, and the purpose behind their actions).

¹³⁰ *Ster-O-Lizer*, 714 F. Supp. at 1165. The court examined, in conjunction with device definitions, those provisions of the Code of Federal Regulations that discuss the meaning of "intended use," including volume 21, sections 801.4, 801.5, 801.119, 801.122. See *id.* The sections refer to intended use as "the objective intent of the persons legally responsible for the labeling of devices" and how this objective intent can be derived. *Id.* (quoting 21 C.F.R. § 801.4 (1998)) (emphasis added).

¹³¹ See *id.*

¹³² See *Action on Smoking & Health v. Harris*, 655 F.2d 236, 240 (D.C. Cir. 1980).

¹³³ See *Nicotine: Jurisdictional Determination*, *supra* note 4, at 44,635-36.

young people utilize smokeless tobacco for relaxation.¹³⁴ FDA findings also indicate that of those smokers aged ten to twenty-two, 70% use cigarettes for relaxation.¹³⁵ Thus, actual consumer use substantiates use that affects the structure or function of the body. *Agnew v. United States*¹³⁶ confirmed that "intended for use" could be inferred from one's actions¹³⁷ by concluding that "[t]he law presumes that every man intends the legitimate consequence of his own acts."¹³⁸ The proposition that one's actions foretell intention has long been a part of this legal theory and should similarly apply to tobacco product regulation.

IV. FORESEEABILITY AS A FACTOR IN GRANTING THE FDA THE AUTHORITY TO REGULATE

Another factor in the FDA's assertion of jurisdiction to regulate tobacco products is based on the foreseeable effects of tobacco products, which can be used to prove a manufacturer's intent.¹³⁹ FDA evidence has indicated that manufacturers' design of cigarettes and smokeless tobacco, combined with a potent dosage of nicotine, show that they foresaw consumer addiction.¹⁴⁰ The district court in *Coyne* made clear that, although Congress did not specifically state that foreseeable use could be considered for determining intended use, nothing prohibits it.¹⁴¹ The court of appeals and the United States Supreme Court did not address foreseeable use in their tightly woven opinions.¹⁴²

The lack of discussion of foreseeable use has left the FDA and proponents of the FDA's jurisdiction over tobacco without

¹³⁴ See *id.* at 44,635-36.

¹³⁵ See *id.* at 44,636.

¹³⁶ 165 U.S. 36 (1897).

¹³⁷ See *id.* at 53.

¹³⁸ *Id.*

¹³⁹ See *Nicotine: Jurisdictional Determination*, *supra* note 4, at 44,633-34 (discussing the pharmacological effects of tobacco on the human body, such as the addictive nature of nicotine, and that the tobacco industry's denial of such effects can not be believed in light of the overwhelming scientific evidence).

¹⁴⁰ See *id.* at 44,636-42.

¹⁴¹ See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1391 (M.D.N.C. 1991), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000).

¹⁴² See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1299-1300 (discussing intended use in general, but not foreseeable use), *aff'g* 153 F.3d 155, 155 (4th Cir. 1998).

one of their most powerful and convincing arguments for the assertion of jurisdiction to regulate tobacco. The Supreme Court and the Court of Appeals in *Brown & Williamson* appellate courts based their decisions on the fact that Congress has had many instances to act on tobacco regulation, and its inaction, as applied to the FDA, indicated specific intent to deny the agency regulatory authority.¹⁴³

The foreseeability test that the FDA relied on stems from evidence that nicotine is addictive and causes "significant pharmacological effects."¹⁴⁴ The FDA also noted that nicotine could have mood altering effects and other qualities that parallel those of opiates.¹⁴⁵ Today, findings of the powerful, addictive nature of nicotine emanate from health agencies.¹⁴⁶ Nicotine is identified by all the pertinent expert organizations as one of the few truly dependence-producing drugs, occupying the list with cocaine, heroin, and alcohol.¹⁴⁷ Thus, the "scientific consensus" and consumer use patterns indicate that manufacturers do foresee that their products have addictive qualities and that consumers use tobacco products for their pharmacological properties.

V. INTERNAL MANUFACTURERS' MEMORANDA AS A FACTOR IN FDA REGULATION

Perhaps the most compelling evidence of manufacturers' intent is their memoranda. Nevertheless, the Fourth Circuit and the United States Supreme Court did not squarely address this issue. The Fourth Circuit simply concluded that manufacturers do not intend for their products to be used as a "drug" or "device."¹⁴⁸ The FDA relied on research and memoranda from

¹⁴³ See *id.* at 1306-14, *aff'g* 153 F.3d 155, 160 (4th Cir. 1998); see also *supra* note 49 and accompanying text.

¹⁴⁴ Nicotine: Jurisdictional Determination, *supra* note 4, at 44,634.

¹⁴⁵ See *id.* at 44,635.

¹⁴⁶ See *id.* at 44,634 (noting that, "[s]ince 1980, nicotine in tobacco products has also been recognized as addictive by the U.S. Surgeon General (1986 and 1988), the American Psychological Association (1988), the Royal Society of Canada (1989), the World Health Organization (1992), the American Medical Association (1993), and the Medical Research Council in the United Kingdom (1994)").

¹⁴⁷ See *id.* at 44,701-12 (discussing the criteria and classification of many addictive substances, including nicotine).

¹⁴⁸ See *Brown & Williamson Tobacco Corp.*, 153 F.3d at 160-161 (4th Cir. 1998) (reasoning that Congress has spoken directly through tobacco-specific legislation), *aff'd* 120 S. Ct. 1291 (2000).

tobacco companies to demonstrate recognition that nicotine has powerful pharmacological effects.¹⁴⁹ For example, according to the FDA's Executive Summary, manufacturers recognized that nicotine is " 'a powerful pharmacological agent with multiple sites of action' and 'a physiologically active . . . substance . . . [which] alters the state of the smoker by becoming a neurotransmitter and a stimulant.' "¹⁵⁰ Even in 1996, when the FDA chose to assert its regulatory jurisdiction over tobacco products, evidence existed which proved manufacturers' knowledge of nicotine's powerful effects.

Since 1996, tobacco litigation has resulted in more company documents surfacing that reveal manufacturer knowledge about the addictive nature of their product.¹⁵¹ For example, internal memoranda from a cigarette producer revealed that several tests were done in the late 1970's and early 1980's to " '[d]etermine the minimum level of nicotine that will allow continued smoking' " and also note that "smoking is 'both physiologically and psychologically motivated,' and that when nicotine levels drop too low 'smokers will quit.' "¹⁵² Even as litigation continues regarding whether tobacco is a drug or device, these manufacturer documents reveal that they clearly knew their products both affected the structure and function of the body and were used by consumers as drug delivery devices.

FDA findings also revealed that tobacco companies specifically designed their products to deliver "a pharmacologically active dose of nicotine to the smoker."¹⁵³ Manufacturer experiments included tests on how to negotiate nicotine and tar levels as well as ammonia manipulation for increasing "free" nicotine levels to smokers.¹⁵⁴ The FDA contends

¹⁴⁹ See Nicotine: Jurisdictional Determination, *supra* note 4, at 44,637.

¹⁵⁰ *Id.* (citing comments regarding nicotine's addictive qualities in Philip Morris' internal documents).

¹⁵¹ Tobacco companies such as Brown & Williamson acknowledged the dangers of smoking and launched a web site to educate consumers on the health risks of smoking. See Suein L. Hwang, *Tobacco Firm Gives Frank Advice Online*, WALL ST. J., Apr. 9, 1999, at B1.

¹⁵² Doug Campbell, *Lorillard Documents Revealing: Documents Discuss Nicotine Levels and Marketing to Teens*, GREENSBORO NEWS & RECORD, June 28, 1998, at A1, A8 (citation omitted).

¹⁵³ Nicotine: Jurisdictional Determination, *supra* note 4, at 44,640-41. The FDA included evidence of blending techniques and filter/ventilation systems that deliver high amounts of nicotine. See *id.* at 44,641.

¹⁵⁴ See *id.* at 44,641.

that tobacco companies intended for their products to be used as drug delivery devices.¹⁵⁵

VI. IS THERE A SIMPLE ANSWER TO REGULATION?

The Supreme Court and the Fourth Circuit's failure to find that the FDA had jurisdiction over tobacco products stemmed directly from congressional inaction and prior actions by the FDA negating assertion of jurisdiction.¹⁵⁶ Both courts determined that the FDA was "attempting to stretch the Act beyond the scope intended by Congress."¹⁵⁷ The courts also found that the agency's rationale for finding authority to regulate tobacco products would require the FDA to ban cigarettes. Such a finding was inconsistent with one of its missions established by Congress—to ensure the safety and efficiency of drugs and devices.¹⁵⁸ The courts also noted that the regulations proposed by the FDA conflicted with the current regulatory practice of eliminating dangerous drugs.¹⁵⁹ Furthermore, the regulations were contrary to the agency's past stance that the FDA was not the proper authority to regulate tobacco products.¹⁶⁰ It appears that the appellate court's reasons are inconsistent with the FDA's ability to conform to changing times and adapt regulatory techniques to meet new scientific findings.

Past agency policy regarding tobacco should not be held to dictate all future regulatory schemes.¹⁶¹ New findings show,

¹⁵⁵ See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1392 (M.D.N.C. 1997), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000).

¹⁵⁶ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1306-14, *aff'g* 153 F.3d 155, 168-71 (4th Cir. 1998).

¹⁵⁷ *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d at 167 (4th Cir. 1998), *aff'd*, 120 S. Ct. 1291 (2000).

¹⁵⁸ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1297-99 (opining that the FDA wants to assert jurisdiction in order to regulate an industry constituting a significant portion of the American economy and that the FDA would then have the authority to ban cigarettes and all smokeless tobacco), *aff'g* 153 F.3d 155, 166-67 (4th Cir. 1998).

¹⁵⁹ See *id.* (noting that "based on the FDA's characterization of tobacco products as unsafe, it is impossible to create regulations which will provide a reasonable assurance of safety[,] and therefore it is impossible for the FDA to promulgate regulations that comply with the FDCA).

¹⁶⁰ See *id.*

¹⁶¹ See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1384 (M.D.N.C. 1997), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.2d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000).

unlike past agency information, that smoking affects the structure and function of the body.¹⁶² Secondary findings show manufacturers intend this to be the case.¹⁶³ The argument that congressional intent prohibits FDA regulation over tobacco products is also misplaced. Congress's failure to explicitly extend to the FDA the authority to regulate tobacco does not mean that regulatory activity is barred indefinitely.¹⁶⁴ The regulatory techniques, though controversial, fulfill the overall intent of the FDCA: to protect consumers who are "unable to protect themselves."¹⁶⁵

If manufacturers discover a formula to make safer cigarettes, should the FDA regulate this type of product?¹⁶⁶ If the FDA can regulate these products, will smoking increase?¹⁶⁷ These are only a few questions regarding FDA regulation. Upon examination of these questions, commentators have agreed that significant price increases might deter smoking and, hence, reduce nicotine addiction in the United States.¹⁶⁸

Critics have noted that the best methods of cigarette control are negative advertisements, rather than a ban on specific advertisement forms.¹⁶⁹ Perhaps this is a more realistic answer

¹⁶² See Regulations Restricting the Sale of Tobacco, *supra* note 7, at 44,397 (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, and 897) ("FDA has determined that cigarettes and smokeless tobacco are intended to affect the structure or function of the body, within the meaning of the act's definitions of 'drug' and 'device.' The nicotine in cigarettes and smokeless tobacco is a 'drug,' which produces significant pharmacological effects in consumers.").

¹⁶³ See *id.* at 44,630 (noting that "[m]anufacturers of cigarettes and smokeless tobacco know that nicotine in their products causes pharmacological effects in consumers, including addiction to nicotine and mood alteration, and that consumers use their products primarily to obtain the pharmacological effects of nicotine").

¹⁶⁴ See *Coyne Beahm, Inc.*, 966 F. Supp. at 1384 (finding that "the text of the FDCA, its legislative history, and the body of evidence consisting of FDA's representations to Congress, unenacted bills, and statements by members of Congress do not clearly indicate that Congress intended to withhold from FDA the authority to regulate tobacco products").

¹⁶⁵ *Kordel v. United States*, 335 U.S. 345, 349 (1948).

¹⁶⁶ See Jon D. Hanson & Kyle D. Logue, *A Critique of the Proposed Tobacco Resolution and a Suggested Alternative*, 41 L. QUAD. NOTES 76, 81 (1998).

¹⁶⁷ See *id.*

¹⁶⁸ See *id.* (noting that "[t]he proposed resolution arguably includes an incentive-based component, insofar as the costs imposed on manufacturers are required to be passed through to consumers in the form of a price hike").

¹⁶⁹ See Mark A.R. Kleiman & Aaron J. Saiger, *Drug Legalization: The Importance of Asking the Right Question*, 18 HOFSTRA L. REV. 527, 549 (1990) (stating that negative advertising is a more powerful deterrent to drug abuse than a ban on advertising).

to regulation. Nevertheless, the answer to regulatory techniques is a complex issue due to the powerful social implications presented by tobacco use.¹⁷⁰ The prevention of smoking must be delicately handled and in a manner suitable to government objectives and existing regulatory techniques. Tobacco addiction, however, can no longer be ignored. A multifaceted examination of consumer use, foreseeability, and closeted manufacturer findings, must be considered when determining whether tobacco or any other product meets the "drug" or "device" criteria and should hence, be regulated.

How should Congress be guided? The United States Supreme Court and the Fourth Circuit relied on the FDA's prior regulatory schemes, congressional inaction, and tobacco-specific legislation.¹⁷¹ That is, these courts focused on historical actions by the FDA and congressional inaction and concluded that the FDA "exceeded the authority granted to it by Congress."¹⁷² In so doing, the FDA's rulemaking to regulate tobacco as a "drug," "device" or "combination product" could not stand.¹⁷³ The follow-up examination of the FDA's past bouts with tobacco regulation is also problematic. The Fourth Circuit ignored, and the United States Supreme Court did not reach the issue of, newly acquired evidence regarding the FDA's jurisdiction over tobacco and the Agency's regulatory premise.¹⁷⁴

Comparison of the district court's decision with that of the United States Supreme Court leads to the conclusion that *Coyne* used a more comprehensive analysis. *Coyne* advanced the jurisdictional analysis a step past the FDA's prior actions and congressional inaction.¹⁷⁵ In its analysis, the *Coyne* court

¹⁷⁰ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291, 1306-10 (2000) (explaining that such a delegation by Congress would have widespread economic and political implications).

¹⁷¹ See *id.*, *aff'g* 153 F.3d 155, 161 (4th Cir. 1998).

¹⁷² *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 176 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000). An "ultra vires" action is one that is unauthorized. See *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 101-02 (1998).

¹⁷³ See *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1297-98, *aff'g* 153 F.3d at 176.

¹⁷⁴ See *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d. at 161 (ignoring the FDA's evidence that tobacco was intended to effect the body, and therefore tobacco products fall under the literal definitions of drug or device), *aff'd* 120 S. Ct. 1291 (2000).

¹⁷⁵ See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1381 (M.D.N.C. 1997),

determined that tobacco products fall within the "drug" or "device" definition of the FDCA.¹⁷⁶ *Coyne* also concluded "that [the] FDA adequately and properly supported its finding of intended use with evidence of foreseeability and consumer use."¹⁷⁷ The *Coyne* analysis appears more complete and legally realistic and serves as a sound basis for Congress to give the FDA authority to regulate tobacco.

CONCLUSION

Congress, as the court did in *Coyne*, must look at the "big picture" regarding tobacco regulation. Although prior tobacco legislation and congressional inaction remain important considerations, they do not solely justify the conclusion that the FDA lacks authority to regulate tobacco. Undoubtedly, a regulatory scheme with adequate resources could help curb America's deadliest preventable killer. Obviously, this is now up to Congress to do so through specific legislation affording FDA an explicit grant of authority.

rev'd sub nom., *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.2d 155 (4th Cir. 1998), *aff'd* 120 S. Ct. 1291 (2000).

¹⁷⁶ *See id.* at 1388.

¹⁷⁷ *Id.* at 1392.