## G. INDUSTRY KNOWLEDGE THAT NICOTINE'S SENSORY EFFECTS ARE SECONDARY TO ITS PHARMACOLOGICAL EFFECTS

Despite the tobacco industry's public assertions that nicotine is in cigarettes only to provide flavor, taste, or mouth feel (immediate sensory effects) to the smoker, <sup>580</sup> the evidence shows that tobacco companies view nicotine's primary role as providing the smoker with the pharmacological effects that smokers seek from tobacco.

As described earlier, the tobacco industry knows that the primary significance of nicotine in tobacco is to provide pharmacological effects, both acute (mood regulation, weight control) and long-term (reinforcing effects that create a continuing physiological need for nicotine).

While nicotine in tobacco has both systemic pharmacological effects and acute sensory effects in the mouth, nose, and throat, <sup>581</sup> the evidence in the preceding sections and other industry documents demonstrates that the acute sensory effects of nicotine are secondary in importance to

<sup>580</sup> See:

Regulation of Tobacco Products (Part 1): 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. 763 (April 14, 1994). (testimony of TF Riehl, Vice President for Research & Development, Brown and Williamson Tobacco Corp.):

We blend for taste, not nicotine.

*Id.* 103 Cong. 2d Sess. 590 (statement of Thomas E. Sandefur, Jr., CEO Brown and Williamson Tobacco Corp.):

Without nicotine, cigarettes simply would not taste like cigarettes.

Statement of Brennan Dawson, Vice President, Tobacco Institute. Face the Nation. March 27, 1994. Page 7:

Nicotine is essential. It has a taste. It has what's called a mouth feel.

<sup>&</sup>lt;sup>581</sup> See, e.g., Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session III. Montreal, Canada. July 9-12, 1984. Pages BW-W2-02709, BW-W2-02698. Breaks down smoke sensations into (1) mouth sensations, including mouth feel, texture and taste; (2) sensations on inhalation, including throat feel, irritation, and impact; and (3) wholebody pharmacological and psychological effects.

the pharmacological effects of nicotine that underlie consumer satisfaction. For example, a 1972 Philip Morris document from a Council for Tobacco Research conference addressing the issue of why people smoke makes clear that:

The <u>primary</u> incentive to cigarette smoking is the immediate salutory <u>effect of inhaled smoke upon body function</u>.... The physiological effect serves as the <u>primary incentive</u>; all other incentives are secondary. 582 [Emphasis added.]

A nicotine monograph prepared for the Tobacco Advisory Council in the United Kingdom also makes clear that smoking satisfaction is dependent on the inhalation of nicotine.

Whilst smoking fulfils [sic] a psychological need in certain individuals it is only the inhaling cigarette smoker who is likely to gain psychopharmacological satisfaction from nicotine and become dependent on it. 583

Many industry documents reveal that the industry draws a clear distinction between nicotine's pharmacological effects and any effects it has on flavor. A 1984 letter from a BATCO Group R&D researcher to a Brown and Williamson executive drew the distinction between nicotine's pharmacological effects and the sensory properties of cigarette smoke, underscoring the distinction by pointing out that people inhale cigarette smoke (an act that occurs after any sensory effects of cigarette smoke are felt in the nose, mouth, and throat) in order to obtain nicotine's pharmacological effects on the brain:

It is well known that nicotine can be removed from smoke by the lung and transmitted to the brain within seconds of smoke inhalation. Since it is the major or sole pharmacologically active agent in smoke, it must be presumed that this is its preferred method of absorption and thus why people inhale smoke. . . . . The organoleptic [sensory] properties of smoke are more complex since they involve

<sup>&</sup>lt;sup>582</sup> Dunn WL. Philip Morris Research Center. *Motives and Incentives in Cigarette Smoking*. Philip Morris Research Center. Richmond, VA. 1972. Pages 3-4.

<sup>&</sup>lt;sup>583</sup> Cohen AJ, Roe FJC. Monograph on the Pharmacology and Toxicology of Nicotine and its Role in Tobacco Smoking. Tobacco Advisory Council. U.K. July 1979. Page 38.

the stimulation of a variety of areas in the mouth, nose and throat. 584

At the 1983 BATCO Research Conference in Rio de Janeiro, the industry discussed its understanding that nicotine "satisfaction" comes from inhalation and absorption of nicotine into the bloodstream rather than from its flavor. There was discussion of possible cigarette modifications to reduce inhalation of toxic smoke components and thus reduce smoker health risk. Smoker risk could be reduced (1) by modifying the cigarette to reduce retention of smoke in the lung, or (2) by increasing smoke irritation to reduce depth of inhalation and thus resulting absorption. The conferees were reminded, however, that such modifications, to the extent that they result in decreased nicotine absorption and resulting pharmacological effects, may threaten smoker "satisfaction." They were told that it was therefore essential to pay attention to the amount of nicotine that was inhaled, to determine whether absorption was adequate with less deep inhalation:

The basic assumption is that nicotine, which is almost certainly the key smoke component for satisfaction, is fully released to the body system before exhalation takes place. It is essential, therefore to attempt to quantify the change in chemical composition between inhaled and exhaled smoke under different conditions of smoking, ie., shallow, medium and deep inhalation. The absorption of nicotine via the nasal cavity should also be investigated. 585

Other BATCO documents also show that the industry treats nicotine's pharmacological

<sup>&</sup>lt;sup>584</sup> Ayres CI. BATCO letter to E.E. Kohnhorst, Brown and Williamson, transmitting partial summary of issues presented at Montebello Research Conference in 1982. Page BW-W2-03949. (Summary prepared in 1984.)

See also a BATCO report in which it was hypothesized that "increased smoker response is associated with nicotine reaching the brain more quickly." Backhurst JD. BATCO R&D. Further Work on "Extractable Nicotine." Report No. RD 437-R. Southampton, England. September 30, 1966. Page 1.

<sup>&</sup>lt;sup>585</sup> BATCO Research Conference. Brazil. July 1983. Page 7.

effects as distinct from the flavor characteristics of tobacco.<sup>586</sup> As described in FINDINGS § II.C.1., <u>supra</u>, "Project Wheat" was an industry study intended to aid BATCO in developing cigarettes with increased consumer acceptance.<sup>587</sup> The Project Wheat researchers emphasized the importance of nicotine delivery over all other product features and specifically distinguished the effects of nicotine from the taste and flavor characteristics of cigarettes:

In considering which product features are important in terms of consumer acceptance, the nicotine delivery is one of the more obvious candidates. Others include the taste and flavour characteristics of the smoke, physical features such as draw resistance and rate of burn, and the general uniformity of the product, to name but a few. The importance of nicotine hardly needs to be stressed, as it is so widely recognised. 588 [Emphasis added.]

Even RJR research scientists publicly acknowledge that the nicotine in cigarettes provides pharmacological and psychological effects to smokers in addition to any mere sensory effects.<sup>589</sup> An internal RJR document from 1972 is more explicit in showing that the industry views nicotine's role as pharmacological and distinct from the smoke components that provide flavor:

If nicotine is the sine qua non of tobacco products, and tobacco products are recognized as being attractive dosage forms of nicotine, then it is logical to design our product - and where possible our advertising - around nicotine delivery rather than around tar delivery or flavor. 589a [Emphasis added.]

<sup>&</sup>lt;sup>586</sup> BATCO Group R&D Sydney, Australia. March 1978. Page 6. According to "Notes on Group Research & Development Conference" written by S.J. Green on April 6, 1978, the conferees were asked to assist in developing "an effective means of obtaining a nicotine-rich, and preferably flavour-rich extract from waste tobacco."

<sup>&</sup>lt;sup>587</sup> See Project Wheat - Part 1, note 204, supra. at p. 1.

<sup>&</sup>lt;sup>588</sup> *Id.* at pp. 3-4.

<sup>&</sup>lt;sup>589</sup> Robinson JH, Pritchard WS. The role of nicotine in tobacco use. *Psychopharmacology*. 1992;108:405.

<sup>&</sup>lt;sup>589a</sup> Hilts PJ. U.S. Convenes Grand Jury to Look at Tobacco Industry. *New York Times*. July 26, 1995. An internal Philip Morris document similarly reveals the industry's understanding that people smoke for the pharmacological effects of nicotine, not for flavor. Reporting on a survey of the reasons

Industry patents also distinguish the role of nicotine from flavorants. An RJR book on flavoring tobacco lists approximately a thousand flavorants, but fails to list nicotine as a flavoring agent. In fact, nicotine's flavor is unpleasant, and the tobacco industry has gone to significant lengths to mask the flavor of increased levels of nicotine in cigarettes.

Moreover, there is evidence that some of the sensory effects associated with nicotine, e.g., irritation and "impact," are sought by smokers at least in part because these effects are always followed by the pharmacological effects they seek. Thus, smokers learn to associate the sensory impact of nicotine (burning in the throat) with the resulting psychoactive effects of nicotine, and thus look for these sensory signals in tobacco products. This is known as secondary reinforcement.<sup>594</sup> Industry documents show that the industry is aware of this

people say they smoke, a Philip Morris researcher says that the reasons given fall into three categories: 1) "as a narcotic, tranquilizer, or sedative," 2) at the beginning or end of a basic activity, and 3) automatic smoking behavior. The researcher concludes:

It should be noted that there was scarcely any unprompted reference to smoking for "taste," or "flavor," until it was suggested-and then everyone agreed that it was the major element in smoking satisfaction.

Memorandum from Al Udow, Philip Morris, New York, NY, to Mr. J.J. Morgan. Why People Start to Smoke. June 2, 1976. *In* 141 Cong. Rec. H7665 (daily ed. July 25, 1995).

<sup>&</sup>lt;sup>590</sup> U.S. Patent No. 3,584,630. Inskeep GE. *Tobacco Product Having Low Nicotine Content Associated with a Release Agent having Nicotine Weakly Absorbed Thereon*. Philip Morris Inc. June 15, 1971. C1:57-58.

<sup>&</sup>lt;sup>591</sup> Leffingwell JC, Yound HJ. *Tobacco Flavoring for Smoking Products*. Winston-Salem, NC: R.J. Reynolds Tobacco Company; 1972.

<sup>&</sup>lt;sup>592</sup> Budavari S, O'Neil MJ, Smith A, Heckelman PE, eds. The Merck Index. 11th ed. Rahway, NJ: Merck & Co., Inc. 1989:1030. *The Merck Index* describes nicotine as having "an acrid, burning taste."

<sup>&</sup>lt;sup>593</sup> See, e.g., U.S. Patent No. 4,830,028. Lawson JW, Bullings BR, Perfetti TA. Salts Provided from Nicotine and Organic Acid as Cigarette Additives. R.J. Reynolds Tobacco Company. May 16, 1989. C1. See also p. 250 et seq.

<sup>&</sup>lt;sup>594</sup> See p. 102. Rose JE, Levin ED. Inter-relationships between conditioned and primary reinforcement in the maintenance of cigarette smoking. *British J. of Addiction.* 1991;86:605-609.

relationship.595

The industry's development of nicotine analogues also demonstrates that the industry is more interested in nicotine's pharmacological effects on the central nervous system than in its sensory effects. The focus of industry research has been to develop compounds that will duplicate the pharmacological effects of nicotine on the central nervous system. Nowhere in the referenced tobacco industry documents concerning nicotine analogues is there mention of concern to duplicate any flavor, taste, or other acute sensory effects that may be associated with nicotine. This fact was acknowledged by Dr. DeNoble in his congressional testimony, as evidenced by the following exchange with Congressman Waxman:

Waxman: Now, you ran a laboratory that was charged with identifying the essential characteristics of nicotine so that a synthetic form of nicotine could be developed, yet you didn't test for the taste of nicotine. Did you ever hear any serious discussion to the effect that Philip Morris leaves nicotine in cigarettes for taste?

DeNoble: No, sir. None at all. 596

In summary, tobacco industry documents make clear that the industry understands that the pharmacological effects of nicotine explain why there is a market for cigarettes, and why

<sup>&</sup>lt;sup>595</sup> BATCO Conference Outline, 1984, note 287, supra, at p. BW-W2-01977:

An immediate sensory affect [sic] associated with nicotine is the "impact" on inhaling. Is this sensation a genuine part of the reward a smoker is seeking, or is it a "cue", i.e., a smoker has learnt by experience, that if he perceives a particular level of impact, he will subsequently receive an acceptable degree of satisfaction.

Other BATCO documents refer to a 1969 BATCO study (B-A.T. R. & D.E. Report No. RD.640-R) whose objective was to determine the relationship between "impact" and physiological response. *See*, *e.g*, BATCO. Relative Contributions of Nicotine and Carbon Monoxide to Human Physiological Response. Nov. 15, 1971. Page 2. RD.640-R was not among the documents provided to Congress by Brown and Williamson.

<sup>&</sup>lt;sup>5%</sup> Regulation of Tobacco Products (Part 2): 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. 16 (April 28, 1994) (testimony of Victor DeNoble).

nicotine's sensory effects are distinct and quite secondary. Tobacco industry documents concerning nicotine analogues further support the conclusion that the pharmacological effects of nicotine are of much greater importance to the industry than nicotine's sensory effects.