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E. INDUSTRY MANIPULATION AND CONTROL OF NICOTINE DELIVERY IN MARKETED TOBACCO PRODUCTS

1. Industry Manipulation and Control of Nicotine in Cigarettes

FDA's investigation has revealed the painstaking attention that tobacco companies pay to nicotine during every phase of cigarette manufacture. This section details the methods used by the industry to manipulate nicotine delivery at each stage of production and some of the effects of these manipulations on the nicotine content (the amount of nicotine in the tobacco rod) and delivery (the amount of nicotine delivered in the smoke for absorption into the bloodstream of the smoker) of modern cigarettes.

At each step -- from tobacco growing, purchasing of tobacco leaves, and blending different types of tobacco, to cigarette design and manufacture -- ensuring adequate nicotine delivery is a central objective of cigarette manufacturers. According to a tobacco industry official:

> *Generally speaking, the nicotine yield of a cigarette is determined by the nicotine content of the tobacco; the static burn rate or amount of tobacco consumed during puffing; the pressure drop of the tobacco column; porosity of the wrapper and or ventilation at the filter; the pressure drop of the filter, the filter material, the surface area of the filter material; and the affinity of the filter material for nicotine particularly as a function of smoke pH. Through the combination of these variables, plant genetics, and commercial processes to remove nicotine from tobacco, it is possible to manipulate the yield of nicotine from about .1 mg to*

4 mg per cigarette.[395a] [Emphasis added.]

The first manufacturing step in nicotine control is the development and selection of raw materials. The tobacco industry has, through breeding and cultivation practices, developed high-nicotine tobacco plants that provide higher-potency raw material, giving manufacturers greater flexibility in blending and in providing uniform and sufficient nicotine deliveries.

Even without the selective breeding and cultivation of plants for nicotine content, careful tobacco leaf purchasing plans permit the manufacturers to control nicotine content in their products. For example, nicotine content varies among types of tobacco and from one crop year to the next. Awareness of these basic differences and monitoring of the nicotine levels in purchased tobacco allows the companies to produce cigarettes with nicotine deliveries consistent to a tenth of one percent, despite variations as high as 25% in the nicotine content of the raw material originating in the same area, from year to year.

The primary control of nicotine delivery (the amount received by the smoker), however, is in the design and careful, sophisticated manufacture of the cigarette, to ensure that the smoker obtains the precise amount of nicotine intended by the manufacturer. FDA's investigation has revealed that despite reductions in the amount of tar delivered by cigarettes over the past several decades, nicotine delivery in low-yield[396] cigarettes has not fallen proportionately with the reductions in tar. Instead, nicotine delivery has apparently risen over the last decade, a result

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[395a] Spears, AW. Lorillard Tobacco Co. *Factors Affecting Smoke Delivery of Nicotine and Carbon Monoxide.* Presented at the 1975 Symposium- Nicotine and Carbon Dioxide. November 17-18, 1975. In Symposium Proceedings-1, at p.12. FDA notes that when the author testified before Congress, he stated that nicotine manipulation does not occur and that nicotine yields simply follow tar yields. *See* note 479, *infra.* In this article he does not mention tar yield as factor in determining nicotine yield.

[396] "Low-yield" is used to denote cigarettes advertised as low-tar and low-nicotine.

that confirms that nicotine delivery is being independently and carefully manipulated by tobacco manufacturers. This newly gathered information, together with the other evidence of the industry's breeding, purchasing, blending, and manufacturing practices, reveals the extent to which manufacturers control the amount of nicotine that is delivered to the consumer from cigarettes and provides further support for the Agency's conclusion that tobacco manufacturers intend their products to affect the structure or function of the human body.

a. Tobacco Leaf Growing

The industry's control and manipulation of nicotine in the production of cigarettes begins long before the cured tobacco leaf reaches the manufacturing plant. The characteristics of leaf tobacco, including nicotine content, are established by the genetic makeup of the plant, developed during growing, and fixed by post-harvest handling. Like other raw agricultural commodities, the physical and chemical properties of tobacco, including nicotine, can vary widely, depending on genetic differences, growing season conditions, and soil type. This subsection describes the methods used by the tobacco industry to control and manipulate nicotine through careful genetic breeding and agronomic practices. As one industry expert stated, "nicotine is the key chemical constituent of the leaf and smoke and the reason for which tobacco is grown."[397]

Modern types of cultivated tobacco (*Nicotiana tabacum L*) have been selected for a relatively high level of nicotine.[398] Five major types of tobacco make up nearly all tobacco

[397] Adapting agronomy to the needs of the low-tar era. *World Tobacco*. October 1977. Page 137.

[398] *Id.*

products marketed in the United States: Burley, flue-cured, Maryland, the Dark tobaccos, and Oriental. These tobaccos vary both in nicotine levels and in pH. The pH of a tobacco can have a significant influence on the amount of, and rate at which, nicotine is absorbed into the bloodstream of the tobacco user and delivered to the brain.

Of the five major types of tobacco, Burley tobacco generally contains the highest nicotine levels compared to other tobacco varieties, and it has an alkaline pH. Flue-cured tobacco represents the major tobacco ingredient in American cigarettes. In comparison with other tobacco varieties, flue-cured tobacco has a medium nicotine content and is somewhat acidic.[399] Maryland tobacco has a low nicotine content in comparison with other varieties and has an alkaline pH. The Dark tobaccos produce an alkaline smoke, and are the traditional tobaccos for cigar wrappers and fillers as well as for chewing tobacco and for many pipe tobacco mixtures. Oriental tobaccos, cultivated in southeastern Europe and Turkey, are used for their characteristic aroma; they have a low nicotine content, and low pH.[400]

American tobaccos of all types have undergone cumulative increases in total nicotine levels since the 1950's.[401] As the following chart demonstrates, nicotine levels in the most widely grown American tobaccos increased almost 10% for Burley and more than 50% for flue-cured between 1955 and 1980:

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[399] Browne CL. *The Design of Cigarettes*. Hoechst Celanese Corporation; 1990. Page 43.

[400] *Id.* at pp. 22, 44.

[401] DeJong DW. The role of American tobacco leaf chemistry in low-yield cigarettes: an agricultural viewpoint. *Tabak Journal International.* May 1985. Pages 376-83. DeJong notes that higher-nicotine American tobaccos are needed in limited quantities to "spike" low yield cigarette blends. He further notes that off-shore tobaccos are invariably lower in nicotine, but serve to provide "filler" style leaf materials deemed necessary for the manufacturing of low-tar cigarettes, which comprise the majority of the U.S. market.

Tobacco Type	Percent Nicotine	
	1955	1980
U.S. BURLEY	2.91	3.18
U.S. FLUE-CURED	1.93	3.07

Two tobacco industry activities over the last several decades appear to be responsible for this increase: 1) the industry's active and controlling participation in the Minimum Standards Program, which ensures that nicotine levels of U.S.-grown and marketed tobacco are maintained within specified ranges;[402] and 2) the industry's breeding and cultivation of tobacco for high nicotine levels.

The Minimum Standards Program, which began in 1963 for flue-cured tobacco and in 1977 for Burley tobacco,[403] is a component of the tobacco price-support program administered by the U.S. Department of Agriculture (USDA). With regard to domestically grown tobaccos, the industry maintains control over which varieties are suitable for growing in the United States

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[402] *Id.* at p. 382.

[403] *See:*

Letter to M. Murray, FDA, from E. Wersman, North Carolina State University, March 23, 1994, transmitting:

1) The Burley Tobacco Quality Committee-Varieties "Testing Procedure to Assure Acceptable Quality In Burly Tobacco Varieties" revised February 24, 1993.
2) The Flue-Cured Tobacco Quality Committee-Varieties "Testing Procedure to Assure Acceptable Quality In Flue-Cured Tobacco Varieties" amended January 1991.

Letter to M. Zeller, FDA, from E.M. Pfeifer, King & Spalding on behalf of the Brown and Williamson Tobacco Corp., pp.1-8, with enclosures:

Attachment 1 "Flue-Cured Tobacco Variety Committee";
Attachment 2 "Burley Variety Evaluation Committee Membership";
Attachment 3 Slides, pp. 90025-90091.

and thereby eligible for price support.

One key objective of the tobacco industry's involvement in the Minimum Standards Program appears to be to ensure that nicotine levels in marketed tobacco do not fall below specified levels. The program was initiated in response to the emergence, in the 1950's , of several so-called "discount" varieties of tobacco (e.g., "Coker 139," "Coker 187-Golden Wilt," "Coker 282," "Coker 140," "Coker 316," and "Reams 64") that failed to meet current industry specifications established, among other things, to control the amount of nicotine delivery when used in manufacturing filtered cigarettes. To insure the elimination of "discount" or low-nicotine varieties from the market, the industry obtained the necessary cooperation from USDA to eliminate these varieties from the price-support program. In fact, to be eligible under this program, growers must certify, even to this day, that "discount" varieties are not being grown.[404]

In 1979, one major U.S. manufacturer requested that the tobacco variety committee under the Minimum Standards Program lower the acceptable nicotine range, established in 1967, for the specific tobacco varieties used as the standard. Support for lowering the acceptable nicotine range was not forthcoming from the rest of the industry and the change was never adopted.[405] In fact, in spite of the trend toward marketing cigarettes advertised as low delivery, the criteria under the Minimum Standards Program for nicotine content of new varieties have not changed since 1967.

While the Minimum Standards Program ensured that nicotine levels in marketed tobaccos

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[404] USDA Agricultural Stabilization and Conservation Service (ASCS) Manual. "Identification of certain flue-cured tobacco varieties under the price support program." April, 1964. Pages 3-5, 8, 10-11. Obtained on June 15, 1994, from USDA-ARS-SAA, Crops Research Laboratory.

[405] Collins WK. Cultural practices increase nicotine content of U.S. flue-cured leaf. *Tabak Journal International.* [4] 1981:328, 330.

did not fall, breeding and cultivation initiatives undertaken by the industry caused nicotine levels to increase. When health concerns prompted the tobacco industry to begin to market low-tar cigarettes in the 1960's and 70's, the industry turned to tobacco breeders to develop tobacco varieties that produced less tar. Breeders found that without intervention in the breeding of these varieties, nicotine levels were reduced along with tars.[406] Thus, the industry has long been able to grow low-tar and low-nicotine varieties of tobacco for use in manufacturing cigarettes.

By 1978, however, the industry had abandoned its interest in the development of low-tar/low-nicotine varieties of tobacco for manufacturing low-yield cigarettes, and instead turned to the development of higher nicotine varieties. According to one expert in the field, it was necessary to focus on developing tobacco that was higher in nicotine, not lower:

> *. . . manufacturers have means of reducing tars but most of the methods reduce nicotine and other constituents at the same time. Therefore it may be desirable to develop levels constant or to develop lines higher in nicotine so that when the tar and nicotine are reduced there will still be enough nicotine left to satisfy the smoker.*[407] [Emphasis added.]

Industry experts agreed, stating in 1981 that the nicotine content of tobacco "will increase if the very low 'tar' brands continue to expand in market share,"[408] They further stated that:

> *[c]urrent research is directed toward increasing the nicotine levels while maintaining or marginally reducing the 'tar' deliveries.*[409]

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[406] Tailoring tobacco plants to meet future demands. *World Tobacco*. October 1978. Page 148. Abbreviation of talk by J.F. Chaplin at meeting of CORESTA scientists in Sofia, Bulgaria.

[407] *Id.*

[408] Spears AW, Jones ST. Chemical and physical criteria for tobacco leaf of modern day cigarettes. *Recent Advances in Tobacco Science.* 1981;7:19-39, 37.

[409] *Id* at p. 31. *See* DeJong, note 401, *supra,* at p. 378. In anticipation of a move toward low-yield cigarettes, USDA was once petitioned by the industry to promulgate regulations to allow for the growing of ultra-low nicotine tobacco. The regulations were actually published in the *Federal Register* in June 1947. The nicotine concentration was to be no higher than 0.8%, which is significantly lower than the

The industry has elsewhere acknowledged that the role of American tobacco is to provide high levels of nicotine in the finished product to offset the diluting effect of bland foreign tobaccos and reconstituted tobacco sheet.[410]

FDA's investigation has revealed that at least one cigarette manufacturer, Brown and Williamson, has developed and marketed a tobacco so high in nicotine that it exceeded the limits imposed for U.S.-grown tobacco under the Minimum Standards Program. These limits cannot be exceeded without significant risk of losing government-administered price support. However, foreign-grown tobaccos are not subject to these specifications and are not subject to testing for nicotine content upon entry into the United States. This high-nicotine tobacco was therefore grown in South America.

FDA found that Brown and Williamson was involved for more than a decade in developing, through a combination of conventional and advanced genetic breeding techniques, a high-nicotine, flue-cured tobacco plant, named "Y-1," for use in a number of low-tar brands of cigarettes in the United States.

Brown and Williamson characterized its achievement in a patent filing in the following way:

> *By the present invention or discovery, applicants have succeeded in developing a tobacco plant that is agronomically and morphologically suitable for commercial tobacco production, i.e. it closely resembles SC 58, and provides a pleasant taste and aroma when included in smoking tobacco products, yet it is possessed of the N. rustica high-nicotine attribute. So far as we know, this has not been*

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concentration of nicotine in domestic tobaccos. These low-nicotine varieties were to be kept entirely separate and marketed under contract. These regulations remain in the Code of Federal Regulations (7 CFR 30), but they have never been taken advantage of, indicating industry's lack of interest in the development of ultra-low nicotine tobaccos.

[410] *See* DeJong, note 401, *supra.*

accomplished before . . . [Emphasis in original.] [411]

The development of Y-1 dates back to at least the mid-1970's. In 1977, James F. Chaplin, who was affiliated with both USDA and North Carolina State University, indicated that tobacco could be bred to increase nicotine levels, by crossbreeding commercial varieties of tobacco with *Nicotiana rustica. N. rustica* is a wild tobacco variety that is very high in nicotine, but is not used in manufacturing cigarettes because of its harshness.[412]

By combining conventional and advanced breeding techniques, Brown and Williamson succeeded in developing commercially viable Y-1 from seeds initially produced by Chaplin's crossbreeding work. The nicotine content of the leaf of this variety is about 6% by weight, which is higher than that of any other varieties of tobacco commercially grown in the United States. (Domestically grown varieties of flue-cured tobacco, for example, naturally contain 2.5% to 3.5% nicotine.[413])

Company officials admitted to FDA that Y-1 was intended as a "blending tool" to enable the company to design products that were lower in tar but not lower in nicotine.[414] The company disclosed to FDA that Y-1 had been used commercially in the manufacturing of Viceroy King Size, Viceroy Lights King Size, Richland King Size, and Richland Lights King Size and it

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[411] U.S. patent application No. 761,312 submitted on September 17, 1991.

[412] Chaplin JF. *Breeding for varying levels of nicotine in tobacco.* Proceedings from a symposium on Recent Advances in the Chemical Composition of Tobacco and Tobacco Smoke. 1977. Page 334.

[413] Letter to D.A. Kessler, FDA, from J. W. Johnston, R.J. Reynolds Tobacco Co. February 28, 1994. Pages 1-2.

[414] Transcript of FDA meeting with Brown and Williamson. June 17, 1994. Pages 18, 29, 85-86, 124.

constituted about 10% of the tobacco blend of these products.[415] These brands were manufactured and distributed throughout the United States in 1993.[416] FDA's investigation revealed that, as of mid-1994, Brown and Williamson still had between 3.5 million and 4 million pounds of this high-nicotine tobacco on hand.[417]

In addition to breeding high-nicotine tobacco varieties, the tobacco industry engages in a number of agronomic practices that increase nicotine levels in tobacco. Heavy application of nitrogen fertilizers, early topping, and tight "sucker" (i.e., bud growth at the junction of stalk and leaves) control have all acted in concert to push nicotine levels upward.[418] In addition, tobacco varieties have been selected for tolerance to brown spot, a leaf disease that makes early harvest necessary. Leaves of disease-resistant varieties tend to remain in the field longer, resulting in maximum nicotine accumulation.[419] Since the introduction in 1965 of the acreage-poundage control system, farmers have reduced the number of harvestable leaves per plant and have tended to increase plant spacing. Both of these practices tend to increase nicotine content in the leaf.[420] Finally, tobacco growers are transplanting tobacco crops earlier, which, coupled with the widespread use of pesticides in the soil, often results in slow early season growth, and also tends

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[415] *Id.* at pp. 153, 165.

[416] *Regulation of Nicotine under the Federal Food, Drug, and Cosmetic Act: hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives,* 103 Cong. 2d Sess. (June 21, 1994)(statement of David A. Kessler, M.D., Commissioner of Food and Drugs, "The Control and Manipulation of Nicotine in Cigarettes," at pp. 9-12). The Commissioner's statement is included as Appendix 8 to this document.

[417] *See* Transcript, note 414, *supra,* at p. 124.

[418] *See* DeJong, note 401, *supra,* at p. 382.

[419] *See* Collins, note 405, *supra,* at p. 330.

[420] *Id.*

to increase nicotine content in the leaves.[421]

These nicotine-raising agronomic practices have been adopted by U.S. growers in recent years, even though over 50% of the U.S. cigarette market is now characterized as low delivery. Thus, the tobacco industry has developed a number of sophisticated methods for manipulating nicotine levels through breeding and cultivation of tobacco plants and has used these methods to maintain and increase concentrations of nicotine in tobacco leaves. These methods enable the industry to use high-nicotine leaf in low-tar cigarettes, so that, paradoxically, certain low-tar cigarettes now contain more of the higher nicotine tobacco in their blend than cigarettes with higher tar deliveries.[422] See p. 261 infra. The use of these methods demonstrates that the industry manipulates nicotine independently of other tobacco components to ensure that cigarettes contain sufficient nicotine to satisfy smokers.

b. Leaf Purchasing

Nicotine is perhaps the most important criterion employed by cigarette companies in the purchase of tobacco leaf. As one tobacco company official stated over 20 years ago in an industry publication:

> *It is believed that one important reason why the consumer smokes cigarettes is for the nicotine which they contain . . . Manufacturers, therefore, must have all options open in selecting leaf to buy.*
>
> *They are most concerned with the nicotine levels in leaf, so that after manufacture of their blends, the nicotine percentages in the cigarettes will vary minimally both*

[421] *See* Collins, note 405, *supra.*

[422] *See* Spears, note 408, *supra,* at p. 22.

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from one to another within a packet, and from packet to packet.[423] [Emphasis added.]

The key factor related to nicotine in leaf purchasing is stalk position. The concentration of nicotine is lowest at the bottom of the plant and highest in the top leaves of flue-cured tobacco.[424] Thus, the position of the leaf on the stalk determines how much nicotine the leaf will contain. In fact, "stalk position" is an industry euphemism for nicotine content. The stalk position of a leaf can be determined by its appearance, shape, color, and thickness, even after harvest.[425] Therefore, an experienced buyer, whose instructions are dictated by the manufacturer's chemists,[426] need only be concerned with these physical characteristics in identifying leaves of varying nicotine content.

The significance of stalk position in leaf purchasing was confirmed when FDA visited cigarette manufacturers. [redacted] [427]

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[423] What changing technology means for leaf producers and packers. *World Tobacco*. September 1971. Page 137. Based upon lecture by J.S. Campbell, American Organisation of the Imperial Tobacco Group Ltd. at a Conference on Social and Economic Issues Confronting the Tobacco Industry in the Seventies, Lexington, KY.

[424] *See* 1977 *World Tobacco* article, note 397, *supra*. *See also* Browne, note 399, *supra*, at p. 15.

[425] *See* 1977 *World Tobacco* article, note 397, *supra*.

[426] Evolving techniques of making cigarettes milder. *World Tobacco*. April 1979. Page 95.

[427] FDA officials Mitch Zeller, Kevin Budich, Barbara Frazier, and Bob Spiller visited the sites of R.J. Reynolds Tobacco Company on April 11-12, 1994, and Brown and Williamson Tobacco Company on May 3, 1994. The following references refer to their summary notes of the visits.

Zeller notes from RJR visit at p. 2.
Budich notes from RJR visit at p. 3.

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Furthermore, this RJR representative revealed that "impact" is a criterion in leaf purchasing and that "impact" is "basically a function of nicotine in tobacco."[428] RJR also indicated that "impact" is measured in the company's laboratories if there is enough time to do so prior to purchase.[429]

Representatives from Brown and Williamson also described the significant role that nicotine plays in the purchase of tobacco leaf. The company stated that stalk position is the "first thing" they look for during leaf purchasing.[430] At Brown and Williamson, the lower stalk positions are considered to have the least amount of "smoke quality," which was defined as including "impact level."[431] The company defines "impact" as "the hit or punch in the back of the throat when you first inhale."[432]

Nicotine levels are so crucial to leaf purchasing at Brown and Williamson that the

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[428] Zeller notes from RJR visit at p. 2.
Budich notes from RJR visit at p. 3.
Frazier notes from RJR visit at p. 2.
RJR overhead was provided at visit.

[429] Zeller notes from RJR visit at p. 2. [redacted]

[430] Zeller notes from B&W visit at p. 2.
Frazier notes from B&W visit at p. 2.
Spiller notes from B&W visit at p. 2.

[431] Zeller notes from B&W visit at p. 2.

[432] Zeller notes from B&W visit at p. 2.
Budich notes from B&W visit at p. 4.
Frazier notes from B&W visit at p. 2.
Spiller notes from B&W visit at p. 2.

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company actually adjusts the stalk positions of its leaf purchases based upon the results of nicotine analyses that are performed during the course of the buying season.[433] In addition, Brown and Williamson employs special measures when purchasing foreign tobacco to ensure adequate nicotine levels. The company stated that foreign Burley and flue-cured tobaccos are smoked prior to their purchase so that they get some sense of the "impact" of the tobacco,[434]

[redacted][435]

c. Leaf Blending

After purchase, tobacco leaves are blended to attain target levels of nicotine and tar in the smoke. FDA's investigation noted particular attention on the part of manufacturers to the nicotine content of the leaf in the blending operation. As noted above, blending practices by manufacturers are designed to: (1) control the naturally occurring variations in nicotine and other components caused by genetics, growing season conditions, and soil type within a given type and grade; and (2) particularly for low-tar cigarettes, to increase nicotine concentrations and thereby maintain an acceptable nicotine level in the cigarettes.

As described above, each type of tobacco has unique characteristics of nicotine and tar delivery. Moreover, within each type, levels of nicotine increase with ascending stalk position

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[433] Frazier notes from B&W visit at p. 2.

[434] Spiller notes from B&W visit at p. 2.
Frazier notes from B&W visit at p. 2.

[435] [redacted]

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(grade). Armed with this knowledge, tobacco manufacturers blend various types of tobaccos and various stalk positions to achieve specific nicotine levels in particular brands.

Manufacturers also pay attention to other features of tobaccos that can affect nicotine delivery during blending. For example, cigarette filling power (bulk), pressure drop or resistance to draw, and static burn rate are all decreased with ascending stalk position. Decreases in burn rate increase the puff count, and thereby result in the delivery of more nicotine to the smoker because less tobacco is burned between puffs.[436]

The pH of cigarette smoke directly affects the delivery of nicotine because it alters the amount of nicotine that is absorbed in the mouth or lungs.[437] PH is controlled by the manufacturer in the selection of the type of tobacco used and blended. For example, smoke-condensate pH is higher from certain tobacco varieties as well as from leaves at upper stalk positions.

Blending techniques have been used to finely control nicotine concentrations in marketed cigarettes. [redacted][438] This is a high

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[436] *See* Browne, note 399, *supra,* at p. 12.

[437] *See* Surgeon General's Report. *Nicotine Addiction.* 1988. Pages 29-31.

[438] [redacted]

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degree of control even in a product manufactured from synthetic, homogeneous materials. It is a remarkable degree of control for a product such as cigarettes, which are made from highly variable biological materials whose nicotine content is ordinarily dependent upon such uncontrollable factors as weather and plant attack by insects and plant diseases.

Significant evidence also demonstrates that tobacco manufacturers have used blending techniques to increase nicotine concentrations in low-tar cigarettes and thereby maintain nicotine delivery while reducing tar delivery. FDA has observed the industry's use of proportionately greater amounts of higher nicotine-containing Burley tobacco in the tobacco blends of the lowest-tar varieties of cigarettes. In fact, Thomas Sandefur, the chief executive officer of Brown and Williamson, admitted to Congress that nicotine levels can be adjusted "up or down" depending on the blend of tobaccos used in a particular cigarette.[439] Industry scientists have also acknowledged that tobacco manufacturers blend high-nicotine tobaccos to compensate for the reductions in nicotine caused by innovations in cigarette design and manufacturing to reduce tar deliveries.[440]

[redacted]

[redacted]

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[439] *Regulation of Nicotine under the Federal Food, Drug, and Cosmetic Act: hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives,* 103 Cong. 2d Sess. (June 23, 1994) (testimony of Thomas E. Sandefur, Jr., CEO, Brown and Williamson Corp., transcript at p.133).

[440] *See:*
DeJong, note 401, *supra.*

Spears, note 408, *supra,* at pages 22-24.

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[redacted][441] These examples demonstrate that tobacco manufacturers deliberately increase the proportion of high-nicotine tobaccos in low-tar cigarettes to prevent reductions in nicotine delivery that would otherwise result in these products.

Moreover, as described above, Brown and Williamson developed "Y-1," its ultra-high nicotine tobacco, for the purpose of having a "blending tool" that could be used to maintain nicotine delivery while reducing tar.

d. Cigarette Design and Manufacture

Cigarettes are not simply cut tobacco rolled into a paper tube. Modern cigarettes, as sold in the United States, are painstakingly designed and manufactured to control the amount of nicotine delivered to the smoker. The following aspects of cigarette design and manufacturing all affect the nicotine delivery of a finished cigarette:

(i) the chemical manipulation of tobacco smoke;

(ii) the use of flavors and casings;

(iii) filtration;

[441] Zeller M, Budich K. Notes from March 22-23, 1994 meeting with Philip Morris and April 10-12, 1994, meeting with RJR. Mitch Zeller's notes, at pp. 2-3, and Kevin Budich's notes at p. 9.

(iv) the use of reconstituted tobacco; and

(v) use of wider tipping paper.

(i) Chemical Manipulation

Tobacco manufacturers add certain chemicals to the tobacco to enhance the efficient extraction by the smoker of nicotine from the tobacco in the rod. For example, certain additives can alter the pH of cigarette smoke, which is known to affect the rate of absorption of nicotine into the bloodstream of the smoker.[442]

FDA's investigation has disclosed efforts by the industry to chemically enhance nicotine delivery. A major American tobacco company's 1991 handbook on leaf blending and product development shows that ammonia from such sources as diammonium phosphate (DAP),[443] ammonium hydroxide, and urea can be used in cigarette manufacturing to increase the amount of nicotine delivered to the smoker.

The handbook states that ammonia in cigarette smoke:

> *can liberate free nicotine from the blend, which is associated with increases in impact and 'satisfaction' reported by smokers.*[444]

The handbook goes on to describe ammonia as an "impact booster":

> *Ammonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine. As a result of such change, the ratio of extractable nicotine to bound nicotine in the smoke may be altered in favor of extractable nicotine. As we know, extractable nicotine contributes to impact in*

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[442] Surgeon General's Report. *Nicotine Addiction.* 1988. Pages 29-31.

[443] *See* Statement of David A. Kessler, note 416, *supra,* at pp. 9-12.

[444] *Id.* at p. 10.

cigarette smoke and this is how ammonia can act as an impact booster.[445]

Ammonia increases the pH of the smoke and thereby enhances the absorption of nicotine by the body.[446] FDA's investigation has revealed at least one common site for the application of ammonia and ammonia-like compounds: reconstituted tobacco. The agency has found levels of these compounds to be as high as 10 % in reconstituted tobacco.

The company handbook describes the benefits of the treated reconstituted tobacco as a source of ammonia to absorb nicotine from higher alkaloid-containing components in the blend. This company handbook also describes the application of ammonia directly to the leaf tobacco.

With regard to the question of the efficiency of this technology in increasing nicotine delivery, the handbook states that smoke analysis shows that an experimental cigarette made of reconstituted tobacco treated with ammonia has almost double the nicotine transfer efficiency of tobacco.[447] This handbook also states that many U.S. tobacco manufacturers utilize ammonia technology. One company has admitted to FDA that it uses DAP in manufacturing cigarettes, and that such use increases nicotine delivery.[448]

(ii) Flavors and Casings

Various substances are added to tobacco components to affect the flavor and palatability of smoke, alter smoke composition and yield, modify burn rate, and alter pH to optimize nicotine

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[445] *Id.*

[446] Surgeon General's Report. *Nicotine Addiction.* 1988. Pages 29-31.

[447] *See* Statement of David A. Kessler, note 416, *supra,* at pp. 10-12.

[448] *See* King and Spalding letter, note 403, *supra,* at p. 6.

delivery. According to one industry expert,[449] the major contribution of the tobacco flavor specialist is to:

> *help provide a rich, clean, full-bodied tobacco flavour, 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 . . .*

So-called "casings" are solutions of usually water-soluble ingredients that provide a means of incorporating flavorings and other additives into the tobacco blend. Casings are often used in tobacco processing to reduce the harshness of nicotine in high-nicotine tobaccos, thus permitting greater use of these tobaccos in cigarette manufacture. This use of casings is described by an industry "flavorist" in the following quote:

> *It is assumed that nicotine is one of the primary satisfaction factors for which tobacco products are used. However, in air-cured tobaccos (cigar, burley, Maryland), the pH of the smoke is generally alkaline and the flavor effect of nicotine is a "harshness" which can be choking and unpleasant. In the case of tobaccos containing sugars (flue-cured, oriental), the tobacco is weakly acidic, the effect of the nicotine is greatly modified, and the harshness is dramatically reduced. This same effect is often achieved by addition of sugars to air-cured tobaccos to "mellow" the smoke and/or by the blending of air-cured tobaccos with flue-cured and oriental. [Citation omitted.] Thus, smoke pH and leaf sugar content are factors which play an important role in the nicotine strength perceived in the smoking process.*[450]

As is clear from this quote, casings are used to permit the incorporation of high-nicotine tobaccos in cigarette blends, despite their unpleasant taste. Casings composed of such additives as sugar, licorice, or cocoa help to overcome the bitterness of nicotine in smoke. The lengths to which tobacco manufacturers go to use high-nicotine tobaccos, despite the harsh taste of

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[449] Hertz AN. The flavourist's role in the cigarette design team. *World Tobacco.* March 1985. Page 97.

[450] Leffingwell JC. Nitrogen components of leaf and their relationship to smoking quality and aroma. *Recent Advances in Tobacco Science.* Volume 2. Page 9.

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nicotine, reveals that the nicotine in these tobaccos is not being used for its taste but for another purpose.

FDA's investigation revealed the following example of the application of casings to permit a use of a high-nicotine tobacco that would otherwise have been unpalatable to consumers. [redacted][451]

Manufacturers also reduce harshness by routinely adding acids to tobacco to lower the pH of the smoke.[452] Manufacturers also use conventional casing materials, such as sugars and cocoa, to produce acids in the smoke and reduce harshness.[453] Harshness from nicotine is also reduced by spraying on top dressings after the tobacco is cut and shredded for cigarette making.[454]

Casings often include a humectant, usually glycerine or a higher glycol, which serves to

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[451] [redacted]

[452] *See* King and Spalding letter, note 403, *supra,* at p. 6.

[453] *Id.*

[454] *Id.*

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keep the tobacco moist and less sensitive to changes in humidity.[455] RJR acknowledged using glycerine as a humectant.[456] Tobacco industry officials acknowledge that controlling moisture content is essential to ensure that nicotine content does not fall.[457] Humectants also act to control particle size in the formation of the smoke aerosol, making the smoke "smoother" or less harsh on the back of the throat. Smoother smoke facilitates inhalation, ensuring that the nicotine will be taken into the lungs and rapidly and completely absorbed.

Nicotine can also be added to cigarettes through application of tobacco extracts in the processing of tobacco. Although calling the contribution of flavored tobacco extracts to the overall nicotine delivery from cigarettes "trivial," tobacco companies admitted to having used such extracts in testimony before Congress,[458] in other public statements,[459] [redacted]

[redacted]

[redacted]

[redacted]

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[455] *See* Browne, note 399, *supra,* at pp. 55-56.

[456] Budich K. Notes from April 10-12, 1994, meeting with RJR. Page 8.

[457] DeBardeleben MZ, Clafin WE, Gannon WF. (Philip Morris Research Center). Role of cigarette physical characteristics on smoke composition. *Recent Advances in Tobacco Science.* Volume 4. Page 98 ("Nicotine decreases on a per puff basis as moisture content increases . . . . The decrease is dramatic as moisture content rises above 12%").

[458] *Regulation of Tobacco Products (Part I): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives,* 103 Cong. 2d Sess. 592, 596 (April 14, 1994) (testimony of Edward A. Horrigan, Jr., Liggett Group, Inc. and Andrew Tisch, Lorillard Tobacco Co.).

[459] Philip Morris press release. *Philip Morris Statement on Nicotine in Cigarettes.* March 25, 1994. Page 2.

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[redacted][460]

(iii) Filtration

The filter plug provides a mouthpiece that captures particulate matter from the smoke and absorbs vapors. The filter can be used as a vehicle to carry filter aids such as charcoal and other solids and liquid additives that permit selective filtration of certain chemicals. The manufacturer's selection of a particular filter is determined largely by the target levels of nicotine and tar.[461]

Significant research has been conducted by the tobacco industry on the use of filter additives to enhance nicotine delivery.[462] FDA's investigation revealed that at least one major cigarette manufacturer has added a chemical to the filters used on its marketed cigarettes that increases the amount of nicotine delivered to smokers, by increasing the amount of nicotine that is eluted from the filter. "Elution" is the process by which nicotine that is initially trapped on a

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[460] *See:*

Hunter J. FDA memo to the record. Conversation with Steve Block of IFF. March 23, 1994.

Layloff T, FDA. Memo to James Hunter, FDA. Tobacco Extract Analyses. February 24, 1995.

[redacted] The actual contribution of tobacco extracts to total nicotine delivered to the smoker by tobacco so treated is unclear. The industry has conducted research to examine the specific activity of added versus naturally occurring nicotine. *See* Jenkins RW, Comes RA. Exogenous vs Endogenous Transfer of Nicotine During Smoking. *Int. J. Appl. Radiat. Isotopes.* 1976;27:323-324.

[461] *See* Browne, note 399, *supra,* at p. 66.

[462] Reynolds ML. Influence of filter additives on smoke composition. Page 54. Undated.

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filter is remobilized into the mainstream smoke by hot vapors and becomes available for inhalation by the smoker. [redacted][463]

Filter ventilation, which is accomplished by making holes in the filter wrap and tipping paper, is also a major means of controlling the nicotine delivery of a cigarette. Ventilation has apparently now largely replaced interest in filter additives as a means of enhancing nicotine delivery.[464] Ventilation holes allow fresh air to be pulled in by the smoker's suction, thereby diluting the smoke. Ventilation does not, however, simply reduce the concentration of each smoke component in proportion to the degree of dilution. Instead (while ventilation does reduce the tar and nicotine deliveries compared to a non-ventilated cigarette), ventilation can be used to increase the proportion of nicotine compared to tar.[465]

Tobacco manufacturers control filter ventilation by (1) changing the number and location

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[463] [redacted]

[464] *See* Reynolds, note 462, *supra,* at p. 61.

[465] Kiefer JE. Ventilated Filters and their Effect on Smoke Composition. In: *Recent Advances in Tobacco Science.* Volume 4. Physical Parameters which Affect the Composition of Cigarette Smoke from 32nd Tobacco Chemists Research Conference. October 30 - November 1, 1978. Montreal, Canada. Pages 78,79.

of holes in the filter tipping paper, which surrounds the filter at the smoker's end of the cigarette rod; and (2) by controlling the porosity of the plug wrap, which underlies the tipping paper and surrounds the filter.[466]

As the amount of ventilation increases, the amount of tar and nicotine are not proportionately reduced. Instead, tar is reduced at a greater rate than nicotine, thereby increasing the proportion of nicotine to tar. For instance in one reported measurement, as the proportion of filter ventilation went from 0% to 50%, mainstream smoke tar dropped 47% (29.38 to 15.71 mg/cigarette), while mainstream smoke nicotine dropped 37% (1.70 to 1.07 mg/cigarette).[467] The effect of using such ventilation is that the manufacturer has selectively reduced tar while delivering a higher percentage of the available nicotine to the smoker.

Filter ventilation can produce low nicotine and tar delivery ratings when measured by the FTC smoking machine, yet still manage to deliver higher nicotine levels to the smoker than indicated by the FTC yield. Research has shown that, unlike the FTC smoking machine, 32% to 69% of low-tar cigarette smokers block the perforations in ventilated filters with their fingers or lips. This behavior is not unexpected because some smokers are unaware of these ventilation holes or their function, and because the holes are generally tiny, laser-generated perforations and difficult for the smoker to see. Blockage of these holes results in greater nicotine yields to the smoker than those measured by the FTC smoking machine.[468] This filter design provides a

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[466] *See* Browne, note 399, *supra,* at p. 10.

[467] *See* Browne, note 399, *supra,* at p. 84.

[468] Kozlowski LT, Frecker RC, Khouw V, Pope MA. The misuse of 'less hazardous' cigarettes and its detection: hole-blocking of ventilated filters. *American Journal of Public Health.* 1980;70(11):1202-1203.

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means of compensating for reductions in nicotine delivery that are produced by unblocked filter ventilation. The ability to block ventilation holes is thus a means of improving a cigarette's "elasticity," i.e., a design feature that allows smokers to "compensate" for nicotine losses that would otherwise be caused by tar-reducing modifications. See p. 229, supra.

Another ingenious compensatory method to boost nicotine delivery has been the development of the so-called channel-ventilated filter system. This system has been employed by Brown and Williamson for its BARCLAY brand launched in 1981, and represents an attempt to avoid some of the reduction in nicotine that can accompany the use of ventilated conventional filters. The channel-ventilated filter functioned differently when tested on the FTC smoking machine than when used by humans. In fact, in an investigation that commenced in 1981, the FTC found that air flow through these channels is indeed compromised during actual smoking and that BARCLAY's channel filter actually delivers considerably more nicotine and tar to the smoker than is obtained using the FTC's testing method.[469] In 1983, the FTC successfully sued to enjoin Brown and Williamson from using nicotine, tar, and carbon monoxide results obtained from the FTC's smoking machine testing method in its BARCLAY advertising.[470] [redacted]

[469] Federal Trade Commission. "Report to Congress Pursuant to the Federal Cigarette Labeling and Advertising Act," for the year 1981(July 1984) and 1984(1986).

[470] FTC v. Brown & Williamson Tobacco Corp., 580 F. Supp. 981, 983, 987, n. 35, and 988 (D.D.C.1983), aff'd in part (affirmed holding that the 1 mg tar claim had a tendency to deceive) and remanded in part, 778 F. 2d 35 (D.C. Cir. 1985). RJR and Philip Morris had complained to the F.T.C. that Brown and Williamson's Barclay advertisement claim of 1 mg tar was inaccurate and misleading, and that "when the cigarette is smoked between human lips its air ventilation system is inevitably obstructed and the cigarette delivers disproportionately more tar and nicotine than other comparably rated cigarettes." 778 F.2d at 37. Brown and Williamson argued, among other things, that Barclay had a higher ratio of nicotine to tar. 580 F. Supp. at 981, 984.

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[redacted] [471]

(iv) Reconstituted Tobacco

Cigarette manufacturers claim that the development and use of reconstituted tobacco sheet represents a cost-cutting measure to minimize tobacco waste. But the role of reconstituted tobacco in reducing tar and in controlling nicotine delivery is also apparent. The first use of reconstituted tobacco occurred in the 1950's by RJR, primarily as a method for reducing tar, in WINSTON cigarettes.[472] RJR estimates that reconstituted tobacco is used in virtually every cigarette brand on the market.[473] U.S. manufacturers generally use between 20% and 25% of this material.[474]

In the reconstitution process, pieces of tobacco material undergo treatment that results in the extraction of some soluble components, including nicotine. The pieces are then physically formed into a sheet of tobacco material, to which the extracted nicotine is re-added. Even if this

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[471] Budich K. Notes from May 3, 1994, meeting with Brown and Williamson. Page 12.

Federal Trade Commission. "Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes." 1994. Pages 9-10.

[472] Chemical and Biological Studies On New Cigarette Prototypes That Heat Instead of Burn Tobacco, R.J. Reynolds Tobacco Co. Winston-Salem, NC. 1988. Page 29. By increasing the use of reconstituted tobacco sheet in the cigarette rod (thereby reducing the amount of cut tobacco leaf needed) and using increasingly more efficient filtration, the levels of tar have been further reduced by the industry since the 1950's.

[473] *Id.*

[474] *See* Browne, note 399, *supra,* at p. 47.

reconstituted material contains only the original nicotine, its recombination with the tobacco material may be viewed as adding nicotine to the cigarette because the nicotine had been removed. Although denied by tobacco executives,[475] it is publicly reported that this process adjusts nicotine levels in the products, and that one manufacturer "readily admits to setting levels of nicotine . . . for the tobacco sheet."[476]

The agency has observed that the primary methods of producing reconstituted tobacco sheet are closely monitored and controlled to preserve the amount of nicotine in the tobacco components. These processes enable the manufacturer to precisely control and evenly disperse nicotine throughout this material, bringing a high degree of uniformity and consistency to the composition of a raw agricultural commodity. This control is so refined that despite the wide variability in the nicotine content of unprocessed tobaccos, reconstituted tobacco contains a generally uniform concentration of nicotine of around 1%, industry-wide. And, as described below, the reconstitution process can actually be used to elevate the level of available nicotine.

At least one company, LTR Industries, LeMans, France, which is involved exclusively in the production of reconstituted tobacco sheet for the cigarette industry, has publicly acknowledged the extent to which the production of such material can be controlled to precisely affect nicotine and tar deliveries.

According to an article appearing in the February 1983 issue of Tobacco Journal International, LTR claims that its process can produce reconstituted tobacco sheet to satisfy any

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[475] *Regulation of Tobacco Products (Part I): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representaives,* 103 Cong. 2d Sess. 543 (April 14, 1994) (testimony of William I. Campbell, President and CEO, Philip Morris U.S.A.).

[476] Sisele S. Tobacco scrap: cigarette makers are taking heat for adjusting nicotine levels. *The Charlotte Observer.* March 6, 1994. Page 1C.

manufacturer's specifications for nicotine delivery. In this article, LTR states that "based on the idea that reconstituted tobacco could be used as a nicotine regulator, we have developed products with reduced or fortified nicotine." LTR has also been identified as having the ability to manipulate nicotine levels in reconstituted tobacco either by working into the scrap and waste new nicotine-rich tobacco of the "*rustica* type," or by adding purified salts of nicotine into the slurry, to boost the levels of nicotine in the finished reconstituted tobacco sheet.[477]

(v) Use of Wider Tipping Paper

Another means to compensate for nicotine losses from tar-reducing design options is the industry's use of wider tipping paper overwrap. According to a study conducted by Grunberg et al.,[478] between 1967 and 1978, the width of the overwrap was increased on 18 brands of filter cigarettes, even though there was smokable tobacco under the widened overwrap. The Grunberg study found that the wider tipping paper reduced the amount of tobacco smoked during the FTC testing method, because the FTC method prescribes that cigarettes be smoked down to within 3 millimeters of the tipping paper rather than until all of the tobacco is burned. Thus, use of wider tipping paper causes a decrease in the FTC yields of tar and nicotine while permitting smokers to obtain a higher yield of both tar and nicotine from the cigarette. Like the use of ventilation holes, use of wider tipping paper constitutes a form of built-in "elasticity" because it increases the amount of nicotine a smoker can obtain from a cigarette over the advertised FTC yield.

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[477] Evolving techniques of making cigarettes milder. *World Tobacco.* April 1979. Pages 93-101.

[478] Grunberg NE, Morse DE, Maycock VA, Kozlowski LT. Changes in overwrap and butt length of American filter cigarettes. *NY State Journal of Medicine.* July 1985. Pages 310-312.

e. Manipulation of Nicotine in Low-Yield Cigarettes

The manipulation and control of nicotine in cigarette design and manufacture is particularly apparent when low-yield cigarettes are analyzed. Since the genesis of the low-tar cigarette, the industry has recognized that the use of tar-reducing modifications, such as those described above, can reduce nicotine delivery. This has led some manufacturers to compensate for the effects of tar reduction to ensure an adequate delivery of nicotine in the low-yield products.[479] As one article in a 1979 industry publication states, the current practice is "to prefer tobaccos rich in flavour elements, even though that may mean their having more nicotine and tar than is desirable, and seeking to reduce the latter without doing too much harm to the former."[480]

To a remarkable degree, the cigarette industry has accomplished the task of maintaining delivery of nicotine while decreasing tar in low-tar products. In 1988, Jacob et al.[481] found that,

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[479] The tobacco industry has repeatedly stated that reductions in tar yields result in proportionate reductions in nicotine yields. *See, e.g. Regulation of Tobacco Products (Part I): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives,* 103rd Cong., 2d Sess. 363 (1994) (statement of R. J. Reynolds Tobacco Company); *Regulation of Tobacco Products (Part I): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives,* 103rd Cong., 2d Sess. 378 (1994) (statement of Alexander W. Spears, Vice Chairman and Chief Operating Officer, Lorillard Tobacco Company); ATC letter to the Honorable Henry A. Waxman, note 355, *supra,* at pp. 2-3 of attachment. The evidence in this section demonstrates that nicotine levels in some cigarettes have not fallen proportionately with tar and, in fact, are subjected to independent manipulation and control.

[480] *See* 1979 *World Tobacco* article, note 426, *supra,* at page 95.

The manipulation of nicotine levels relative to tar levels in European cigarettes was noted in *The Lancet* in 1979. The author reported that the tar-to-nicotine ratio had declined from 1973 to 1979 and concluded that "the consistent fall in tar yield relative to nicotine over a period of years suggests an element of conscious manipulation." Tar: nicotine ratio of cigarettes 1973-79. *The Lancet.* No. 8139. August 25, 1979. Pages 422-423. [Emphasis added.]

[481] *See:*
Jacob P, Benowitz NL, Shulgin AT. Recent studies of nicotine metabolism in humans. *Pharmacology, Biochemistry, and Behavior.* 1988. Volume 30. Pages 249-250. In a more recent study, Benowitz states that cigarettes currently contain 8 to 9 mg of nicotine. Benowitz NL, Henningfield JE. Establishing a nicotine threshold for addiction. *N Engl J Med.* 1994;331:123-125.

regardless of the labeled and advertised FTC nicotine yields and manufacturers' claims of low-nicotine delivery for certain brands, all cigarettes contained at least about 10 mg of nicotine in the cigarette rod. Consistent with this finding, a study by Benowitz and Hall et al.[482] in 1983 demonstrated that cigarettes advertised as having a low-nicotine yield do not contain less nicotine than high-yield cigarettes. Moreover, the nicotine yield of cigarettes, as defined by the FTC smoking machine tests, correlates inversely with nicotine concentrations in the tobacco.[483] In other words, cigarettes advertised as low-tar and low-nicotine have higher concentrations of nicotine, by weight, than high-yield cigarettes. This has been accomplished by a combination of the methods described above for boosting nicotine delivery to compensate for nicotine losses from the application of tar-reducing design modifications.

FDA's analysis of marketed cigarettes has disclosed similar results. There is little variation in nicotine content from one U.S. brand to another. FDA also measured the actual amount of nicotine contained in several brands of cigarettes, and the amount of nicotine in three varieties of the Merit brand of cigarettes: one regular, one low-tar, and one ultra low-tar. The results of this testing showed that the variety labeled and advertised as the lowest in nicotine actually had the highest nicotine concentration, suggesting that the nicotine content was

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Benowitz NL. Dosimetric studies of compensatory cigarette smoking. In: Wald N, Froggatt P, eds. *Nicotine, Smoking and The Low Tar Programme.* Oxford, England: Oxford University Press; 1989:chap 10.

[482] Benowitz NL, Hall SM, Herning RI, Jacob III P, Jones RT, Osman A. Smokers of low yield cigarettes do not consume less nicotine. *New England Journal of Medicine.* 1983;309:139-142.

[483] *Id.*

manipulated to compensate for reductions caused by design features intended to reduce tar.[484]

In addition, FDA evaluated the tar and nicotine data for domestically marketed cigarettes published by the FTC for 1994. These data demonstrate that the lowest tar products have a markedly higher ratio of nicotine to tar than higher tar products. None of the 153 products with 14 or more milligrams of tar (high tar) had a nicotine to tar ratio greater than 1 to 12. By contrast, 88 of the 93 products with 6 or fewer milligrams of tar (ultra-low tar) had a nicotine to tar ratio greater than 1 to 12.[485]

The increase in nicotine-to-tar ratios between 1972 and 1994, see note 485, especially in low tar cigarettes, is particularly revealing in the light of industry research dating from the 1970's showing that the "optimum" nicotine-to-tar ratio for acceptability of low tar cigarettes is higher than the "natural" ratio. As described earlier, a 1975 Philip Morris study showed that "the optimum nicotine-to-tar (N/T) ratio for a 10mg [low] tar cigarette is somewhat higher than

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[484] According to FDA's analysis, whereas Merit Regular 100's contained 1.46% nicotine, Merit Low Tar 100's contained 1.67% nicotine, and Merit Ultra Low Tar 100's contained 1.99% nicotine. *See Regulation of Tobacco Products (Part I): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representarives,* 103 Cong. 2d Sess. 121 (March 25, 1994) (statement of David A. Kessler, M.D., Commissioner of Food and Drugs, "The Control and Manipulation of Nicotine in Cigarettes," Chart P). The Commissioner's statement is included as Appendix 7 to this document.

[485] Federal Trade Commission. 1994 report of the tar and nicotine content of domestic cigarettes. (FDA's analysis included only those products that were evaluated by the Tobacco Industry Testing Laboratory.) By contrast, only 2 of the 142 marketed cigarettes included in the FTC report for 1972 had a nicotine to tar ratio greater than 1 to 12. (Federal Trade Commission. 1972 report of the tar and nicotine content of domestic cigarettes.) On a percentage basis, only 1.4 percent of the 1972 products had a nicotine to tar ratio greater than 1 to 12. In 1994, that figure grew to 26.3 percent overall, and rose to 95 percent for the 93 products in the lowest tar category. This suggests that as the market for lower yield cigarettes has grown over the last 20 years, the cigarette industry has altered the traditional ratio of nicotine to tar.

occurring in smoke from the natural state of tobacco."[485a] [Emphasis added.] The Philip Morris researchers went on to say that this study would be used to "attempt to make a 10 mg [low tar] cigarette that will equal a Marlboro in subjective acceptability and strength." According to these researchers, the naturally occurring nicotine-to-tar ratio was 0.07, while the optimal ratio was about 0.1. See p. 223, supra.[485b]

As noted above, tobacco industry officials have repeatedly stated that nicotine yields are not manipulated and are simply a function of tar yields, i.e., that reductions in tar yields result in proportionate reductions in nicotine yields. For example, the chief operating officer of Lorillard

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[485a] Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication. Approved by W.L. Dunn and distributed to H. Wakeham. October, 1975. *In* 141 Cong. Rec. H8009 (daily ed. July 31, 1995)(statement of Rep. Waxman). *Also in* Hilts PJ. Documents Disclose Philip Morris Studied Nicotine's Effect on Body. *New York Times.* June 8, 1995.

[485b] According to an analysis of FTC nicotine and tar delivery levels conducted by a member of Congress, at least two Philip Morris low-tar products show evidence that the data on "optimal" nicotine-to tar ratios was applied by the company to make changes in the nicotine-to-tar ratios of marketed cigarettes. One marketed cigarette underwent an increase in its nicotine-to-tar ratio, beginning in 1978, that closely corresponds to the change from the "natural" ratio to the "optimum" ratio described by Philip Morris researchers in 1975. From 1968 to 1978, tar and nicotine levels in regular Benson & Hedges filtered cigarettes dropped from 21 mg tar and 1.29 mg nicotine to 0.9 mg tar and 0.06 mg nicotine. Throughout this period, the nicotine-to tar ratio in the cigarettes remained stable, i.e., tar and nicotine delivery levels were falling proportionately. The ratio during this period was 0.7, the ratio described by Philip Morris researchers as "natural" for tobacco. Then, beginning in 1978, nicotine delivery from Benson & Hedges began to increase, while tar remained stable. By 1983, the nicotine delivery had jumped from 0.06 to 0.1, an increase of over 60%. The result was an increase in the nicotine-to tar ratio to 0.11, approximately the same level found by Philip Morris researchers to be "optimal." Congressman Waxman reported that the chance that this change in the nicotine-to-tar ratio could have been due to random fluctuations in tar and nicotine levels is less than 1 in 100,000. The tar-to-nicotine ratio for Benson & Hedges dropped back to 0.07 in 1984 and 1985. Although the reasons for this change are unknown, Congressman Waxman noted that the change could have been due to a decision to phase out the product or to the use of technologies that permit manipulation of the amount of nicotine delivered to the smoker but that do not affect the amount of nicotine measured by a smoke machine. Waxman also analyzed Philip Morris product, Merit Ultra Lights. This product was introduced in 1981 with a nicotine/tar ratio of 0.11, which corresponds to the "optimal" ratio found by Philip Morris researchers, rather than to the "natural" ratio of 0.07. The elevated nicotine-to-tar ratio in Merit Ultra Lights has remained constant in the years since its introduction. 141 Cong. Rec. H8009-10 (daily ed. July 31, 1995)(statement of Rep. Waxman). Philip Morris denied that the changes were deliberate. Hilts PJ. Philip Morris Denies Charge By Lawmaker. *New York Times.* August 2, 1995.

Tobacco Co. testified before Congress in 1994 that:

> *We do not set nicotine levels for particular brands of cigarettes. Nicotine levels follow the tar level . . . . The correlation coefficient of 0.975 is essentially perfect correlation between tar and nicotine and shows that there is no manipulation of nicotine.*[485c]

The significant increase in the nicotine to tar ratio for low delivery products contradicts these statements and provides strong evidence that nicotine deliveries are independently manipulated. In fact, an industry document states that the nicotine-to-tar ratios in ultra low tar cigarettes are higher than would be expected if nicotine fell proportionately with tar. In 1978, Philip Morris surveyed the nicotine-to-tar ratios in its competitors' ultra low tar products (5-7 mg tar) and found that these ultra low tar cigarettes "seem to be higher in nicotine delivery than we would otherwise expect" and found further that "nicotine/tar ratios go up as tar goes down":

> *The table [of nicotine-to-tar ratios for a range of low tar brands] suggests that Philip Morris brands (asterisked) have lower nicotine/tar ratios than do other brands with about the same FTC tar delivery . . . . The table also suggests that nicotine/tar ratios go up as tar goes down, and that our competitors' brands . . . seem to be higher in nicotine delivery than we would otherwise expect from our own experience with low delivery cigarettes . . . .*
>
> *It appears therefore that the mechanics of cigarette engineering and the deliberate decisions of our competitors are such as to suggest high nicotine/tar ratios be used at ultra low tar levels.*[485d] [Emphasis added.]

The Philip Morris researchers suggest that the high nicotine-to-tar ratios in the low tar products of Philip Morris' competitors have been achieved through certain kinds of filters and by "the use of

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[485c] *Regulation of Tobacco Products (Part I): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives,* 103rd Cong., 2d Sess. 378 (1994) (statement of Alexander W. Spears, Vice Chairman and Chief Operating Officer, Lorillard Tobacco Company)

[485d] Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1979. December 6, 1978. *In* 141 Cong. Rec. H7670 (daily ed. July 25, 1995).

high alkaloid blends,"[485e] i.e., the use of tobaccos containing high nicotine levels.

FDA also analyzed other information supplied by the FTC that was derived from the FTC's database on nicotine levels in cigarettes. FDA's analysis of the FTC data demonstrates two very important results. First, there is an apparent increase in the sales-weighted FTC nicotine delivery ratings, for all cigarettes, since 1982 (the earliest year for which the computer database is available). Second, consistent with the data on the increase in nicotine to tar ratios, when FDA segmented FTC's sales data into high-tar, low-tar, and ultra low-tar cigarettes, nicotine yields had the greatest increase in the ultra low-tar group.[486] These findings are depicted in the following charts:

[485e] *Id.*

[486] *See:*

Kessler, note 484, *supra,* at charts Q, R, S, T. "Sales-weighted" nicotine delivery ratings represent the average nicotine yield of all cigarette brands sold in a given year, adjusted (weighted) to reflect the actual sales of the brands.

Hoffman D, Hoffman I. On the Reduction in Cigarette Smoke. In: Wald and Froggatt, note 481, *supra,* at pp. 200-201.

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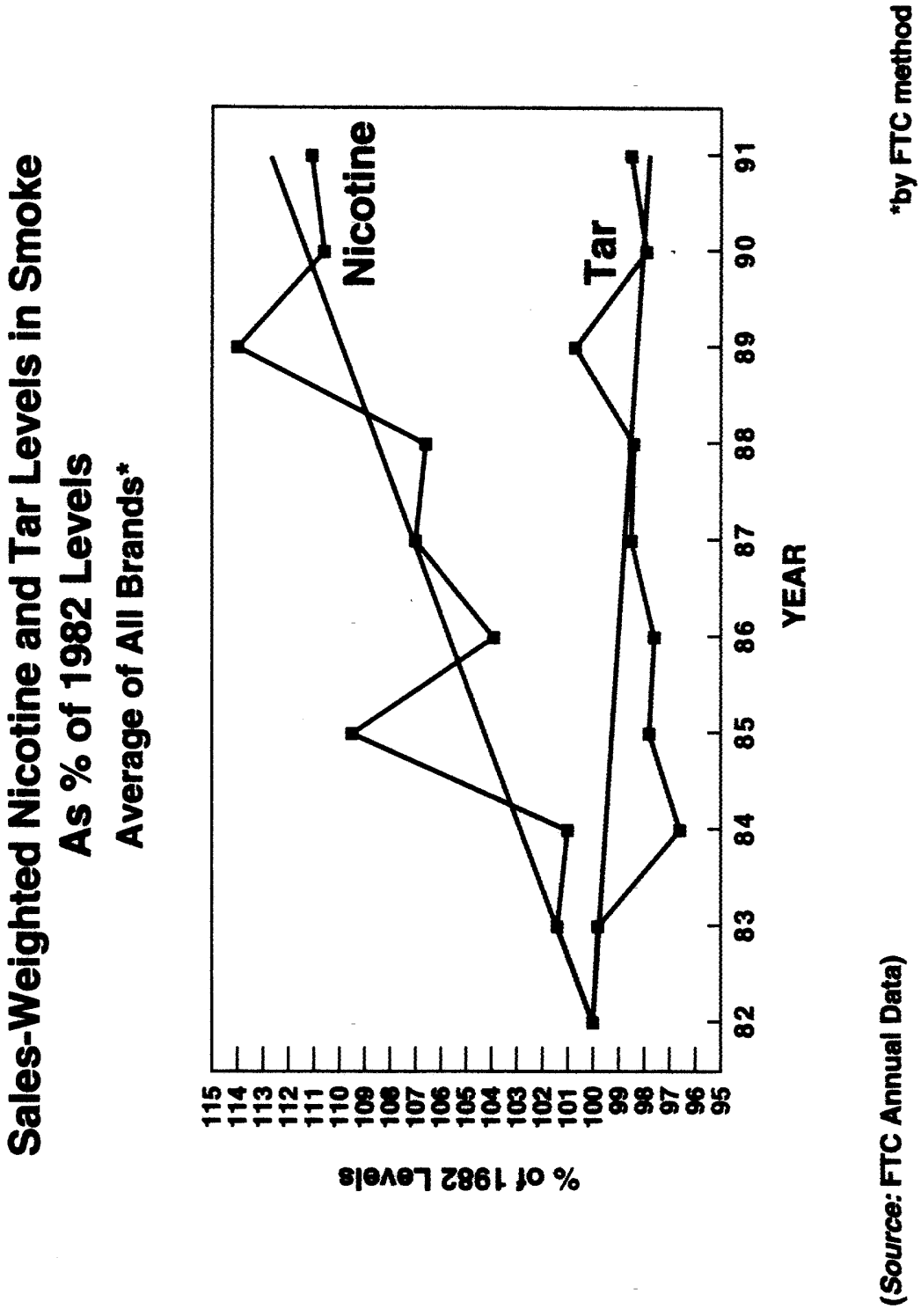
Sales-Weighted Nicotine and Tar Levels in Smoke
As % of 1982 Levels
Average of All Brands*
Nicotine
Tar
% of 1982 Levels
YEAR
115 114 113 112 111 110 109 108 107 106 105 104 103 102 101 100 99 98 97 96 95
82 83 84 85 86 87 88 89 90 91
*by FTC method
(Source: FTC Annual Data)

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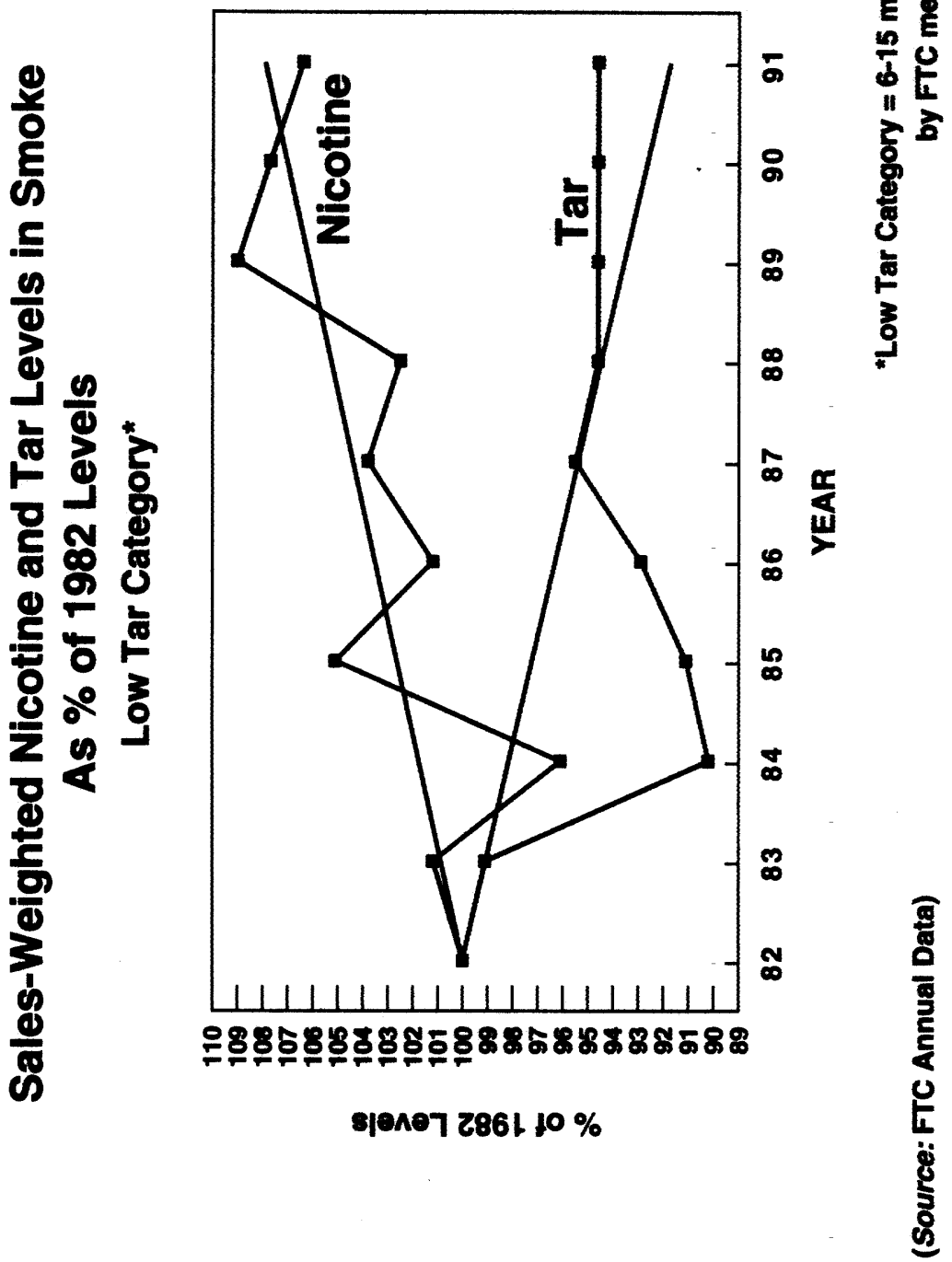
Sales-Weighted Nicotine and Tar Levels in Smoke
As % of 1982 Levels
Low Tar Category*
Nicotine
Tar
% of 1982 Levels
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*Low Tar Category = 6-15 mg tar
by FTC method
(Source: FTC Annual Data)

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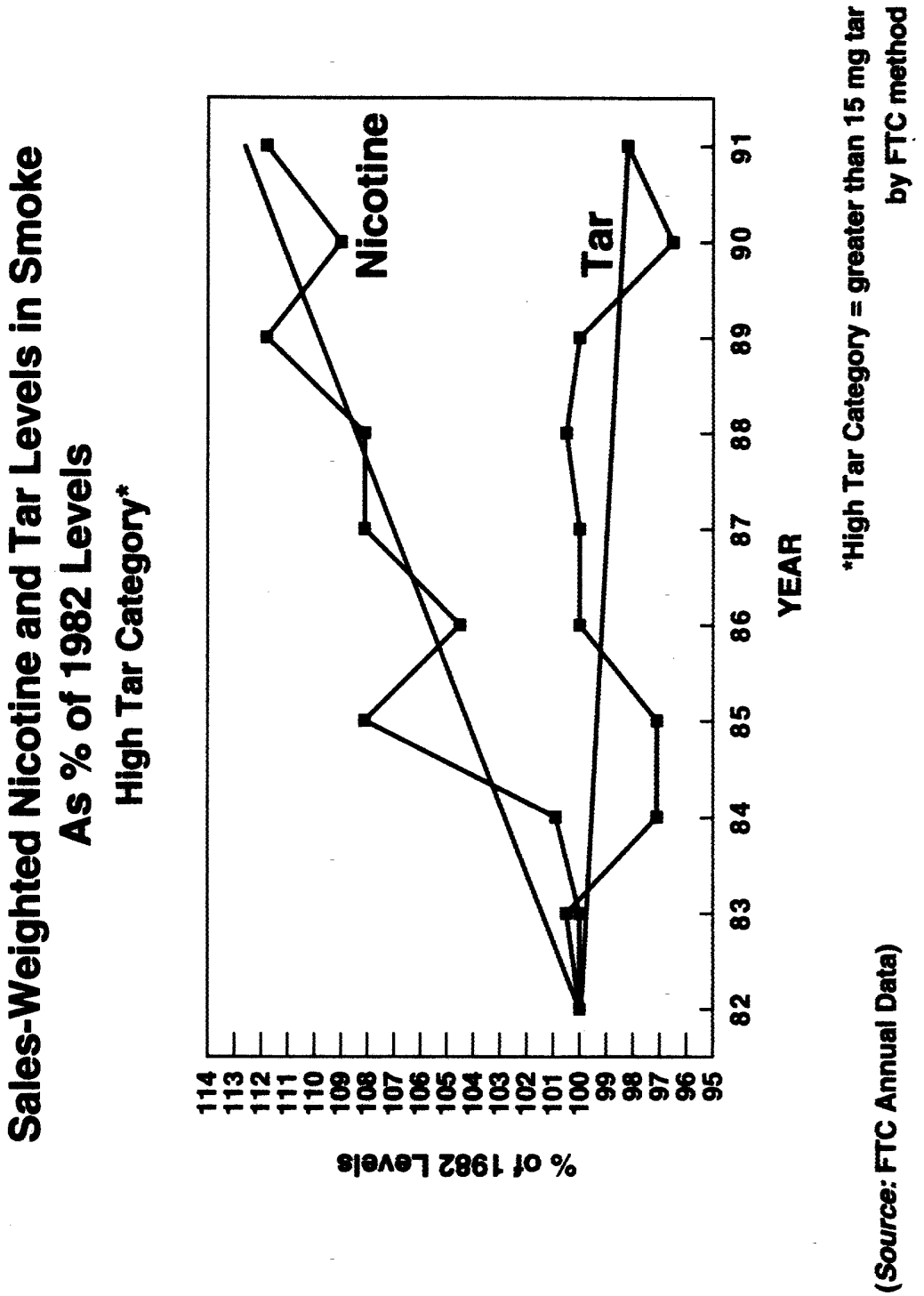
Sales-Weighted Nicotine and Tar Levels in Smoke
As % of 1982 Levels
High Tar Category*
Nicotine
Tar
% of 1982 Levels
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*High Tar Category = greater than 15 mg tar by FTC method
(Source: FTC Annual Data)

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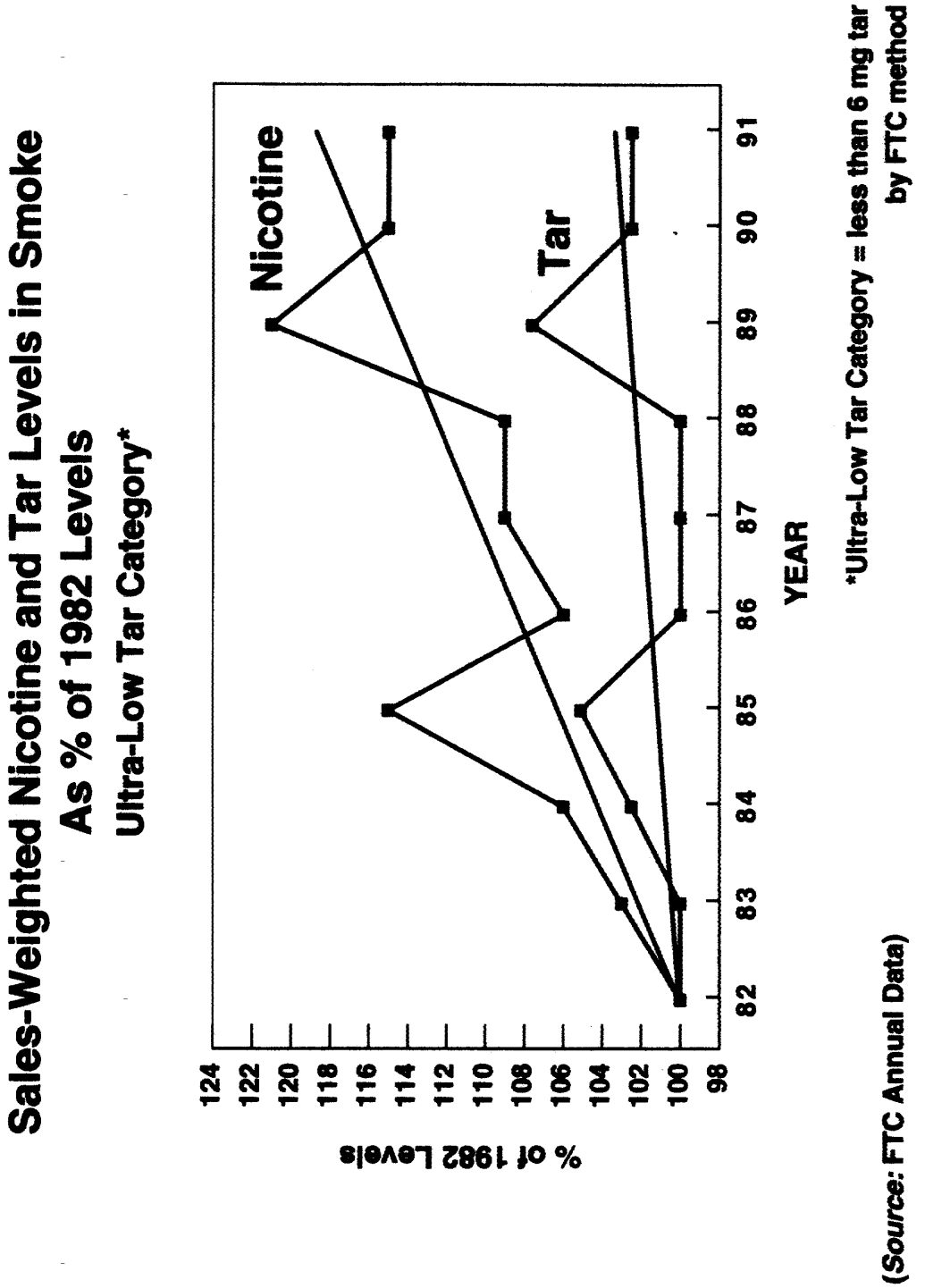
Sales-Weighted Nicotine and Tar Levels in Smoke
As % of 1982 Levels
Ultra-Low Tar Category*
Nicotine
Tar
% of 1982 Levels
124
122
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YEAR
*Ultra-Low Tar Category = less than 6 mg tar by FTC method
(Source: FTC Annual Data)

f. Conclusion

The information in the preceding sections demonstrates that cigarette manufacturers manipulate and control the delivery of nicotine in marketed products. Cigarettes are designed to supply nicotine at consistent levels despite the wide variations in the nicotine levels of the raw materials, the immensely complicated combustion chemistry, and the complex chemical flow properties of a modern cigarette.

Manufacturers use many techniques to control nicotine deliveries. The application of these modifications in cigarette design and their interactive nature pose complex problems in maintaining brand uniformity and consistency regarding nicotine delivery. Yet, the nicotine content and delivery of each brand of cigarettes is remarkably consistent from batch-to-batch and year-to-year. This level of control is analogous to that of the pharmaceutical industry in the production of prescription drugs. In fact, to determine how well nicotine content is controlled in cigarettes, FDA laboratories compared the content uniformity of drugs in tablet or capsule form to the content uniformity of nicotine in cigarettes. The results showed that nicotine content varies from cigarette to cigarette no more than the content of active ingredients in marketed pharmaceuticals.[487]

FDA's investigation has also disclosed that the tobacco industry uses a number of methods to boost nicotine delivery in low-yield cigarettes. The cigarette industry has successfully used these methods to maintain adequate nicotine delivery from low-yield products. Without the independent manipulation of nicotine, many of the techniques used to reduce tar

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[487] FDA, CDER, DDA, Report on Analysis of Packages of Cigarettes, April 4, 1994. *See* Kessler, note 416, *supra*, at p. 12.

would also substantially reduce nicotine. Instead, regardless of differences in labeled/advertised FTC nicotine yields and manufacturers' claims of low-nicotine delivery for certain brands, all cigarettes contain approximately the same amount of nicotine in the rod, and deliver about 1 mg of nicotine, enough to produce pharmacological effects. See p. 108, supra. Moreover, studies by FDA and others have demonstrated that the lowest-yield cigarettes have the highest concentrations of nicotine, demonstrating that nicotine delivery has been independently manipulated.

The tobacco industry's control and manipulation of nicotine delivery from cigarettes provides additional evidence of the industry's intent to deliver pharmacologically satisfying levels of nicotine to smokers.

2. Industry Manipulation and Control of Nicotine in Smokeless Tobacco

Smokeless tobacco manufacturers control the delivery of nicotine from smokeless tobacco to produce a line of smokeless products that deliver nicotine in graduated amounts. Products that deliver lower doses of nicotine are marketed to new users of smokeless tobacco. Smokeless tobacco marketing then encourages them to "graduate" to products that deliver higher doses of nicotine. Smokeless tobacco manufacturers' manipulation of nicotine deliveries and marketing of low-nicotine products to new users and high-delivery nicotine products to experienced users demonstrates their intention to market products that facilitate nicotine dependence, a significant effect on the structure and function of the body. Smokeless tobacco manufacturers' products are thus intended to affect the structure and function of the body.

Moist snuff is the most popular form of smokeless tobacco. U.S. Tobacco Co. ("UST"), which accounts for 85% of the moist snuff sales in the U.S.[488] markets a line of moist snuff products that includes Skoal Bandits, Skoal Long Cut, Original Fine Cut Skoal, and Copenhagen. Skoal Bandits deliver a very small amount of absorbable nicotine, Skoal Long Cut and Original Fine Cut Skoal deliver sequentially more absorbable nicotine, while Copenhagen delivers the highest amount of absorbable nicotine. UST representatives in fact acknowledge that the company's products provide users with a range of nicotine deliveries.[489]

Smokeless tobacco manufacturers produce graduated nicotine delivery products primarily

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[488] *See* Appendix 5.

[489] *Marsee v. U.S. Tobacco,* note 317, *supra.* (Remarks of Mr. Finnegan, attorney for U.S. Tobacco.) In: 1.7 TPLR 3.202.

See also deposition of Erik Lindqvist, Senior Vice President for Marketing, U.S. Tobacco, in *Marsee v. U.S. Tobacco.* Transcript of Jury Trial Proceedings, at pp. 1648-1676.

by manipulating the pH of the tobacco.[490] Smokeless manufacturers add compounds and manipulate the design of each smokeless product to create a specific pH. The higher the pH of a product, the more nicotine is transformed from the salt form to "free nicotine." Both forms of nicotine are highly soluble in saliva. However, the free form of nicotine is absorbed more rapidly in the mouth of smokeless tobacco users and into the bloodstream for delivery to the brain. Raising the salivary pH from 7.0 to 8.0 increases the percentage of free nicotine available for absorption from 10% to 50%, a fivefold increase.[491]

Various documents show that UST understands the relationship between the pH of its products and their nicotine delivery. For example, in a deposition, UST's Senior Vice President for Marketing acknowledged that he had written a memo in which he had recommended a specific pH level for a new product and that he understood that there was a relationship between pH and nicotine.[492] When asked whether pH affected nicotine absorption, he agreed:

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[490] *See:*

Henningfield JE, Radzius A, Cone EJ. Estimation of available nicotine content of six smokeless tobacco products. (Submitted to *Tobacco Control* November 17, 1994.)

U.S. Food and Drug Administration. *Report on study of smokeless tobacco products: pH and free base nicotine.* November 4, 1994.

U.S. Food and Drug Administration. National Forensic Chemistry Center. Cincinnati Laboratory. *National survey of smokeless tobacco products.* December 13, 1994, memo from Laura Ciolino, Research Chemist to Fred Fricke, Director.

[491] *See:*

Armitage AK. Some recent observations relating to the absorption of nicotine from tobacco smoke. In: Dunn WL. ed. *Smoking Behavior: Motives and Incentives.* Washington, DC: VH Winston & Sons; 1973. Pages 86 (figure 2) and 87.

Henningfield JE, Radzius AC, Cooper TM, Clayton RR. Drinking coffee and carbonated beverages blocks absorption of nicotine from nicotine polacrilex gum. *JAMA.* 1990;264(12):1560.

[492] Transcript of Jury Trial Proceedings, *Marsee v. U.S. Tobacco*, note 317, *supra,* at pp. 1666-8.

Q. Mr Lindqvist, is it your understanding that as the pH of the product is lowered, that the rate of absorption of nicotine by the user is also lowered?

A. That would be my understanding, yes.[493]

The major smokeless tobacco manufacturers in the United States each market products that range from low to high pH, producing a corresponding graduation in the amount of "free nicotine" delivered by these products. The products with the lowest pH deliver the least amount of absorbable nicotine, while those with the highest pH deliver a significantly higher amount of absorbable nicotine.[494]

FDA laboratories comprehensively analyzed several marketed snuff products.[495] The following table demonstrates the characteristics of marketed smokeless tobacco products related to nicotine delivery.[496]

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[493] *Id.* at p. 1668.
See also:
U.S. Tobacco Company documents discuss the pH of various brands, also suggesting a knowledge of the relationship between pH and nicotine absorption:
Red Seal Menthol. . . 2. Lower pH than Skoal through flavor if possible. . . Premium project. . . Full tobacco flavor, pH at the level of Copenhagen or higher.
U.S. Tobacco memo from Erik Lindqvist. (This document was discussed in the trial in *Marsee v. U.S. Tobacco*, note 317, *supra*. These quotes were authenticated by Erik Lindqvist, the author, in his deposition. Transcript of Jury Trial Proceedings, at pp.1666-1671.)

According to the trial transcript of *Marsee*, UST recognizes that pH can affect how much of the nicotine is free. (U.S. Tobacco document No. 4486792, dated Oct. 5, 1981. In: 1.7 TPLR 3.208, July/August 1986.)

[494] The amount of absorbable nicotine is dependent on the pH and not the total amount of nicotine that is in the product. For this reason, the total amount of nicotine in the products throughout the product line can remain relatively constant and still permit graduated nicotine delivery.

[495] FDA laboratories in St. Louis and Cincinnati performed these studies. The results are summarized in two separate reports. *See* note 490, *supra*.

[496] This table reflects the two separate studies which were performed by the two FDA laboratories in St. Louis, MO and Cincinnati, OH. Both laboratories used the same analytical procedures for these analyses.

MANUFACTURER/ PRODUCT NAME	pH		% Free Nicotine*		Total Nicotine Content (mg/gm)**	
	St. Louis	Cinc.	St. Louis	Cinc.	St. Louis	Cinc.
U.S. Tobacco Co.						
Skoal Key	--	8.22	--	61.3	--	12.4
Copenhagen Snuff	8.14	7.71	56.5	32.7	13.2	13.8
Skoal L.C. Class.	8.04	7.92	51.1	45.5	12.7	13.8
Skoal L.C. Wint.	7.50	7.57	23.1	26.0	12.7	13.9
Skoal L.C. Mint.	7.35	7.52	17.6	24.0	13.2	13.7
Skoal L.C. Spear	7.20	7.50	14.0	23.3	12.5	13.8
Skoal Or.F.C. Wint.	--	7.41	--	19.7	--	13.6
Skoal L.C. Strai.	7.47	7.41	22.0	19.5	12.1	13.8
Skoal L.C. Cherry	7.15	7.38	12.3	18.5	12.5	13.6
Skoal Band. Mint	6.83	7.06	6.4	9.9	6.7	8.8
Skoal Band Wint.	6.56	6.72	3.3	4.8	7.8	8.2
Happy Days L.C. Mint	--	6.00	--	0.9	--	13.9
Skoal Band. Strai.	--	5.48	--	0.3	--	10.8
Skoal Band. Class.	5.61	5.23	0.39	0.2	10.4	9.9
Helme Tobacco Co.						
Redwood Full Flavor	--	7.52	--	24.0	--	12.6
Silver Cr. L.C.	--	7.22	--	13.7	--	6.0
Cooper Wint. L.C.	--	6.99	--	8.5	--	5.7
Gold River L.C.	--	5.77	--	0.6	--	6.4
C.C. Conwood Co.						
Kodiak Wint.	8.20	8.22	59.9	61.0	11.4	11.7
Kodiak Choice Wint.	--	7.98	--	47.7	--	11.4
Kodiak Straight	7.39	7.82	19.0	38.4	10.6	10.4
Hawken Wint.	5.56	5.58	0.35	0.4	4.4	4.0
Pinkerton Tobacco Co.						
Redman F.C. Ex. Wint.	--	7.58	--	12.3	--	--
Renegade Wint.	6.81	7.17	5.8	13.2	11.8	--

L.C. = long cut

* Calculated using the Henderson-Hasselbach equation for acid-base equilibrium. This calculation strictly is dependent on the pH determination. Any error in the pH determination will affect the percent free nicotine calculation.

** Measured on wet basis.

This table demonstrates that each of the smokeless tobacco companies whose products were tested by the FDA laboratories markets products that have low, medium, and high pH values, delivering corresponding low, medium, and high levels of free nicotine to the users of the products.[497] It is apparent from the data that providing graduated nicotine deliveries through manipulation of pH is an industry-wide practice. Other researchers have described similar findings.[498]

Other features of these products demonstrate how the smokeless tobacco companies use product design features to control nicotine delivery. For example, UST's Skoal Bandits and Pinkerton's Renegades are packaged in teabag-like pouches, which both limits the amount of snuff that is placed into the mouth and creates a barrier that retards nicotine release from the product. FDA laboratory analysis shows that the effect of the Bandits' pouch is to delay nicotine release by an average factor of three, compared to the same tobacco tested outside of the pouch, during the first 2 minutes of the study.[499] Thus, users of Skoal Bandits get less nicotine into their mouth, and the nicotine is released into their mouths at a slower rate.

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[497] In the chart, the first column lists the products marketed by specific manufacturers. For each manufacturer, the products are listed in descending order of nicotine delivery. The second and third columns list the pH of each product as measured by two separate FDA labs. The fourth and fifth columns list the amount of absorbable (free) nicotine in each product, calculated from the pH measured at each of the two labs. The sixth and seventh columns list the total nicotine content of each of the products as measured by each of the two labs.

[498] *See* Henningfield, note 490, *supra,* at p. 2. This study found that Skoal Bandits have a pH of about 6.9, providing only 7% of its nicotine in the free form. Skoal Long Cuts have a pH of about 7.4-7.5, providing 19%-23% free nicotine. Original Fine Cut Skoal has a pH of about 7.6, providing 28% free nicotine. Copenhagen was found to be a potent form of snuff, with a pH of about 8.6, producing 79% free nicotine, a very high level for absorption. Page 2 and figure 1.

[499] Department of Health and Human Services, FDA, National Forensic Chemistry Center. *Relative Buffering Capacity of Saliva and Moist Snuff* and *Moist Snuff Nicotine Content Code Date Survey.* Memorandum from Laura A. Ciolino to Elizabeth Berbakos and Thomas Layloff. September 28, 1994.

Smokeless tobacco products are also engineered in such a way that users get a bolus dose of nicotine within the first 5 minutes of inserting the product into the mouth.[500] After the first 5 minutes, nicotine is still released from the product but at a much slower rate. An FDA study showed widely divergent results when comparing Copenhagen and Skoal Bandits under typical use conditions.[501] The amount of nicotine released from a usual "pinch" of Copenhagen (about 1.5 gm) was 12 times higher than from a pouch of Bandits (about 0.5 grams) in the first 2 minutes of the experiment. The bolus dose results in nicotine concentrations in the bloodstream that produce a peak pharmacological concentration in users. These pharmacological concentrations are then maintained by the slow continued release of nicotine from the products following the bolus dose.

Both nicotine release and pH of smokeless products are also affected by the tobacco fermentation process used to make smokeless tobacco products. Tobacco fermentation causes an increase in pH with fermentation time.[502] The age of packaged smokeless products is thus a factor in each product's pH because fermentation can continue within the package due to the high

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[500] *See:*

U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Analysis. *Nicotine Studies of Chewing and Smokeless Tobacco Products.* Memorandum from Henry D. Drew, Chief, Drug Monitoring Branch, to Elizabeth Berbakos. September 22, 1994. Table 4.

U.S. Food and Drug Administration. National Forensic Chemistry Center. Cincinnati Laboratory. *Moist Snuff Nicotine Release Studies.* September 28, 1994, memo from Laura Ciolino, Research Chemist to Fred Fricke, Director. Page 1.

[501] *Id.* September 28, 1994, memorandum.

[502] Tso TC. *Kirk-Othmer Encyclopedia of Chemical Technology.* John Wiley and Sons; 1970;20:510. This occurs because organic acids are lost through oxidation and decarboxylation.

moisture content of the tobacco.[503] Because fermentation increases pH, and increasing pH increases free nicotine, continued fermentation increases the amount of nicotine that is delivered to smokeless tobacco users. Fermentation also breaks down the plant tissue. This results in nicotine release from the plant intracellular tissue, causing much of the nicotine to come to the surface of the tobacco leaf.[504]

Manufacturers also add humectants to their products to increase or maintain the moisture content. The resulting high moisture content of smokeless products affects nicotine delivery by ensuring that tobacco leaves are well wetted, thus allowing nicotine easily to go into solution (i.e., saliva).

The evidence demonstrates that smokeless tobacco manufacturers design their products to deliver controlled amounts of nicotine to the user by manipulating pH, placing starter products in pouches, and using additives that control the moisture content of the products. Smokeless manufacturers use these sophisticated design features to manipulate the pharmacological response of the user to the product. In doing so, manufacturers intend to market products that affect the structure or function of the body.

The marketing practices of the smokeless tobacco industry further demonstrate the intent of manufacturers to factilitate nicotine dependence among smokeless tobacco users. Until the 1970's, smokeless tobacco companies were marketing only products with high nicotine delivery.

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[503] Andersen RA, Fleming PD, Hamilton-Kemp TR, Hildebrand DF. pH changes in smokeless tobaccos undergoing nitrosation during prolonged storage: effects of moisture, temperature, and duration. *J. Agric. Food. Chem.* 1993;41:968-972.

[504] This may explain the fast nicotine release from the tobacco products studied by FDA under *in vitro* conditions.

Their market was steadily diminishing because these products were not well tolerated by new users. Evidence from the files of smokeless tobacco companies shows that, in the late 1960's or early 1970's, these companies began to try to entice new users of smokeless tobacco, including people as young as 15 years old.[505] To do so, they developed low-nicotine products in teabag-like pouches to encourage people to begin using smokeless tobacco. A UST document describes the company's rationale for developing a new oral snuff product under the code name "The Lotus Project":

AIM: *To make it easier for a new user to use tobacco in the mouth.*

TARGET GROUP: *New users, mainly cigarette smokers age group 15-35*

PRODUCT: *A. Strength*

1. Nicotine Satisfaction

Mild like Happy Days [a low-nicotine product]
Instant but not shocking

2. Feeling in the mouth

As little harshness as possible on the gum and in the throat

* * *

PACK: *A. Size of Pinch*

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[505] *See* documents on "Lotus Project":
Undated document entitled "The Lotus Project." From *Marsee v. U.S. Tobacco*, note 317, *supra*, Trial Exhibit 159.

U.S. Tobacco Co. Intra-company Correspondence from W.W. Watson, President - United Scandia International to Mr. L.A. Bantle, President. June 2, 1972. From *Marsee v. U.S. Tobacco*, Trial exhibit 158.

Minutes from a Meeting in Greenwich at Mr. L.A. Bantle's Office. July 18, 1972. From *Marsee v. U.S. Tobacco*, Trial exhibit 159.

> ***Small enough for a new user to manage . . . This point has to be closely worked out, takes into consideration the desired effect mentioned under "Strength."***[506]

This document clearly discloses UST's intention to develop a low-nicotine product suitable for "new users," i.e., those not yet tolerant to the harsh effects of nicotine on the gum and throat, and not yet requiring high levels of nicotine for "satisfaction."

Another UST document that discusses the "Lotus Project" and product development discloses the company's intent to produce products with varying amounts of nicotine.[507] The document states:

> *"[t]here should be three products of three different tastes and strengths of nicotine . . .*
>
> *a. High nicotine, strong tobacco flavor . . .*
>
> *b. Medium strength of nicotine. . .*
>
> *c. Low nicotine, sweet product. . ."*[508]

By acknowledging that the objective is to produce products with varying strengths of nicotine and differentiating strength from taste, the document demonstrates the company's intent to manufacture products with distinct pharmacological effects based on the nicotine delivery.

A document that posed potential questions and answers related to UST's introduction of Skoal Bandits in a new market also demonstrates the manufacturer's intention to provide nicotine

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[506] *Id.* Trial Exhibit 159 (minutes from July 18, 1972, meeting).

[507] *See* Watson, note 505, *supra,* at p. 2.

[508] *Id.*

for absorption and thereby to produce "satisfaction" in the user of the product.[509] The document provides the following questions and anwers about Skoal:

> *3. - How does it work ?*
>
> > *It gives the satisfaction from tobacco want* [sic]. *It is real tobacco and contains nicotine. . .*
>
> *4. - How much nicotine does it contain ? Is it absorbed ?*
>
> > *The nicotine contents are more or less equivalent to that of a good quality cigarette of average strength. The nicotine is absorbed, given [sic] satisfaction to the smoker.*

A senior UST official stated in another memorandum that "satisfaction" refers to the "kick" that users obtain from tobacco products.[510]

Shortly after the "Lotus Project" documents were written, UST began to aggressively market the low-nicotine "starter" products to new users of smokeless tobacco. An early advertisement for "Happy Days," one of the first low-nicotine products, targeted the product "for you guys just starting out."[511] The marketing of starter products relied heavily on "sampling," a technique in which company representatives distribute free samples on college campuses and sports events, and encourage nonusers to use smokeless tobacco.[512] Advertisements then

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[509] *Potential Questions and Answers.* Bate stamp nos. 2054948-2054951, submitted in *Marsee v. U.S. Tobacco*, note 317, *supra.*

[510] *Marsee v. U.S. Tobacco*, note 317, *supra.* Deposition of Erik Lindqvist, Senior Vice President, Marketing. Transcript of Jury Trial Proceedings, at p.1662.

[511] Connelly GN. In the search for a perfect starter product: manipulation of nicotine in oral snuff brands. August 1994. (Unpublished.)

[512] U.S. Tobacco Company. College Representative Manual. Revised July 31, 1985:

> *Success in reaching the college students today will determine the continued popularity and growth for our products in our adult market segments tomorrow.*
>
> *Achieving these goals will require strong consumer sampling efforts. Success in this area can*

encouraged established users to graduate to higher-nicotine products. For example, an advertisement for Copenhagen, the highest nicotine product, said "Sooner or Later, It's Copenhagen."[513]

In the 1980's, "long cut" smokeless tobacco products were introduced. An internal UST memorandum, dated June 8, 1984, reported that customers and distributors of the Skoal "Long Cut" considered it a "'perfect' starter product," in part due to its relatively low "strength" (i.e., low delivery of nicotine).[514] This memorandum also acknowledges the role of low-nicotine products in facilitating graduation to high-nicotine brands like Copenhagen. In a long list of positive anecdotes about the introduction of Long Cut, the memorandum states that college representatives reported that "Long Cut makes it easier to become accustomed to using Cope[enhagen]" as well as "having sampled a person with Long Cut, and then seeing that person weeks later as a regular Cope consumer."[515] The same memorandum reports that Copenhagen sales "continue to rise on a weekly basis since the intro of Long Cut."[516]

A chart prepared by UST's marketing department further demonstrates the company's knowledge that consumer use of its products follows the graduated nicotine deliveries of those products and shows the company's desire to capitalize on a "graduation process" to enhance sales

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only be achieved with an aggressive, efficient program. . .

[513] Connelly, note 511, *supra*, at p. 5.

[514] U.S. Tobacco Company. Intra-company Correspondence from K.C. Carlsen to O.M. Bryant. *Skoal Long Cut.* June 8, 1984. Page 1.

[515] *Id.* at pp. 2-3.

[516] *Id.* at p. 2.

of its highest nicotine products.[517] The chart is labeled "graduation process" and shows a hierarchy of products, with arrows pointing from Skoal Bandits to Happy Days and Skoal Long Cuts, and culminating with Copenhagen. This "graduation" corresponds exactly to the progression of nicotine deliveries from the listed products.

The company's reliance on the graduation process is further evidenced in a UST document entitled "Expanding User Base", which depicts a "bullseye" chart that lists the company's moist snuff products.[518] The chart follows:

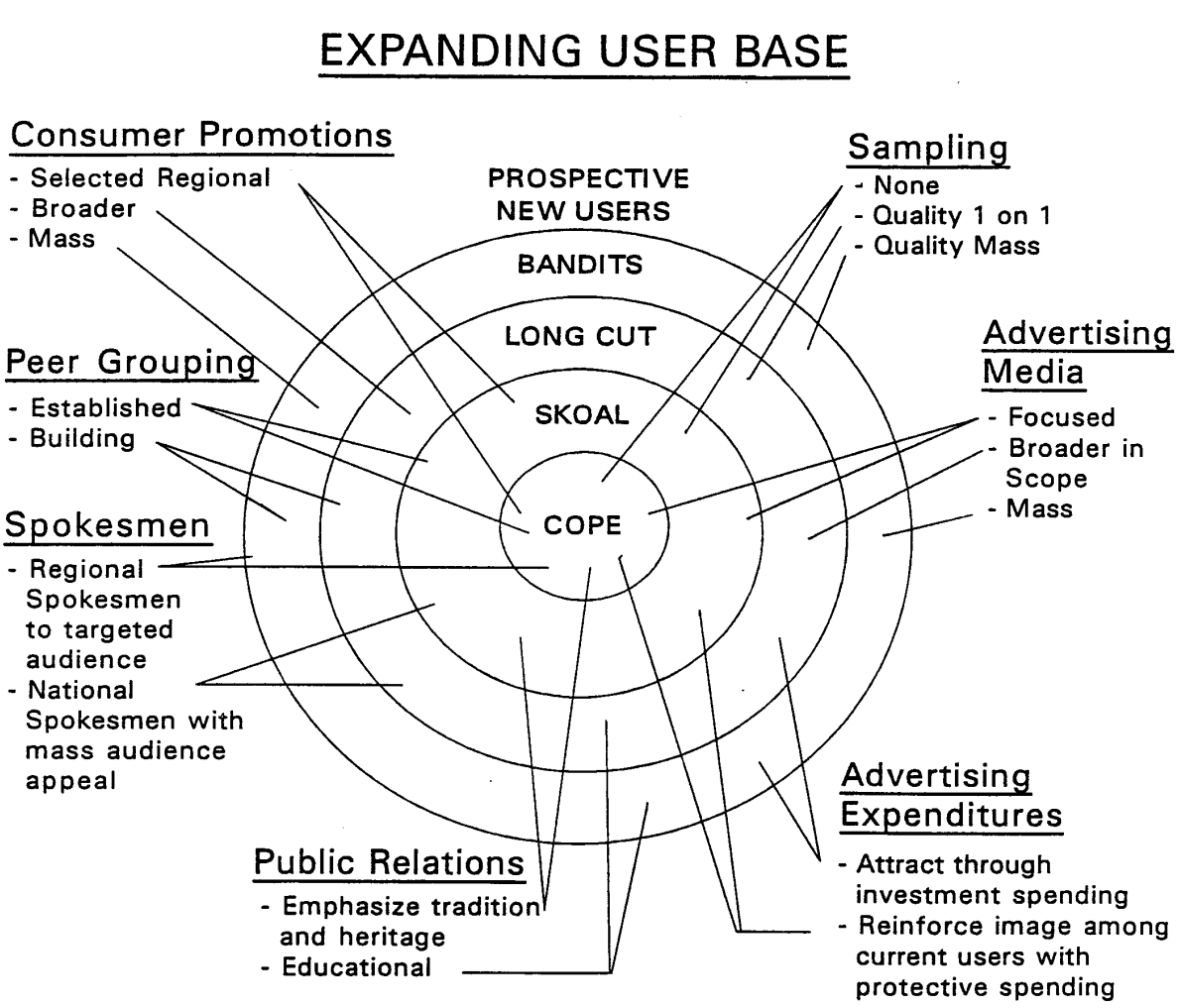
[517] *Marsee v. U.S. Tobacco*, note 317, *supra*, Plaintiff's Exhibit 100, "Graduation Process." (Undated.)

See also U.S. Tobacco Company. One-on-one interview with Mr. Manuel Leitao, Executive Vice President, U.S. Tobacco and President Tobacco Division. *Up to Snuff.* Autumn 1984:2:

> *Some people will remain with the Bandits, and some people will get into a sort of graduation process. The bottom line, and we must never forget the bottom line, is that Bandits is a vehicle that is going to expand the use of smokeless tobacco.*

Another company document sets out a similar strategy for entering new markets. The strategy involved starting users on the lower nicotine Skoal Bandits with an eye toward "establishing a normal graduation process." U.S. Tobacco Company. International Division-Very Optimistic About U.S. Tobacco's Worldwide Expansion. *Up to Snuff.* March 15, 1988. Page 2.

[518] U.S. Tobacco Company. *Expanding User Base.* (Undated.) This document was disclosed during discovery in *Marsee v. U.S. Tobacco,* note 317, *supra.* The document was authenticated by Dr. Jack Henningfield in a letter to Rep. Henry Waxman (D-Ca), in which Dr. Henningfield states his awareness of the origins of the chart as "provided by the United States Tobacco Company to the plaintiffs in the *Marsee v. United States Tobacco Company* law suit in which I served as an expert witness in 1986. This chart was provided to me by the plaintiffs attorney, Mr. Braly, to review." Letter from Jack E. Henningfield, Ph.D., Chief, Clinical Pharmacology Branch, National Institute on Drug Abuse to The Honorable Henry A. Waxman, Chairman, Subcommittee on Health and the Environment, House of Representatives (Dec. 13, 1994).



Adapted from a chart provided by U.S. Tobacco during discovery in Marsee v. U.S. Tobacco

Outside the outermost ring of the chart is the label "Prospective New Users"; the subsequent concentric rings are labeled "Bandits," "Long Cut, and "Skoal," respectively, and a ring labeled "Cope" (representing Copenhagen) is the bullseye in the middle. The rings of the chart thus progress from the lowest delivery nicotine products on the outside to the highest nicotine delivery products in the center of the bullseye. The chart's further annotations - - "Consumer Promotions," "Peer Grouping," "Spokesmen," "Public Relations," "Advertising Expenditures," "Advertising Media," and "Sampling" - - clearly demonstrate the company's intent to advertise, promote, and provide free samples of the lower delivery nicotine products, which are on the lowest level of the "graduation process," to new users. The highest nicotine products, however, are to be advertised only to current users in a highly focused manner.

Several other company documents discuss the graduation process. A UST document discussed in a trial transcript mentions Skoal Bandits and the company's intent to use the product to fuel the graduation process:

> *Skoal Bandits, which is at the bottom of the previous graduation chart, 'will continue to fuel the new user base to assure graduation to our priority moist brands'.*[519]

Another UST document, discussed in the same trial transcript, again acknowledges the company's deliberate use of the graduation process:

> *. . . sample Skoal Bandits often and intensively in and around the retail account to create new customers and feed the graduation process.*[520]

These marketing strategies for smokeless tobacco have been extremely successful in

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[519] UST document No. 2077832, in *Marsee v. U.S. Tobacco,* note 317, *supra.* In:1.7 TPLR 3.209. Another U.S. Tobacco document (no. 1023186-89), discussed in *Marsee* mentions introducing a product that will fill the gap between Bandits and Skoal in the graduation process. In:1.7 TPLR 3.209.

[520] UST document No. 2101576, discussed in *Marsee v. U.S. Tobacco*, note 317, *supra* (1.7 TPLR 3.210).

recruiting new users. Use of smokeless tobacco products has risen substantially since the 1970's: overall, consumption of moist snuff almost tripled from 1972 through 1991; use by adolescent males aged 18 to 19 increased almost 1,500% between 1970 and 1991.[521] The success of the graduation strategy in getting users to the point where they want to consume the high-nicotine products is demonstrated by the market share of various products. While the majority of advertising dollars are spent on the low and medium nicotine products like Skoal Long Cuts, the great bulk of the increased sales is in Copenhagen, the high-nicotine product.[522] The consistently small market share for the low-nicotine products shows that they serve only as a steppingstone to the high-nicotine products. Consistent with the graduation strategy, a recent study found that older smokeless tobacco users are more likely to purchase the brands that deliver high levels of nicotine than are younger smokeless tobacco users.[523]

The evidence of manipulation of nicotine delivery in smokeless tobacco and the deliberate marketing of higher and higher nicotine-containing products shows clearly that smokeless tobacco manufacturers intend consumers to become tolerant to, and dependent on, the

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[521] *See:*

Centers for Disease Control and Prevention. Office of Smoking and Health. Unpublished data from 1970 and 1991 National Household Interview Surveys. (Rate of snuff use among 18-19 year-old males was 0.5% in 1970 and 7.6% in 1991).

Marcus AC, Crane LA, Shopland DR, Lynn WR. Use of smokeless tobacco in the United States: Recent estimates from the current population survey. In: *Smokeless Tobacco Use in the United States: NCI Monographs.* 1989;8:17-23.

Sullivan LW. Keynote Address. In: *Smokeless Tobacco or Health: An International Perspective: Smoking and Tobacco Control Monograph 2.* National Cancer Institute. NIH Pub. No. 92-3461. 1992.

[522] *See* Connolly, note 511, *supra,* at p. 5.

[523] Hatsukami D, Nelson R, Jensen J. Smokeless tobacco: current status and future directions. *Brit. J. of Addiction.* 1991; 86:559-563.

nicotine in smokeless tobacco. Both tolerance and dependence are effects on the structure and function of the body produced by nicotine. Accordingly, smokeless tobacco products, as designed and marketed by the tobacco industry, are intended to affect the structure or function of the body.