

A. INDUSTRY STATEMENTS ON NICOTINE'S DRUG EFFECTS

Recently disclosed industry documents contain explicit statements, made by high-ranking tobacco company officials over more than three decades, acknowledging nicotine's drug effects and the central role those effects play in tobacco use. These documents also include research reports and conference summaries describing the specific pharmacological and physiological effects of nicotine, including, in some cases, its addictive properties. Covering a period of more than 30 years, these company documents show that tobacco companies have long recognized that nicotine in tobacco is a drug, that nicotine is the primary reason people use cigarettes and smokeless tobacco, and that cigarettes and smokeless tobacco are nicotine delivery systems. Internal statements of company officials and researchers reflect the industry's true knowledge and real intentions. The internal statements contained in these documents confirm that tobacco manufacturers intend nicotine-containing cigarettes and smokeless tobacco to be used as drugs. The extent of these statements was not known to FDA at the time of its earlier determinations about the intended use of tobacco.

1. Statements That Nicotine's Drug Effects Are Essential to Tobacco Use

Tobacco company researchers have, for more than 30 years, studied the effects of nicotine on the body. Industry documents reveal that the manufacturers' research has convinced the industry that nicotine in tobacco produces pharmacological effects in tobacco users and that these effects are the major reason that consumers use tobacco products. These documents reveal further that tobacco company executives and senior officials share these convictions about the central role of nicotine's drug effects in tobacco use.

a. Tobacco Company Researchers' Views

A wide range of industry documents reveals that tobacco company researchers have known for several decades that nicotine in tobacco functions as a drug and that nicotine's drug effects are the central reason that consumers use tobacco.

More than 30 years ago, in 1962-63, BATCO received the results of its Project HIPPO study (HIPPO I and HIPPO II), the aim of which was to "understand some of the activities of nicotine -- those activities that could explain why smokers are so fond of their habit."¹⁶¹ A second purpose of the Project HIPPO study was to compare the effects of nicotine with those of then-new tranquilizers, "which might supersede tobacco habits in the near future."¹⁶² Thus,

¹⁶¹ See:

Hersch J, Libert O, Rogg-Effront C. *Final Report on Project HIPPO I*. Battelle Memorial Institute. International Division. Geneva, Switzerland. January 1962. (Hereafter cited as Final Report on Project HIPPO I.)

Haselbach CH, Libert O. *Final Report on Project HIPPO II*. Battelle Memorial Institute. International Division. Geneva, Switzerland. March 1963. Pages 1-3. (Hereafter cited as Final Report on Project HIPPO II.)

¹⁶² *Id.* Final Report on Project HIPPO II. Page 1.

these researchers believed that nicotine-containing tobacco and tranquilizers were used for the same purposes by consumers. The researchers concluded that, despite some similarities, nicotine has different drug effects than tranquilizers:

both kinds of drugs [nicotine and tranquilizers] act quite differently, and [] nicotine may be considered (its cardiovascular effects not being contemplated here) as more "beneficial" or less noxious — than the new tranquilizers from some very important points of view.

The so-called "beneficial" effects of nicotine are of two kinds:

- 1. Enhancing effect on the pituitary adrenal response to stress;*
- 2. Regulation of body weight.¹⁶³ [Emphasis added.]*

In the final conclusion of the HIPPO study, the researchers discuss the effect of nicotine in the "stress reaction":

The understanding and thorough investigation of this effect seems of the greatest importance: it is by this very effect that nicotine acts as a 'tranquilliser'.¹⁶⁴

The Project HIPPO reports were disseminated to officials of Brown and Williamson (B&W).¹⁶⁵ The exchange of information between BATCO and B&W is important because it

¹⁶³ Final Report on Project Hippo II. Page 2. Based on studies of rats, the Project HIPPO I researchers also concluded:

We have been in a position to show a definite enhancing effect of nicotine in the normal mechanism of defence [sic] against stress, i.e., in the stimulation of the release of the pituitary corticotropic hormone (ACTH).

Final Report on Project HIPPO I. Page 2.

¹⁶⁴ Final Report on Project HIPPO I. Page 48.

¹⁶⁵ These reports were also circulated to various other U.S. tobacco companies, and the Tobacco Industry Research Committee, the forerunner to the Council for Tobacco Research (Little, CC. "Report of the Scientific Director," 1963, at p. 5), demonstrating that at least some of the industry's nicotine research was shared. See, e.g.:

June 28, 1963, letter from Sir Charles Ellis, Scientific Advisor to the Board of BATCO to A. Yeaman of B&W.

August 5, 1963, letter from A. Yeaman to E.J. Jacob of R.J. Reynolds Tobacco Co.:

demonstrates B&W's awareness of the results of studies such as Project HIPPO,¹⁶⁶ which was just one of a number of studies commissioned by BATCO to study the physiological and pharmacological effects of nicotine. For example, a 1980 report addresses the critical role of nicotine's drug effects:

*Nicotine is an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical, and physiological responses in vivo . . . In some instances, the pharmacological response of smokers to nicotine is believed to be responsible for an individual's smoking behaviour, providing the motivation for and the degree of satisfaction required by the smoker.*¹⁶⁷

The BATCO documents include not only some of the research reports themselves, but also summaries or minutes of numerous BATCO research and development (R&D) meetings at which nicotine's drug effects and importance to the industry were discussed. These papers demonstrate both the consistency and the extent of industry's interest in and knowledge of

I suggest to you and Henry that it is now timely to release these reports to the S.A.B. [Scientific Advisory Board of the Tobacco Institute Research Council].

June 19, 1963, note for Mr. Cutchins of B&W, noting that Sir Charles Ellis had sent Mr. Cutchins reports of research that BATCO had sponsored at Battelle :

. . . showing the beneficial effects of nicotine . . . BAT decided to make this research available to the T.R.C. [Tobacco Research Council of the U.K.] . . . Todd, of T.R.C. is to-day sending copies to T.I.R.C. [Tobacco Industry Research Committee of the U.S.] with a request that they consider whether it would help the U.S. industry for these reports to be passed on to the Surgeon General's Committee.

¹⁶⁶ Appendix 2 contains a detailed description of how the research was shared between B&W and BATCO. The B&W/BATCO documents that recently were made public offer an extraordinary glimpse into the workings of the third largest U.S. tobacco company. Although the five other leading U.S. tobacco companies received requests from FDA on July 11, 1994, for similar documentary evidence, to date the companies have failed to provide the requested information. See Appendix 3. Tobacco industry material is cited throughout the Legal Analysis and Findings sections of this document that refers to the workings of the five U.S. tobacco companies. This material constitutes just a representative sample of the internal information still in the possession of those companies.

¹⁶⁷ BATCO Group R & D. Southampton, England. *Method for Nicotine and Cotinine in Blood and Urine*. Report No. RD.1737-C. May 21, 1980. Page 2.

nicotine as the primary pharmacological agent in tobacco. For example, at a 1974 BATCO

Group R&D Meeting, it was noted that:

Nicotine (which has been assumed to be the main pharmacologically active component in smoke) may act in a bi-phasic manner, either as a stimulant (CNV increase) or depressant (CNV decrease).¹⁶⁸

In addition, a 1977 report concerning an International Smoking Behavior Conference includes the following statements about nicotine's effects:

Nicotine was the focal point of the conference. In many cases, psychological and physiological changes observed in subjects . . . were shown to be due to nicotine.

Most researchers conclude that the nicotine effect is biphasic and dosage dependent; small doses stimulate and large doses depress.¹⁶⁹

Subsequent BATCO research conferences offer equally revealing statements about the drug effects of nicotine. A BATCO Group R&D Smoking Behaviour-Marketing Conference held in 1984 focused almost entirely on the role of nicotine pharmacology in smoking. Summaries of the presentations at that conference include numerous references to the pharmacological effects of nicotine and the importance of these effects in maintaining tobacco use. For example, one presentation included the following observation:

Smoking is then seen as a personal tool used by the smoker to refine his behaviour and reactions to the world at large.

It is apparent that nicotine largely underpins these contributions through its role as a generator of central physiological arousal effects which express

¹⁶⁸ BATCO Group R&D. Southampton, England. *Interaction of Smoke and the Smoker, Part 3: The Effect of Cigarette Smoking on the Contingent Negative Variation*. Report No. RD.1164-R. December 12, 1974. Page 1.

¹⁶⁹ BATCO International Smoking Behavior Conference: Trip Report. Chelwood Vachery, England. November 27-30, 1977. Pages 1-2.

*themselves as changes in human performance and psychological well-being.*¹⁷⁰
[Emphasis added.]

Reporting on a study testing the hypothesis that extroverts smoke for nicotine and introverts smoke for the motor activity provided by smoking, another presentation concluded:

*Extraverts [sic] relied principally on nicotine and did not pay attention to the motor aspects of smoking except to gain nicotine and so did not show well developed motor potentials preceding the motor act. However, the effect of nicotine is to enhance the extravert's motivation to act, and this increases motor activity rate after smoking (as was shown in the tapping rate recorded for extraverts after smoking) For preparatory smokers (extraverts): Smoking functions as a kind of portable, stationary generator inducing the effects of activity on the CNS [central nervous system] without the usual requirement of stressful activity to achieve those effects.*¹⁷¹

Finally, another BATCO conference focusing on nicotine was held in 1984. One of the presentations was characterized by a Brown and Williamson official:

*The presentation was concerned with summarising and outlining the central role of nicotine in the smoking process and our business generally. . . There are two areas of nicotine action that are of primary importance: (i.) to identify to what extent the pharmacological properties or responses to nicotine are influenced by blood and tissue levels of nicotine. (ii) what is the significance and role of nicotine in eliciting the impact response and upper respiratory tract responses . . . [Emphasis added.]*¹⁷²

¹⁷⁰ Ferris RP. *The role of smoking behavior in product development: some observations on the psychological aspects of smoking behaviour*. In: Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session III. July 9-12, 1984. Page 79.

¹⁷¹ Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session III. July 9-12, 1984. Slides. Pages BW-W2-02772-02775.

¹⁷² Ayres CI. Notes from the GR&DC [Group Research and Development Centre] Nicotine Conference June, 1984. Page 62. The conference was devoted predominantly to nicotine's pharmacological effects. The conference's seven sessions are listed as follows:

Session I - Nicotine Dose Requirement - Background; Session II - Nicotine Dose Estimation; Session III - Sensory and Psychological Effects of Nicotine; Session IV - Effect of Nicotine - Interaction with the Brain (Pharmacology); Session V - Effects of Nicotine - Interaction with Peripheral Tissues (Physiology); Session VI - Product Modification for Maximal Nicotine Effects; Session VII - General Session. Pages BW-W2-02639, 12641-46.

See also:

As described in FINDINGS § II.B., *infra*, comparable research on the pharmacological effects of nicotine has been conducted or sponsored by all the major tobacco companies. For example, researchers at the R.J. Reynolds Tobacco Co. have published studies in which they freely acknowledge the pharmacological effects of nicotine in tobacco and the importance of those effects to smokers:

*The beneficial effects of smoking on cognitive performance . . . are a function of nicotine absorbed from cigarette smoke upon inhalation.*¹⁷³

BATCO R&D Conference. Hilton Head, SC. September 24-30, 1968. Page 3. The conferees recognized "that the reasons why people smoke are partly pharmacological and partly psychological."

BATCO R&D Conference. Montreal, Canada. October 25, 1967. Page 6. The conferees concluded: *While recognizing the importance of psychological factors in smoking and the possibility that some smokers would accept non-nicotine cigarettes, it was felt that nicotine is important for the majority of smokers and that the form of nicotine can be significant.* [Emphasis added.]

BATCO R&D Conference. Kronberg, Germany. June 2-6, 1969. Page 7 of summary: *The Conference agreed that all the evidence continues to demonstrate the importance of nicotine to the smoker, and again emphasises the importance of keeping separate TPM and nicotine figures.* [Emphasis added.]

BATCO Group R&D report. Southampton, England. *Preparation and Properties of Nicotine Analogues*. Report No. RD 953-R. November 9, 1972.

BATCO Group R&D Conference on Smoking Behavior. Southampton, England. October 11-12, 1976. Pages BW-W2-02145-02149, BW-W2-02150-02165, BW-W2-02292-02311.

February 9, 1984, letter from C.I. Ayres to E.E. Kohnhorst (both of Brown and Williamson) summarizing the August 30-September 3, 1982, BATCO R&D Conference. Montebello, Canada.

¹⁷³ Robinson JH, Pritchard WS, Davis RA (R.J. Reynolds Tobacco Co.). Psychopharmacological effects of smoking a cigarette with typical "tar" and carbon monoxide yields but minimal nicotine. *Psychopharmacology*. 1992;108:471.

See also Pritchard WS, Robinson JH, Guy TD (R.J. Reynolds Tobacco Co.). Enhancement of continuous performance task reaction time by smoking in non-deprived smokers. *Psychopharmacology*. 1992;108:437-442.

Pritchard WS, Gilbert DG, Duke DW (R.J. Reynolds Tobacco Co.). Flexible effects of quantified cigarette smoke delivery on EEG dimensional complexity. *Psychopharmacology*. 1993;113:95-102.

*An enduring question regarding human cigarette smoking is the basis of the so-called "nicotine paradox." Although the peripheral effects of smoking appear to be stimulatory (e.g., increased heart rate, especially for the initial cigarette of the day [citation omitted]) and many smokers say that smoking increases their mental alertness, other smokers report that smoking helps them to function in the face of environmental stress by having a calming effect on their mood [citation omitted].*¹⁷⁴

*We recognize that nicotine plays an important role in smoking behavior for many people.*¹⁷⁵ [Emphasis added.]

Philip Morris researchers conducted extensive research on nicotine pharmacology from the late 1960's until at least the mid-1980's. See note 240a, *infra*. The nature and magnitude of the research, as well as statements made in internal documents, show that the Philip Morris researchers strongly believed that nicotine has potent psychoactive effects and that these effects provide a primary motivation for smoking. For example, in 1969, a Philip Morris researcher proposed a study whose purpose was to show that cigarette smoking is more likely in stressful situations. The researcher stated that such a study would demonstrate "one of the advantages of smoking, its use as an anxiety reducer."^{175a} In 1974, Philip Morris researchers began a study designed to test their theory that hyperkinetic children take up

¹⁷⁴ Pritchard WS (R.J. Reynolds Tobacco Co.). Electroencephalographic effects of cigarette smoking. *Psychopharmacology*. 1991;104:485-490. Page 00033640. (Smokers who inhale lightly appear to use tobacco to achieve "mental activation and performance enhancement" while those who inhale more deeply achieve effects in the portion of their brains that is associated with anxiety reduction after administration of benzodiazepines. *Id.* at p. 00033643. [Benzodiazepines are drugs used as sedatives and to treat anxiety.]

See also Gibert DG, Robinson JH, Chamberlin CL (R.J. Reynolds Tobacco Co.), and Spielberger, CD. Effects of smoking/nicotine on anxiety, heart rate, and lateralization of EEG during a stressful movie. *Psychophysiology*. 1989;26(3):311-319. (High-nicotine cigarettes associated with reductions in anxiety and activation of the right hemisphere of the brain.)

¹⁷⁵ Robinson J, Pritchard W. The role of nicotine in tobacco use. *Psychopharmacology*. 1992;108:405.

^{175a} Memorandum to W.L. Dunn from F.J. Ryan. Proposed Research Project: Smoking and Anxiety. December 23, 1969. In 141 Cong. Rec. H7648 (daily ed. July 25, 1995).

smoking in adolescence because nicotine may perform the same pharmacological function as prescription medications used to treat hyperkinesis:

It has been found that amphetamines, which are strong stimulants, have the anomalous effect of quieting these children down . . . Many children are therefore regularly administered amphetamines throughout grade school years We wonder whether such children may not eventually become cigarette smokers in their teenage years as they discover the advantage of self-stimulation via nicotine. We have already collaborated with a local school system in identifying some such children in the third grade.^{175b} [Emphasis added.]

In 1976, a Philip Morris researcher wrote a memo explaining why people smoke. In his memo, he reported on a survey in which smokers were asked why they smoked. The researcher concluded that

the circumstances in which smoking occurs may be generalized as follows:

- 1. As a narcotic, tranquilizer, or sedative. Smokers regularly use cigarettes a times of stress.*
- 2. At the beginning or ending of a basic activity*
- 3. Automatic smoking behavior. . . .^{175c} [Emphasis added.]*

In a research paper funded by the Council for Tobacco Research, U.S.A. (CTR),¹⁷⁶

^{175b} Dunn WL. 1600/Smoker Psychology/May 1-31, 1974 [Monthly Report]. June 10, 1974.

See also:

Memorandum from W.L. Dunn to P.A. Eichorn. Quarterly Report- February-March, 1972. April 4, 1972. This memo reports on a study conducted by Philip Morris comparing the "arousal response" produced by nicotine, caffeine, and placebo. The researchers reported that the "arousal response was clearly present with nicotine" and that the caffeine response was nearer to placebo. In 141 Cong. Rec. H7651 (daily ed. July 25, 1995).

^{175c} Memorandum from A. Udow, Philip Morris, New York, NY, to Mr. J.J. Morgan. Why People Start to Smoke. June 2, 1976. In 141 Cong. Rec. H7664 (daily ed. July 25, 1995).

¹⁷⁶ In January, 1954, 14 presidents of tobacco manufacturers, growers, and warehousemen organized the forerunner organization to CTR, known as the Tobacco Industry Research Committee (TIRC), to sponsor a research program into questions of tobacco use and health. (By-laws of the Tobacco Industry Research Committee, subscribed and adopted on January 1, 1954.) TIRC was founded in response to growing concern by tobacco executives over the appearance of published articles claiming an established relationship between cigarette smoking and lung cancer.

reporting on the "beneficial" pharmacological effects of nicotine in cigarettes, the authors said:

*Nicotine is recognized as the primary psychoactive compound in cigarette smoke.*¹⁷⁷

Many other industry documents refer to the central role of nicotine's drug effects for smokers and, therefore, for the industry.¹⁷⁸ Nicotine is repeatedly identified as a primary

The driving force behind the creation of TIRC was Paul M. Hahn, President of the American Tobacco Company. Other original signers of the TIRC by-laws were Timothy V. Hartnett, President of Brown and Williamson Tobacco Corp., Herbert A. Kent, Chairman of P. Lorillard & Co., O. Parker McComas, President of Philip Morris & Co., E.A. Darr, President of R. J. Reynolds Tobacco Co., J.W. Peterson, President of U.S. Tobacco Co., and Joseph F. Cullman, President of Benson & Hedges. (Minutes of the Meeting of the Presidents of the Leading Tobacco Companies at the Hotel Plaza, December 15, 1953. Page 1.)

By 1963, grants had been made to 140 scientists from \$6,250,000 appropriated by TIRC from its member companies. In January, 1964, TIRC changed its name to the Council for Tobacco Research (CTR), its current name. The current members of CTR include Philip Morris, R.J. Reynolds, Brown and Williamson, American Tobacco, Lorillard Corp., and U.S. Tobacco. By 1993, CTR had funded more than \$223 million in research. Annual Reports issued by CTR reveal that the organization has provided extensive funding to research on nicotine pharmacology. See note 195, *infra*.

¹⁷⁷ Levin ED, Briggs SJ, Christopher NC, Rose JE. Persistence of chronic nicotine-induced cognitive facilitation. *Behavioral and Neural Biology*. 1992;58:152-158.

¹⁷⁸ For example, the American Tobacco Company (ATC) published a document entitled *A Summary of Biological Research on Tobacco Supported in Whole or in Part by the American Tobacco Company* (April 1962). In a chapter entitled "Role of Nicotine in the Cigarette Habit," ATC referred to a 1945 study and stated that "[t]he authors concluded that with some individuals, nicotine becomes a major factor in their cigarette habit." Page 66. (See Finnegan JK, Larson PS, Haag B. The role of nicotine in the cigarette habit. *Science*. 1945;102:94.)

See also:

Willey LC, Kellett ND (for Imperial Tobacco Group Ltd.). *Effects of Nicotine on the Central Nervous System*. Huntingdon Research Centre. 1971. Page 9:

We aim, by using various different schedules of behavioural training, and by comparing the effects of many different drugs on these schedules, to be able to classify the effect of nicotine, when given intermittently in smoking doses, as similar to a known class of drug acting on the central nervous system. Alternatively, it may, perhaps, act like one type of drug in some tests and at some doses and like another type in other tests.

U.S. Patent No. 4,340,072. Bolt AJ, Chard B. *Smokable Device*. Imperial Group Ltd. 1982. C1: *Among the reasons why most people smoke conventional cigarettes is that they wish to*

reason consumers smoke or use other nicotine-containing products. A "Proposal for Low Delivery Project for B&W" prepared by a marketing firm hired by B&W in the late 1970's contained the following statement that a sufficient dose of nicotine is essential to sell cigarettes and, implicitly, to maintain market share based on nicotine addiction:

Current market trends clearly indicate a major trend toward low-tar brands although current "ultra" low "tar" brands, have had limited success because of their failure to deliver satisfaction/maintain an adequate nicotine level. An ancillary concern relative to nicotine delivery is that if a satisfying, low-nicotine cigarette were to be developed, it could represent an effective means of withdrawal . . . with severe implications for long-term market growth. [Emphasis added.]¹⁷⁹

Finally, a 1976 BATCO Conference on Smoking Behavior underscores tobacco industry researchers' awareness of the fundamental importance (to the huge majority of smokers) of nicotine's effects on the brain:

Some insight into the likely benefits of smoking follows from a consideration of the properties of nicotine, which is considered to be the reinforcing factor in the smoking habit for at least 80% of smokers . . . [Emphasis added.]¹⁸⁰

inhale an aerosol containing nicotine.

Note from S.J. Green (BATCO R&D) to Dr. G. Hook (BATCO R&D). June 11, 1974.

¹⁷⁹ Lisher & Company Inc. memo. Proposal for Low Delivery Project for B&W. On the copy of this proposal, lines 3 - 7, beginning with "maintain an adequate nicotine level," are crossed out. The unedited quote makes clear that the term "satisfaction" is a euphemism used by the industry to refer to satisfaction of the desire for nicotine.

¹⁸⁰ BATCO Group R&D Conference on Smoking Behavior. Group Research and Development Centre. Southampton, England. October 11-12, 1976. "*Benefits of Smoking*. (Pages BW-W2-02152 and 02153). The summary of a presentation at this conference also notes that all types of tobacco usage -- smoking, chewing and snuffing -- allow nicotine to go directly into the blood and to the brain. The speaker observed that nicotine is not ingested, a route that converts nicotine to a pharmacologically inactive metabolite, cotinine, before it can affect the brain. The summary then notes:

It would therefore be surprising if nicotine, which is known to be pharmacologically active in the brain (unlike cotinine), and which is obtained in the ways most likely to enable it to reach the brain unchanged, were not involved in the reasons why people smoke.

Id., Session II: Current Views on the Role of Nicotine in Smoking Behaviour. Page BW-W2-02145.

b. Tobacco company executives' and senior officials' views

Internal and published documents demonstrate that tobacco company executives and senior officials have also long understood that nicotine is a drug and that nicotine's pharmacological effects are essential to consumer satisfaction.

In 1988, during the case Cipollone v. Liggett, Joseph Cullman III, former CEO of the Philip Morris Tobacco Company, testified as follows:

Q: Let me ask you the question, then, Mr. Cullman. Is nicotine a drug?

A: Well it's so described in every book on pharmacology.

Q: So then you agree that it's a drug?

A: I have no reason to disagree with books on pharmacology.¹⁸¹

In 1981, the Tobacco Advisory Council, representing the United Kingdom tobacco manufacturers¹⁸² (including BATCO), published a monograph on nicotine pharmacology and toxicology that expressly treats nicotine as a drug delivered by tobacco.¹⁸³ The monograph states that "nicotine is regarded as the most pharmacologically-active compound in tobacco smoke" and states that nicotine's main effects, "at doses absorbed by inhalers (i.e. 1 mg approx per cigarette)" are:

central stimulation and/or depression (which vary with the individual), transient hyperpnoea, peripheral vasoconstriction (usually associated with a rise in systolic pressure), suppression of appetite, stimulation of peristalsis and, at larger nicotine intakes, nausea of central origin, associated with

¹⁸¹ Transcript of proceedings in Cipollone v. Liggett Group, Inc., at p. 3290 (D.N.J. Feb. 23, 1988). (Civil Action No. 83-2864 (SA)).

¹⁸² 1981 document of the Tobacco Advisory Council (corrections sheet).

¹⁸³ Cohen AJ, Roe FJC. *Monograph on the pharmacology and toxicology of nicotine*. Tobacco Advisory Council. Occasional paper 4. 1981. Page 1.

vomiting.¹⁸⁴

More than three decades ago, in 1961, a presentation by Dr. Helmut Wakeham, a senior Philip Morris research scientist, to the company's Research and Development Committee noted that:

*Low nicotine doses stimulate, but high doses depress functions . . . It is also recognised that smoking produces pleasurable reactions or tranquility, and that this is due at least in part to nicotine . . .*¹⁸⁵

Dr. Wakeham also noted that "nicotine is believed essential to cigarette acceptability,"¹⁸⁶ a view later restated by William Dunn, Jr., another high-ranking Philip Morris official. In summarizing a 1972 conference sponsored by the Council for Tobacco Research, Dr. Dunn reported:

*Most of the conferees would agree with this proposition: The primary incentive to cigarette smoking is the immediate salutary effect of inhaled smoke upon body function. [Emphasis added.]*¹⁸⁷

After describing "the physiological effect" as "the primary incentive" for smoking, Dr.

Dunn continued:

¹⁸⁴ *Id.* at p.17.

¹⁸⁵ Wakeham H. *Tobacco and Health -- R&D Approach*. In: 3.10 Tobacco Products Liability Reporter (TPLR) 8.129. See also Wakeham H. Presentation to R & D Committee at meeting held in New York Office on November 15, 1961.

Later, when Wakeham was a Vice President at Philip Morris, his introduction to a tobacco industry symposium included the following acknowledgment that nicotine produces psychoactive effects: "Tobacco and other psychoactive plants have probably been part and parcel of our cultural baggage for thousands of years..." Wakeham H. *Tobacco Smoke: Its Formation and Composition*. 31st Tobacco Chemists Research Conference. October 5-7, 1977. Greensboro, NC. In: *Recent Advances in Tobacco Science*. 1977;3:iii.

¹⁸⁶ *Id.*, TPLR 8.129.

¹⁸⁷ Dunn, note 133, *supra*, at p. 3.

The majority of the conferees would go even further and accept the proposition that nicotine is the active constituent of cigarette smoke. Without nicotine, the argument goes, there would be no smoking. Some strong evidence can be marshalled to support this argument:

- 1) *No one has ever become a cigarette smoker by smoking cigarettes without nicotine.*
- 2) *Most of the physiological responses to inhaled smoke have been shown to be nicotine-related.*
- 3) *Despite many low nicotine brand entries in the market place, none of them have captured a substantial segment of the market . . . [Emphasis added.]*¹⁸⁸

In 1969, Dr. Wakeham, then Vice President for Research and Development, briefed the Philip Morris Board of Directors on why people smoke. A draft of his remarks, which contains the notation "delivered with only minor changes," includes several unequivocal statements that cigarettes are smoked for the pharmacological effects of nicotine:

[T]he psychosocial motive is not enough to explain continued smoking. Some other motive force takes over to make smoking rewarding in its own right. Long after adolescent preoccupation with self-image has subsided, the cigarette will even preempt food in times of scarcity on the smoker's priority list We are of the conviction . . . that the ultimate explanation for the perpetuated cigarette habit resides in the pharmacological effect of smoke upon the body of the smoker, the effect being most rewarding to the individual under stress.^{188a}

¹⁸⁸ *Id.* at p. 4.

^{188a} Ryan/Dunn Alternate -Third version of Board presentation. Fall, 1969. *In* 141 Cong. Rec. H7648 (daily ed. July 25, 1995).

See also:

Memorandum to P.A. Eichorn from W.L. Dunn. Five-year Objectives and Plans for Project 1600. September 25, 1970. *In* 141 Cong. Rec. H7650, *supra*. This document details Philip Morris' plans to study the "short-term psychological and psychophysiological" effects of smoking "as manifested through changes in autonomic, perceptual, cognitive and central nervous system processes and motor performance." The author goes so far toward presuming the essential role of nicotine as to propose that research be undertaken to answer the question: "Can the smoking habit be sustained in the absence of nicotine?"

Dunn WL. 1600/Smoker Psychology/January 1- January 31, 1973 [Monthly Report]. February 9, 1973. *In* 141 Cong. Rec. H7650, *supra*. This report shows that several studies were underway at Philip Morris

A 1974 annual report on the Behavioral Research program at Philip Morris approved by Thomas Osdene (later Vice President for science and technology) and distributed to Dr. Wakeham, also reflects the view that cigarettes are drugs consumed for pharmacological effects. The report states that a person regulates smoke intake "to achieve his habitual quota of the pharmacological action [of the components of smoke]." ^{188b}

In the following year, the annual report on the "Behavioral Research" program explicitly acknowledged that nicotine is a stimulant drug. Describing a theory concerning the effect of an individual's CNS arousal level on performance efficiency, the report says that while one way to increase the CNS arousal level is to seek out stimulating situations, another way is to:

consume socially approved chemicals which would have a similar effect on the

to determine the effects of nicotine on the central nervous system and on performance, including studies on the effects of smoking on: electrical activity in the brain, the "arousal mechanisms of the central nervous system," and "spare mental capacity."

Philip Morris Research Center. Behavioral Research Annual Report (Part II). November 1, 1974. *In* 141 Cong. Rec. H7658, *supra*. The report lists the following "working hypotheses" of Philip Morris researchers:

- 1A. Cigarette smoke improves efficiency in the performance of complex psychological tasks.*
- 1B. Cigarette smoking attenuates, modulates or otherwise influences emotional arousal such as to be gratifying or rewarding to the smoker, thus reinforcing the smoking act.*

.....
IIA. Dose-control continues even after the puff of smoke is drawn into the mouth.

Dunn WL, Ryan FJ, Martin P. Behavioral Research Annual Report. July 18, 1975. *In* 141 Cong. Rec. H7658, *supra*. This report describes a study being undertaken by Philip Morris, entitled "Nicotine as a Modulator of CNS Arousal." The study was to be conducted because the researchers believed that previous studies had provided evidence that nicotine reduces emotional responsiveness:

[Previous] observations imply the influence of nicotine upon some control mechanism governing affective responsiveness, the net effect upon overt behavior being to reduce the intensity of the emotionally-toned response, or raise the threshold for the elicitation of that response.

^{188b} Philip Morris Research Center. Behavioral Research Annual Report, Part II. Approved by T.S. Osdene. November 1, 1974. *In* 121 Cong. Rec. H7660 (daily ed. July 25, 1995).

body--such as the stimulant drugs caffeine and nicotine.^{188c}

Two years later, William Dunn provided a detailed description of the pharmacological effects produced by nicotine that cause smokers to continue smoking:

[T]he doses of nicotine inhaled produce definite, mild, and transient neuropsychopharmacological effects which are positively reinforcing and thus promote repetition of smoking. These effects include: (a) modulation of conditioned behavior; (b) mixed depression and facilitation of the neural substrates of reward; (c) transient (in minutes) EEG and behavioral arousal crudely reminiscent of d-amphetamine but pharmacologically quite different; and at the same time (d) skeletal muscle relaxation.^{188d}

Finally, a memorandum from a Philip Morris official in 1980 confirms the company's view that nicotine's pharmacological effects on the central nervous system are critical to the tobacco industry's success:

Nicotine is a powerful pharmacological agent with multiple sites of action and

^{188c} Dunn WL, Ryan FJ, Martin P. Behavioral Research Annual Report. July 18, 1975. In 141 Cong. Rec. H7655 (daily ed. July 25, 1995). The same report states that the authors have proposed an international industry conference on "the regulatory influence of nicotine upon behavior."

^{188d} Memorandum to T.S. Osdene from W.L. Dunn. Rationale for Investigating the Effects of Smoking upon Electroencephalographic Phenomena. December 22, 1976. [Citing Domino EF, in Dunn (ed.). Smoking Behavior: Motives and Incentives. 1973.] In 141 Cong. Rec. H7665 (daily ed. July 25, 1995). See also:

Philip Morris. Research and Development Five Year Plan-1979-1983. September 1978. In 141 Cong. Rec. H7668 (daily ed. July 25, 1995):

Nicotine may be the physiologically active component of smoke having the greatest consequence to the consumer.

Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1980. January 7, 1980. In 141 Cong. Rec. H7671 (daily ed. July 25, 1995). The author reports:

Cigarette smoking results in EEG changes associated with arousal, while smoke deprivation results in . . . [brain] waves associated with drowsiness . . . [S]moke appears to have opposite effects on visual and auditory evoked potentials . . . [N]icotine, rather than being a general stimulant, may be exerting a selective influence on brain structures. [Emphasis added.]

The same document describes a new research program underway at Philip Morris intended to study, among other things, "how . . . cigarette smoking can have psychosocial consequences through its . . . central-nervous-system-mediated effects upon the coping abilities of the smoking social participant." [Emphasis added.] *Id.*

*may be the most important component of cigarette smoke. Nicotine and an understanding of its properties are important to the continued well being of our cigarette business since this alkaloid has been cited often as 'the reason for smoking' and theories have been advanced for 'nicotine titration' by the smoker. Nicotine is known to have effects on the central and peripheral nervous system as well as influencing memory, learning, pain perception, response to stress and level of arousal. [Emphasis added.]*¹⁸⁹

¹⁸⁹ Philip Morris Interoffice Correspondence from J.L. Charles to Dr. R.B. Seligman. Nicotine Receptor Program-University of Rochester. March 18, 1980. Other Philip Morris documents contain similar statements. See, e.g.:

Wakeham H. *Smoker Psychology Research. Presented to the PM Board of Directors, November 26, 1969. Page 11:*

We are of the conviction, in view of the foregoing, that the ultimate explanation for the perpetuated cigaret habit resides in the pharmacological effect of smoke upon the body of the smoker, the effect being most rewarding to the individual under stress.

Ryan, FJ. Philip Morris Research Center Special Report. *Exit-Brand Cigarettes: A Study of Ex-smokers.* March 1978. Page 2.

We think that most smokers can be considered nicotine seekers, for the pharmacological effect of nicotine is one of the rewards that comes from smoking. When the smoker quits, he foregoes his accustomed nicotine. The change is very noticeable, he misses the reward and so he returns to smoking.

Philip Morris employee (almost certainly W.L. Dunn). *Smoker Psychology Program Review.* Date not specified. Page 5. This paper states the theory that the reinforcing effects of smoking are

likely to be found among the chemical compounds being introduced into the bloodstream . . .

Without the chemical compound, the cigarette market would collapse, P.M. would collapse, and we'd all lose our jobs and our consulting fees.

The same paper later says that the research program at Philip Morris is based on "a strong conviction about the central role of the pharmacologic effects of inhaled smoke." Page 8.

Ryan, FJ, Jones, BW, Martin, PG, Dunn, WL. Behavioral Research Annual Report. July 18, 1975. Pages 18-22, 25.

Memo to H. Wakeham from W.L. Dunn. *Stating the Risk Study Problem.* July 29, 1969. (Tobacco is used by consumers to modulate arousal level, and to avoid withdrawal.)

Memo to W.L. Dunn from T.R. Schori. *Smoking and Caffeine: A Comparison of Physiological Arousal Effects.* May 17, 1972. This memo attaches a report of the same name by Schori and B.W. Jones, which concludes that caffeine and nicotine, which is generally "administered by smoking," both have stimulant effects, but that the effects of caffeine are more like those of placebo than those of smoking. Pages 1, 7 of report.

Memo to T.S. Osdene from W.L. Dunn. Plans and Objectives - 1982. November 5, 1981. Memo says that Philip Morris is conducting research on the effects of nicotine on electrical activity in the brain "on the premise that events which reinforce the smoking act are central nervous system events." Page 4.

BATCO documents also make clear that top company officials recognize nicotine's drug effects and recognize that the company's sales are tied to those effects. In a July 1962 meeting, Sir Charles Ellis, who served as the science advisor to the BATCO board, gave a presentation in which he affirmed the central role of nicotine in tobacco use and enthusiastically endorsed its pharmacological benefits to smokers as similar to those provided by stimulants and tranquilizers:

It is my conviction that nicotine is a very remarkable beneficent drug that both helps the body to resist external stress and also can as a result show a pronounced tranquilising effect. You are all aware of the very great increase in the use of artificial controls, stimulants, tranquilisers, sleeping pills, and it is a fact that under modern conditions of life people find that they cannot depend just on their subconscious reactions to meet the various environmental strains with which they are confronted: they must have drugs available which they can take when they feel the need. Nicotine is not only a very fine drug, but the techniques of administration by smoking has considerable psychological advantages and a built-in control against excessive absorption.¹⁹⁰ [Emphasis added.]

Dr. Sidney J. Green, a BATCO board member as well as the firm's director of research, frequently acknowledged, in internal documents, the central role of nicotine's pharmacological effects in tobacco use. In a 1967 memo on BATCO research needs, Dr. Green pointed out that:

There has been significant progress in understanding why people smoke and opinion is hardening in medical circles that the pharmacological effects of nicotine play an important part and that these effects on balance may be beneficial. [Emphasis added.]¹⁹¹

In a paper on future research policy entitled "B.A.T. Group Research" (1968), Dr. Green wrote

Dunn, WL. *Smoking as a Possible Inhibitor of Arousal*. Submitted to Philip Morris Manuscript Review Board on August 16, 1976.

¹⁹⁰ BATCO Research Conference. Southampton, England. Presentation by Sir Charles Ellis entitled *The Smoking and Health Problem*. 1962. Pages 15-16.

¹⁹¹ Green SJ. March 2, 1967, memorandum to D.S.F. Hobson entitled *Smoking and Health: Some Recent Findings*. Appendix I, page 1. In the same document at Appendix II, page 1, Dr. Green also wrote that "[t]here is now no doubt that nicotine plays a large part in the action of smoking for many smokers."

that there were four motives for smoking, at least three of which depend on the pharmacological and addictive effects of nicotine:

There appear to be four recognisable types of smoking behaviour:

1. *Habitual*
2. *Addictive*
3. *Enhancing desirable emotions and feelings such as enjoyment or excitement.*
4. *Decreasing undesirable emotions and feelings such as anger, fear and shame.*¹⁹²

In another paper a few years later, Dr. Green wrote more forcefully:

*The tobacco smoking habit is reinforced or dependent upon the psychopharmacological effects mainly of nicotine.*¹⁹³

Attorneys for some of the major U.S. tobacco manufacturers have asserted that the "benefits" of smoking include a range of significant pharmacological effects. For example, attorneys for R.J. Reynolds Tobacco Company described the following pharmacological benefits of smoking in a court filing:

*[S]atisfaction; stress reduction; relaxation; stimulation; aided concentration; increased memory retention; alleviation of boredom and fatigue; avoidance of loss of vigilance in repetitive and sustained tasks. . .*¹⁹⁴

CTR has also supported research on the psychopharmacology of nicotine and has concluded that nicotine's drug effects play an important role in why people use tobacco. CTR's annual report for 1966-67 described reports of smokers that they liked or needed to smoke

¹⁹² Green SJ. Lecture notes of Chelwood talk. BATCO Group Research Conference. Chelwood Vachery, England. September 4, 1968. Pages 1, 2.

¹⁹³ Green SJ. *The Association of Smoking and Disease*. July 26, 1972. Page 1.

¹⁹⁴ Reply to Interrogatories, *Gilboy v. American Tobacco Co. et al.*, No. 314002 (La. 19th Jud. Dist. Ct.). Attorneys for Lorillard Tobacco Company similarly characterized the pharmacological effects of smoking in a Reply to Interrogatories filed in *Covert v. Lorillard et al.*, No. 88-1018-B (M.D. La):
Some of the benefits that are commonly reported by various smokers are. . .relaxation; relief of anxiety and stress; reduction of boredom; increased alertness; improvement in concentration. . .

because smoking gave them a "pickup" or relaxed them.¹⁹⁵ The report went on to say

¹⁹⁵ Report of the Scientific Director, 1966-67. Council for Tobacco Research. 1967. Page 12. CTR's annual reports disclose that the organization has funded research on nicotine's effects on the central nervous system continuously since the 1960's. See, e.g.:

Report of the Scientific Director, 1964-65. Council for Tobacco Research-U.S.A. Page 22:

Systematic study of the mode of action of nicotine at various synapses has been continued. Meanwhile increasing emphasis has been placed upon the psychopharmacology of nicotine . . . Specific actions on the central nervous system have been described and the effects of these upon behavior are being sought.

Report of the Scientific Director, 1968-1969. Council for Tobacco Research-U.S.A. Page 14:

Some of the bases for human use of tobacco . . . might also be found in the realm of psycho-pharmacology, that is, in the effects of smoking and/or nicotine on the central nervous system . . . The effects of nicotine on the brain are not always the same. Depending on the state of the nervous system and on the dosage, an "arousal" or "wake-up" effect may occur which is reflected both in brain waves and in behavior . . . In larger doses or in a different state of the nervous system, a peculiar steady state of longer duration is produced . . . [which] has been described as a "tranquilizer effect."

Report of the Scientific Director, 1969-1970. Council for Tobacco Research-U.S.A. Page 13.

Most of the pharmacological studies currently being supported by The Council are concerned with the effects of nicotine and/or smoking on the central nervous system (the brain) with the object of learning more about why people like, want, or need to smoke.

Annual Report of The Council for Tobacco Research - U.S.A., Inc. 1971. Pages 16-17, 59 *passim*.

Report of The Council for Tobacco Research - U.S.A., Inc. 1972. Page 11.

The Council is currently supporting five studies in the field of psychopharmacology that are directed toward further elucidating the paradoxical arousal and tranquilizing effects of nicotine and its facilitation of the learning process in animals. . . . Because human smokers ordinarily receive nicotine chronically . . . a new emphasis has developed concerning habituation effects on the psychopharmacological responses to nicotine.

Report of The Council For Tobacco Research-U.S.A., Inc. 1973. Pages 13-14, 52 *passim*.

Report of the Council for Tobacco Research-U.S.A., Inc. 1974. Page 43 *passim*.

Report of the Council for Tobacco Research-U.S.A., Inc. 1975. Page 47 *passim*.

Report of the Council for Tobacco Research-U.S.A., Inc. 1977. Page 45 *passim*.

Report of the Council for Tobacco Research-U.S.A., Inc. 1978. Page 49 *passim*.

Report of the Council for Tobacco Research-U.S.A., Inc. 1979. Page 39 *passim*.

Report of the Council for Tobacco Research-U.S.A., Inc. 1981. Page 65 *passim*.

Report of the Council for Tobacco Research-U.S.A., Inc. 1982. Page 60 *passim*.

that the study of nicotine in the "new field" of psychopharmacology was providing scientific substantiation for smokers' subjective views that tobacco could both "arouse the lethargic and calm the agitated."¹⁹⁶

Thus, industry documents reveal that tobacco company researchers and top officials understand and unequivocally state that nicotine is a drug and that consumers of tobacco products use them for the pharmacological effects of nicotine.

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- Report of the Council for Tobacco Research-U.S.A., Inc. 1983. Page 80 *passim*.
Report of the Council for Tobacco Research-U.S.A., Inc. 1984. Page 83 *passim*.
Report of the Council for Tobacco Research-U.S.A., Inc. 1985. Page 89 *passim*.
Report of the Council for Tobacco Research-U.S.A., Inc. 1986. Page 68 *passim*.
Report of the Council for Tobacco Research-U.S.A., Inc. 1987. Page 85 *passim*.
Report of the Council for Tobacco Research-U.S.A., Inc. 1988. Page 88 *passim*.
Report of the Council for Tobacco Research-U.S.A., Inc. 1990. Page 101 *passim*.
Report of the Council for Tobacco Research-U.S.A., Inc. 1991. Page 90 *passim*.
Report of the Council for Tobacco Research-U.S.A., Inc. 1992. Page 97 *passim*.

¹⁹⁶ See *id.*, Report of the Scientific Director, 1966-67, at p. 13.

2. Statements Recognizing That Nicotine Is Addictive

Tobacco company documents show that company researchers and executives not only have acknowledged that nicotine's pharmacological effects play a central role in consumer satisfaction with tobacco products, but have recognized nicotine's addictive properties. These documents demonstrate that tobacco companies understand that nicotine addiction is one of the major reasons that consumers use their products.

a. Tobacco Company Researchers' Views

In 1963, a report was completed for BATCO that specifically addressed the mechanism of nicotine addiction in smokers. The report, dated May 30, 1963, and titled "A Tentative Hypothesis on Nicotine Addiction,"¹⁹⁷ describes nicotine's effects on the brain, specifically through hypothalamo-pituitary stimulation. The report states that initially, small doses of nicotine are sufficient to trigger this mechanism, which helps people to cope with stress. However, chronic intake of nicotine, such as occurs with regular smokers, creates a situation where:

*ever-increasing dose levels of nicotine are necessary to maintain the desired action. Unlike other dopings, such as morphine, the demand for increasing dose levels is relatively slow for nicotine. [Emphasis added.]*¹⁹⁸

After noting that when chronic smokers are deprived of nicotine, their endocrine system becomes unbalanced, the report states:

¹⁹⁷ Haselbach C, Libert O. BATCO R&D. *A Tentative Hypothesis on Nicotine Addiction*. Southampton, England. May 30, 1963. Pages 1-3. A copy of this report was personally sent by Sir Charles Ellis of BATCO to Addison Yeaman, the General Counsel of B&W. See letter from Ellis to Yeaman, dated June 28, 1963.

¹⁹⁸ *Id.*, Haselbach et al, at p. 1.

*A body left in this unbalanced status craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine. [Emphasis added.]*¹⁹⁹

The report concludes:

*In conclusion, a tentative hypothesis for the explanation of nicotine addiction would be that of an unconscious desire to restore the normal physiological equilibrium of the corticotropin releasing system in a body in which the normal functioning of the system has been weakened by chronic intake of nicotine. [Emphasis added.]*²⁰⁰

In the decades that followed this report, tobacco industry researchers repeatedly recognized nicotine's addictive properties.²⁰¹ In an article reporting on a study supported by a grant from the Tobacco Industry Research Committee (TIRC), the researcher stated that smoking is addictive:

*Addiction to smoking is found to be consistently greater among men in military service than in civilian life, irrespective of peace or war, and greater in veterans than in nonveterans. [Emphasis added.]*²⁰²

Similarly, a report prepared for Liggett & Myers in anticipation of the 1964 Surgeon General's Report implicitly acknowledged that nicotine dependence and withdrawal are the reasons smokers have difficulty quitting:

If reliance is to be placed on stopping cigarette smoking by men with warnings of high

¹⁹⁹ *Id.* at p. 2.

²⁰⁰ *Id.* at p. 3.

²⁰¹ Recognition of nicotine's addictive properties apparently extended to the smokeless tobacco industry. In a Wall Street Journal article, Larry D. Story, a former U.S. Tobacco Co. (UST) chemist, was quoted as saying, "There used to be a saying at UST that 'There's a hook in every can' . . . [a]nd that hook is nicotine." Freedman AM. Juiced up: how a tobacco giant doctors snuff brands to boost their 'kick'. Wall Street Journal. October 26, 1994:A.

²⁰² Seltzer CC. Why people smoke. *Atlantic Monthly*. July 1962. Page 42. In a TIRC memo to the Scientific Advisory Board from R.C. Hockett, "Papers by grantees of the Tobacco Industry Research Committee," Carl Seltzer was identified as a recipient of a TIRC grant-in-aid.

*mortality, then heavy research is badly needed . . . on means enabling such smokers to stop smoking more easily and effectively. Use of declining doses of injected nicotine or orally administered nicotine analogs during withdrawal were reported as providing some benefit . . .*²⁰³

In Project Wheat,²⁰⁴ a study of smoking behavior conducted by BATCO, researchers concluded that consumer preferences for different cigarette types could be predicted using only two factors: 1) "Inner Need," a measure of the extent to which a smoker uses cigarettes for drug-type uses (to relieve stress, to aid concentration, as a substitute for food); and 2) concern for health. The researchers felt their conclusion to be:

*very much in line with that made by Russell who . . . concluded that it might prove more useful to classify smokers according to their position on a single dimension of pharmacological addiction rather than in terms of their profiles on the six types of smoking.*²⁰⁵

Nicotine addiction/dependence is also acknowledged in a number of other BATCO studies and other documents.²⁰⁶

²⁰³ L&M Littlefield. January 17, 1963, memo from Harry B. Wissman to C.J. Kensler.

²⁰⁴ See:

BATCO. Project Wheat - Part 1: Cluster profiles of U.K. male smokers and their general smoking habits. Southampton, England. July 10, 1975.

BATCO. Project Wheat - Part 2: U.K. male smokers: their reactions to cigarettes of different nicotine delivery as influenced by inner need. Southampton, England. January 30, 1976. (Project Wheat is described in greater detail in FINDINGS § II.C., *infra*.)

²⁰⁵ *Id.*, Part 2, at p. 49.

²⁰⁶ See:

Proceedings of the BATCO Smoking Behaviour-Marketing Conference. Session III. July 9-12, 1984. Ferris slides (BW-W2-02737-02759). One chart (BW-W2-02750), entitled *Role of Nicotine: Hypotheses*, states: "If smokers are ADDICTED to nicotine then . . . 1. The nicotine smokers get from cigarettes may be replaced by nicotine from alternative sources. 2. Cigarettes of different strengths should be smoked differently, e.g., smokers given a low/reduced delivery cigarette should smoke it more intensively (and vice versa)." [Emphasis in original.] Subsequent slides show both that nicotine replacement reduced smokers intake of cigarettes, and that cigarette consumption increased as nicotine yields decreased. Pages BW-W2-02751-02759.

In addition, a Philip Morris researcher who studied a group of smokers in a small town that had gone through a cold turkey campaign described at length the withdrawal symptoms of those who had quit smoking. Even after eight months quitters were apt to report symptoms such as feeling depressed, being restless and tense, being ill-tempered, having a loss of energy, being apt to doze off.²⁰⁷ They were further troubled by constipation and weight gains which averaged about five pounds per quitter.²⁰⁸ The researcher stated:

This is not the happy picture painted by the Cancer Society's anti-smoking commercial which shows an exuberant couple leaping in the air and kicking their heels with joy because they've kicked the habit. A more appropriate

Armitage AK. *Appraisal of Report: "The Fate of Nicotine in the Body."* August 28, 1963. Armitage wrote:

The authors themselves admit (p.27) that the present results offer no conclusive evidence for any particular mechanism involved in tolerance to nicotine, nor do they indicate a lead to the phenomenon of addiction. This important problem was, I imagine, the main object of the research.

Final Report on Project HIPPO II, note 161, *supra*, at page 4:

A quantitative investigation of the relations with time of nicotine - and of some possible brain mediators - on adreno-corticotrophic activity could give us the key to the explanation of both phenomena of tolerance and of addiction, in showing the symptoms of withdrawal.

In the Minutes of the BATCO R&D Conference in Montreal (October 24, 1976), the list of "assumptions" includes the statement: "Smoking is an addictive habit attributable to nicotine." (The word "addictive" has been crossed out.) Page 2.

A report of the BATCO Group R&D Conference Part I, February 5-9, 1979, attended by Sanford and Reynolds of Brown and Williamson, under the heading "Behavioral Research," states: "With regard to dependence [the researcher] wants to study the nature and effect of dependence on smoking behavior and break smokers down into dissonant and consonant smokers." Page BW-W2-03526.

A report of the BATCO Group R&D Psychology Research (1984-86) states:

Activity continues in the area of researching the functional significance of smoking in everyday life, current emphasis being placed on the role of personality in relation to nicotine dependence [sic] and personal requirements of the product. Page BW-W2-02004.

²⁰⁷ Ryan FJ (Philip Morris). *Bird-1, A study of the Quit-Smoking campaign in Greenfield, Iowa, in Conjunction with Movie, Cold Turkey.* 1971. Summary, pages 30-33. See FINDINGS § II.C.4, *infra*.

²⁰⁸ *Id.*

*commercial would show a restless, nervous, constipated husband bickering viciously with his bitchy wife who is nagging him about his slothful behavior and growing waistline.*²⁰⁹

In his report, the Philip Morris researcher also observed that some smokers "need" tobacco, and that this need may be correlated with use of high-nicotine cigarettes.²¹⁰ In 1976, the same Philip Morris researcher elaborated on his view that smokers smoke many cigarettes to satisfy their physiological "need" for a specific level of nicotine in the blood:

Although nicotine intake appears a critical mainstay of tobacco consumption, not all people smoke for nicotine on all occasions . . . All . . . cigarettes contribute to the total nicotine in the system, so that a cigarette smoked out of habit will delay the time until a cigarette is smoked out of need.^{210a}

A BATCO report, as well as a report by the American Tobacco Company, also implicitly acknowledge that nicotine produces withdrawal/physical dependence.²¹¹

Nicotine's capacity to produce "tolerance," often cited as a defining feature of addiction, see p. 81, is also acknowledged in several internal documents. For example, the BATCO-commissioned report "Fate of Nicotine in the Body" acknowledges that nicotine produces tolerance and/or addiction:

²⁰⁹ *Id.* at p. 33.

²¹⁰ *Id.* at p. 20.

^{210a} Ryan FJ. Habit and Need Cigarettes. In Dunn WL. 1600/Smoker Psychology/October 1-31, 1977 [Monthly Report]. November 11, 1977. In 141 Cong. Rec. H7665 (daily ed. July 25, 1995).

²¹¹ *See:*

BATCO R&D. *Relative Contributions of Nicotine and Carbon Monoxide to Human Physiological Response*. Report No. RD.839-R. November 15, 1971. Page 20:

All the regular smokers in this trial were required not to smoke for at least half an hour before the trials, which may have caused an additional stress factor, shown as a stimulation due to the ending of a period of forced abstinence. . .

The American Tobacco Company, note 178, *supra*, at p. 66.

In addition, the alkaloid [nicotine] appears to be intimately connected with the phenomena of tobacco habituation (tolerance) and/or addiction.

Notes from a BATCO Nicotine Conference²¹² include a chart titled "Session IV -- Effects of Nicotine-interaction with the Brain (Pharmacology)." The chart includes the statement "Nicotine and smoke exposure causes adaptation of the nicotine receptor," a change that has been recognized as being associated with tolerance.

Perhaps the most telling admissions that nicotine is addictive come from marketing research studies prepared for tobacco companies. In these documents, the market researchers candidly assert nicotine's addictiveness, in a manner that appears to assume that the tobacco company recipients of the reports will not find the assertion unusual or controversial. For example, in a market research report prepared for Imperial Tobacco Ltd., on attitudes of adolescent smokers, the authors state:

*until a certain nicotine dependence has been developed [taste] is somewhat less important than other things . . .*²¹³

Another market research firm refers to attitudes of adolescents "[o]nce addiction does take place . . ."²¹⁴ and states that "addicted they do indeed become."²¹⁵ The same firm, discussing its research on smokers' attempts to quit, reported that:

²¹² See Ayres note 172, *supra*, at p. BW-W2-02643.

²¹³ Spitzer, Mills & Bates. *The Player's Family: A Working Paper*. Report prepared for Imperial Tobacco Ltd. March 25, 1977. Page 12.

²¹⁴ Kwechansky Marketing Research. *Project Plus/Minus*, in "Study Highlights." Report prepared for Imperial Tobacco Ltd. May 7, 1982.

²¹⁵ *Id.* at p. 26. This same documents notes that: "The desire to quit seems to come earlier now than before, even prior to the end of high school. In fact, it often seems to take hold as soon as the recent starter admits to himself that he is hooked on smoking. However, the desire to quit, and actually carrying it out, are two quite different things, as the would-be quitter soon learns." *Id.* in "Study Highlights."

*Recidivism has several causes Another is the belief that after a few weeks off cigarettes, one could begin again to smoke "just a few" This "just a few" business is actually a surrender to addiction while trying to save face for an interim period, to pretend to oneself and to others that addiction is no longer present, which is nonsense.*²¹⁶

A market research report that was widely circulated in Britain included the following editorial comment, contained in a description of smokers' views of the role played by tar and nicotine in smoking-related health problems:

Another idea was that nicotine and tar combined to have a harmful effect upon health (i.e., quite apart from nicotine's addictive function).²¹⁷ [Emphasis added.]

Later in the same study, the researchers reported under the heading "Nicotine's addictive function" that:

*Most respondents, with a bias towards men, realised that nicotine was the attribute in cigarettes causing addiction. It was also usually seen as the component providing satisfaction.*²¹⁸ [Emphasis added.]

²¹⁶ *Id.* at p. 36-37. The same document also says, at page ii:

It is likely more difficult to break the ritualistic aspects of smoking than it is to overcome the physical withdrawal.

See also an advertising strategy document prepared for Imperial Tobacco which recommends the following advertisement:

The chosen scene should ideally depict a pause or moment of relaxation before, during or after the activity. This moment should correspond to the physiological need for smoking. Publicite BCP. *Player's Filter '81 Creative Guidelines*. January 25, 1980. [Emphasis added.]

²¹⁷ *Attitudes Towards Smoking and Health*. Page 11. Transmitted by letter dated July 26, 1979, to Dr. H.E. Bentley, Imperial Tobacco Ltd., from A.H. Johnston, Market Research Manager, Carreras Rothmans Ltd.

²¹⁸ *Id.* at p. 12.

b. Tobacco Company Executives' and Senior Officials' Views

High-ranking tobacco company officials have also acknowledged that nicotine is addictive and that this is the reason why people use tobacco.²¹⁹

For example, in the aforementioned July 1962 tobacco industry meeting, BATCO board science advisor Sir Charles Ellis stated:

*Smoking is a habit of addiction.*²²⁰

In an internal memo, the general counsel to Brown and Williamson makes the same point in clear, simple language:

*Moreover, nicotine is addictive . . . We are, then, in the business of selling nicotine, an addictive drug . . . [Emphasis added.]*²²¹

Dr. Green, the director of research for BATCO, also repeatedly stated his view that some portion of smoking behavior was due to its addictive effects.²²² In a note to Dr. G. Hook, another scientist at BATCO, Dr. Green wrote, "If you consider Russell's study on cigarette dependence and his five types of smoking you can conceive a pattern as follows . . ." The note follows with a hand-drawn triangle symbolizing the reasons for smoking, with the three points of the triangle labeled "sensory rewards," "psychosocial rewards," and "pharmacological rewards." In the corner of the triangle near "pharmacological rewards" are

²¹⁹ One tobacco company, which markets a cigarette brand called "Death Cigarettes," now states on the package that "cigarettes are addictive." FDA was informed on December 23, 1994, by John D. Slade, M.D., that "Death Cigarettes" stands for "Daring Enterprises Against Tobacco Hypocrisy." The company, owned by Charles and Amelie Southwood, has a post office box in Venice, CA, and an office in Marina Del Ray, CA.

²²⁰ Ellis C. *The Smoking and Health Problem*. BATCO Research Conference. Smoking and Health-Policy on Research. Southampton, England. 1962. Page 4.

²²¹ Yeaman, A. Implications of Battelle Hippo I and II and the Griffith Filter. July 17, 1963. Page 4.

²²² See Green, note 191, *supra*, at Appendix I.

the words "addictive smoking."²²³

In a handwritten note about the likely continued success of the tobacco industry, Dr.

Green wrote:

*The main factor ensuring the continuation of the habit is the dependency induced in smokers. . . . Certainly large numbers of people will continue to smoke because they are unable to give it up. If they could they would do so. They can no longer be said to make an adult choice. And many new smokers become dependent.*²²⁴ [Emphasis added.]

In a handwritten paper entitled "Marketing Cigarettes in the 80's," Dr. Green again stated that addiction is a major reason that people smoke. Noting various failures and constraints in the marketing of cigarettes, including a "close down in advertising" and "the U.K. tar premium,"²²⁵ he writes:

Nevertheless smokers will continue - addiction . . .

Perhaps 50-60% dissonant smokers [smokers who continue despite desire and motivation to quit] . . .

Regard cig[arettes] as catering for addicts.

Finally, in a paper stating that there was adequate evidence that smoking causes disease, written shortly after he retired from BATCO, Dr. Green wrote that, while it may be up to the individual, "if he is able," to decide whether to accept the "considerable risk" from smoking:

on behalf of those unable to make judgments such as children and addicted smokers, the social apparatus must be used to exercise value judgments on the

²²³ Green SJ. Note to Hook G. BATCO R&D. Southampton, England. June 11, 1974. Also in the end of the triangle marked "pharmacological rewards" were "stimulation smoking" and "tranquilisation smoking."

²²⁴ Green SJ. Transcript of handwritten note. Undated. Attached to documents, Green SJ, *Cigarette Smoking and Causality*, and Green SJ, *Smoking, Associated Diseases and Causality*.

²²⁵ The U.K. tar premium is a tax imposed on products on the basis of tar content.

*acceptability of the risks.*²²⁶ [Emphasis added.]

In 1961, Dr. Wakeham of Philip Morris noted in a presentation to the company's Research and Development Committee that "continued usage [of nicotine] develops tolerance."²²⁷

William Dunn, a senior scientist at Philip Morris, made numerous statements reflecting the position that nicotine has the properties of an addictive drug. In 1969, Dunn wrote a memorandum to his supervisor, entitled "Objectives and Plans - 1600," describing the research Philip Morris planned to undertake in the coming year. One of the planned research projects were designed to investigate the addictive properties of nicotine, by teaching rats:

to seek the inhalation of cigarette smoke . . . ultimately through the reinforcing effect of the psychopharmacological effects of the inhaled smoke.^{227a}

As described in § I.B.3., supra, the ability of a substance to function as "positive reinforcer" in animals is one of the most significant pieces of evidence that the substance will be addictive in humans. By 1980, Dunn reported that Philip Morris researchers had successfully demonstrated that rats will self-administer nicotine,

making it quite clear that nicotine can function as a positive reinforcer for rats.^{227b}

²²⁶ Green, note 224, *supra*, at p. 92238.

²²⁷ Wakeham, note 185, *supra*.

^{227a} Dunn WL and Eichorn PA. Objectives and Plans - 1600. January 8, 1969. *In* 141 Cong. Rec. H7646 (daily ed. July 25, 1995). A second research project planned for 1969 was intended to discover "any product that can potentially replace the cigarette in need-gratification."

^{227b} Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives - 1981. November 26, 1980. *In* 141 Cong. Rec. H7682 (daily ed. July 25, 1995). Philip Morris undertook a range of animal studies on nicotine that constitute the classic methods for assessing the addictive properties of drugs, including self-administration, tolerance, and discrimination studies:

Other statements are equally revealing. A 1974 annual research report from the Behavioral Research program at Philip Morris, which was approved by Thomas Osdene (later Philip Morris' Vice President for science and technology) and distributed to the Vice President for research and development, states that people continue to smoke because the "pharmacologically active components of smoke" are "reinforcing":

A general premise in our model of the cigarette smoker is that the smoking habit is maintained by the reinforcing effect of the pharmacologically active components of smoke. A corollary to this premise is that the smoker will regulate his smoke intake so as to achieve his habitual quota of the pharmacological action.^{227c}

The report goes on to acknowledge that stopping smoking produces a withdrawal syndrome like that of other habit-forming drugs. Commenting on a proposed study to test the hypothesis that smoking decreases aggressivity, the researchers note that any increase in

Nicotine discrimination, self-administration, and tolerance studies will enable us to examine the cueing and reinforcing properties of nicotine and nicotine analogues in rats. These are the state-of-the-art bioassays for central nervous system activity which we believe will serve as useful models of human smoking behavior. [Emphasis added.]

Memorandum to T.S. Osdene from J.I. Seeman et al. Nicotine Program: Specific Implementation. March 31, 1978. *In* 141 Cong. Rec. H7668, *supra*. In 1980, Philip Morris decided to perform yet another study of "the rewarding properties of nicotine" using a technique developed to study the similar properties of morphine:

Mucha and Van der Kooy (1979) have reported that a place preference paradigm may be used to demonstrate the rewarding properties of morphine. We plan to use a similar paradigm to examine the rewarding properties of nicotine.

Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1980. January 7, 1980. *In* 141 Cong. Rec. H7671, *supra*.

^{227c} Philip Morris Research Center. Behavioral Research Annual Report (Part II). *In* 141 Cong. Rec. H7660 (daily ed. July 25, 1995). Approved by T.S. Osdene and distributed to H. Wakeham et al. November 1, 1974. Philip Morris officials consistently held the view that the reinforcing properties of cigarette smoking have a pharmacological basis, as shown by a document written six years later, in which the following statement appears:

It is our belief that the reinforcing properties of cigarette smoking are directly relatable to the effects that smoking has on the electrical and chemical events within the central nervous system.

Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1981. November 26, 1980. *In* 141 Cong. Rec. H7681, *supra*.

aggressivity following deprivation

may be as readily explained as the emergence of reactions to [cigarette] deprivation, not unlike those to be observed upon withdrawal from any of a number of habituating pharmacological agents.^{227d}

A Philip Morris research report written by Dunn again acknowledged that cigarette deprivation produces a withdrawal syndrome in 1980, and stated that those smokers who suffered withdrawal in the absence of sufficient nicotine showed "nicotine dependence." The report began by stating the Philip Morris had attempted to identify

two smoking population subgroups, one of which has greater nicotine needs than the other. We have described these people in the past as compensators and noncompensators, and attempted to define them by their consumption changes when nicotine deliveries were moderately shifted. . . . Now we may have two extra tools to use: PM cigarettes of ultra low tar and nicotine, and salivary nicotine concentrations. . . . We therefore propose a shift study in which smokers are shifted to an ultra low brand, and the key dependent variable becomes the presence or absence of the withdrawal syndrome. Those who show evidence of nicotine dependence and those who do not can then be used to test our hypotheses on the relationship of salivary concentration to smoking behavior.^{227e} [Emphasis added.]

CTR documents also refer to the addictive properties of nicotine. In a section of its annual report for 1966-67 entitled "Nicotine and the Central Nervous System," CTR described research in which monkeys self-administered nicotine.²²⁸

Much more recently, tobacco companies have attempted to rely on the "common

^{227d} Behavioral Research Annual Report, Part II. Approved by T.S. Osdene. November 1, 1974. In 141 Cong. Rec. H7660 (daily ed. July 25, 1995).

^{227e} Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1980. January 7, 1980. In 141 Cong. Rec. H7672 (daily ed. July 25, 1995).

²²⁸ See Report of the Scientific Director, 1966-67, note 195, *supra*, at pp. 12-13. As discussed earlier, it is well-established that self-administration of a substance by animals, under laboratory conditions, demonstrates that the substance is a "positive reinforcer," one of the hallmark properties of addictive drugs. See p. 96.

knowledge" that nicotine is addictive to defend against product liability cases brought by smokers. For example, in Rogers v. R.J. Reynolds et al., attorneys for Philip Morris, R.J. Reynolds, the American Tobacco Co., and the Liggett Group argued that the plaintiff could not claim that her deceased husband was not adequately warned that cigarettes were addictive, because their addictive properties are so well known:

There can be no serious suggestion that ordinary consumers do not expect to find nicotine in cigarettes, or that ordinary consumers have not long been well aware that it may be very difficult to stop smoking. [Footnote omitted.] The common knowledge of the alleged habituating or "addicting" properties of cigarettes has resulted in almost casual references to these properties in decisions from around the country throughout this century.²²⁹

Finally, F. Ross Johnson, the former chief executive of RJR Nabisco, has openly acknowledged that tobacco is addictive and that its addictive properties are why people smoke. In an interview for an article in the Wall Street Journal, Mr. Johnson was asked about tobacco. He responded:

Of course it's addictive. That's why you smoke . . .²³⁰

Accordingly, it is clear that high-ranking officials of tobacco companies have long known that nicotine is an addictive drug and, more importantly, that the market for tobacco products in large part depends on the addictive effects of nicotine.

²²⁹ Rogers v. R.J. Reynolds et al (Sup.Ct. Ind.)(No. 49A02-8904 CV 164)(1990), Appellees Brief in Reply to Appellants' Opposition to Petition for Transfer, at pp. 7-8.

²³⁰ Shapiro E. Big spender finds new place to spend. *The Wall Street Journal*. October 6, 1994.

3. Statements That Tobacco Products Are Nicotine Delivery Systems

Internal and published documents also show that top-ranking tobacco industry officials intend to offer tobacco products to consumers as nicotine delivery systems. In summarizing the 1972 conference sponsored by CTR, William Dunn, Jr., of Philip Morris characterized the cigarette as a nicotine delivery system:

Think of the cigarette pack as a storage container for a day's supply of nicotine

.....

Think of the cigarette as a dispenser for a dose unit of nicotine:

- 1) *It is readily prepped for dispensing nicotine.*
- 2) *Its rate of combustion meters the dispensing rate, setting an upper safe limit for a substance that can be toxic in large doses.*
- 3) *Dispensing is unobtrusive to most ongoing behavior.*

Think of a puff of smoke as the vehicle of nicotine:

- 1) *A convenient 35 cc mouthful contains approximately the right amount of nicotine.*
- 2) *The smoker has wide latitude in further calibration: puff volume, puff interval, depth and duration of inhalation. . . .*
- 3) *Highly absorbable: 97% nicotine retention.*
- 4) *Rapid transfer: nicotine delivered to blood stream in 1 to 3 minutes*

Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.²³¹

In a document entitled "RJR confidential research planning memorandum on the nature of the tobacco business and the crucial role of nicotine therein," quoted in the New York Times, RJR executive Claude Teague, Jr. wrote:

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

²³¹ See Dunn Summary, note 133, *supra*. (Indeed, when interviewed by FDA officials in May 1994, Dunn stated that he was known as "the Nicotine Kid" at Philip Morris. See handwritten notes summarizing meeting May 10, 1994, between FDA and Dr. W.L. Dunn.)

variety of physiological effects.^{231a}

The memo goes on:

If nicotine is the sine qua non of tobacco products, and tobacco products are recognized as being attractive dosage forms of nicotine, then it is logical to design our products - and where possible our advertising - around nicotine delivery rather than around tar delivery or flavor.^{231b}

As noted above, Sir Charles Ellis, BATCO's scientific advisor, considered smoking a method of administering nicotine as early as 1962:

*Nicotine is not only a very fine drug, but the techniques of administration by smoking has [sic] considerable psychological advantages and a built-in control against excessive absorption.*²³²

Dr. S.J. Green, BATCO board member and research director, also viewed the cigarette as a vehicle for delivering nicotine. In a document describing BATCO's research needs, he made the following statement:

*It may be useful, therefore, to look at the tobacco industry as if for a large part its business is the administration of nicotine (in the clinical sense).*²³³

In a draft of another document entitled "A Blueprint for B.A.T. Scientific Departments,"

Green repeated this belief:

^{231a} Hilts PJ. U.S. Convenes Grand Jury to Look at Tobacco Industry. *New York Times*. July 26, 1995.

^{231b} *Id.*

²³² Ellis C. *The Smoking and Health Problem*. BATCO Research Conference. Smoking and Health-Policy on Research. Southampton, England. 1962. Page 16.

²³³ Green, note 191, *supra*, at Appendix II.

See also Green, note 192, *supra*, at p. 2:

[w]hile other factors cannot be ignored and their influence is not completely understood, it seems a good assumption that nicotine plays a predominant role for many smokers. So that a good part of the tobacco industry is concerned with the administration of nicotine to consumers . . . [T]hus a large part of our research problem can be identified as the improvement in quality by improving the administration of nicotine . . .

*We must assume that the main objective is the administration of nicotine . . .*²³⁴

In a handwritten chart, attached to a paper entitled "The Association of Smoking and Disease," Green described all forms of tobacco as different methods of nicotine administration.²³⁵

The 1981 monograph on nicotine pharmacology and toxicology published by the British Tobacco Advisory Council expressly states that nicotine is a drug and that tobacco is simply a vehicle for its administration.²³⁶ After setting forth the purpose of the monograph -- to help medical authorities decide whether smoking-related illness should be handled by eliminating smoking altogether, by progressively reducing smoke deliveries, or by developing a cigarette that delivers "an adequate dose of nicotine without the necessity of inhaling large doses of toxic vehicle" -- the introduction states succinctly:

*In a nutshell our approach has been to regard nicotine as a "drug" to which man is exposed in various "vehicles" and by various routes.*²³⁷

A presentation at the 1984 BATCO Smoking Behaviour-Marketing Conference included the following slides:

Relationship Between Smoking Behaviour and Nicotine Intake

Is there any commonalty [sic] in the process [of smoking]:

- broad similarities in wholebody nicotine dose of nicotine across smoking groups*
- strong indirect evidence of smokers smoking for nicotine*
- is this cause and effect or a reflection for something else*

²³⁴ Undated draft of *A Blueprint for B.A.T. Scientific Departments*. Page 4.

²³⁵ See Green, note 193, *supra*. Handwritten chart attached.

²³⁶ Cohen, note 183, *supra*, at p. 1.

²³⁷ *Id.* at p. 1. (Emphasis added.)

What is the Significance of this Observation:

*-underlying smoking maintenance through nicotine, and as a consequence probably provides the basis of smoking satisfaction - in its simplest sense puffing behaviour is the means of providing nicotine dose in a metered fashion [Emphasis added.]*²³⁸

Finally, in a list of expected changes in cigarettes over the next several years, a BATCO official suggested that cigarettes could become delivery systems for drugs in addition to nicotine:

*"Increases in the use of drugs other than nicotine. Potential legalisation of the use of marijuana. Possible introduction of caffeine." [Emphasis added.]*²³⁹

Thus, tobacco company executives have both recognized that nicotine's drug effects are central to the use of tobacco and stated their clear understanding that cigarettes are being sold to and used by smokers as nicotine delivery systems. On the basis of this evidence, these products are intended to affect the structure or function of the body.

²³⁸ Proceedings of the BATCO Smoking Behaviour-Marketing Conference. Session I. July 9-12, 1984. Slides.

²³⁹ FH [Initials of BATCO employee]. BATCO R&D. *Technical and Product Developments Envisaged Over the Next Five Years*. January 22, 1974. Page 1.