actions." Lee v. Lee County Bd. of Ed., 639 F.2d 1243, 1267 (5th Cir. 1981).[4]

Subsection A, infra, demonstrates that an objective intent standard is the appropriate standard under the FDCA. The evidence in subsection B, infra, demonstrates that tobacco manufacturers "intend" cigarettes and smokeless tobacco products to affect the structure or any function of the body within the meaning of the FDCA.

A. OBJECTIVE INTENT IS THE APPROPRIATE STANDARD.

The FDCA is a consumer protection statute which has as its explicit purpose the "prohibit[ion of] the movement in interstate commerce of adulterated and misbranded foods, drugs, devices, and cosmetics." Pub. L. No. 75-717, 75th Cong. 3d. Sess. (1938); see also H.R. Rep. No. 2139 at 1-2, reprinted in 6 Legislative History at 300-01 ("this act seeks to set up effective provisions against abuses of consumer welfare"; "the old law . . . contains serious loopholes [and] is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions"; the 1938 Act "amplifies and strengthens the provisions [of the 1906 act] designed to safeguard the public health and prevent deception, and it extends the scope of the old law to include . . . certain drugs that now escape regulation").

Given the Act's focus on consumer welfare and public health protection, interpreting

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[4] Subjective intent, on the other hand, considers the actual state of mind of the responsible actor. *See, e.g.*, Ellington v. Metropolitan Life Ins. Co., 696 F. Supp. 1237, 1242 (S.D. Ind. 1988) (a subjective intent test requires a determination that the defendant actually foresaw the result of his conduct and persisted nonetheless). This standard, which focuses on the actor's actual desires and knowledge, has been applied in certain areas of criminal law when the critical issue is the culpability of a particular actor. *See, e.g.*, Morisette v. United States, 342 U.S. 246, 250-52 (1952). It is not used as a standard of proof for intent in public health and welfare statutes such as the FDCA.

the phrases "intended for use" and "intended to affect" to require a showing of subjective intent -- which would limit the relevant evidence to what is in the mind of the manufacturer or vendor as shown by express representations, promotional claims, or otherwise -- would frustrate those legislative policy goals. As one court found, in determining that an objective intent standard is appropriate in construing a consumer protection statute: "[t]he subjective interpretation of intent urged by claimant could seriously diminish the effectiveness of FHSA [the Federal Hazardous Substances Act] because it would enable a manufacturer to introduce dangerous articles into commerce on the unreasonable but good faith belief that the articles would not be used by children." Baby Rattles, 614 F. Supp. at 232. The court further noted that "the language of the FHSA . . . nowhere speaks specifically of the manufacturer's subjective intent," and that a subjective intent standard could not possibly comport with Congress' intent in enacting the FHSA. Id. 231-32. The same reasoning extends to the Federal Food, Drug, and Cosmetic Act. The language and purposes of the FDCA support an objective intent standard that allows consideration of information about the foreseeable uses of the product for pharmacological purposes, as well as any statements or actions by the vendor that might show the vendor's actual purpose in marketing a product, or refute the vendor's claims regarding the product's intended use.

Although the FDCA is not primarily a criminal statute designed to punish law breakers, it does include criminal penalties to enforce its provisions. See, e.g., 21 U.S.C. § 333. It is relevant that the Act imposes a strict liability standard that is applicable to criminal prosecutions and assesses criminal liability even where there is no evidence of actual knowledge of the alleged conduct on the part of the corporate defendant. 21 U.S.C. § 331;

see United States v. Dotterweich, 320 U.S. 277, 280-81 (1943); United States v. Park, 421 U.S. 658, 670-73 (1975); see also Smith v. California, 361 U.S. 147, 152 (1959) (some penal statutes "dispense with any element of knowledge on the part of the person charged, food and drug legislation being a principal example . . . . The usual rationale for such statutes is that the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors -- in fact an absolute standard which will not hear the distributor's plea as to the amount of care he has used.").

Moreover, FDA's regulations interpreting sections 201(g)(1) and 201(h), which were adopted after notice and comment rulemaking, and therefore have the force and effect of law, explicitly adopt an objective intent standard. Those regulations, which were originally promulgated in 1952, describe the evidence relevant to determining intent to include:

> *such [manufacturers' or vendors'] expressions or . . . by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such [manufacturers or vendors] or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such [manufacturers or vendors] or their representative, offered and used for a purpose for which it is neither labeled nor advertised . . .*

21 C.F.R. § 201.128 (1994) (drugs) (emphasis added); see 21 C.F.R. § 801.4 (1994) (parallel provision for devices); see also 17 Fed. Reg. 6818 (July 24, 1952). Thus, under these regulations, evidence of objective intent is not limited to expressions in labeling or advertising, but may be based on the totality of the relevant evidence showing the seller's awareness of how its product is actually used and affects the structure or function of the body, regardless of how the product is labeled or advertised.

The foregoing interpretation of the statutory language is also consistent with FDA's

regulatory policy decisions and actions. As demonstrated in the Appendix to Legal Analysis, FDA has used both general knowledge and recognition of products' nature and effects, as well as their actual uses and effects, to determine whether products fall within the statutory definitions of drug or device.

FDA has used the known or inherent pharmacological effects of particular ingredients to determine that products are "intended to affect the structure or any function of the body," even where there are no public expressions by the seller that the product is to be used for those effects. See Appendix to Legal Analysis. For example, in the context of a proposed rule on vaginal products for over-the-counter use, the Agency stated:

> *If an active ingredient is present in a therapeutic concentration, the product is a drug, even if that product does not claim to produce the effect which will result from the action of the therapeutically effective ingredient.*

48 Fed. Reg. 46694, 46701 (October 13, 1983). In its tentative conclusion to comments on this issue, the Agency reiterated:

> *[t]he type and amount of ingredient(s) present in a product, even if that product does not make explicit drug claims, must be considered in determining its regulatory status. For example, the mere presence of a pharmacologically active ingredient could make a product a drug even in the absence of explicit drug claims. In these cases, the intended use would be implied because of the known or recognized drug effects of the ingredient (e.g., fluoride in a dentifrice).*

59 Fed. Reg. 5226, 5227 (February 3, 1994) (emphasis added).

Thus, products containing ingredients or components with known pharmacological effects, including fluoride and hormones, have -- on that basis alone and in the absence of express claims -- been determined to be "intended to affect the structure or function of the body" because they contained a pharmacologically active ingredient. See Appendix to Legal

Analysis. FDA has also regulated as devices products that affect the structure or function of the body, even when the vendor makes no claims regarding the products. For example, FDA regulates as devices noncorrective tinted contact lenses that are expressly promoted only for their cosmetic effect of enhancing eye color because they have physiological effects on the eye. See Appendix to Legal Analysis.

The courts have consistently held that the statutory language imposes an objective intent standard. United States v. Undetermined Quantities . . . "Pet Smellfree", 22 F.3d 235, 236, 239 (10th Cir. 1994) (referring to "objective intent" in the context of considering whether a product is a drug); United States v. Kasz Enterprises, Inc., 855 F. Supp. 534, 542 (D.R.I. 1994) ("it is the objective intent of the vendor, not the vendor's subjective explanations and disclaimers, which determines the intended use of a product") (emphasis added), judgment modified on other grounds, 862 F. Supp. 717 (D.R.I. 1994); Clinical Reference Laboratory v. Sullivan, 791 F. Supp. 1499, 1506 n.8 (D. Kan. 1992) ("intended use . . . depends upon the objective intent of the persons responsible for its labeling") (emphasis added), aff'd in relevant part, rev'd in part on other grounds sub nom., United States v. An Undetermined Number of Unlabeled Cases, 21 F.3d 1026 (10th Cir. 1994); United States v. Two Plastic Drums, 761 F. Supp. 70, 72 (C.D. Cal. 1991) ("In determining . . . intended use . . , the inquiry should focus on the vendor's objective intent") (emphasis added); United States v. Articles of Drug . . . Neptone, No. C-83-0864-EFL, CCH Food and Drug Reporter ¶ 38,240 at 39,294 (N.D. Cal. October 25, 1983) ("objective manifestations of intent are clearly sufficient").

The Environmental Protection Agency (EPA) and the Consumer Product Safety

Commission (CPSC) have also adopted an objective intent standard in construing similar provisions in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Hazardous Substances Act (FHSA), and courts have uniformly upheld those interpretations. See e.g., N. Jonas & Co. Inc. v. EPA, 666 F.2d 829, 833 (3d Cir. 1981); United States v. Focht, 882 F.2d 55, 58-60 (3d Cir. 1989); Baby Rattles, 614 F. Supp. at 231-32. Judicial constructions of those statutes demonstrate that evidence of actual consumer use, knowledge by the manufacturer of such actual use, general knowledge about the effectiveness of the product for a particular use, and other circumstances surrounding its distribution, can be used to determine the "intended use" of a product for purposes of a public welfare statute such as the FDCA.

In Jonas, the issue was whether "Scorch," a product labeled for swimming pool sanitation and maintenance, was a pesticide. The product's label contained a disclaimer stating: "Scorch is not to be used for daily disinfection or algae control of your pool." 666 F.2d at 831. The manufacturer contended that a product's intended use can be determined only from the company's express representations concerning the product. Id. at 832. EPA took the position that "intended use" should be based on the use to which a reasonable consumer would put the product based on "the collectivity of the circumstances." EPA also argued that "[t]he fact that the product may have other uses does not affect" whether it qualifies as a pesticide. Id. The court, relying in part on cases under the FDCA, agreed with EPA and held that the statutory phrase "intended use" refers to objective intent and, as a result, the manufacturer "intends those uses to which the reasonable consumer will put its products." Id. at 832-33.

In deciding whether sufficient evidence exists to support a finding of objective intent, the court in Jonas stated that "the inquiry cannot be restricted to a product's label and to the producer's representations." Id. at 833. Instead, the court determined that relevant evidence could come from, among other things, "general public knowledge" of the usefulness of similar products as pesticides, the "effectiveness" of the product for a pesticidal use (that is, its actual inherent effects), and the collectivity of all the circumstances. Id.

Similarly, in Baby Rattles, the court held that the phrase "any toy or other article intended for use by children" in 15 U.S.C. § 1261(f)(1)(D) requires application of an objective intent standard, and that this standard is met if evidence exists that "a reasonable person would believe that the object is a toy or article intended for use by children." 624 F. Supp. at 231. The court found that this standard was met with respect to a rattle marketed by the manufacturer as a "party favor" based on "evidence of its use as a toy and the common sense observation that children would be likely to use it as a toy." Id. at 231 n.9.

The court observed that even if it accepted the manufacturer's argument that the "intended use" language in the FHSA should be interpreted as requiring a subjective intent standard, such intent would have been established by evidence that the manufacturer knew that its rattles were used on babies' shoes and were given as gifts at baby showers: "[C]laimant could not possibly have ignored the possibility that children would use the rattles, regardless of whether he intended such use of the rattles and whether reasonably prudent parents would give such objects to their children." Id.

Finally, in Focht, component parts of fireworks sold by the Fochts were held to have been "intended to produce banned fireworks" under the FHSA, based on evidence that the

parts were likely to be used by consumers to make banned fireworks, and despite evidence that the components could also be used for numerous legal purposes. An expert testified at trial that 90% of consumers who purchased the components in question would use them to make illegal fireworks, and that, if the components were filled in the "traditional manner," they would contain over the legal limit of explosive. 882 F.2d at 59-60. The court held that "[i]ntended use . . . objectively defined, necessarily encompasses foreseeability" and that this testimony made it "foreseeable that the components in question will be used to build banned fireworks. Such knowledge must be attributed to the Fochts." Id. at 60. Accordingly, a finding that a product is intended to affect the structure or function of the body may be appropriately based on evidence that use of a product leading to such effects in a large proportion of consumers is foreseeable.

Objective intent may also be established by evidence, alone or in combination with other evidence, that consumers use a product for pharmacological purposes. See Action on Smoking and Health [ASH] v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980) (consumer use may be relevant source of evidence of intended use); National Nutritional Foods Assn [NNFA] v. Mathews, 557 F.2d 325, 333-34 (2d Cir. 1977) (product's use for therapeutic purposes was evidence of intended use); United States v. Two Plastic Drums, 761 F. Supp. 70, 72 (C.D. Cal. 1991) (consumer use is relevant to intended use); see also Medical Devices Amendments of 1976, H.R. Rep. 94-853, 94th Cong., 2d Sess. at 14 (1976) (in interpreting "intended for use" and "intended to affect," FDA "may consider the ultimate destination of a product . . . just as [it] may consider actual use of a product"); Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Proposed Rule, 58 Fed. Reg.

28194, 28204 (May 12, 1993) (objective evidence of intent may be derived from "the consumer's intent in using the product").

In ASH, the D.C. Circuit stated that "the near-exclusivity of consumer use of cigarettes with the intent 'to affect the structure or any function of the body of man,'" would be sufficient by itself to establish that cigarettes are drugs within the meaning of the FDCA. 655 F.2d at 240; see also NNFA, 557 F.2d at 336 (demonstration that high dosage vitamins were "taken 'almost exclusively' for therapeutic purposes" would show an objective intent that the products be used as drugs and be sufficient for a determination that the products are drugs within the FDCA's meaning).

Evidence of consumer use may also be used in combination with other evidence to establish intended use or intended effects. FDA has relied on evidence of consumer use to establish the intended use of a drug or device product, even though the extent of consumer use had not been quantified. For example, beginning in the early 1980's, FDA regulated as unapproved drugs imports of catha edulis, or "khat," a shrub whose leaves act as a stimulant narcotic that affects the central nervous system when chewed or used as tea, even though the Agency did not have any evidence that vendors represented the product as a stimulant. Instead, FDA relied on information about the product's use and effects from United Nations reports, and other sources of information that described international customs and practices related to the substance. See Appendix to Legal Analysis.

Similarly, physicians' use of a product to treat or diagnose patients or to affect the structure or function of patients' bodies may provide evidence of intended use. FDA has classified products as drugs or devices based on physician use of the product. For example,

FDA undertook an enforcement action against a metal tube containing a light bulb, round metal discs, and colored glass filters used by a medical practitioner in his office in the treatment of various eye malfunctions and conditions. A district court upheld the Agency's conclusion that this use made the tube a device, even though the practitioner made no claims for the product. United States v. An Article of Device . . . Labeled in Part: "Cameron Spitler Amblo-Syntonizer", 261 F. Supp. 243, 245 (D. Neb. 1966). In another example, FDA established a due diligence requirement regarding manufacturers' distribution of interferon, a biologic product composed of proteins. See 48 Fed. Reg. 52644 (Nov. 21, 1983). At the time, interferon could be used only for investigational purposes in laboratory animals and tests in vitro. However, interferon received wide media coverage as a potential "miracle cure" in the treatment of cancer and viral infections in humans. Because of its concern over diversion of interferon to unapproved uses, the Agency issued the notice to prevent use of interferon in humans.

Finally, a vendor's behavior or statements may also be used as evidence of objective intent. See, e.g. United States v. An Article . . . Consisting of 216 Cartoned Bottles . . . "Sudden Change", 409 F.2d 734, 739-741 (2d Cir. 1969) (lotion promoted on product box, leaflets, and advertising as providing a "face lift" is intended to affect the structure of the body and is a drug); "Pet Smellfree", 22 F.3d at 239-40 (compound labeled and marketed as eliminating odor from a pet's breath and waste material is intended to affect the animal's digestive and elimination functions and is a drug).

Awareness that a product will achieve pharmacological effects, actual use of the product for a pharmacological purpose, and the totality of circumstances surrounding

distribution of the product constitute "objective manifestations of intent [that] are clearly sufficient." Neptone, CCH Food and Drug Reporter at 39,294. Moreover, evidence that a manufacturer actually knows that its product is being widely used for pharmacological purposes, and has taken steps to facilitate that use, provides compelling evidence of "intended use."

As shown below, the evidence now available to FDA demonstrates that tobacco manufacturers "intend" that their products have addictive and pharmacological effects which make cigarettes and smokeless tobacco products drugs within the meaning of the Act.

B. THE EVIDENCE DEMONSTRATES INTENT TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY.

As demonstrated above, in order to establish that a product has an intended use that subjects it to FDA's jurisdiction, it is sufficient to demonstrate foreseeable drug uses or effects in a large proportion of users, predominant or "nearly exclusive" consumer use for drug effects, or the subjective intent of the manufacturer, as evidenced by behavior and statements, that the product be used as a drug. As shown below, the facts before the agency demonstrate, based on each of these three grounds, that tobacco products are intended to affect the structure or function of the body and are, therefore, "drugs" and "devices." Moreover, the combined evidence before the agency from all three categories plainly demonstrates that tobacco products are "drugs" and "devices" within the meaning of the Act.[5]

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[5] Since 1980, when the Agency last evaluated its legal authority to regulate cigarettes as drugs or devices and declined to do so, *see* Action on Smoking and Health [ASH] v. Harris, 655 F.2d 236 (1980), the evidence regarding intended use has changed dramatically. As discussed *infra*, since 1980, the Surgeon General of the United States and virtually every major public health organization have concluded that nicotine in tobacco products leads to addiction. Since that time, the Agency has also exercised

1. The Addictive, Psychoactive, and Other Pharmacological Effects of Nicotine Are Widely Known and Foreseeable by Any Reasonable Person in the Position of a Tobacco Manufacturer.

As summarized below, a large body of compelling and widely accepted scientific evidence now exists that establishes that nicotine is addictive. Nicotine's addictive properties and its other significant pharmacological effects are now so well documented and commonly understood that these effects on the structure or function of the body must be held to be foreseeable by any manufacturer of cigarettes or smokeless tobacco products that contain nicotine. Although the manufacturers' claimed purpose may be to provide "taste" or "smoking pleasure," manufacturers may nevertheless be held, under an objective intent standard, to intend the foreseeable consequences of consumers' use of nicotine-containing cigarettes and smokeless tobacco products.

a. Addictive Effects. Until the 1980's, nicotine was not widely appreciated to be an addictive drug.[6] Overwhelming scientific evidence and broad recognition that nicotine is an addictive or dependence-producing substance emerged in the 1980's. See p. 78. Almost all

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jurisdiction over alternative nicotine delivery systems such as "Favor," a plug impregnated with a nicotine solution inserted within a small tube corresponding in appearance to a conventional cigarette, and "Future Free," a roll-on transdermal applicator containing nicotine in the form of a liquified raw tobacco extract, nicotine gums, and nicotine transdermal patches. Finally, the Agency's investigation has identified a wealth of evidence consisting of industry statements, research and actions acknowledging nicotine's drug effects and the role of nicotine in the manufacture of cigarettes and smokeless tobacco. As the Court explicitly acknowledged in ASH, the FDCA "calls for case-by-case analysis," and an agency may "depart from its prior interpretations" so long as it "provide[s] a reasoned explanation for its action." 655 F.2d at 242 n. 10; *see also* Chevron, U.S.A., Inc. v. National Resources Defense Council, Inc. 467 U.S. 837, 842-845, (1984); Bell v. Goddard, 366 F. 2d 177, 181 (7th Cir. 1966) ("An interpretation of the statute prohibiting such new application of existing information would do violence to the paramount interest in protecting the public from unsafe drugs."). In this document, the Agency has provided such a reasoned explanation.

[6] While some evidence of the addictive nature of nicotine existed at the time FDA last considered the regulation of nicotine-containing cigarettes and smokeless tobacco products in the late 1970's, the evidence available to FDA since that time has grown exponentially. *See* FINDINGS § I.B.

the leading experts and public health organizations in the United States and in the international community, including the vast majority of scientists funded by the tobacco industry now recognize nicotine's addictive effects. In 1986, the Office of the U.S. Surgeon General published a finding that nicotine in smokeless tobacco is addictive. See p. 80. Two years later, the Surgeon General issued his landmark report concluding that: cigarettes and smokeless tobacco products are addicting; nicotine is the drug in tobacco that causes addiction; and the pharmacological and behavioral processes that cause tobacco addiction are similar to those that cause addiction to drugs such as heroin and cocaine. See p. 82.

Since 1980, nicotine has been recognized as addictive or dependence-producing[7] by the World Health Organization, the American Medical Association, the American Psychiatric Association, the American Psychological Association, the American Society of Addiction Medicine, the Royal Society of Canada, and the Medical Research Council in the United Kingdom. See p. 82. In a 1991 survey, the vast majority of scientists funded by the tobacco industry stated that they believe that cigarette smoking is addictive. See p. 83. Indeed, among the principal investigators of research projects funded by the tobacco industry in 1989, 83.3% strongly agreed and 15.3% agreed somewhat that cigarette smoking is addictive. See p. 83.

More recently, on August 2, 1994, FDA's Drug Abuse Advisory Committee concluded unanimously that cigarettes and other forms of tobacco are addicting and that nicotine is the drug in tobacco that causes addiction. See p. 83. The FDA Advisory Committee also

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[7] The terms "addictive" and "dependence-producing" are generally used interchangeably; both refer to the persistent and repetitive intake of psychoactive substances despite evidence of harm and a desire to stop using the substance. *See* p. 78. The terms are used interchangeably in this document.

concluded that all currently marketed cigarettes contained addicting levels of nicotine. Id.

Tobacco use is also recognized as an addiction in the leading psychiatric manuals defining mental illnesses. The two most widely used clinical definitions of addiction in the United States are those in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) and World Health Organization's International Classification of Diseases (ICD). Nicotine has been recognized as dependence-producing under the DSM criteria since 1980. The ICD has recognized tobacco as dependence-producing since 1992. See pp. 84-85.

The current, scientifically accepted method of identifying addictive substances relies on the knowledge that there is a pharmacologic basis to addiction. See p. 79. Addictive substances achieve their addictive effects by exerting psychoactive (mood-altering) effects, and by producing chemical reactions in the brain that motivate repeated, compulsive use of the substance. See pp. 79-80. These pharmacologic effects create psychological or physiological dependence in the user. Id. Nicotine has been shown in animal and human studies to be a powerful psychoactive agent and to produce effects in the brain that are characteristic of other addictive substances, such as heroin and cocaine. See p. 94 et seq. Nicotine has also been shown to act as a "positive reinforcer," perhaps the most important hallmark of an addictive substance. See p. 96.

Current, widely accepted definitions of substance addiction place primary emphasis on: compulsive, regular use of the substance; inability to stop using the substance despite a desire to quit and/or harmful consequences; and the existence of tolerance and/or withdrawal symptoms (physiologic dependence). See p. 84. Using the contemporary definition of

addiction, evidence from epidemiological studies has now established that many cigarette smokers and smokeless tobacco users are addicted to nicotine.

Numerous studies have documented the characteristics of addiction among cigarette and smokeless tobacco users. First, consumers use tobacco regularly and compulsively. For example, 87% of people who smoke cigarettes smoke every day. See p. 86. Nearly two-thirds of smokers need their first cigarette within the first half-hour after awakening. Id.

Second, the failure rate of people who attempt to stop or reduce their smoking is dramatic, even in the face of life-threatening, tobacco-related illnesses. See pp. 86-87. Each year, nearly 15 million people -- almost one-third of all smokers -- try to quit smoking in the United States. Only about 3% of would-be quitters achieve long-term success. Indeed, cigarettes and smokeless tobacco products may be the only elective consumer product that a majority of users want to quit using, but cannot. In response to the 1993 National Health Information Survey, 70% of current smokers reported that they would like to completely stop smoking cigarettes. See p. 87. Sixty-eight percent of smokeless tobacco users in one study reported an average of four previous unsuccessful attempts to quit using smokeless tobacco. See p. 91. Moreover, tobacco use persists despite harmful and often deadly consequences. In one survey, 90% of smokers agreed with the general proposition that smoking is harmful to health, 65% believed that smoking had already adversely affected their health, and 77% believed that they could avoid or decrease serious health problems by quitting smoking. See p. 87. Almost half of the smokers who have surgery for lung cancer resume smoking. See p. 87. Even when smokers have their larynxes removed, 40% try smoking again. See p. 87.

Third, consumers who abstain from tobacco products experience withdrawal symptoms and nicotine has been shown to produce tolerance (the lessening of the desired effect over time or the need for higher doses to produce the same effect) among tobacco users. See pp. 88, 92, 99. For example, abstinence from smoking is often accompanied by powerful cravings for a cigarette, and the range of other symptoms produced by abstinence can disrupt personal life. Id. Among smokeless tobacco users, one study showed that of users 10 to 22 years old who had tried to quit, 93% had suffered withdrawal symptoms. See p. 93.

Accordingly, nicotine satisfies the classic criteria for an addictive substance. In fact, major recent clinical studies have demonstrated that between 75% and 90% of frequent smokers, and more than one-third of smokeless tobacco users are addicted to tobacco. See pp. 91, 115 et seq.. Further, cigarette users themselves recognize that cigarettes are addictive. According to a national household survey conducted by the U.S. Department of Health and Human Services in 1991-92, 83% to 87% of cigarette smokers who smoke more than 26 cigarettes a day believe they are addicted. See p. 87.

The success of nicotine replacement therapies provides further evidence of nicotine's addictive qualities. Nicotine replacement therapies (nicotine gum and nicotine patches) have been shown to be effective in assisting dependent tobacco users to quit. See p. 88 et seq. Nicotine replacement could only significantly increase the success of smoking cessation efforts if nicotine dependence were the major factor preventing tobacco users from quitting. Id.

To summarize, the widely known, well-publicized evidence of the addictive nature of nicotine and the very high frequency of addiction among frequent smokers, ranging, in major

recent studies, from 75% to 90%, has resulted in virtually universal acceptance that nicotine produces addiction.[8] Thus, nicotine's addictive effects are now undeniably foreseeable to manufacturers of cigarettes and smokeless tobacco products. Because it is also well known that nicotine addiction produces a physiological and psychological need for additional doses of nicotine, it is foreseeable that a large proportion of consumers will use tobacco to satisfy their addiction.

b. Other Pharmacological Effects. In addition to its addictive effects, nicotine produces a range of other significant pharmacological effects, which manufacturers of cigarettes and smokeless tobacco products can reasonably be expected to foresee. See p. 73 et seq. A large body of published evidence demonstrates that nicotine produces both stimulative and depressant effects on mood. See p. 75; see also p. 171. These psychoactive effects have been confirmed using electroencephalographic (EEG) analysis. Id. When smokers are in a stressful situation, smoking has a depressant effect on the EEG profile. When smokers are under conditions of low arousal, induced by mild sensory isolation, cigarette smoking has a stimulant effect. See pp. 75-76. In his 1988 report, the Surgeon General reviewed the epidemiological literature on the effects of smoking on mood. The report concluded:

> *The conclusion from this literature is that in the general population, persons perceive that smoking has functions that are relevant for mood regulation. Persons report that they smoke more in situations involving negative mood, and they perceive that smoking helps them to feel better in such situations . . . .*

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[8] This evidence distinguishes nicotine from caffeine-containing beverages and alcohol. If beverages containing caffeine are addictive, they are addictive in a very small percentage of users. Griffiths RR. Editorial: Caffeine dependence should be kept in proper perspective. *JAMA* 1994;272(13):1065-66. Beverages containing alcohol are addictive in fewer than 15% of users. Id. at p. 1066; Grant BF, Harford T, et al. Prevalence of DSM-II-R Alcohol Abuse and Dependence in the U.S., 1988. Alcohol Health and Research World Epidemiologic Bulletin No. 27, 1991;15(1):91.

See p. 118.

In addition, nicotine is widely believed to regulate weight gain in smokers. See p. 119. The 1988 Surgeon General's Report summarized the large number of clinical studies establishing an inverse relationship between cigarette smoking and body weight and animal studies demonstrating that nicotine plays an important role in the relationship between smoking and body weight. Id. Numerous studies show that smokers believe that smoking keeps weight down and that weight control is a significant motivation for continued smoking. Id.

This evidence plainly satisfies the objective standard for "intended use" set forth above. The widespread knowledge and acceptance of the very significant pharmacological effects of nicotine establish that any reasonable person would know that marketing nicotine-containing cigarettes and smokeless tobacco products will result in these effects and lead to addiction in millions of users.

This evidence is at least as strong as the evidence that the courts found to be sufficient to establish intended use in Jonas, Baby Rattles, and Focht, supra. As discussed above, in each of those cases, the defendant had a plausible argument that its product could be used for purposes that fell outside the jurisdiction of the relevant statute (e.g., baby rattles as party favors, firework components for use in legal fireworks). Nevertheless, the courts in each case found that the product fell within the jurisdiction of the applicable regulatory agency based on evidence that a foreseeable use of the product fell within the ambit of the statute. The pharmacologic effects and uses of nicotine-containing cigarettes and smokeless tobacco products are at least as foreseeable as the uses of the products at issue in Jonas, Baby Rattles,

and Focht.

2. Consumers Use Tobacco Products to Obtain the Pharmacological Effects of Nicotine and to Satisfy Their Addiction to Nicotine.

As previously explained, the intent that a product be used as a drug may also be shown by evidence, alone or in combination with other evidence, that consumers use it for pharmacological purposes. Here, the evidence establishes that consumers use tobacco for three pharmacological purposes: to satisfy a nicotine addiction; to receive the accompanying psychoactive effects, such as relaxation and stimulation; and to control weight. Moreover, the evidence shows that consumers use cigarettes nearly exclusively for pharmacological purposes. As discussed above, under the most widely used definitions, major recent studies show that 75% to 90% of frequent cigarette users are addicted to cigarettes. See p. 26. Studies also reveal that a large proportion of consumers use tobacco for other pharmacological effects, including relaxation, reduction of negative feelings, and for controlling weight. See p. 118 et seq. Under ASH, 655 F.2d at 240, and NNFA, 557 F.2d at 336, the high percentage of smokers who use cigarettes for their pharmacological effects, particularly to satisfy an addiction, one of the most significant drug effects on the body possible, is sufficient by itself to classify cigarettes and smokeless tobacco products as drug delivery systems within the meaning of the Act.

Even if the evidence of consumer use of tobacco products to satisfy addiction and to obtain other pharmacological effects were not alone sufficient to establish the intended use of cigarettes and smokeless tobacco products, the evidence of consumer use, in combination with the other evidence presented here, provides compelling support for the determination

that these products are intended to be used for pharmacological purposes. Indeed, the nature of consumer use of these products underscores nicotine's classification as a drug. Because nicotine is an addictive product that the vast majority of consumers use on a daily basis for a period of years, if not a lifetime, to satisfy an addiction, nicotine unquestionably functions as a pharmacological product at the consumer level. See also LEGAL ANALYSIS § II.B.3, infra (tobacco manufacturers recognize and acknowledge that consumers use their products to obtain the pharmacological effects of nicotine).

In summary, consumers' use of cigarettes and smokeless tobacco products for nicotine's pharmacological effects, viewed in combination with the other evidence presented here, supplies more than sufficient evidence to show that nicotine-containing cigarette and smokeless tobacco products are drug delivery systems within the meaning of the Act.

3. Tobacco Manufacturers Know That Nicotine Has Pharmacological Effects and That Consumers Use Tobacco for Those Effects, and Have Acted to Facilitate That Use.

Nicotine's psychoactive and addictive effects on tobacco users are plainly foreseeable to tobacco manufacturers, not only because they are widely known and published in scientific, governmental, and lay publications, but because for over 30 years the manufacturers themselves have engaged in intensive research on nicotine's psychoactive and addictive effects. In addition, tobacco industry documents reveal numerous statements by both industry researchers and executives in which they express their own views that nicotine in tobacco products acts as a psychoactive and addictive drug. Tobacco manufacturers' own research also demonstrates that consumers use cigarettes to obtain the pharmacological effects of

nicotine. Finally, tobacco manufacturers have conducted numerous studies to identify the dose of nicotine that will elicit the psychoactive effects sought by tobacco users, and manipulate the amount of nicotine delivered by tobacco products.

a. Tobacco Manufacturers' Studies and Statements Demonstrate Knowledge That Nicotine in Tobacco Is Addictive and Has Psychoactive Effects.

(i.) Addiction. Over the last 35 years, the tobacco industry has conducted many studies that collectively demonstrate that nicotine has the properties of an addictive drug. As described in FINDINGS § I.A.2., infra, substances are shown to have addictive properties by studies of the substance in animals, studies of human reactions to the substance, and studies of effects on the brain caused by the substance.

Two kinds of animal studies are highly predictive of a substance's addictive properties: self-administration studies and drug discrimination studies. See pp. 94-97. A substance is considered a "positive reinforcer" that is highly likely to be addictive in humans if studies show that animals self-administer the substance. Id. In drug discrimination studies, potentially addictive substances are identified by comparing the effects of one substance to those of other psychoactive substances. Id.

As noted above, under 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; i.e., mood altering;
- patterns of use are regular and compulsive, despite attempts to quit 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.

See p. 79 et seq.

The tobacco industry has conducted or funded studies in both animals and humans showing that nicotine bears each of these hallmark properties of an addictive substance. Industry-conducted and sponsored research has shown that animals self-administer nicotine and that animals experience nicotine's psychoactive effects. See p. 180 et seq. Industry research also demonstrates that the human response to nicotine in tobacco meets generally accepted definitions of addiction. Tobacco industry research demonstrates that nicotine has psychoactive effects, see p. 171, that most tobacco consumers continue daily use of tobacco, despite serious attempts to quit and despite concerns about the adverse health consequences of tobacco use, see p. 206 et seq., and that abstinence from tobacco use produces a withdrawal syndrome. See pp. 146, 182. Tolerance to the pharmacological effects of nicotine has also been closely studied by the tobacco industry and demonstrated in both animals and humans. See p. 181. Finally, tobacco industry studies have shown that nicotine acts on the mesolimbic system in the brain and triggers the release of the chemical dopamine. See p. 170. It is believed that dopamine release is the mechanism by which several of the most significant drugs of abuse, including cocaine and amphetamines, exert their addictive effects. See p. 74. Thus, the tobacco industry's own research demonstrates that nicotine has all the properties of an addictive drug.

Numerous tobacco company documents contain statements by company researchers and executives acknowledging that nicotine is, in fact, addictive. See p. 143 et seq. More

than 30 years ago, a report was completed for British-American Tobacco Co. (BATCO)[9] that specifically addressed the mechanism of nicotine addiction in smokers. See p. 143. The researchers concluded that chronic intake of nicotine, such as that which occurs in regular smokers, creates a need for ever-increasing levels of nicotine to maintain the desired action: "[u]nlike other dopings, such as morphine, the rate of increasing demand for greater dose levels is relatively slow for nicotine." Id. The report continues:

> *A body left in this unbalanced state craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine.*

See p. 144.

Dr. Sidney J. Green, the director of research for BATCO for 20 years and a member of the company's board of directors, repeatedly acknowledged that nicotine is addictive. See p. 150. Dr. William L. Dunn, a senior scientist at Philip Morris similarly made repeated statements that reflect the view that nicotine has the properties of an addictive substance. See pp. 152-154.

On the basis of research that had been sponsored by the industry in the early 1960's, the general counsel to Brown and Williamson reached the conclusion that "[w]e are, then, in the business of selling nicotine, an addictive drug . . . ." See p. 150. There have been more recent acknowledgements by the industry that nicotine is addictive, although industry representatives have been much more reticent in the statements they have made about nicotine's addictive properties since the 1970's, when product liability concerns began to

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[9] BATCO and Brown and Williamson Tobacco Corp, both part of the multi-national BAT Industries, PLC, shared both the funding and the results of their nicotine-related research. *See* Appendix 2.

mount. Throughout the 1970's and 1980's, industry-funded researchers have repeatedly stated that nicotine produces addiction, dependence, and withdrawal. See p. 145 et seq., 179-80. Moreover, in 1994, a recently retired CEO of a major tobacco company openly stated that tobacco is addictive and that its addictive properties are why people smoke. In an interview for an article in the Wall Street Journal, the former chief executive of RJR Nabisco, F. Ross Johnson, was asked about nicotine in cigarettes, and he responded, "Of course it's addictive. That's why you smoke . . ." See p. 155.

(ii.) Psychoactive Effects. The tobacco industry has conducted and funded, both as individual companies and through the jointly-operated Council for Tobacco Research (CTR),[10] hundreds of studies evaluating nicotine's pharmacological effects on the brain, including nicotine's specific physiological effects on brain structure and chemistry; its effects on mood, performance, and cognition; and its capacity to produce the characteristic features of addiction. See FINDINGS § II.B., infra, at p. 160 et seq.

Internal company documents reveal that the industry conducted and funded this research effort on the effects of nicotine on the brain because the tobacco manufacturers strongly suspected, as long as 30 years ago, that nicotine's drug effects were the basis for the world tobacco market. See p. 161. For example, in 1963, researchers for one company urged further study of nicotine because "nicotine is the key factor in controlling, through the central nervous system, a number of beneficial effects of tobacco smoke." See p. 161 (emphasis added). In the early 1960's, a prominent industry scientist, Sir Charles Ellis, the scientific

[10] The Council for Tobacco Research is an industry trade association that represents almost all of the major tobacco producers in the United States. *See* note 176, *infra.*

advisor to the board of directors of BATCO, explained that industry-sponsored research was underway "to elucidate the effects of nicotine as a beneficent alkaloid drug," and stated "we are in a nicotine rather than a tobacco industry." See p. 161. Indeed, the industry as a whole was sponsoring substantial research on nicotine pharmacology because of the shared belief that the drug effects of nicotine were central to tobacco use. See pp. 140-42.

Over the next 30 years, the tobacco industry conducted numerous studies on the drug effects of nicotine that appear similar to the studies conducted by pharmaceutical companies. Before marketing prescription drugs, a pharmaceutical company studies the pharmacokinetics of the drug (how it is absorbed into the body, metabolized, and excreted), the pharmacodynamics of the drug (what specific effects the drug has on the body's chemistry and metabolism as it makes its way through the body), and the clinical effects of the drug (whether the drug is effective in producing the desired therapeutic or physiological effect). The tobacco industry has conducted and funded hundreds of studies on nicotine's pharmacokinetics, pharmacodynamics, and clinical effects. See p. 160 et seq. As a result, the tobacco industry appears to have an understanding of the pharmacological effects produced by the nicotine in tobacco analogous to that which a pharmaceutical company has in marketing a new drug.

For example, the tobacco industry has developed sophisticated techniques for determining, quantitatively and qualitatively, the presence of nicotine and its metabolites in blood, urine, and tissue. See p. 174. Studies sponsored by tobacco companies using these techniques have shown that nicotine from tobacco is absorbed into the bloodstream and delivered to the brain, see p. 176, and that, once delivered to the brain, nicotine acts on the

receptors in the brain that produce a range of significant effects on brain chemistry and metabolism. See pp. 164, 169.

The tobacco industry has also sponsored many studies on the ultimate psychoactive effects produced by nicotine. Studies sponsored by the tobacco industry have repeatedly demonstrated that nicotine induces moods changes, which, under different conditions, provide both stimulant and depressant (relaxant) effects. See pp. 171-72. Moreover, tobacco industry studies have shown that nicotine's effects on mood are correlated to EEG changes (a measurement of electrical activity in the brain that is indicative of pharmacological activity on the central nervous system). Id. The tobacco industry has also conducted many studies that attempt to show that nicotine improves performance efficiency. See p. 173.[11]

Internal tobacco company documents reveal that all of this research has convinced company researchers and executives that nicotine in tobacco functions as a drug with powerful psychoactive effects. For example, in 1962, even before much of this research had been completed, Sir Charles Ellis, of BATCO, expressed his view that nicotine in tobacco functions as a drug much like stimulants and tranquilizers:

> *It is my conviction that nicotine is a very remarkable beneficent drug that both helps the body to resist external stress and also can as a result show a pronounced tranquilising effect. You are all aware of the very great increase in the use of artificial controls, stimulants, tranquilisers, sleeping pills, and it is a fact that under modern conditions of life people find that they cannot depend just on their subconscious reactions to meet the various environmental strains with which they are confronted: they must have drugs available which they can take when they feel the need. Nicotine is not only a very fine drug, but the techniques of administration by smoking has considerable psychological advantages and a built-in control against excessive absorption.*

[11] In fact, these studies show only that tobacco users perform better on some cognitive tasks when they are given nicotine than when deprived of cigarettes or nicotine. The studies do not show that tobacco users perform better than non-tobacco users. *See* FINDINGS § II.A.2., *infra*.

See p. 139 (emphasis added). In the decades that followed this statement, BATCO and Brown and Williamson held many research conferences, some of which were devoted entirely to discussing nicotine's pharmacological effects. The records of these conferences demonstrate that, at almost every conference, tobacco company officials from around the world discussed the results of research on nicotine pharmacology and reached agreement that nicotine had been shown to have pharmacological effects on tobacco users. See p. 125 et seq.

Researchers and executives from the other major tobacco companies and associated with CTR have also made statements revealing their knowledge that nicotine is a psychoactive drug. For example, the authors of a research paper funded by CTR reporting on the "beneficial" pharmacological effects of nicotine in cigarettes said that "[n]icotine is recognized as the primary psychoactive compound in cigarette smoke." See p. 131.

Researchers at RJR have published studies in which they freely acknowledge the pharmacological effects of nicotine in tobacco. In one study, they concluded that "the beneficial effects of smoking on cognitive performance . . . are a function of nicotine absorbed from cigarette smoke upon inhalation." Another published RJR study discusses the "nicotine paradox": the effects of smoking that appear to be stimulating (e.g., increased heart rate) and to increase mental alertness are inconsistent with nicotine's calming and stress-reduction effects. See p. 129. As discussed in the following subsection, documents containing statements from Philip Morris officials and officials at U.S. Tobacco, the largest smokeless tobacco manufacturer, show that executives at these companies also believe that nicotine in tobacco is a psychoactive drug.

b. Tobacco Manufacturers Know That Consumers Use Tobacco Products for the Pharmacological Effects of Nicotine.

Industry documents show that tobacco manufacturers have thoroughly researched consumer use of tobacco products and understand that consumers use tobacco to obtain the pharmacological effects of nicotine. In fact, tobacco manufacturers believe that consumers will not accept cigarettes that contain insufficient levels of nicotine to produce pharmacological effects.

BATCO reports, research conference proceedings, and other internal documents from BATCO contain repeated assertions that consumers use tobacco largely to obtain nicotine's pharmacological effects. See p. 125 et seq. A BATCO Group R&D Smoking Behaviour-Marketing Conference held in 1984, which focused almost entirely on the role of nicotine pharmacology in smoking, included a presentation in which the following statement was made:

> *Smoking is then seen as a personal tool used by the smoker to refine his behaviour and reactions to the world at large.*
>
> . . . .
>
> *It is apparent that nicotine largely underpins these contributions through its role as a generator of central physiological arousal effects which express themselves as changes in human performance and psychological well-being.*

See pp. 126-27 (emphasis added). At a 1976 BATCO Smoking Behavior Conference, the conferees were so convinced that obtaining a dose of nicotine was the reason people smoke that they thought that other, non-pharmacological reasons for smoking might emerge only after the smoker had achieved a "maximum nicotine level" and had satisfied his desire for nicotine. See p. 194. Many other industry statements described in FINDINGS, § II.A.1 and C., infra, also show that the tobacco industry knows that the pharmacological effects of

nicotine are the primary reason consumers use cigarettes and smokeless tobacco products.

Industry documents also reveal that tobacco manufacturers appreciate that consumers will not accept individual tobacco products unless they provide a pharmacologically satisfying dose of nicotine. Dr. Helmut Wakeham of Philip Morris stated in 1961 that the pleasures of smoking derive at least in part from nicotine's pharmacological effects and that "nicotine is believed essential to cigarette acceptability." See p. 134. This view was later adopted and enlarged by William Dunn, Jr., another high-ranking Philip Morris official. In summarizing a 1972 conference sponsored by CTR, Dunn reported that "[t]he primary incentive to cigarette smoking is the immediate salutary effect of inhaled smoke upon body function." See p. 134. Dunn continued:

> *The majority of the conferees would go even further and accept the proposition that nicotine is the active constituent of cigarette smoke. Without nicotine, the argument goes, there would be no smoking. Some strong evidence can be marshalled to support this argument:*
>
> *1) No one has ever become a cigarette smoker by smoking cigarettes without nicotine.*
>
> *2) Most of the physiological responses to inhaled smoke have been shown to be nicotine-related.*
>
> *3) Despite many low nicotine brand entries in the market place, none of them have captured a substantial segment of the market . . . .*

See p. 135 (emphasis added).

Tobacco industry documents on "satisfaction" also demonstrate industry knowledge that delivery of a pharmacologically active dose of nicotine is essential to consumer acceptance of tobacco products, see FINDINGS § II.C.1., infra, and that "satisfaction" is a tobacco industry euphemism for the pharmacological response to nicotine that smokers seek

to obtain from smoking. See p. 185. For example, a BATCO scientist, in a 1969 presentation describing the research activities of BATCO Group Research & Development, stated that:

> *Nicotine has well documented pharmacological action. It is claimed to have a dual effect, acting both as a stimulant and a tranquilliser. It is believed to be responsible for the "satisfaction" of smoking, using this term in the physiological rather than the psychological sense.*

See p. 186. An RJR Marketing Summary Report from 1983 similarly concludes that the primary reason people smoke "is probably the physiological satisfaction provided by the nicotine level of the product." See p. 186 (emphasis added). These and other industry statements set forth in FINDINGS § II.C.1., infra, further demonstrate the tobacco manufacturers' awareness that consumer "satisfaction" from tobacco products depends upon delivery of pharmacologically satisfying amounts of nicotine.

The industry's study of "compensation" behavior by smokers provides further telling evidence of the industry's awareness that consumers use tobacco to obtain a carefully titrated dose of nicotine. See FINDINGS § II.C.3., infra, p.198 et seq. "Compensation" refers to the behavior of smokers when given cigarettes that provide a lower nicotine yield than their regular brands (as measured by a smoking machine). When using lower-dose products, smokers often smoke more cigarettes or smoke the cigarette more intensely, for example, by taking larger or more puffs. Tobacco company documents reveal that the industry recognizes both that smokers compensate and that the purpose of compensation behavior is to allow smokers to achieve a dose of nicotine that satisfies their physiological need for nicotine. Id.

The tobacco industry has conducted studies on compensation that show that each smoker tends to obtain close to the same dose of nicotine from each cigarette, despite differences in the yield as measured by a smoking machine. See pp. 202-04. In other words,

industry studies show that tobacco users seek a specific dose of nicotine from tobacco and adjust their smoking behavior to obtain their customary dose of nicotine from cigarettes with different yields. For example, in 1974, BATCO researchers reported on a study that found that "the smoker adjusts his pattern to deliver his own nicotine requirements (about 0.8 mg per cigarette)." See p. 202. Thus, the tobacco industry's studies demonstrate that smokers use the cigarette as a nicotine delivery system and vary their smoking behavior to obtain specific doses of nicotine.

Tobacco company documents demonstrate not only the tobacco industry's awareness of the fundamental importance of nicotine's effects on the brain, but their knowledge that these effects motivate almost all smoking. A 1977 BATCO report entitled "Some 'Benefits' of Smoking" contained the following statement:

> *Some insights into the likely benefits of smoking follow from a consideration of the properties of nicotine, which is considered to be the reinforcing factor in the smoking habit of at least 80% of smokers* . . . .

See p. 132 (emphasis added). High-ranking officials agreed with this assessment. Dr. S.J. Green of BATCO, the Director of Research and member of the Board of Directors of BATCO, wrote in 1972 that the "[t]he tobacco smoking habit is reinforced or dependent upon the psycho-pharmacological effects mainly of nicotine." See p. 140.

The smokeless tobacco industry also recognizes that almost all consumers use tobacco products to obtain the pharmacological effects of nicotine. The senior vice-president for marketing of U.S. Tobacco wrote in a 1981 letter on new product development:

> *Flavorwise we should try for innovation, taste and strength, nicotine should be medium . . . Virtually all tobacco usage is based upon nicotine, "the kick," satisfaction.*

See pp. 186-87 (emphasis added).

The importance of nicotine delivery to consumer acceptance of tobacco products is so well-recognized by the tobacco industry that tobacco company officials themselves consider tobacco products to be nicotine delivery systems, i.e., vehicles for administering doses of nicotine. At the 1984 BATCO Smoking Behaviour-Marketing Conference, which focused heavily on the central role of nicotine's pharmacological effects in tobacco use, one of the presentations included a slide that read "in its simplest sense puffing behaviour is the means of providing nicotine dose [sic] in a metered fashion." See p. 159.

Tobacco company documents demonstrate that high-ranking tobacco company officials share the view that tobacco is a nicotine delivery system. See FINDINGS § II.A.3., infra, at p. 156 et seq. Dr. Green repeatedly asserted that tobacco is simply a vehicle for delivering nicotine. See p. 157. RJR executive Claude Teague, Jr. wrote:

> *In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized, and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiological effects . . . . If 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 . . .*

See pp. 156-57.

In summarizing a 1972 conference sponsored by the CTR, William Dunn, of Philip Morris, characterized the cigarette as a nicotine delivery system in the following language:

> *Think of the cigarette pack as a storage container for a day's supply of nicotine . . . Think of the cigarette as a dispenser for a dose unit of nicotine . . . Think of a puff of smoke as the vehicle of nicotine . . . Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.*

See p. 156.

Thus, tobacco company researchers and executives have not only acknowledged that nicotine's drug effects are central to the use of tobacco, but have also stated their intention that tobacco products be used as delivery systems to administer doses of nicotine.

c. Tobacco Manufacturers Have Acted to Facilitate and Sustain the Consumer Use of Tobacco Products for Their Pharmacological Effects.

The amount of nicotine that reaches the bloodstream of the smoker is determined by the nicotine content of the leaf, the chemical additives used during processing of the tobacco, and the design of the cigarette or smokeless tobacco product. FDA's investigation has revealed that tobacco manufacturers have conducted numerous studies to identify the dose of nicotine that will elicit the pharmacological effects sought by the products' users. See FINDINGS § II.C.2, infra, at p. 188 et seq. Furthermore, the investigation has shown that cigarette and smokeless tobacco companies manufacture their products to specifications that ensure that the final product will contain precise levels of nicotine. See FINDINGS § II.E., infra at p. 232 et seq. This evidence also demonstrates that tobacco manufacturers know and intend that the nicotine in their products have pharmacological effects on consumers.

(i.) Product Development Research. The tobacco industry is not only keenly aware that consumers use tobacco for nicotine's pharmacological effects, but has conducted product development research designed to ensure that tobacco products deliver a sufficient dose of nicotine to provide a pharmacological response that satisfies the users' need for nicotine. See FINDINGS §§ II.C.1. and 2., infra. The industry has developed sophisticated technology to

determine the amount of nicotine absorbed by tobacco users. See p. 191. Using this technology, tobacco manufacturers have shown that tobacco users have a "daily nicotine requirement." See p. 192. Industry research and statements also show that the industry has devoted substantial resources to determine what dose of nicotine must be delivered by each cigarette and has attempted to establish the "minimum dose of [ ] nicotine that can provide pharmacological satisfaction for the smoker." See p. 190. The tobacco industry has also focused a significant portion of its product development research on methods of ensuring that nicotine is delivered at levels that do not fall below a pharmacologically satisfying dose.

In 1972, William Dunn, Jr., of Philip Morris expressed the widely held industry view that there is a minimum level of nicotine that must be delivered in tobacco products to provide pharmacological effects, and that below that level there would be few, if any, tobacco sales:

> *[C]ritics of the industry would do well to reflect upon the indifference of the consumer to the industry's efforts to sell low-delivery brands. 94% of the cigarettes sold in the U.S. deliver more than 1 mg of nicotine. 98.5% deliver more than 0.9 mg. The physiological response to nicotine can be readily elicited by cigarettes delivering in the range of 1 mg of nicotine.*

See p. 189 (emphasis added).

The industry has conducted many studies designed to establish the daily dose of nicotine obtained by tobacco users and the amount of nicotine that individual tobacco products must deliver to the consumer to provide that dose. See FINDINGS § II.C.1. and 2., infra. For example, Project Wheat was a multi-part study intended to aid BATCO in developing cigarettes with increased consumer acceptance and, specifically, to establish smokers' preferred nicotine level in tobacco products. See pp. 183-84. Reports of the study

make clear that the research was designed to identify the dose of nicotine that would produce desired physiological responses, rather than to identify the correct level of nicotine for taste or flavor. One report states:

> *In considering which product features are important in terms of consumer acceptance, the nicotine delivery is one of the more obvious candidates. Others include the taste and flavour characteristics of the smoke, physical features such as draw resistance and rate of burn, and the general uniformity of the product, to name but a few. The importance of nicotine hardly needs to be stressed, as it is so widely recognized.*

See p. 184 (emphasis added). The researchers offered cigarettes containing different levels of nicotine to smokers and studied their responses. The study report concludes that there was an optimum nicotine delivery for smokers. The study also found that there was a minimum level of nicotine necessary to satisfy all smokers and that cigarettes that provided nicotine below that level were unacceptable. See p. 189. Project Wheat and similar industry studies and statements, FINDINGS § II.C.1. and 2., infra, reveal that tobacco manufacturers know that tobacco products must deliver a pharmacologically active level of nicotine to maintain consumer acceptance, and that manufacturers have acted to identify that level.

Other tobacco industry research reveals that the tobacco industry has taken action to ensure that tobacco products in fact deliver pharmacologically satisfying doses of nicotine. See FINDINGS § II.D., infra, at p. 213 et seq. As described above, the industry is well aware that tobacco products must provide a certain level of nicotine to elicit the pharmacological effects sought by consumers and that consumers will not continue to purchase tobacco products that fall below that threshold. As a result, the industry has focused substantial attention on methods of manipulating nicotine delivery in marketed products. In particular, the industry has devoted considerable research to reducing tar while maintaining a level of

nicotine delivery that would satisfy consumers' desire for the pharmacological effects of nicotine. See FINDINGS § II.D.2., infra at p. 222 et seq. As stated in one industry patent:

> *Maintaining the nicotine content at a sufficiently high level to provide the desired physiological activity, taste, and odor . . . can thus be seen to be a significant problem in the tobacco art. The addition of nicotine to tobacco in such a way that it remains inert and stable in the product and yet is released in a controlled amount into the smoke aerosol when the tobacco is pyrolyzed, is a result which is greatly desirable.*

See p. 213-14 (emphasis added).

As early as 1965, a Brown and Williamson official reported to other Brown and Williamson executives that BATCO research was focused on "the smoking and health problem." The goal was "to find ways of obtaining maximum nicotine for minimum tar." See p. 225. Approaches being used include: (a) chemical treatment of filters; (b) nicotine fortification of cigarette paper; (c) addition of nicotine containing powders to tobacco; (d) alteration of blends." Id.

An abundance of industry studies and patents show that in the decades since 1965, the tobacco industry has invested substantial resources to develop methods and technologies, the declared purpose of which is to facilitate the design of cigarettes in which the tar has been lowered but the amount of nicotine delivered has been maintained or increased. See FINDINGS § II.D.2., infra. These methods and technologies include: increasing the nicotine content of tobaccos by, for example, adding commercial nicotine to the tobacco or other parts of the cigarette, see pp. 214-16; transferring nicotine from one tobacco to another or by adding tobacco extracts, see p. 217; adding chemicals to tobacco and filters to increase delivery of nicotine, without altering nicotine content, see p. 228; and altering the "puff-by-puff" delivery of nicotine, see p. 227.

Tobacco manufacturers have also attempted to help smokers compensate for lower nicotine yields, that is to obtain more nicotine from a cigarette than its machine-tested yield, by designing cigarettes with "elasticity." See p. 229 et seq. ("Elasticity" refers to the ability of a cigarette, whatever its machine-measured nicotine yield, to deliver enough smoke to permit a smoker to obtain the amount of nicotine he needs, for example, through more or longer puffs, or by covering ventilation holes.) BATCO researchers described corporate policy on compensation and elasticity at a 1984 conference:

> *Compensation by modifying smoking regime [increasing or decreasing puff volume, duration, puff frequency, amount inhaled] is a topic which is being explored at GR & DC and this includes designing products which aid smoker compensation.*
>
> *The marketing policy concerning this type of product is not clear but it is believed it will depend largely on the degree of elasticity in the design and how overtly this elasticity is achieved. The consensus is that small improvements in elasticity which are less obvious, visually or otherwise is likely to be an acceptable route.*

See p. 230 (emphasis added). BATCO documents reflect numerous examples of research on different methods to improve elasticity. See p. 230.

In summary, the tobacco industry's product development research confirms that: tobacco manufacturers know that consumers use tobacco for its pharmacological effects; have acted to establish the dose that consumers require to obtain pharmacological satisfaction from tobacco products; and have worked to develop technology that will ensure that marketed products deliver a pharmacologically satisfying dose of nicotine.

(ii.) Control Over Nicotine Levels. Tobacco manufacturers also deliberately control the level of nicotine in cigarettes by monitoring and adjusting nicotine levels at each stage of the manufacturing process. The ultimate objective of these efforts is to ensure that the finished cigarette delivers the desired level of nicotine.[12]

Perhaps the best example of manufacturers' control of nicotine levels is the effort that the companies make to ensure that low-tar cigarettes deliver an adequate amount of nicotine. As described in the preceding subsection, tobacco industry research activities have focused on developing technologies for maintaining and increasing nicotine levels as tar is reduced. FDA's investigation has also shown that tobacco manufacturers actually use a number of techniques to ensure that nicotine levels in marketed products do not fall below a certain level, such as incorporating high nicotine tobaccos to ensure "adequate" levels of nicotine and using chemical additives to enhance nicotine delivery.

Tobacco manufacturers have a sophisticated understanding of the nicotine levels in various types of tobacco and in the various parts of the tobacco plant. By monitoring nicotine levels in the tobacco they purchase and by blending the tobaccos in accordance with their nicotine levels, tobacco companies are able to manufacture tobacco products with nicotine levels that vary only minimally within cigarette packs and from pack to pack. See p. 271.

Officials at R.J. Reynolds and Brown and Williamson have confirmed the importance

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[12] A number of techniques of cigarette production and manufacture can be used to lower nicotine levels. Probably the most significant technique is the design of low-tar cigarettes which lower nicotine levels when they lower tar levels. The filters that are used in 95% of cigarettes sold in the United States remove a certain amount of nicotine. The techniques described in FINDINGS § II.E., *infra*, are used by the tobacco industry to offset these reductions in nicotine levels and ensure that each cigarette delivers an amount of nicotine necessary to ensure consumer "satisfaction," i.e., to provide an adequate dose of nicotine to produce desired pharmacological effects.

of nicotine levels in leaf growing and purchasing. See p. 243. At least one company has actually developed a high-nicotine tobacco to use in manufacturing low-tar cigarettes. Brown and Williamson used a combination of conventional and advanced genetic breeding techniques to develop a high-nicotine, flue-cured tobacco plant, named "Y-1," that has approximately twice the nicotine level of American-grown flue-cured tobacco. Brown and Williamson used Y-1 tobacco in its cigarettes. See p. 239 et seq.

Once purchased, tobacco leaves are blended to attain target levels of nicotine. In fact, nicotine content is maintained at levels that would represent a high degree of control for a conventional drug manufactured from synthetic, homogeneous materials. See pp. 246-47. This level of control is remarkable for a product such as cigarettes, which are made from biological materials with a highly variable content.

Where design features aimed at reducing tar levels have also lowered nicotine levels, the manufacturer can use tobacco leaves with higher nicotine content to increase the nicotine level. For example, filters that are designed to reduce tar can also reduce nicotine. Yet, the industry is known to use proportionally greater amounts of higher nicotine-containing tobaccos in the tobacco blends of the lowest-tar varieties of cigarettes to maintain a higher nicotine level in those products. See p. 247. For example, "Y-1," Brown and Williamson's high-nicotine tobacco, was developed as a "blending tool" to permit the company to reduce tar and yet maintain nicotine delivery in its low-tar cigarettes. See p. 240.

Chemical additives are also used to enhance nicotine delivery. A major American tobacco company's 1991 handbook on leaf blending and product development identified ammonia as being effective to increase the amount of nicotine delivered to the smoker.

According to the handbook, ammonia in cigarette smoke "can liberate free nicotine from the blend, which is associated with increases in impact and 'satisfaction' reported by smokers." See p. 249. American tobacco companies often use ammonia in reconstituted tobacco; when cigarettes containing this type of tobacco are burned, the reconstituted tobacco serves as a source of ammonia in the cigarette smoke. See p. 250.

Tobacco companies also use a number of other chemicals to optimize nicotine delivery. Nicotine has a naturally harsh taste. To maintain sufficiently high levels of nicotine in tobacco products, manufacturers moderate nicotine's harshness by adding flavors such as sugar, licorice, cocoa, menthol, and other alcohol-based aromic substances to tobacco. According to one industry expert, the major contribution of the tobacco flavor specialist is to "help provide a rich, clean, full-bodied tobacco flavor, to keep to a minimum hotness and irritation in the mouth, and to ensure high satisfaction from an adequate level of nicotine per puff[,] requirements that guarantee the consumer a pleasurable smoke." See p. 251. In addition, glycerine/glycol in aerosol formulation is used to enhance "smoothness," ensuring that smoke will be inhaled into the lungs, thereby facilitating rapid and complete absorption of nicotine. See p. 253.

To a remarkable degree, the cigarette industry has accomplished the task of delivering sufficiently high levels of nicotine in low-tar products. A 1983 study showed that cigarettes advertised as having a low-nicotine yield contain as much nicotine as high-yield cigarettes. See p. 262. Moreover, all marketed cigarettes deliver sufficient nicotine to produce pharmacological effects on smokers. See p. 108 et seq. These findings are consistent with FDA's findings that the industry employs a number of methods to boost nicotine delivery to

compensate for nicotine losses from the application of tar-reducing designed modifications. Without the use of such methods, the techniques used to reduce tar should result in corresponding nicotine reductions. Instead, studies by FDA and others have demonstrated that the nicotine yield of cigarettes, as defined by the Federal Trade Commission (FTC) smoking machine tests, correlates inversely with nicotine concentrations in the tobacco, i.e., that some of the lowest-tar cigarettes have the highest concentrations of nicotine. See p. 262 FDA's analysis of FTC data also reveals an apparent increase in the sales-weighted FTC nicotine delivery ratings since 1982 (the earliest year for which the computer database is available), i.e., an overall increase in nicotine delivery from U.S. cigarettes. See p. 266.

Tobacco manufacturers' actions to manipulate nicotine deliveries from marketed cigarettes further demonstrate that nicotine is the central component of tobacco products, and that tobacco manufacturers have taken deliberate steps to maintain the level of nicotine that smokers receive.

(iii.) Alternative Product Research. Tobacco manufacturers have researched and developed alternatives to conventional tobacco products and to nicotine, largely in response to concerns about the health effects of conventional tobacco products. See FINDINGS § II.F., infra, p. 289 et seq. Industry documents explaining the nature and purpose of these alternative products provide confirmation that tobacco manufacturers: 1) understand that nicotine's pharmacological effects on the brain are essential to the successful marketing of tobacco products, and 2) have taken actions to ensure that alternative tobacco products will continue to provide these pharmacological effects.

Internal documents from both Philip Morris, Inc., and Brown and Williamson show

that these companies have had substantial research programs to identify "nicotine analogues," chemicals that are closely related to nicotine. See FINDINGS § II.F.1., infra. Company documents reveal that both Philip Morris and Brown and Williamson were seeking analogues that would produce effects on the central nervous system similar to nicotine, that could be substituted for nicotine if nicotine-containing tobacco became regulated or unattractive to consumers, and that could be added to currently marketed products to enhance the effects of nicotine. See p. 289. These programs were also designed to identify substances that shared nicotine's "desired" effects on the central nervous system, without producing its undesirable effects on the cardiovascular system. See p. 290.

The industry's nicotine analogue research programs were expressly based on the companies' view that "[s]hould nicotine become less attractive to smokers, the future of the tobacco industry would become less secure .... A commercial threat would arise if either an alternative [nicotine] product became acceptable or the effect of nicotine was changed [by an antagonist to nicotine]." See p. 292. In 1968, BATCO researchers, acknowledging the critical importance of nicotine in tobacco, recommended that the industry search for nicotine substitutes with the "desired" pharmacological effects on the brain:

> *In view of its pre-eminent importance, the pharmacology of nicotine should continue to be kept under review and attention paid to the possible discovery of other substances possessing the desired features of brain stimulation and stress-relief without direct effects on the circulatory system. The possibility that nicotine and other substances together may exert effects larger than either separately (synergism) should be studied and if necessary the attention of Marketing Departments should be drawn to these possibilities.*

See p. 290 (emphasis added). Various BATCO documents show that the company had an extensive program to identify nicotine analogues. See FINDINGS § II.F.1., infra.

Internal documents from Philip Morris' nicotine analogue program reveal that this company also sought nicotine analogues with pharmacological effects on the central nervous system, including effects associated with addiction. See p. 293 et seq. Philip Morris documents state explicitly that the purpose of the research on nicotine analogues was to find nicotine substitutes that were behaviorally active and had the same "reinforcing properties" in animals as nicotine. In an internal report on Philip Morris research, a section entitled "Nicotine Analogues" includes the following "research objectives":

1. *Determine if behaviorally active nicotine analogues can be directly substituted for nicotine in rats for which nicotine is functioning as an intravenously delivered positive reinforcer.*

2. *Establish nicotine analogues as an intravenously delivered positive reinforcer.*

3. *Compare the potencies of nicotine analogues to nicotine in producing positive reinforcing effects.*

See p. 296. As described in FINDINGS § I.B., infra, it is well established that the ability of a substance to act as a "positive reinforcer" is one of the hallmarks of an addictive substance. Philip Morris documents show that the company also tested nicotine analogues using "prostration" studies and "drug discrimination" studies. See p. 295. These studies provide evidence about whether a substance acts on the brain in the same manner as nicotine and has properties of an addictive substance. See FINDINGS § I.B., infra.

Philip Morris has also conducted pharmacological and behavioral research on another constituent of cigarette smoke, acetaldehyde, that was believed to have reinforcing effects. See FINDINGS § II.F.2, infra. This research was intended to find a combined dose of acetaldehyde and nicotine in cigarettes that would produce "maximal reinforcing effects."

See p. 298. The reinforcing efficacy of a substance is a measure of its ability to cause addiction in users. Id. In undertaking research on how to maximize the reinforcing effects of cigarettes, Philip Morris demonstrated its understanding of the addictive nature of cigarettes and its intention to produce, and even increase, these effects in tobacco users.

These company documents show that tobacco manufacturers have sought substitutes for nicotine that had psychoactive effects and other recognized characteristics of an addictive substance. At least one company conducted research on how to increase the reinforcing properties of cigarettes. This evidence compellingly shows that manufacturers intend tobacco products to have pharmacological effects and result in addiction.

Tobacco companies have also developed a number of cigarette alternatives. See FINDINGS § II.F.3., infra. In developing cigarette alternatives, the companies have sought to eliminate many of the traditional components and characteristics of cigarettes and cigarette smoke, such as tar and carbon monoxide. Tobacco companies have consistently recognized, however, that cigarette alternatives must deliver adequate amounts of nicotine to satisfy consumers. As a result, most of the alternative cigarette products developed by tobacco companies are simply nicotine delivery systems. For example, R.J. Reynolds has developed two "smokeless cigarettes," Premier and Eclipse. See p. 302 et seq. Nicotine is virtually the only compound (other than the paper and the filter) that is contained in these products in quantities similar to conventional cigarettes. Although these alternative products are very different from one another, they are strikingly the same in their ability to administer a consistent level of nicotine. Industry documents and patents show that other tobacco companies' cigarette alternatives are also intended to be nothing more than nicotine delivery

systems. See pp. 305-07. For example, BATCO developed cigarette alternatives that it characterized as "devices for the controlled administration of nicotine." See p. 307.

A 1970 BATCO R&D conference included a telling illustration of the tobacco industry's recognition of the central importance of nicotine in cigarette alternatives:

> *It was agreed that, if and when total cigarette consumption declined, great opportunities for supplying the demands of other socially acceptable habits could follow. Discussion followed on those opportunities which might arise. Amongst those discussed were a) chewing products, and b) wet snuff [both of which are smokeless tobacco products]. It was felt that this whole area, much of which is already in the tobacco industry, should be examined more thoroughly. Particular attention should be given to buccal administration of nicotine and other physiologically active ingredients. At the same time, it was re-affirmed that we would not contemplate the incorporation of nicotine in edible products.*

See p. 308 (emphasis added). As this passage makes clear, tobacco manufacturers understand that the common feature of cigarettes and smokeless tobacco products is the ability to administer nicotine to consumers, and that the purpose of the nicotine is to produce pharmacological effects in the consumer.

Thus, company documents related to the development of alternatives to both nicotine and conventional tobacco products establish tobacco manufacturers' knowledge that nicotine's psychoactive effects are critical to maintaining a successful market for cigarettes and smokeless tobacco, and that consumers use these products primarily for nicotine's pharmacological effects. The fact that the tobacco industry considers alternative cigarettes that are simply nicotine delivery systems to be functionally equivalent to traditional cigarettes demonstrates that tobacco companies intend their currently marketed tobacco products to be used for pharmacological purposes by consumers.

d. Smokeless Tobacco Manufacturers Manipulate Nicotine Delivery and Foster Graduation of Users From Low to High Nicotine Products.

Smokeless tobacco manufacturers control the delivery of nicotine from smokeless tobacco through a variety of additives and design features. Manufacturers use these additives and features to produce lines of smokeless products that deliver nicotine in increasing amounts. Evidence exists that smokeless tobacco manufacturers employ a "graduation process" to market these products. Low-nicotine products are marketed to new users of smokeless tobacco. After these new users become tolerant to the low-nicotine products, manufacturer marketing encourages smokeless tobacco consumers to "graduate" to higher nicotine products. The goal of the graduation process is to establish and maintain a market for the smokeless tobacco products with the highest nicotine delivery. Smokeless tobacco manufacturers' deliberate manipulation of levels of nicotine delivery, and the marketing of low-nicotine products to new users and high-nicotine products to experienced users, demonstrates the manufacturers' intent to facilitate nicotine addiction. This evidence establishes that smokeless tobacco manufacturers intend to affect the structure and function of the body.

Until the 1970's, smokeless tobacco companies in the United States marketed only products with high nicotine delivery that were not well tolerated by new users and the number of consumers using their products was steadily diminishing. See pp. 279-80. Evidence from the files of smokeless tobacco companies shows that, in the late 1960's or early 1970's, these companies began to entice new users of smokeless tobacco. Id. To do so, they decided to develop low-nicotine products in teabag-like pouches to encourage people to begin using smokeless tobacco. See pp. 280-81. Company documents also reveal that manufacturers

deliberately set out to produce a range of products with low, medium, and high nicotine delivery, see p. 281, and that they understood that nicotine's pharmacological effects were essential to the success of their products. As noted above, the senior vice president for marketing of the largest smokeless tobacco company wrote in a memorandum on new product development that "virtually all tobacco usage is based upon nicotine, 'the kick,' satisfaction." See pp. 186-87.

Analyses, by FDA and others, of current smokeless tobacco products show that smokeless tobacco companies have successfully developed product lines with graduated nicotine deliveries. See p. 276. Abundant evidence exists that manufacturers deliberately manipulate smokeless tobacco products to provide these graduated nicotine deliveries. Smokeless tobacco manufacturers do so primarily by adding various acidic or buffered compounds to the tobacco to alter its "pH," i.e., its relative acidity or alkalinity. See pp. 273-275. By increasing the pH of a product, manufacturers increase the amount of nicotine that is transformed from the "salt" or "bound" form of nicotine into "free nicotine." Only free nicotine can be readily absorbed through the mouths of smokeless tobacco users into the bloodstream. Small adjustments in pH can dramatically raise delivery of free nicotine. For example, raising the salivary pH from 7 to 8 increases the percentage of free nicotine from 10% to 50%, a five-fold increase. See p. 274. Analyses of currently marketed smokeless tobacco products reveal that the "starter" products have a pH in the range of 5 to 7, while the products for experienced users, like Copenhagen, have a pH of 8 or more. The amount of free nicotine delivered from these products correspondingly ranges from 5% to 20% for the starter products and 50% to 80% for the high-end products. See p. 276.

Other features of these products are also designed to lower nicotine absorption at the low (starter) end of the product range and to raise nicotine absorption at the top end. For example, humectants are added to the products to increase moisture content. See p. 279. High moisture content and other design features of smokeless tobacco have the effect of providing an intense "bolus" dose of nicotine to the user when the user first places a wad of tobacco in the mouth. See p. 278. On the other hand, "starter products" like Skoal Bandits are often packaged in a miniature pouch designed to be placed in the user's mouth; the pouch serves to limit the amount of snuff that is placed in the mouth and to create a barrier that decreases the rate of nicotine release from the product. See p. 277. Thus, starter products like Bandit deliver less total nicotine at a slower rate than the high-nicotine products offered by the same companies.

Internal documents from United States Tobacco Co. (UST), the largest smokeless tobacco producer in the United States, demonstrate that the company developed low nicotine snuff products for the specific purpose of creating "starter" products for new users who could not tolerate products with more nicotine. These low-nicotine products were then aggressively marketed to new users through advertising and by offering free samples at college campuses and sports events. See p. 282 et seq. UST documents, including internal memoranda and advertising, demonstrate that smokeless tobacco manufacturers know and intend that their customers will "graduate" upward through the range of nicotine products to the highest nicotine products. For example, a chart prepared by UST's marketing department is labeled "graduation process" and shows a hierarchy of products, with arrows going from Skoal Bandits, to Happy Days and Skoal Long Cuts, and culminating with Copenhagen. See p. 284.

This "graduation" corresponds exactly to the progression of the nicotine levels delivered by the listed products.

The product development and marketing strategies for smokeless tobacco have been extremely successful at recruiting new users. Use of smokeless tobacco products has risen substantially since the 1970's: overall, moist snuff sales almost tripled from 1972 through 1991, while use by male adolescents aged 18 to 19 increased almost 1,500% between 1970 and 1991. See p. 287.

The deliberate marketing of products that deliver graduated amounts of nicotine demonstrates that smokeless tobacco manufacturers know that their products are used to satisfy consumers' desire for increasing amounts of nicotine. The evidence of manipulation of nicotine delivery in smokeless tobacco shows that manufacturers have taken steps to create and sustain the need for nicotine. This evidence is more than sufficient to demonstrate that smokeless tobacco manufacturers intend consumers to become tolerant to, and addicted to, the nicotine in smokeless tobacco. Both tolerance and addiction are effects on the structure and function of the body produced by nicotine. Accordingly, smokeless tobacco products are intended to affect the structure or function of the body.