

RESEARCH PLANNING MEMORANDUM

ON

THE NATURE OF THE TOBACCO BUSINESS AND THE CRUCIAL

ROLE OF NICOTINE THEREIN

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PLAINTIFF'S EXHIBIT

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## **MEMORANDUM:**

In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects. Related alkaloids, and probably other compounds, with desired physiological effects are also present in tobacco and/or its smoke. Nicotine is known to be a habit-forming alkaloid, hence the confirmed user of \_tobacco products is primarily seeking the physiological "satisfaction" derived from nicotine -- and perhaps other active compounds. His choice of product and pattern of usage are primarily determined by his individual nicotine dosage requirements and secondarily by a variety of other considerations Theluding flavor and irritancy of the product, social patterns and needs, physical and manipulative gratifications, convenience, cost, health consider amng the like. Thus a tobacco product is, in essence, a vehicle for delivery micotine, designed to deliver the nicotine in a generally acceptable and ሜቲtractive form. Our Industry is then based upon design, manufacture and sã of attractive dosage forms of nicotine, and our Company's position in our ■Industry is determined by our ability to produce dosage forms of nicotine within Mave more overall value, tangible or intangible, to the consumer than those of our competitors.

The habituated user of tobacco products is said to derive "satisfaction" from nicotine. Although much studied, the physiological actions of nicotine are still poorly understood and appear to be many and varied. For example, in different situations and at different dose levels, nicotine appears to act as a stimulant, depressant, tranquilizer, psychic energizer, appetite reducer, anti-fatigue agent, or energizer, to name but a few of the varied and often

contradictory effects attributed to it. Nany of these same effects may be achieved with other physiologically active materials such as caffeine, alcohol, tranquilizers, sedatives, euphorics, and the like. Therefore, in addition to competing with products of the tobacco industry, our products may, in a sense, compete with a variety of other products with certain types of drug action. All of these products, tobacco and other, appear to have certain common attributes in that they are used largely to relieve, in one way or another, the fatigues and stresses which arise in the course of existence in a complex society.

Happily for the tobacco industry, nicotine is both habituating and writing in its variety of physiological actions, hence no other active materia of combination of materials provides equivalent "satisfaction". Whether too time will, over the long term, maintain its unique position is subject to some reasonable doubt. With increased sophistication of knowledge in the biological and pharmaceutical areas, a superior or at least equivalent product or product mixture may emerge. For this reason, it would be a mistain assume that the tobacco industry, as we now know it, is immortal or that reflect competition from organizations outside of the tobacco industry will were occur. It is safe to assume, however, that nicotine will retain its unique position throughout the present ten year planning period, and probably a much longer span of time.

If nicotine is the <u>sine qua non</u> 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 "tar" delivery or flavor. To do this we need to

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develop new data on such things as the physiological effects of nicotine, the rate of absorption and elimination of nicotine delivered in different doses at different frequencies and by different routes, and ways of enhancing or diminishing nicotine effects and "satisfactions". In the absence of such data, we may survey the market and conclude that current cigarette products delivering about 1.3 mg. of nicotine appear to "satisfy" the typical smoker. This, somewhat crudely, establishes a target dosage level for design of new products. An accompanying Research Planning Proposal describes that approach in some detail. However, if we knew more about nicotine absorption, action, elimination, enhancement and the like, it should, in theory, be possible to more precisely specify, and deliver, the optimum amounts of nicotine activity in sophisticated products which would be more satisfying and desirable to the user. This area merits consideration and activity.

Before proceeding too far in the direction of design of dosage forms for a cotine, it may be well to consider another aspect of our business; that the factors which induce a pre-smoker or non-smoker to become a habituated amoker. Paradoxically, the things which keep a confirmed smoker habituated "satisfied", i.e., nicotine and secondary physical and manipulative gratifications, are unknown and/or largely unexplained to the non-smoker. He does not start smoking to obtain undefined physiological gratifications or reliefs, and certainly he does not start to smoke to satisfy a non-existent, craving for nicotine. Rather, he appears to start to smoke for purely psychological reasons -- to emulate a valued image, to conform, to experiment, to defy, to be daring, to have something to do with his hands, and the like. Only after experiencing smoking for some period of time do the physiological "satisfactions" and habituation become apparent and needed. Indeed, the first

smoking experiences are often unpleasant until a tolerance for nicotine has been developed. This leaves us, then, in the position of attempting to design and promote the same product to two different types of market with two different sets of motivations, needs and expectations. The same situation is encountered in some industries, but the problem is usually not as severe.

If what we have said about the habituated smoker is true, then products fesigned for him should emphasize nicotine, nicotine delivery efficiency. 弱cotine satisfaction, and the like. What we should really make and sell yould be the proper dosage form of nicotine with as many other built-in attractions and gratifications as possible -- that is, an efficient nicotin selivery system with satisfactory flavor, mildness, convenience, cost, etc In the other hand, if we are to attract the non-smoker or pre-smoker, there is nothing in this type of product that he would currently understand or gesire. We have deliberately played down the role of nicotine, hence the mon-smoker has little or no knowledge of what satisfactions it may offer html and no desire to try it. Instead, we somehow must convince him with wholl frational reasons that he should try smoking, in the hope that he will for himself then discover the real "satisfactions" obtainable. And, of course 🖾 n the present advertising climate, our opportunities to talk to the pre-smoker re increasingly limited, and therefore increasingly ineffective. Would 🗺 not be better, in the long run, to identify in our own minds and in the minds of our customers what we are really selling, i.e., nicotine satisfaction? This would enable us to speak directly of the virtues of our product to the confirmed smoker, and would educate the pre-smoker, perhaps indirectly but effectively, in what we have to offer and what it would be expected to do for him.

But again, the picture is not quite all that clear. Critics of tobacco products increasingly allege that smoking is dangerous to the health of the smoker. Part of this alleged danger is claimed to arise from ingestion of nicotine and part is claimed to arise from smoke components or smoke "tar". If, as proposed above, nicotine is the sine qua non of smoking, and if we meekly accept the allegations of our critics and move toward reduction or elimination of nicotine from our products, then we shall eventually liquidate our business. If we intend to remain in business and our business is the manufacture and sale of dosage forms of nicotine, then at some point we wust make a stand. We should know more, rather than less, than our critics about the physiological effects of nicotine, and we should in all ways scientifically validate and speak to the beneficial effects and "satisfactions" gerived from use of nicotine. Essentially all commercial drugs give rise to some undesirable side effects, but we continue to use them with great benefic to humanity because of their overriding beneficial effects. Might we not 🕮 🕯 leaf from that book in our approach to nicotine? Unless we do, our long prospects become unattractive.

Our critics have lumped "tar" and nicotine together in their allegations about health hazards, perhaps because "tar" and nicotine are generated together in varying proportions when tobacco is smoked. An accompanying Research Planning Memorandum suggests an approach to reducing the amount of "tar" is cigarette smoke per unit of nicotine. That is probably the most realistic approach in today's market for conventional cigarette products. However, another more futuristic approach is possible which goes more directly to the fundamentals of the alleged problem.

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In the present real situation, where nothing has been done to counteract the adverse allegations about nicotine and where conventional products delivering adequate amounts of nicotine dominate the marketplace, no abrupt change in our posture or strategy would be appropriate or reasonable. The approaches advocated above are aimed at stopping and eventually reversing a trend that may in the long term put us out of business, and are intended to lay a framework of philosophy around which research efforts may now begin. Hopefully, some day we will rejoice rather than despair when a new crop of tobacco shows an unusually high content of nicotine, our primary product. Hopefully, with time we will be able to develop sophisticated and improved manimum dosage forms for nicotine which will be more satisfying to the user and free of alleged health hazards. And hopefully, by that time, we will see been able to establish and use information showing that use of nicotine wills real, demonstrable human needs, the beneficial effects overriding the allegedly harmful side effects.

## PROICATED RESEARCH DEPARTMENT ACTIVITIES AND APPROACHES:

If the above is a valid line of reasoning, then our long-term future course:

- Recognize the key role of nicotine in consumer satisfaction, and design and promote our products with this in mind.
- 2. Hore precisely define the minimum amount of nicotine required for "satisfaction" in terms of dose levels, dose frequency, dosage form, and the like. This would involve biological and other experiments.
- 3. Sponsor in-depth studies of the physiological, psychological and other effects of nicotine, aimed at demonstrating the beneficial effects of nicotine and at disproving allegations that nicotine produces major adverse effects.

- 4. Study, design and evaluate new or improved systems for delivery of nicotine which will provide the minimum satisfying amount of nicotine in attractive form, free of allegedly harmful combustion products.
- Study means for enhancing nicotine satisfaction via synergists, alteration of pH, or other means, to minimize dose level and maximize desired effects.
- 6. Honitor developments in materials and products which may compete with nicotine products or which might be combined with nicotine products to provide added advantages or satisfactions.
- Monitor work by others which might be aimed at improved nicotine delivery systems of the type proposed here.
- 8. Search for and evaluate other physiologically active components of tobacco or its smoke which may provide desired effects to the smoker.

Claude E. Teague, Jr/

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