

# Should Nicotine Be Defined as a Drug, Invoking the Jurisdiction of the United States Food and Drug Administration?

## INTRODUCTION

Tobacco use is the most common single preventable cause of death and disease in our society.<sup>1</sup> An estimated 400,000 deaths occur each year from tobacco products.<sup>2</sup> In the United States there are almost fifty million people who smoke cigarettes and another six million people that use smokeless tobacco products.<sup>3</sup> Each day, approximately 3,000 children become regular smokers.<sup>4</sup> On the average, children and adolescents consume between 516 million and 947 million packs of cigarettes and 26 million containers of smokeless tobacco products each year.<sup>5</sup> In 1993, the tobacco industry spent a total of \$6.2 billion on the advertising, promotion, and marketing of cigarettes and smokeless tobacco.<sup>6</sup> Moreover, tobacco use is a major risk factor for diseases of the heart and blood vessels; chronic bronchitis, and emphysema; cancers of the lung, larynx, pharynx, oral cavity, esophagus, pancreas, and bladder; and other problems such as respiratory infections and stomach ulcers.<sup>7</sup>

On August 11, 1995, the Food and Drug Administration (FDA) proposed new regulations governing the sales and distribution of cigarettes and smokeless tobacco products containing nicotine in order to protect the public against the serious health problems caused by the use of and addiction to these products.<sup>8</sup>

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<sup>1</sup> United States Dep't of Health & Human Services, HEALTHIER PEOPLE, 2000. PHS PUB. NO. (PHS) 91-50212, 136 (1991).

<sup>2</sup> 60 Fed. Reg. 41314 (1995) (to be codified at 21 C.F.R. § 801) (proposed Aug. 11, 1995).

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.* at 41315.

<sup>6</sup> *Id.*

<sup>7</sup> United States Dep't of Health & Human Services, *supra* note 1, at 136.

<sup>8</sup> 60 Fed. Reg. at 41314.

The FDA wants to classify tobacco as a "drug" so that it can be regulated as a "device" by the FDA under the Federal Food, Drug and Cosmetic Act (FDCA).<sup>9</sup> The proposal contains recommendations that would ban cigarette vending machines, strengthen enforcement of existing laws against tobacco sales to minors, restrict tobacco advertising and promotions that appeal to young people, and require the tobacco industry to fund a \$150 million anti-smoking campaign.<sup>10</sup> The proposal, however, does not restrict the use of tobacco products by adults.<sup>11</sup> Rather, it is aimed at reducing children's and adolescents' access to cigarettes and smokeless tobacco products while decreasing the positive imagery which makes tobacco products appealing to them.<sup>12</sup>

This comment gives an overview of the FDA's proposal to regulate cigarette and smokeless tobacco products. The comment discusses the historical background of major tobacco legislation such as: the Federal Cigarette Labeling Advertising Act,<sup>13</sup> the Public Health Cigarette Smoking Act, the Comprehensive Smoking Education Act,<sup>14</sup> and the Alcohol, Drug and Mental Health Block Grants Reorganization Act (ADAMHA).<sup>15</sup> Additionally, this comment analyzes the FDA's and the tobacco companies' perspectives on whether cigarettes and smokeless tobacco products can be classified as drugs and regulated as devices under the FDCA. This comment also explores the FDA's previous attempts to have Congress pass legislation to regulate tobacco products. It analyzes previous case law which has limited the FDA's authority to regulate tobacco products only where vendors and manufacturers have made specific health claims pertaining to tobacco use. The comment concludes that nicotine is a drug under FDCA and therefore subject to regulation by the FDA.

#### I. SUMMARY OF THE FDA'S PROPOSAL

The FDA proposes that nicotine-containing cigarettes and smokeless tobacco products should be regulated as restricted de-

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<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> 15 U.S.C.S. § 1331 (1965).

<sup>14</sup> 15 U.S.C.S. § 1331 (1965) (amended 1969).

<sup>15</sup> 42 U.S.C.S. § 290bb to 23(a)(c) (Law. Co-op. Supp. 1996).

vices within the meaning of the FDCA.<sup>16</sup> The proposal's goal is to "decrease the rates of death and disease caused by tobacco products by substantially reducing the number of young people who begin using cigarettes or smokeless tobacco products."<sup>17</sup> The proposal supports state laws regarding sales to minors by limiting access to and reducing the appeal of cigarettes and smokeless tobacco to persons under eighteen years of age.<sup>18</sup> It contains five subparts which set forth the various provisions limiting the labeling, advertising, sale, and distribution of cigarettes and smokeless tobacco.<sup>19</sup>

The proposed regulation is limited to cigarettes and smokeless tobacco products containing nicotine since these are predominantly used by young people.<sup>20</sup> It does not apply to pipe tobacco or cigars.<sup>21</sup> Provisions of the proposal place strict restrictions on the sale and distribution of cigarettes and smokeless tobacco. Manufacturers of the product would be responsible for the removal of all self-service displays, violative advertising, labeling, and other manufacturer or distributor-supplied items from each point of sale.<sup>22</sup> Retailers would be required to make their employees check photographic identification cards with a birthdate before selling tobacco products.<sup>23</sup> Additionally, the proposal prevents retailers from using any electronic or mechanical device (i.e. vending machines) for the purpose of providing cigarettes or smokeless tobacco products.<sup>24</sup>

The proposal prohibits manufacturers, distributors, and retailers from distributing free samples of tobacco products.<sup>25</sup> All mail-order sales and redemption of mail-order coupons would be prohibited because mail-order sales provide no protection against underage purchasing.<sup>26</sup> It would prohibit contests, lotteries, or games of chance that are linked to the purchasing of tobacco

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<sup>16</sup> 60 Fed. Reg. at 41321.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> 60 Fed. Reg. at 41322.

<sup>22</sup> *Id.* at 41323.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.* at 41324.

<sup>25</sup> *Id.* at 41326.

<sup>26</sup> *Id.* at 41325.

products.<sup>27</sup> Moreover, the proposal prohibits a “sponsored event from being identified with a cigarette or smokeless tobacco product brand name or any other brand-identifying characteristic.”<sup>28</sup> Outdoor advertising of tobacco products would be prohibited from appearing on buildings within 1,000 feet of an elementary or secondary school or playground.<sup>29</sup> Cigarette and smokeless tobacco manufacturers would be required to fund a national educational program in order to educate and discourage young people from using their products. Ultimately, the goal of the proposal is to limit youth access, prevent early addiction, and reduce the appeal of cigarettes and smokeless tobacco products.<sup>30</sup>

Regulation of tobacco products is long overdue. The tobacco industry has existed and flourished in the United States since 1612.<sup>31</sup> In order to understand the FDA’s proposal, it is necessary to examine the history behind past regulatory attempts.

## II. HISTORICAL BACKGROUND

### A. *The Cigarette Labeling and Advertising Act*

In July 1965, Congress enacted the Federal Cigarette Labeling and Advertising Act (FCLAA) in response to the Surgeon General’s Advisory Committee report on cigarettes.<sup>32</sup> The report linked smoking to lung cancer and emphysema, and declared, “[c]igarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action.”<sup>33</sup> The 1965 Act required health warnings on cigarette packages but barred the requirement of such warnings in cigarette advertising. The primary purpose of the Act was to adequately inform the public that cigarette smoking may be hazardous to their health, and to protect the national economy from the burden imposed

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<sup>27</sup> *Id.* at 41334.

<sup>28</sup> *Id.* at 41336.

<sup>29</sup> *Id.* at 41334.

<sup>30</sup> *Id.* at 41321.

<sup>31</sup> The Growers’ Cooperative, *FLUE-CURED TOBACCO COOPERATIVE STABILIZATION CORPORATION* (1995), (non-titled pamphlet on file with San Joaquin Agricultural Law Review).

<sup>32</sup> Marry Ann K. Bosack, *Note, Cigarette Act Preemption—Refining the Analysis*, 66 N.Y.U.L. REV. 756, 770 (1991).

<sup>33</sup> U.S. DEP’T OF HEALTH & HUMAN SERVICES, U.S. SURGEON GENERAL’S ADVISORY COMMITTEE, *SMOKING AND HEALTH* 33 (1964), discussed in Fed. Reg., *supra* note 2 at 41539.

by diverse, non-uniform and confusing cigarette labeling and advertising regulations.<sup>34</sup> Additionally, the Act contained a preemption provision which restricted states from enacting their own regulations.<sup>35</sup> The Act took effect on January 1, 1966, and provided that its provision affecting the regulation of advertising would terminate on July 1, 1969.<sup>36</sup>

### *B. The Public Health Cigarette Smoking Act*

In 1969, Congress enacted the Public Health Cigarette Smoking Act which amended the 1965 Cigarette Labeling and Advertising Act.<sup>37</sup> The purpose of the Act was to provide adequate warning to the public of the hazards of cigarette smoking through strengthened cautionary labeling on all cigarette packages.<sup>38</sup> It also banned cigarette advertising in "any medium of electronic communication subject to Federal Communications Commission

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<sup>34</sup> 15 U.S.C.S. § 1331 (1965) states:

It is the policy of the Congress, and the purpose of this Act to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

<sup>35</sup> 15 U.S.C.S. § 1334 (1965) (amended 1970) states:

(a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package. (b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

<sup>36</sup> S. REP. NO. 566, 91st Cong., 2d Sess., at 2676 (1969).

<sup>37</sup> *Id.* at 2652.

<sup>38</sup> 15 U.S.C.S. § 1333 (1969) (amended 1984) states:

It shall be unlawful for any person to manufacturer, import, or package for sale or distribution within the United States any cigarettes the package of which fails to bear the following statement: 'Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous To Your Health.' Such statement shall be located in a conspicuous place on every cigarette package and shall appear in conspicuous and legible type in contract by typography, layout, or color with other printed matter on the package.

jurisdiction.”<sup>39</sup> Additionally, the Act modified the original pre-emption provision by barring not simply “statements” but rather “requirement[s] or prohibitions . . . imposed under State law.”<sup>40</sup>

### C. *The Comprehensive Smoking Education Act*

In 1984, Congress enacted the Comprehensive Smoking Education Act to increase public awareness of the adverse health effects of smoking.<sup>41</sup> This Act changed the label requirements for cigarettes and required the display of four specific health warning labels on cigarette packages and cigarette advertising to be displayed on a quarterly basis.<sup>42</sup> Further, the Act required cigarette manufacturers to annually submit to the secretary of Health and Human Services (HHS) a list of chemical ingredients added to tobacco.<sup>43</sup> Congress would be given periodic reports by the Secretary on the health effects of the additives.<sup>44</sup> Additionally, the Act

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<sup>39</sup> 15 U.S.C.S. § 1334 (1969) (amended 1970).

<sup>40</sup> *Id.*

<sup>41</sup> H.R. REP. NO. 805, 98th Cong., 2nd Sess. 3718 (1984).

<sup>42</sup> 15 U.S.C.S. § 1333(a) (1984) states:

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, 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 Smoking Contains Carbon Monoxide.

<sup>43</sup> 15 U.S.C.S. § 1335a states: “Each person who manufactures, packages, or imports cigarettes shall annually provide the Secretary with a list of the ingredients added to tobacco in the manufacture of cigarettes which does not identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients.”

<sup>44</sup> 15 U.S.C.S. § 1333a(b)(1) states:

At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a), respecting — (A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of cigarettes and the findings of such research; (B) information pertaining to any such ingredient which in the judgment [judgment] of the Secretary poses a health risk to cigarette smokers; and (C) any other

established an Interagency Committee within the HHS on Smoking and Health in order to coordinate federal and private sector efforts to inform the public of any harmful health effects of smoking.<sup>45</sup>

#### *D. The ADAMHA Reauthorization Act*

In 1992, Congress passed the ADAMHA Reauthorization Act which directed the states to enact and enforce laws aimed at curbing youth smoking.<sup>46</sup> The Act required states to prohibit the sale and distribution of tobacco products to minors, take steps to enforce the prohibition, and report annually to HHS.<sup>47</sup> Moreover, the states had to comply with the requirements of the Act as a condition for receiving certain federal substance abuse grants.<sup>48</sup>

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information which the Secretary determines to be in the public interest.

<sup>45</sup> 15 U.S.C.S. § 1341 states:

(a) The Secretary of Health and Human Services shall establish and carry out a program to inform the public of any dangers to human health presented by cigarette smoking. In carrying out such program, the Secretary shall — (1) conduct and support research on the effect of cigarette smoking on health and develop materials for informing the public of such effect; (2) coordinate all research and educational programs and other activities within the Department of Health and Human Services which relate to the effect of cigarette smoking on human health and coordinate with similar activities through the Interagency Committee on Smoking and Health, such activities of other Federal agencies and of private agencies; (3) establish and maintain a liaison with appropriate private entities, other Federal agencies, and State and local public agencies respecting activities relating to the effect of cigarette smoking on human health . . . .

<sup>46</sup> 142 CONG. REC. E172 (daily ed. Feb. 5, 1996) (statement of Sen. Tanner).

<sup>47</sup> 42 U.S.C.S. § 290bb-23(a)(c) (1992) states:

(a) The Secretary, through the Director of the Prevention Center, shall make grants to public and nonprofit private entities for projects to demonstrate effective models for the prevention, treatment, and rehabilitation of drug abuse and alcohol abuse among high risk youth. (c) The Secretary shall ensure that projects under subsection (a) include strategies for reducing the use of alcoholic beverages and tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products.

<sup>48</sup> *Id.* § 290bb-23(e) states:

In order to receive a grant for a project under this section for a fiscal year, a public or nonprofit private entity shall submit an application to the Secretary, acting through the Prevention Center. The

As a result of the Congressional scheme, every state has adopted statutes prohibiting tobacco sales to minors.<sup>49</sup>

### III. THE FDA'S LEGAL AUTHORITY TO ASSERT JURISDICTION OVER CIGARETTES AND SMOKELESS TOBACCO PRODUCTS

#### A. *Nicotine Contained Within Cigarettes and Smokeless Tobacco Products Should be Considered a Drug Within the Provisions of the FDCA*

The FDCA is a federal statute enacted to safeguard the public health and to protect consumer welfare.<sup>50</sup> The Act Gives the FDA the jurisdiction to regulate consumer products, such as foods, drugs, medical devices, biologics, and cosmetics.<sup>51</sup> The FDA has the authority to classify products as drugs where the product is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body."<sup>52</sup> The FDA can regulate a device when it is "intended for use in the cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure of any function of the body."<sup>53</sup> Based on extensive investigation and re-

Secretary may provide to the Governor of the State the opportunity to review and comment on such application. Such application shall be in such form, shall contain such information, and shall be submitted at such time as the Secretary may by regulation prescribe.

<sup>49</sup> 142 CONG. REC. E172, *supra* note 44.

<sup>50</sup> 60 Fed. Reg. at 41463.

<sup>51</sup> 21 U.S.C. §§ 301-394 (1995).

<sup>52</sup> *Id.* § 321 (g)(1)(B), (C). The term "drug" means "(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure of any function of the body of man or other animals . . . ."

<sup>53</sup> *Id.* § 321(h)(2), (3).

The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is — (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) 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 (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal 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 any of its principal



search, the FDA claims that nicotine in cigarettes and smokeless tobacco products is a drug within the meaning of the Act as it is "intended to affect the structure or function of the body." Moreover, the Administration claims that cigarettes and smokeless tobacco products can be regulated as devices because the products are "drug delivery systems whose purpose is to deliver nicotine to the body in a manner in which it can be most readily absorbed."<sup>54</sup>

The FDA interpreted the provisions of the FDCA to "encompass products that intrinsically have pharmacological or physiological effects, even though they are not promoted for therapeutic purposes."<sup>55</sup> Sunscreen products are classified as drugs under the Act since sunscreen products "alter the normal physiological response to solar radiation," despite the fact that they may not be promoted for therapeutic purposes.<sup>56</sup> Tanning booths have also been considered devices by the FDA as they are "intended to affect the structure or function of the body" by exposing the body to ultraviolet rays.<sup>57</sup> Additionally, in *United States v. Undetermined quantities of Cal-Ban 300*,<sup>58</sup> the defendant marketed a product to the public for the purpose of weight reduction, appetite suppression, and prevention of colon cancer, which was classified by the FDA as a drug under the FDCA. The court found that "legislative history indicates that [section 321(g)(1)(c) of the FDCA] was enacted to expand the drug definition beyond those products used exclusively to treat or prevent disease so as to protect the consumers . . . ." <sup>59</sup> Further, the court held that "the term 'drug' should be interpreted broadly and not limited to only products which are commonly known as drugs."<sup>60</sup> Courts, however, have distinguished between remote physical effects which arguably might fall within the literal language of section 201(g)(1)(c) or section 201(h)(3) of the FDCA and significant effects on structure or function which clearly fall within the provisions' ambit.<sup>61</sup>

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intended purposes.

<sup>54</sup> 60 Fed. Reg., at 41346.

<sup>55</sup> *Id.* at 41468.

<sup>56</sup> *Id.* at 41531.

<sup>57</sup> *Id.*

<sup>58</sup> *United States v. Undetermined Quantities of Cal-Ban 3000*, 776 F. Supp. 249 (E.D.N.C. 1991).

<sup>59</sup> *Id.* at 253.

<sup>60</sup> *Id.*

<sup>61</sup> 60 Fed. Reg. at 41469; *see generally* *E.R. Squibb & Sons, Inc. v. Bowen*, 870

There are significant pharmacological and addictive effects caused by tobacco products. Cigarettes and smokeless tobacco products act as drug delivery systems of nicotine. Cigarettes consist of a drug, nicotine, and device components which include tobacco, rolling paper, and filter.<sup>62</sup> "When [nicotine] is inhaled in cigarette smoke, [it] is absorbed into the lungs and then rapidly enters the bloodstream."<sup>63</sup> Smokeless tobacco consists of a mixture of flavored ingredients combined with nicotine-containing tobacco leaves.<sup>64</sup> "In smokeless tobacco, [nicotine] is absorbed through tissues of the mouth or nose and then enters the bloodstream. Once it is in the bloodstream, nicotine crosses the blood-brain barrier and is rapidly distributed to the brain."<sup>65</sup>

Research and studies have proven that "nicotine is a psychoactive drug which affects the brain, the skeletal muscles, the cardiovascular system, and other systems throughout the body."<sup>66</sup> Exposure to nicotine produces lasting changes in the body's structure, which affects the brain's development for tolerance and dependence.<sup>67</sup> The nicotine binds with receptors in the brain which cause the release of other chemicals in the brain that produce ef-

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F.2d 678 (D.C. Cir. 1989). The petitioner manufactured and marketed four oral combination drugs which contained antibiotic tetracycline and antifungal agents. The FDA announced that it would delete from the list of certifiable drugs in its regulations those drugs containing the combination of the petitioners antibiotic and antifungal agents as the drugs act only upon non-human organisms and does not affect the structure or function of the human body. The court held that the "structure or . . . function definition . . . is relatively narrow, and was not intended to encompass all articles that might have some remote physical effect upon the body." *Id.* at 682.

<sup>62</sup> 60 Fed. Reg. at 41347.

<sup>63</sup> *Id.* at 41535.

<sup>64</sup> *Id.* at 41348.

<sup>65</sup> *Id.* at 41535.

<sup>66</sup> *Id.* at 41534. See 60 Fed. Reg. 41492-41493, which states:

the major definitions of addiction, a substance is recognized as producing addiction (dependence) on the basis of studies on human responses to the substance if: the substance is psychoactive such as mood altering; patterns of use are regular and compulsive, despite attempts to quiet and harmful consequences; it causes physical dependence characterized by a withdrawal syndrome; and/or tolerance develops, causing diminished effects after repeated use and increased intake.

<sup>67</sup> Neal L. Benowitz, *Cigarettes and addiction: regulation of tobacco products is inconsistent with their effects on health* Editorial, BRIT. MED. J., April 19, 1995, at 14.

fects on mood, alertness, and cognition.<sup>68</sup>

In 1986, nicotine in smokeless tobacco was declared addictive in a report issued by the Office of the U.S. Surgeon General.<sup>69</sup> In 1988, the Surgeon General issued another report concluding that nicotine in cigarettes and other forms of tobacco is addictive.<sup>70</sup> Nicotine's addictive qualities are compared with illegal substances such as amphetamines and cocaine which all produce pleasurable effects by stimulating the release of dopamine.<sup>71</sup>

In light of nicotine's pharmacological and addictive effects on the body, the FDA asserts that cigarettes and smokeless tobacco products "affect the structure or any function of the body" within the meaning of the FDCA. There are strong public policy reasons to support the FDA's proposal. Tobacco products are used by a large segment of the population, including children and adolescents, at an increasing rate. The protection of our children from this danger should be paramount in the minds of our legislature.

*B. Evidence Suggests that Tobacco Companies Knew that Cigarettes and Smokeless Tobacco Products Containing Nicotine Would Affect the Structure and Function of the Human Body*

It has been well documented, and is commonly understood that nicotine in tobacco products is a highly addictive or dependence-producing substance.<sup>72</sup> Studies show that between 75% and 90% of cigarette users and more than one-third of smokeless tobacco users are addicted to tobacco.<sup>73</sup> Studies also show that 87% of people who use tobacco smoke everyday.<sup>74</sup> "Nearly two-thirds of people who smoke need their first cigarette within the first half-hour after awakening."<sup>75</sup> Additionally, "nearly 15 million peo-

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<sup>68</sup> 60 Fed. Reg. at 41534.

<sup>69</sup> U.S. DEP'T OF HEALTH & HUMAN SERVICES, THE HEALTH CONSEQUENCES OF USING SMOKELESS TOBACCO: A REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL, (1986), discussed in 60 Fed. Reg. at 41541.

<sup>70</sup> U.S. DEP'T OF HEALTH AND HUMAN SERVICES, THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION, REPORT OF THE U.S. SURGEON GENERAL, (1988), Fed. Reg., *supra* note 2 at 41541.

<sup>71</sup> Benowitz, *supra* note 67, at 13.

<sup>72</sup> U.S. DEP'T OF HEALTH AND HUMAN SERVICES, THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION, REPORT OF THE U.S. SURGEON GENERAL, (1988), Fed. Reg., *supra* note 2 at 41542.

<sup>73</sup> 60 Fed. Reg. at 41487.

<sup>74</sup> *Id.* at 41486.

<sup>75</sup> *Id.* at 41486.

ple each year try to stop smoking and approximately 3% actually achieve long-term success."<sup>76</sup> Consumers who abstained from tobacco products experienced withdrawal symptoms such as recurrent cravings for a cigarette and irritability.<sup>77</sup> Nicotine replacement therapies, such as nicotine patches and nicotine gum, have been shown to be effective in controlling withdrawal symptoms.<sup>78</sup> In addition to its addictive effects, nicotine produces significant pharmacological effects, including relaxation, reduction of negative feelings, and weight control.<sup>79</sup>

For over thirty years, tobacco manufacturers have conducted research on nicotine's psychoactive and additive effects.<sup>80</sup> Tobacco industry documents reveal that "the [tobacco] company's researchers used laboratory methods customarily employed in assessing drugs to study the effects of nicotine on smokers, and wrote about what they described as the 'pharmacologic' effects of nicotine."<sup>81</sup> Additionally, tobacco manufacturers conducted studies focusing on the different levels of nicotine in cigarettes to elicit the psychoactive effects sought by tobacco users.<sup>82</sup>

The tobacco industry has sponsored many studies on animals and humans to show the addictiveness of nicotine.<sup>83</sup> In a 1983 study, researchers from the Philip Morris Tobacco Company demonstrated that rats self-administered nicotine and experienced nicotine's psychoactive effects.<sup>84</sup> "Tobacco industry studies have [also] shown that nicotine acts on the mesolimbic system in the brain and triggers the release of the chemical dopamine."<sup>85</sup> The release of chemical dopamine occurs in several significant addictive drugs of abuse including cocaine and amphetamines.<sup>86</sup> A principal scientist of the Philip Morris Tobacco Company stated: "the smoking habit is maintained by the reinforcing effect

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<sup>76</sup> *Id.* at 41486.

<sup>77</sup> *Id.* at 41487.

<sup>78</sup> Philip J. Hiltz, *Nicotine is Addictive, FDA Panel Declares*, INT'L HERALD TRIBUNE, August 4, 1994, at 52.

<sup>79</sup> 60 Fed. Reg. at 41490.

<sup>80</sup> *Id.* at 41491.

<sup>81</sup> Philip J. Hiltz & Glenn Collins, *Records Show Philip Morris Studied Influence of Nicotine*, N.Y. TIMES, June 8, 1995, § A, at 1.

<sup>82</sup> *Id.*

<sup>83</sup> 60 Fed. Reg. at 41493.

<sup>84</sup> Bernice Wuethrich, *Black cloud over tobacco industry; Nicotine*, CHEMISTRY & INDUSTRY, May 2, 1994, at 327, 328.

<sup>85</sup> 60 Fed. Reg. at 41493.

<sup>86</sup> *Id.* at 41493.

of the pharmacologically active components of smoke.”<sup>87</sup> Additionally, research studies found that “nicotine was not just calming or stimulating, but it was having its effect centrally, in the brain, and that people were smoking for brain effects — a mild high that induces craving.”<sup>88</sup> Thus, the tobacco industry’s own research supports the proposition that nicotine is an addictive drug.

The tobacco companies’ internal documents also reveal that the tobacco industry conducted and funded research on the effects of nicotine on the brain. Philip Morris Tobacco Company researchers found that “Nicotine affects the brain, body and behavior, including changing heart rate, intestinal action, endocrine function, brain waves and general arousal . . . . In general, the many effects of smoking come from the action of smoke components on the central nervous system.”<sup>89</sup>

The nicotine content of a tobacco leaf, chemical additives used during processing of the tobacco, and the design of the cigarettes or smokeless tobacco products determine the amount of nicotine that reaches the bloodstream of a smoker.<sup>90</sup> Philip Morris researchers conducted studies to determine if there are ideal levels of nicotine in cigarettes, which could be obtained by altering the blend and the way the tobaccos are processed.<sup>91</sup> A research and development executive for the R. J. Reynolds Tobacco Company stated “[i]f nicotine is the *sine qua non* of tobacco products, and tobacco products are recognized as being attractive dosage forms of nicotine, then it is logical to design our products — and where possible our advertising — around nicotine delivery rather than around tar delivery of flavor.”<sup>92</sup> Researchers have measured nicotine levels in saliva before, during, and after taking a puff of a cigarette including the nicotine levels in the blood of smokers.<sup>93</sup>

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<sup>87</sup> Philip J. Hilt & Glenn Collins, *Records Show Philip Morris Studied Influence of Nicotine*, N.Y. TIMES, June 8, 1995, § A, at 2.

<sup>88</sup> *Id.* at 2.

<sup>89</sup> *Id.* at 3.

<sup>90</sup> 60 Fed. Reg. at 41504.

<sup>91</sup> Philip J. Hilt & Glenn Collins, *Records Show Philip Morris Studied Influence of Nicotine*, N.Y. TIMES, June 8, 1995, § A, at 3.

<sup>92</sup> Philip J. Hilt, *U.S. Convenes Grand Jury To Look at Tobacco Industry*, N.Y. TIMES, July 26, 1995, § A, at 3.

<sup>93</sup> Philip J. Hilt & Glenn Collins, *Records Show Philip Morris Studied Influence of Nicotine*, N.Y. TIMES, June 8, 1995, § A, at 3.

Thus, the FDA contends that physiological, psychological, and pharmacological effects of nicotine addiction are undeniably foreseeable to manufacturers of cigarettes and smokeless tobacco products. The FDA believes that the tobacco companies' own evidence demonstrates that the tobacco companies manufactured their products with the knowledge and intent that nicotine in their products have pharmacological effects on consumers.

*C. Tobacco Manufacturers had the Knowledge and Intended that Their Products have Addictive and Pharmacological Effects*

Evidence suggests that the tobacco manufacturers' own studies and statements support findings that nicotine in tobacco products is addictive and has psychoactive and pharmacological effects on the body.<sup>94</sup> Based on the high foreseeability of consumer addiction to nicotine contained in tobacco products and the manufacturers' own research recognizing the harmful consequences of the use of their products, cigarettes and smokeless tobacco products should be classified as "drugs" and "devices" within the meaning of the FDCA.

1. The FDCA Should be Given an Objective Intent Standard

The FDCA supports the use of an objective intent standard in interpreting the language of the Act because it allows consideration of information about the foreseeable uses of a product's pharmacological purposes, in addition to any claims regarding the use and effects the product may have.<sup>95</sup> An objective intent standard "may be determined by what a reasonable person would understand in the circumstances presented or whether a reasonable person would believe that the defendant's conduct would lead to certain events."<sup>96</sup> In construing statutory language, courts have held that such language imposes an objective intent standard.<sup>97</sup> Allowing a subjective interpretation of the phrases "intended for use" and "intended to effect" would undermine the FDCA focus on consumer welfare and public health protection. Such an interpretation would limit the relevant evidence to what is in the

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<sup>94</sup> 60 Fed. Reg. at 41491.

<sup>95</sup> *Id.* at 41473.

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

<sup>97</sup> See generally *United States v. Undetermined Quantities Of Bottles*, 22 F.3d 235, 239 (10th Cir. 1994).

mind of the manufacturer or vendor as shown by express representations, promotional claims, or otherwise, thereby frustrating the legislative policy goals.<sup>98</sup>

In *N. Jonas and Co., Inc. v. United States Environmental Protection Agency*,<sup>99</sup> the petitioners produced and distributed a product labeled for swimming pool sanitation and maintenance without registering it as a pesticide.<sup>100</sup> The petitioners represented that the product's "intended use" could be determined by the company's express representations concerning the product.<sup>101</sup> The Environmental Protection Agency argued that the "intended use" provision of the statute should be based on the use of a reasonable consumer under "the collectivity of the circumstances."<sup>102</sup> The court held that the statutory phrase "intended use" can be interpreted using an objective intent standard based on the reasonable consumer's belief in the use of the product. Further, the court stated that "in determining intent objectively, the inquiry cannot be restricted to a product's label and to the producer's representations."<sup>103</sup>

Similarly, in *United States v. Focht*,<sup>104</sup> the appellees sold component parts of fireworks in a national mail order catalog in violation of the Federal Hazardous Substances Act (the "Act").<sup>105</sup> The purpose of the Act was to protect the general public from extremely hazardous products.<sup>106</sup> The court held that the "intended use" language in the Act encompassed all foreseeable uses by reasonable consumers and should be defined objectively.<sup>107</sup> Moreover, the court based its holding on the evidence that parts were likely to be used by consumers to make banned fireworks rather than for legal purposes.<sup>108</sup>

Thus, the FDA believes that an objective intent standard should be used in interpreting the provisions of the FDCA as such a

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<sup>98</sup> 60 Fed. Reg. at 41473.

<sup>99</sup> *N. Jonas & Co., Inc. v. United States Env'tl. Protection Agency*, 666 F.2d 829 (3rd Cir. 1981).

<sup>100</sup> *Id.* at 830.

<sup>101</sup> *Id.* at 831-832.

<sup>102</sup> *Id.* at 833.

<sup>103</sup> *Id.*

<sup>104</sup> *United States v. Focht*, 882 F.2d 55 (3rd Cir. 1989).

<sup>105</sup> *Id.* at 57. See generally 15 U.S.C. § 1261 (1982 & Supp. V 1987).

<sup>106</sup> *Id.* at 58.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.* at 59, 60.

standard would comport with Congressional intent in enacting the Act.

*D. Case Law Interpreting the FCLAA Suggests that Congress Did Not Intend to Preclude Regulation of the Tobacco Industry by the FDA*

The primary purpose of Congress in enacting the FCLAA was to ensure uniformity and enforceability over the regulation of cigarette labeling and advertisements.<sup>109</sup> The Act contained a preemption provision that prohibited states from imposing their own labeling requirements when cigarette packages contained labeling which conformed with the provisions of the Act.<sup>110</sup>

Several cases interpret the FCLAA preemption provision to apply only to state regulations and do not prohibit against federal regulation.<sup>111</sup> In *Banzhaf v. Federal Communications Commission*,<sup>112</sup> the court held that the preemption provision does not prohibit the Federal Communications Commission from requiring radio and television stations to broadcast anti-smoking messages.<sup>113</sup> The court stated that "nothing in the Act indicates that Congress had any intent at all with respect to other types of regulation by other agencies — much less that it specifically meant to foreclose all such regulation."<sup>114</sup> Additionally, the Supreme Court in *Cipollone v. Liggett Group Inc.*<sup>115</sup> considered whether the FCLAA preempted an action by an individual against three cigarette companies on theories of strict liability, negligence, express warranty and intentional torts.<sup>116</sup> The court found that the FCLAA preemption provision "only preempt[s] state and federal rule making cautionary statements" and held that preemption provisions do not constitute an absolute prohibition against all federal and state action.<sup>117</sup>

Recently, the California Supreme Court in *Mangini v. R.J. Reynolds Tobacco Co.*,<sup>118</sup> considered whether the FCLAA preempted a

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<sup>109</sup> 15 U.S.C.S. § 1334 (1965).

<sup>110</sup> *Id.*

<sup>111</sup> See generally, *Banzhaf v. Fed. Communications Comm'n*, 405 F.2d 1082 (D.C. Cir. 1968), *cert. denied*, 396 U.S. 842. See generally, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

<sup>112</sup> 405 F.2d 1082.

<sup>113</sup> *Id.* at 1087, 1088.

<sup>114</sup> *Id.* at 1089.

<sup>115</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

<sup>116</sup> *Id.* at 509.

<sup>117</sup> *Id.* at 519.

<sup>118</sup> *Mangini v. R.J. Reynolds Tobacco Co.*, 875 P.2d 73 (Cal. 1994).



state court action seeking to prohibit cigarette advertising targeted at minors from engaging in an unlawful, unfair, or fraudulent business acts or practice by using unfair, deceptive, untrue, or misleading advertising.<sup>119</sup> The petitioners alleged that R.J. Reynolds' advertisement cartoon character, Old Joe Camel, was targeted at minors for the purpose of inducing and increasing their illegal purchases of cigarettes.<sup>120</sup> The court found that in allowing the petitioners' state law claim to proceed it would not violate the Congressional preemption policy.<sup>121</sup> Furthermore, the court held that "a cause is preempted by the FCLAA only if it is covered by the express language of section 1334(b)."<sup>122</sup> The court also noted that "[C]ongress left the states free to exercise their police power to protect minors from [advertisements] that encourage[s] them to violate the law."<sup>123</sup> Thus, the court found that the petitioners' cause of action would not be preempted by the FCLAA.<sup>124</sup>

Case law interpretation of the FCLAA preemption provision indicates that Congress did not intend to preclude regulation of the tobacco industry by other federal agencies. Applying this interpretation, the FDA could invoke jurisdiction and not be precluded from regulating nicotine as a "drug" under the FDCA.

#### IV. TOBACCO COMPANIES MAINTAIN THAT LEGAL AUTHORITY PROHIBITS THE FDA FROM ASSERTING JURISDICTION OVER CIGARETTE AND SMOKELESS TOBACCO PRODUCTS

##### A. *Legislative History*

Tobacco companies maintain that the FDA's proposal to regulate cigarettes and smokeless tobacco products is unacceptable because the agency has no legal authority to regulate tobacco products.<sup>125</sup> The tobacco companies claim that Congress has on at least twenty different occasions specifically rejected proposed

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<sup>119</sup> *Id.* at 73.

<sup>120</sup> *Id.* at 78.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.* at 78.

<sup>123</sup> *Id.* at 83.

<sup>124</sup> *Id.*

<sup>125</sup> *Federal Document Clearing House, Inc.: Tobacco Industry's Comments on the FDA Proposed Regulation of Tobacco Products, in Washington, D.C.* (interview with Steven Parrish and others, Jan. 2, 1996) (transcript on file with FDCH) [hereinafter *Federal Document Clearing House, Inc.*].

legislation to grant FDA jurisdiction over tobacco products.<sup>126</sup> The tobacco companies believe that Congress enacted a comprehensive regulatory approach for tobacco products which specifically excluded the FDA's role in the regulation of cigarettes and smokeless tobacco products.<sup>127</sup> Moreover, Congress has recently passed legislation to allow the states to enact and enforce laws to curb tobacco sales to minors, thus ignoring any potential FDA role in regulating tobacco products.<sup>128</sup>

For nearly ninety years, Congress has on at least twenty different occasions rejected proposed bills to authorize FDA jurisdiction over tobacco products.<sup>129</sup> Several proposed bills have included measures requesting that the FDA be given authority to regulate tobacco products in order to promulgate standards for cigarette manufacturing and establish tolerance levels for toxic substances in cigarette smoke.<sup>130</sup> Additionally, proposed bills have asserted that since the FDA can limit the nicotine content in food, it should also be allowed some measure of control over tobacco products that contain nicotine.<sup>131</sup> Congress, however, refuses to allow the FDA regulation of tobacco products because "it is and has long been the clear mandate of the Congress that the basic regulation of tobacco and tobacco products is governed by the legislation dealing with the subject, and that any further regulation . . . be reserved for specific Congressional action."<sup>132</sup>

Additionally, in 1989, the Tobacco and Nicotine Health and Safety Act, was introduced into Congress in order to amend the FDCA.<sup>133</sup> The purpose behind the Act was to permit the federal government to take a role in regulating the sale of tobacco products.<sup>134</sup> Congress, however, rejected the bill. When the bill was re-

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<sup>126</sup> *Id.*

<sup>127</sup> THE TOBACCO INSTITUTE, CIGARETTE COMPANIES FILE COMMENTS ON FDA PROPOSED RULES, (JAN. 2, 1996).

<sup>128</sup> *Federal Document Clearing House, Inc.*, *supra* note 121.

<sup>129</sup> 140 CONG. REC. E2184 (daily ed. Oct. 8, 1994) (statement of Sen. Boehner).

<sup>130</sup> H.R. 279, 96th Cong., 1st Sess. (1979), S. 1682, 88th Cong., 1st Sess. (1963), H.R. 5973, 88th Cong., 1st Sess. (1963), H.R. 7168, 95th Cong., 1st Sess. (1977).

<sup>131</sup> H.R. 5973, 88th Cong., 1st Sess. (1963)

<sup>132</sup> 140 CONG. REC. E2184 (daily ed. Oct. 8, 1994) (statement of Sen. Boehner).

<sup>133</sup> S. 769, 101st Cong., 1st Sess. (1989).

<sup>134</sup> *Id.*, The act would do the following: (1) provide the Secretary of the Department of Health and Human Services with the authority to reduce the levels

vised in 1992, it proposed that the FDA be given jurisdiction to regulate nicotine, additives, and other constituents in tobacco products, or sales of cigarettes to minors.<sup>135</sup> The bill was again rejected by Congress, since there was no statute or expression of congressional intent to authorize jurisdiction to the FDA over tobacco products.<sup>136</sup>

In 1995, a bill was sponsored in direct response to the FDA's proposed regulation of cigarettes and smokeless tobacco products.<sup>137</sup> The proposed legislation would prohibit the FDA or any agent of the Department of Health and Human Services from regulating the sale or use of tobacco products.<sup>138</sup> The bill asserts that Congress, when it enacted the FCLAA, declared that the Act be set up as a comprehensive federal program to deal with cigarette labeling and advertising.<sup>139</sup> Further, the language of the FCLAA suggests that actions not plainly authorized by the Act are beyond the powers of the executive branch (such as the FDA).<sup>140</sup> Thus, the tobacco companies believe that the FDA has no legal authority to assert jurisdiction over tobacco products because the FDA attempted to issue regulations without express authority from Congress.<sup>141</sup>

Historically, tobacco products have been subject to direct regulation by Congress.<sup>142</sup> The tobacco companies assert that the FDA's proposal to regulate cigarettes and smokeless tobacco products is just another attempt to assume powers rightfully reserved

of harmful additives to tobacco products or prohibit the use of those additives entirely, (2) provide the FDA with authority to regulate non-tobacco products that contain nicotine which shall be categorized as drugs, (3) require the tobacco manufacturers fully disclose the chemical additives in tobacco products, (4) prohibit the distribution of free samples and coupons for cigarettes.

<sup>135</sup> 138 CONG. REC. E483 (daily ed. Feb. 27, 1992) (statement of Rep. Synar). The Act would do the following: (1) create a new section in the FDCA authorizing FDA regulation of tobacco products. (2) require tobacco manufacturers to fully disclose all chemical additives in tobacco products, (3) give the FDA the authority to reduce the level of harmful additives or to prohibit the use of those additives altogether, (4) prohibit the sale of tobacco products to any person under the age of 18.

<sup>136</sup> 142 CONG. REC. E172 (daily ed. Feb. 5, 1996) (statement of Rep. Tanner).

<sup>137</sup> 141 CONG. REC. E1736 (daily ed. Sept. 7, 1995) (statement of Rep. Payne.)

<sup>138</sup> *Id.*

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.*

<sup>142</sup> 140 CONG. REC. E2184 (daily ed. Oct. 8, 1994) (statement of Sen. Boehner).

by Congress and the individual states.<sup>143</sup> The tobacco companies believe that previous legislative enactments provide a comprehensive regulatory approach for tobacco products and illustrate Congress' intent to reserve for itself the authority to regulate tobacco products without involving the FDA.<sup>144</sup> The ADAHMA Reorganization Act,<sup>145</sup> which directed the states to enact and enforce their own laws prohibiting tobacco sales to minors, demonstrates congressional intent to allow the states the primary responsibility for handling tobacco sales to minors. Moreover, the FDA Commissioner's own statements suggest that cigarettes should be subject to direct regulation by Congress.<sup>146</sup> The tobacco companies claim that legislative history clearly illustrates that Congress never intended to give the FDA the jurisdiction to regulate tobacco products. Congress, however, would never have intended that the FDA abrogate its responsibility to control the use and distribution of drugs where the states fail to comply with the ADAHMA Reorganization Act. States may be tempted to forgo regulation of tobacco products as a result of huge donations by tobacco companies. Thus, allowing the FDA the authority to regulate cigarettes and smokeless tobacco products will ensure uniformity and enforceability over the control and distribution of tobacco products to minors.

### *B. Case Law*

Courts recognized the FDA's assertions of jurisdiction over tobacco as a drug, when health claims were made by the vendors or manufacturers of tobacco products.<sup>147</sup> In the past, the FDA rejected petitions to regulate cigarettes containing nicotine on the basis that nicotine did not fall within the meaning of a drug as defined in the FDCA.<sup>148</sup> The FDA maintains that cigarettes do not

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<sup>143</sup> 142 CONG. REC. E172 (daily ed. Feb. 5, 1996) (statement of Rep. Tanner).

<sup>144</sup> *Id.*

<sup>145</sup> 42 U.S.C.S. § 290bb-23(a)(c) (1996).

<sup>146</sup> 141 CONG. REC. E1658 (daily ed. Aug. 5, 1995) (statement of Rep. Tanner). In 1972, FDA Commissioner Charles Edwards testified that: "The regulation of cigarettes is to be the domain of Congress." In 1994, FDA Commissioner Dr. Kessler wrote anti-smoking groups, stating: "We recognize that the regulation of cigarettes raises societal issues of great complexity and magnitude. It is vital in this context that Congress provide clear direction to the Agency."

<sup>147</sup> See generally *United States v. 46 Cartons*, 113 F. Supp. 336 (1953), See also *United States v. 354 Bulk Cartons*, 178 F. Supp. 847 (1959).

<sup>148</sup> *Action On Smoking And Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

fall within the provisions of the FDCA absent evidence of vendor or manufacturer representations that their products are intended to affect the structure or any function of the body.<sup>149</sup> Case law suggests that if Congress intended that tobacco products be included as an article within the FDCA, it would have specified tobacco products within the provisions.<sup>150</sup>

In *United States v. 46 Cartons, More Or Less, Containing Fairfax Cigarettes*,<sup>151</sup> the claimant shipped cigarettes with leaflets suggesting that the cigarettes were effective in preventing respiratory and other diseases.<sup>152</sup> The FDA argued that the statements in the leaflets suggested that cigarettes were an effective drug in preventing diseases and thus, should be classified as a drug within the meaning of the FDCA.<sup>153</sup> Based upon the representations in the leaflets, the court held that the cigarettes were a drug within the FDCA, and allowed the FDA to regulate them.<sup>154</sup> Further, the court stated "[t]he clear import of the leaflet is at least that the smoking of the cigarettes will make it less likely that the smoker will contract colds or other virus infections. This is enough to bring the product within the statutory meaning of 'drug.'"<sup>155</sup>

Additionally, in *United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes*,<sup>156</sup> the claimant labeled its cigarettes as Trim Reducing-Aid Cigarettes. The packages on the cigarettes guaranteed success in weight reduction.<sup>157</sup> The FDA argued that the cigarettes contained a combustible tartaric acid that was known not to be safe for use in cases of obesity.<sup>158</sup> Further, the FDA contended that the cigarettes were misbranded and should be classified as a drug within the meaning of the FDCA.<sup>159</sup> The court held that the FDA had jurisdiction over the cigarettes because of the vendor's claims that cigarettes were effective in reducing weight

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<sup>149</sup> *Id.* at 239.

<sup>150</sup> *Fed. Trade Comm'n v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573, 577 (S.D.N.Y. 1952).

<sup>151</sup> *United States v. 46 Cartons*, 113 F. Supp. 336 (1953).

<sup>152</sup> *Id.* at 337.

<sup>153</sup> *Id.*

<sup>154</sup> *Id.* at 338-339.

<sup>155</sup> *Id.* at 339.

<sup>156</sup> *United States v. 354 Bulk Cartons*, 178 F. Supp. 847 (1959).

<sup>157</sup> *Id.* at 849.

<sup>158</sup> *Id.* at 848.

<sup>159</sup> *Id.*

gain.<sup>160</sup>

Both of these cases indicate that the FDA has successfully asserted jurisdiction over tobacco products under the FDCA in the past. However, this jurisdiction is limited to situations where the manufacturers or vendors have expressly claimed health benefits from smoking cigarettes.

In *Action On Smoking And Health v. Harris*,<sup>161</sup> the appellants filed a petition with the FDA requesting that the agency assert jurisdiction over cigarettes containing nicotine as a "drug" or a "device" under the FDCA.<sup>162</sup> The FDA refused, however, to assert jurisdiction over cigarettes based upon the agency's consistent position that cigarettes will not be deemed a drug unless health claims are made by the vendors or manufacturers.<sup>163</sup> Further, Commissioner of the FDA stated that "labeling or banning cigarettes is a step that can be taken only by Congress."<sup>164</sup> The court held that the FDA's refusal to assert jurisdiction over cigarettes under the FDCA was not "arbitrary or capricious in light of the consistent administrative and judicial emphasis upon manufacturer and vendor intent . . . ."<sup>165</sup> Furthermore, the court stated that "if the statute requires expansion, that is the job of Congress."<sup>166</sup>

Additionally, in *Federal Trade Commission v. Liggett & Meyers Tobacco Co.*,<sup>167</sup> the Federal Trade Commission (FTC) sought to enjoin the dissemination of allegedly false advertising of cigarettes.<sup>168</sup> The defendant's advertisement stated that "Chesterfield cigarettes can be smoked by any smoker without inducing any adverse affect upon the nose, throat, and accessory organs of the smoker."<sup>169</sup> The FTC argued that the defendant's advertisement affirmatively claimed a therapeutic purpose for Chesterfield cigarettes, thereby making it a drug within the meaning of the Federal Trade Commission Act.<sup>170</sup> The court held that the FTC

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<sup>160</sup> *Id.* at 852.

<sup>161</sup> *Action on Smoking and Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

<sup>162</sup> *Id.* at 239.

<sup>163</sup> *Id.* at 237.

<sup>164</sup> *Id.* at 241.

<sup>165</sup> *Id.* at 242.

<sup>166</sup> *Id.*

<sup>167</sup> *Fed. Trade Comm'n v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573 (S.D.N.Y. 1952).

<sup>168</sup> *Id.*

<sup>169</sup> *Id.* at 573.

<sup>170</sup> *Id.* at 574.

lacked jurisdiction to classify cigarettes as a drug since it is the job of Congress to determine if cigarettes should be regulated as a drug.<sup>171</sup> The court stated as follows:

The legislative history, such as it is, coupled with indications of contemporaneous administrative interpretation leads me to the conclusion that Congress, had the matter been considered, would not have intended cigarettes to be included as an article "intended to affect the functions of the body of man" or in any other definition of "drug."<sup>172</sup>

The holdings in both these cases suggest that the FDA's authority to regulate tobacco products should not go beyond the literal interpretations of the FDCA.<sup>173</sup> Rather, it is the legislators' job to determine if a statute requires expansion. The tobacco companies believe that the FDA lacks the legal authority to classify cigarettes or smokeless tobacco products that contain nicotine as a "drug" or a "device" within the FDCA. Several cases, however, have given a broad interpretation to the provisions of the FDCA in order to protect consumers from the dangerous effects of drugs.<sup>174</sup> Thus, the harmful pharmacological and addictive effects of nicotine in cigarettes and smokeless tobacco products would clearly constitute a drug within the parameters of the FDCA.

#### CONCLUSION

In light of the detrimental effects that cigarettes and smokeless tobacco products have on our nation's children and adolescents, FDA regulation of this product has been mandated. The FDA was established by Congress for the primary purpose of safeguarding our society against the use of harmful drugs. The FDA's major function is to regulate and control the distribution and consump-

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<sup>171</sup> *Id.* at 577.

<sup>172</sup> *Id.*

<sup>173</sup> *Id.* at 576. The court stated:

Anything which stimulates any of the senses may be said, in some perhaps insignificant degree, to affect the functions of the body of man. Consequently any article which, used in the manner anticipated by the manufacturer thereof, comes into contact with any of the sense may be said to be an article intended to affect the functions of the body of man . . . Surely, the legislature did not mean to be as all-inclusive as literal interpretation of this clause would compel us to be.

<sup>174</sup> *United States v. Undetermined Quantities of Cal-Ban 3000*, 776 F. Supp. 249 (E.D.N.C. 1991).

tion of drugs within the United States. Congress enacted the FDCA to provide the FDA with the necessary impetus and authority to regulate drugs. Cigarettes and smokeless tobacco products contain nicotine which has been unequivocally established as a highly addictive drug.<sup>175</sup> Additionally, numerous studies have revealed that the nicotine in tobacco products cause pharmacological and psychoactive effects on the body.<sup>176</sup> Therefore, the FDA must have the authority to regulate and control the use of cigarettes and smokeless tobacco products.

Opponents of the FDA's proposal contend that Congress, under the ADAHMA Reorganization Act, directed the states to enact and enforce their own laws prohibiting the distribution and use of tobacco products to minors.<sup>177</sup> This argument, however, loses sight of the fact that Congress would never have intended that the FDA abrogate its responsibility to control the use and distribution of drugs where the states fail to comply with the ADAHMA Reorganization Act. Congress created the FDA to address serious regulatory problems facing our nation. Allowing each state the ability to enact their own individual laws will ultimately lead to a lack of uniformity and enforceability over the control and distribution of tobacco products to minors. States may be tempted to forego regulation in this critical area as a result of falling prey to huge donations by tobacco companies.

The FDA's goal in making the proposal is to decrease the use and consumption of cigarettes and smokeless tobacco products among a segment of our society most vulnerable and susceptible to the use of this addictive drug.<sup>178</sup> This goal is best achieved by limiting access and reducing appeal of cigarettes and smokeless tobacco products to minors.<sup>179</sup>

Numerous studies and experiments have been conducted by the tobacco industry to learn of the effects that nicotine has on the human body.<sup>180</sup> This research conclusively establishes that the nicotine contained within tobacco products has the same harmful effects on the brain, as do many dangerous and illegal drugs such

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<sup>175</sup> UNITED STATES DEP'T OF HEALTH & HUMAN SERVICES, THE HEALTH CONSEQUENCES OF USING SMOKELESS TOBACCO: A REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL, (1986), discussed in 60 Fed. Reg. at 41484.

<sup>176</sup> 60 Fed. Reg. at 41487.

<sup>177</sup> 42 U.S.C.S. § 290bb to 23(a)(c) (Law. Co-op. Supp. 1996).

<sup>178</sup> *Id.* at 41322.

<sup>179</sup> *Id.*

<sup>180</sup> 60 Fed. Reg. at 41493.



as cocaine and amphetamines.<sup>181</sup> The FDA has regulated products with less directly harmful pharmacological effects than tobacco, such as topical hormones, sunscreens and tanning booths. The physiological, psychological, and pharmacological effects of nicotine on the body are equal to, if not greater than, products presently regulated by the FDA.

Nicotine is an addictive, harmful, and dangerous drug. It must be regulated by the FDA, since it falls within the parameters of the FDCA. Delegation of this responsibility to the FDA would be a monumental step forward in assuring that our nation's precious youth can be protected from the harmful and addictive consumption of cigarettes and smokeless tobacco products.

BRIAN L. SOTTILE

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<sup>181</sup> *Id.*