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> 1950's to the filtered, low tar cigarette demanded by many smokers for the last 30-40 years. *The objective of industry scientists and product developers, simply stated, was to provide the consumer with the same pharmacological satisfaction derived from nicotine* in the natural blends and flavor of the full strength cigarettes of the 1950's as the marketplace shifted to the naturally less flavorful and satisfying low tar and nicotine cigarette demanded by the more health conscious consumer.[591]

The declaration of Ian Uydess, an associate senior scientist at Philip Morris from 1977 to 1989, confirms the company's extensive interest in nicotine delivery. According to Uydess, "*Philip Morris wanted to know everything there was to know about nicotine*."[592] Sophisticated equipment, such as liquid and gas chromatographs, mass spectrometers, infra-red spectrometers, and nuclear magnetic resonance instruments, was acquired by Philip Morris to research questions such as:

> (1) How nicotine levels varied in the tobacco plant with regard to cultivar, stalk position, seasonal variations and 'ripeness,' (2) What happened to nicotine after 'curing' and during processing, (3) What chemical 'forms' was it in, and (4) How much of it wound up in the smoke when burned under different conditions (such as . . . in the presence . . . of varying amounts of other tobacco constituents, etc.).[593]

The evidence in the administrative record shows that to achieve the goal of maintaining an acceptable and pharmacologically active nicotine level, Philip Morris developed ways to manipulate the ratio of nicotine to tar delivered by the cigarette. This

[591] *Id.* at 7 (emphasis added). These statements and those by another former Philip Morris employee discussed below corroborate the other evidence before the Agency indicating that the tobacco industry conducted extensive research on nicotine levels.

[592] Declaration of Uydess IL (Feb. 29, 1996), at 14 (emphasis added). *See* AR (Vol. 638 Ref. 1).

[593] *Id.* at 14.

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research was conducted in the 1970's and had as its goal "to determine what combinations of tar and nicotine make for optimal acceptability in a low delivery cigarette."[594]

The nicotine/tar ratio in cigarettes compares the amount of nicotine delivered by a cigarette with the amount of tar delivered by the cigarette. In public statements, officials of the tobacco industry have maintained that, as tar levels have been reduced through techniques such as filtration and ventilation, nicotine levels have been automatically reduced by a corresponding amount. For instance, one industry executive testified before Congress in 1994, "[w]e do not set levels of nicotine for particular brands of cigarettes. Nicotine follows the tar levels. . . . The correlation . . . is essentially perfect correlation between tar and nicotine and shows that there is no manipulation of nicotine."[595] Thus, according to the cigarette manufacturers, a proportional reduction of tar and nicotine demonstrates that the industry has not manipulated nicotine deliveries.

The goal of Philip Morris' research, however, was to determine whether cigarette acceptability could be improved by changing this "essentially perfect correlation" between tar and nicotine, i.e., by allowing tar to fall but maintaining a *disproportionately* high level

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[594] Dunn WL, *et al.* (Philip Morris Inc.), *Plans for 1972* (Sep. 8, 1971), in 141 Cong. Rec. H8128 (daily ed. Aug. 1, 1995). *See* AR (Vol. 711 Ref. 6).

There is evidence that Philip Morris' product research and development on maintaining adequate nicotine deliveries may have begun before the 1970's. A comment submitted to the Agency the handwritten notes of a Philip Morris research executive, Ronald A. Tamol. According to 1965 note from Tamol, an objective of his research at that time was to "*determine minimum nicotine. . . to keep normal smoker 'hooked.'*" Tamol RA (Philip Morris), Handwritten Notes (Feb. 1, 1965) (emphasis added). *See* AR (Vol. 700 Ref. 593). The Agency is not relying on these notes, however, because it has not independently authenticated the notes.

[595] *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*, 103d Cong., 2d Sess. 143, 378 (Mar. 25, 1994) (statement of Alexander Spears). *See* AR (Vol. 707 Ref. 1).

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of nicotine. To this end, Philip Morris researchers in 1970 began to alter cigarette designs to study:

> *the effect of systematic variation of the nicotine/tar ratios upon smoking rate and acceptability measures.* Using the Marlboro as a base cigarette, *we will reduce the tar delivery incrementally by filtration and increase the nicotine delivery incrementally by adding a nicotine salt.* All cigarettes will be smoked for several days by each of a panel of 150 selected volunteers.[596]

The search for the optimal nicotine/tar ratio was a significant research priority at Philip Morris. In 1973, a 5-year research and development plan stated: "This program comprises a number of studies expected to provide insight leading to new cigaret designs. These include *studies of optimum nicotine/tar ratios, [and] nicotine/menthol relationships.*"[597]

That same year, the director of research at Philip Morris, Thomas Osdene, distributed a five-year plan stating that "R&D management will concentrate a large part of the resources at its disposal" on two "major long-range" programs, one of which was directed at achieving:

> *a dramatic reduction in cigaret tar level while maintaining the subjective responses equal to our present major brands . . . . The task requires . . . discovering which constituents contribute positively to the smoker's response . . . and . . . developing means of increasing the relative concentration of desirable constituents.*[598]

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[596] Eichorn PA, Dunn WL (Philip Morris Inc.), *Quarterly Report of Projects 1600 and 2302* (Dec. 31, 1970), in 141 Cong. Rec. H8127-8128 (daily ed. Aug. 1, 1995) (emphasis added). *See* AR (Vol. 711 Ref. 6).

[597] Philip Morris USA, *Research and Development Five Year Plan, 1974-1978* (May 1973), in 141 Cong. Rec. H8130-8131 (daily ed. Aug. 1, 1995) (emphasis added). *See* AR (Vol. 711 Ref. 6).

[598] Osdene TS (Philip Morris Inc.), *Five-Year Plan* (Oct. 29, 1973) attaching Dunn WL, Lowitz DA, Will F, *R&D Strategy Outline*, in 141 Cong. Rec. H8131-8132 (daily ed. Aug. 1, 1995) (emphasis added). *See* AR (Vol. 711 Ref. 6).

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According to the Philip Morris researchers, the natural nicotine/tar ratio in tobacco is about 0.07.[599] By 1974, the researchers found that by boosting this natural ratio to about 0.12 (i.e., by raising the level of nicotine in relation to the level of tar) they could make a low-delivery cigarette that was "comparable to the Marlboro in terms of both subjective acceptability and strength."[600] A follow-up study in 1975 also found "evidence that *the optimum nicotine to tar (N/T) ratio for a [low-delivery] tar cigarette is somewhat higher than that occurring in smoke from the natural state of tobacco.*"[601] Thus, Philip Morris' research showed that for low-tar cigarettes, it was "optimal" to supply a higher proportion of nicotine than would occur naturally. The distribution lists accompanying both the 1974 study and the 1975 follow-up show these studies were distributed to senior officials at Philip Morris, including Helmut Wakeham, the vice president for research and development.

As Philip Morris enhanced its ability to reduce tar levels, it continued to research the optimum nicotine levels to accompany these ever-lower tar levels. It also conducted research on nicotine deliveries in its competitors' low-tar brands. The Philip Morris researchers concluded that the nicotine-to-tar ratios in their competitors' products "go up as tar goes down."[602] They further stated that "the mechanics of cigarette engineering

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[599] Dunn WL, Johnston M, Ryan F, *et al.* (Philip Morris Inc.), *Plans for 1972* (Sep. 8, 1971), in 141 Cong. Rec. H8128 (daily ed. Aug. 1, 1995). *See* AR (Vol. 711 Ref. 6).

[600] Philip Morris Research Center, *Behavioral Research Annual Report (Part II),* distributed by Osdene TS (Nov. 1, 1974), in 141 Cong. Rec. H7659 (daily ed. Jul. 25, 1995). *See* AR (Vol. 14 Ref. 175a).

[601] Jones B, Houck W, Martin P (Philip Morris Inc.), *Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication* (Oct. 1975), in 141 Cong. Rec. H8132 (daily ed. Aug. 1, 1995) (emphasis added). *See* AR (Vol. 711 Ref. 6).

[602] Dunn WL (Philip Morris Inc.), *Plans and Objectives–1979* (Dec. 6, 1978), in 141 Cong. Rec. H7670 (daily ed. Jul. 25, 1995). *See* AR (Vol. 14 Ref. 175a).

and the deliberate decisions of our competitors are such as to suggest that *high* nicotine/tar ratios be used at ultra low tar levels."[603]

This extensive research on deliberately altering nicotine/tar ratios shows that Philip Morris did not, in fact, want to allow nicotine to "follow the tar level" but instead wanted to supply an optimum nicotine level that required independent manipulation of the nicotine delivery of cigarettes. In addition to the research on optimal nicotine/tar ratios, Philip Morris scientists have conducted other product development research relating to the delivery of nicotine. In the 1980's, Philip Morris conducted extensive research to find "nicotine analogues" that could replace nicotine in cigarettes. As described in section II.C.2.a.ii., above, this research was designed to find analogues that would specifically retain nicotine's pharmacological effects on the brain, revealing both Philip Morris' recognition of the pharmacological effects of nicotine and its intent to maintain these pharmacological effects even if compelled to cease the use of nicotine.

Philip Morris also conducted research to determine whether a second component of tobacco smoke, acetaldehyde, acted synergistically with nicotine to produce reinforcing effects on the brain. The culmination of this research was Philip Morris' attempt to establish the "maximally reinforcing" ratio of acetaldehyde to nicotine in cigarette smoke. This research demonstrates again Philip Morris' objective of identifying pharmacologically active doses of nicotine and of enhancing those effects where possible. A 1982 Philip Morris report on research plans and objectives stated:

> Since both acetaldehyde and nicotine are reinforcing agents and each are contained in smoke *it becomes important to determine ratio[s] of acetaldehyde to nicotine which produce maximal*

[603] *Id.* at H7670 (emphasis added).

> *reinforcing effects . . . . This will allow us to determine the optimum ratio of acetaldehyde to nicotine that maintains the most behavior.*[604]

Philip Morris' patents further reflect and corroborate its interest in developing methods of enhancing nicotine deliveries. For example, among other patents related to nicotine, Philip Morris holds patents to permit the "release in controlled amounts and when desired of nicotine"[605] and for "releasing nicotine into tobacco smoke."[606] The purpose of the patented method is to "*[m]aintain[] the nicotine content at a sufficiently high level to provide the desired physiological activity*, taste and odor which this material imparts."[607]

Collectively, the documents in the administrative record show that ensuring an adequate delivery of nicotine has been a dominant consideration in Philip Morris product research and development for nearly 30 years. As Project Table indicates, Philip Morris' research on the optimum way to deliver nicotine to smokers continues to this day. *See* section II.C.2.a.iii., above.

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[604] DeNoble VJ (Philip Morris Inc.), *Project Number 1610 (Behavioral Pharmacology) Objectives and Plans–1982-1983* (Jul. 20, 1982), at 2 (emphasis added). *See* AR (Vol. 54 Ref. 1921).

[605] U.S. Patent No. 3,280,823, Bavley A, Air B, Robb II EW, assigned to Philip Morris Inc., *Additive-Releasing Filter for Releasing Additives into Tobacco Smoke* (Oct. 25, 1966), at C2:39-40. *See* AR (Vol. 26 Ref. 352).

[606] U.S. Patent No. 3,584,630, Inskeep GE, assigned to Philip Morris Inc., *Tobacco Product Having Low Nicotine Content Associated with a Release Agent Having Nicotine Weakly Absorbed Thereon* (Jun. 15, 1971), at C2:5-15. *See* AR (Vol. 27 Ref. 387).

[607] *Id.* at C1:39-41 (emphasis added).

U.S. Patent No. 3,280,823, Bavley A, Air B, Robb II EW, assigned to Philip Morris Inc., *Additive-Releasing Filter for Releasing Additives into Tobacco Smoke* (Oct. 25, 1966), at C1:43-45. *See* AR (Vol. 26 Ref. 352).

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b. RJR's Product Research and Development Efforts

RJR has also conducted product research and development to ensure that its cigarettes deliver levels of nicotine to smokers that provide desired pharmacological effects. A presentation from RJR's researchers to its marketing department in approximately 1977, for example, reveals that RJR understood the importance of maintaining adequate nicotine deliveries as tar deliveries declined and had identified a range of nicotine delivery levels capable of producing pharmacological effects. According to this presentation, nicotine has two roles in cigarettes. First, it contributes to the "mouth taste" or "mouth satisfaction" derived from a cigarette.[608] Second, and even more important, it "acts upon the central nervous system and produces in the average smoker a sensation one could describe as either stimulating or relaxing."[609] Moreover, according to the presentation, "a confirmed smoker attempts to get a certain desired level of nicotine. About one half hour after smoking, after all the nicotine has been biologically or pharmacologically inactivated, the smoker experiences a need for nicotine and lights up another cigarette."[610] For these reasons, the researchers reported that "a zero nicotine cigarette . . . really has no potential to provide smoking satisfaction. It produces no taste in the mouth, but even more seriously *it fails to provide the ultimate satisfaction in the lungs*."[611]

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[608] Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking*, (1976/1977), at 7-9. *See* AR (Vol. 700 Ref. 593).

[609] *Id.* at 3.

[610] *Id.* at 5.

[611] *Id.* at 9 (emphasis added).

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The researchers observed that RJR's competitors "*are fully aware of the advisability of maintaining a low tar value and also maintaining the nicotine as high as possible*."[612] They cited True, which is produced by Lorillard Tobacco Co., as an example of a cigarette in which tar levels had been reduced dramatically while nicotine levels had been left essentially unchanged, stating:

> [T]he old True had 11 mg tar [and] .6 mg nicotine -- the new True is 5 mg tar [and] .5 mg nicotine. So although the tar was reduced 6 mg from 11 mg to 5 mg, *nicotine was dropped only .1 mg. . . .*[613]

The researchers then recommended that RJR develop cigarettes that reduced tar but maintained nicotine at levels sufficient to provide "(1) mouth satisfaction—quality of nicotine" and "(2) ultimate physiological satisfaction—quantity of nicotine."[614] Specifically, RJR recommended that a new brand deliver 5 mg tar and 0.5 to 0.8 mg nicotine, stating that "*on inhalation into the lungs, 0.5 mg to 0.8 mg of nicotine would provide sufficient nicotine to the blood to produce the stimulation and relaxation effects desired by the smoker*."[615] As discussed in section II.C.4.a.ii., below, RJR appears to have implemented these recommendations.

Similar recommendations were made by Claude Teague, Jr., RJR's assistant director for research. As noted in section II.C.2.b.i., above, a 1972 memorandum written by RJR's assistant director for research, Charles Teague, referred to efforts at RJR to

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[612] *Id.* at 10 (emphasis added).

[613] *Id.* (emphasis added).

[614] *Id.* at 11.

[615] *Id.* at 11-12 (emphasis added).

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"reduc[e] the amount of 'tar' in cigarette smoke per unit of nicotine."[616] In its comments, RJR confirms that it has conducted research on cigarettes with enhanced nicotine-to-tar ratios.[617]

In addition to developing low-tar cigarettes that maintain adequate nicotine deliveries, RJR has been particularly active in developing novel tobacco products that deliver nicotine but few other components of tobacco smoke. As noted in section II.C.2.b.i., above, Teague first recommended such a "futuristic" product in 1972, urging that *"[t]here should be some simpler, 'cleaner', more efficient and direct way to provide the desired nicotine dosage than the present system involving combustion of tobacco."*[618]

RJR actually developed and marketed such an alternative tobacco product, called Premier, in the late 1980's. As described in section II.C.2.b.iii., above, RJR conducted comparative studies of the blood levels of nicotine produced by Premier and by conventional cigarettes to ensure that Premier delivered normal doses of nicotine to the user. However, because the tobacco in the product was heated rather than burned, it delivered the vapor recommended by Teague, with virtually no tar and other non-nicotine components of normal tobacco smoke.

Currently, RJR is test-marketing a similar product, "Eclipse." As described in section II.C.2.b.iii., above, Eclipse, like Premier, is intended to rely primarily on heating

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[616] Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 6 (emphasis added). *See* AR (Vol. 531 Ref. 125).

[617] R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 3. *See* AR (Vol. 519 Ref. 103).

[618] Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 7 (emphasis added). *See* AR (Vol. 531 Ref. 125).

rather than burning tobacco and to deliver levels of nicotine similar to a conventional ultra-low-tar cigarette, but much reduced levels of other cigarette smoke constituents.

RJR's extensive efforts to develop and market alternative cigarettes that deliver nicotine and little else show that it regards nicotine as the essential ingredient of tobacco. The efforts also show that RJR regards cigarettes as, in effect, devices for the delivery of nicotine.

Like Philip Morris, RJR also holds various patents on ways to manipulate nicotine deliveries, including patents intended to "provide a cigarette which delivers a larger amount of nicotine in the first few puffs than in the last few puffs"[619] and intended to mask the harsh flavor of cigarettes with increased levels of nicotine.[620] Regardless of whether the patents have been actually used in commercial cigarettes, they are further evidence of RJR's interest in developing ways to control and manipulate nicotine deliveries.

c. Brown & Williamson's Product Research and Development Efforts

Like Philip Morris and RJR, Brown & Williamson and its parent BATCO have conducted research to identify the minimum and optimum doses of nicotine necessary to produce desired pharmacological effects and they have invested considerable resources to develop cigarettes that optimize the delivery of nicotine to smokers. In the case of Brown & Williamson and BATCO, these efforts have spanned over three decades and show a consistent focus on methods to maintain nicotine deliveries at levels sufficient to provide

[619] U.S. Patent No. 4,595,024, Greene TB, Townsend DE, Perfetti TA, assigned to R.J. Reynolds Tobacco Company, *Segmented Cigarette*, (Jun. 17, 1986), at C2:23-26. *See* AR (Vol. 26 Ref. 370).

[620] U.S. Patent No. 4,830,028, Lawson JW, Bullings BR, Perfetti TA, assigned to R.J. Reynolds Tobacco Company, *Salts Provided from Nicotine and Organic Acid as Cigarette Additives* (May 16, 1989), at C1. *See* AR (Vol. 34 Ref. 593).