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U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

2415 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6118

KAREN NELSON, STAFF DIRECTOR

PUBLIC HEARING

Time and Date:

9:00 a.m. on Thursday, April 14, 1994

Place:

2123 Rayburn House Office Building

Subject:

Oversight hearing on tobacco products

William I. Campbell President and CEO Phillip Morris U.S.A. 120 Park Avenue New York, N.Y. 10017

Development

accompanied by Dr. Kathy Ellis, Director of Research and Harold Burnely, Director of Process

Joseph Taddeo
President
U.S. Tobacco Company
100 West Putnam Avenue
Greenwich. CT 06803

accompanied by: Dr. Robert Lawrence,
Executive Vice-President, Richard H.
Verheij, Senior Vice President and
General Counsel and Timothy M. Finnegan,
outside counsel

James W. Johnston Chairman and CEO RJ Reynolds RJR Tobacco Company 401 N. Main Street Winston Salem, N.C. 27102

accompanied by: Andy Schindler, Head of Manufacturing, Carl Ehman, Head of Research and Development and Richard Cooper, outside Counsel

Andrew H. Tisch Chairman and CEO Lorillard Tobacco Company 1 Park Avenue New York, N.Y. 10016

accompanied by Dr. Alexander W. Spears, Vice-Chairman and Chief Operating Officer

Edward A. Horrigan, Jr. Chairman and CEO Liggett Group Inc. 300 N. Duke Street P.O. Box 1572 Durham, N.C. 27702

accompanied by Gregory A. Sulin, Vice President of Operations

Thomas E. Sandefur, Jr.
Chairman and CEO
Brown and Williamson Tobacco Corp.
1500 Brown and Williamson Tower
Louisville, KY 40202

accompanied by: T.F. Riehl, Vice President for Research and Development and Jay N. Jewell, Vice President for Manufacturing

Donald S. Johnston
President and CEO
American Tobacco Company
Management Center
P.O. Box 10380
Stamford, CT 06904-2380

accompanied by Robert S. Sprinkle, III, Executive Vice-President for Research and Quality Assurance. Statement of William I. Campbell President and Chief Executive Officer of Philip Morris U.S.A.

before the

Subcommittee on Health and the Environment House Energy and Commerce Committee

April 14, 1994

Mr. Chairman and distinguished Members of the Subcommittee. I am here today at your request, and I would like to take this opportunity to set the record straight on charges that have recently been made against the industry and Philip Morris. First, Philip Morris does not add nicotine to our cigarettes. Second, Philip Morris does not "manipulate" or independently "control" the level of nicotine in our products. Third, Philip Morris has not used patented processes to increase or maintain nicotine levels. Fourth, cigarette smoking is not addictive. Fifth, Philip Morris has not hidden research which says that it is. And, finally, consumers are not misled by the published nicotine deliveries as measured by the FTC method.

Mr. Chairman, I trust that you and the other Members of the Subcommittee are sincerely interested in learning the facts about the various issues raised a few weeks ago in Commissioner Kessler's presentation -- issues which, I might add, are not new. The claim that

cigarette smoking is addictive has been made for many years. The fact that tar and nicotine levels vary among our many products has been publicized for over 20 years. The process by which cigarettes are manufactured, and which, at our invitation, FDA representatives saw firsthand several weeks ago, has been publicly known for over 50 years. And the call for the FDA to assert, or be given, jurisdiction over cigarettes has been made and rejected by the FDA and the courts on several occasions in the past.

There were a number of incorrect statements or assumptions in Dr. Kessler's presentation. Many require a detailed rebuttal. To the extent possible in the time available today, I will try to respond to them and to the Subcommittee's questions.

I. PHILIP MORRIS DOES NOT ADD NICOTINE TO OUR CIGARETTES

The claim that Philip Morris secretly adds nicotine during the manufacturing process to "keep smokers addicted" is a false and irresponsible charge. The processes used to manufacture cigarettes have been publicly disclosed for years in patents and the published literature. And the results of that

processing -- cigarettes with varying levels of tar and nicotine reflecting varying customer preferences -- have been closely monitored and reported by the FTC, and the manufacturers themselves in every advertisement, for 25 years.

Contrary to the claim that we are committed to maintaining, or even increasing, nicotine delivery in our products, the fact is that tar <u>and nicotine</u> levels have decreased dramatically over the past 40 years.

Today, the market is populated with a number of "ultra low" brands which deliver less than 5% of the tar <u>and nicotine</u> of popular brands 20 years ago.

Philip Morris and other manufacturers have reduced delivery in a number of ways. The most important is the use of increasingly efficient filters which substantially reduce many smoke components, including both tar and nicotine. Filtration reduces nicotine delivery 35% to 45% in today's brands, as compared to a "standard" cigarette made simply of tobacco and paper.

Through a process called ventilation, nicotine levels are reduced by 10% to 50%. Through the use of expanded tobacco -- a process developed by Philip

Morris, in which tobacco is "puffed" much like puffed rice cereal -- tar and nicotine levels are reduced still further.

There has been a fair amount of recent discussion of the reconstituted tobacco process. Again, that process has been thoroughly described for years in the published literature. In that process, stems and small leaf parts are re-formed into a paper-like sheet. The reconstituted leaf process does not increase nicotine levels in tobacco or cigarettes. To the contrary, 20% to 25% of the nicotine in the tobacco used to make reconstituted leaf is lost and not replaced.

These processes, when combined in the cigarettes
Philip Morris sells today, reduce nicotine delivery
levels by more than 50% in the case of Marlboro, to 96%
in the case of Merit Ultima, as compared to a "standard"
cigarette made of nothing but tobacco and paper.

Ignoring these reductions, some critics have focused on minute amounts of nicotine that are found in tobacco extracts and denatured alcohol -- which together have no measurable effect on nicotine delivery of our cigarettes.

Philip Morris uses denatured alcohol to spray flavors on the tobacco. The alcohol is denatured -- that is, it is made to taste bitter so that no one will drink it -- under a formula required by the BATF and found in the Federal Register.

Again, the small amount of nicotine found in denatured alcohol and tobacco extracts cannot be measured in cigarette smoke.

The expenditure of millions of dollars to reduce tar and nicotine in these various ways undercuts any suggestion that Philip Morris is "intent" on adding nicotine to its cigarettes in an effort to "maintain" nicotine levels or to "addict" smokers.

II. PHILIP MORRIS DOES NOT "MANIPULATE" OR INDEPENDENTLY "CONTROL" THE LEVEL OF NICOTINE IN OUR PRODUCTS

The cigarette industry markets and advertises products by tar category to satisfy a variety of consumer preferences. Within tar categories, we attempt to provide a competitive advantage by providing the best possible taste.

When creating a cigarette for a tar category, we select a particular tobacco blend and flavors to provide "uniqueness" for the product. The most significant parameters for determining tar delivery are the amount of expanded tobacco used, filtration efficiency, and ventilation.

So, how do we "manipulate" or independently "control" nicotine as our critics charge? The answer is we don't. We accept the nicotine levels that result from this process.

As representatives of the FDA learned when, at our invitation, they recently visited our manufacturing center in Richmond, nicotine levels in tobacco are measured at only two points in the manufacturing process -- at the stemmery, where tobacco leaves are prepared for processing, and then 18 months later after those leaves have been manufactured into finished cigarettes. Although Philip Morris maintains over 400 quality control checkpoints in the manufacturing process -- for example, moisture levels, weight, etc. -- none measures, reports or analyzes nicotine levels in tobacco.

III. PHILIP MORRIS HAS NOT USED PATENTED PROCESSES TO INCREASE OR MAINTAIN NICOTINE LEVELS

Commissioner Kessler spent a great deal of his recent testimony attempting to support the proposition that Philip Morris may be using secret patented processes to increase or maintain nicotine delivery in our cigarettes. We are not.

The processes described in the patents referred to by Commissioner Kessler are not at all secret but, rather, were publicly disclosed years ago, first to the U.S. government and then to the world.

Philip Morris in fact has never used any of the processes described in these patents to increase, or even maintain, nicotine levels in any of its products.

To the contrary, the only patents cited by Commissioner Kessler which Philip Morris has ever used were for the reduction and in some cases the virtual elimination of nicotine.

IV. CIGARETTE SMOKING IS NOT ADDICTIVE

During the March 25 hearing, Dr. Kessler and some Members of the Subcommittee contended that nicotine is

an addictive drug and that, therefore, smokers are drug addicts. I object to the premise and to the conclusion.

Many people like to smoke. Some people like the look and feel of the pack or the smell of tobacco. Some like to hold and fiddle with a cigarette. And, of course, there is the taste and aroma of the tobacco, and the sight of the smoke.

Cigarettes contain nicotine because it occurs naturally in tobacco. Nicotine contributes to the taste of cigarettes and the pleasure of smoking. The presence of nicotine, however, does not make cigarettes a drug or smoking an addiction.

People can and do quit smoking. According to the 1988 Surgeon General's Report, there are over 40 million former smokers in the United States, and 90% of smokers quit on their own, without any outside help.

Further, smoking is not intoxicating. No one gets drunk from cigarettes, and no one has said that smokers cannot function normally. Smoking does not impair judgment. No one is likely to be arrested for driving under the influence of cigarettes.

In short, our customers enjoy smoking for many reasons. Smokers are not drug addicts.

V. PHILIP MORRIS RESEARCH DOES NOT ESTABLISH THAT SMOKING IS ADDICTIVE

At the March 25 hearing, Commissioner Kessler repeated the charges of Dr. Jack Henningfield, that in 1983, a company, later publicly identified as Philip Morris, suppressed research by one of its scientists which allegedly concluded that nicotine was an addictive substance. That claim is false.

In fact, that scientist published two full papers and five abstracts concerning the work in question <u>prior</u> to the creation of the manuscript in question. That manuscript, which was subsequently provided to the Subcommittee by Commissioner Kessler, did present some evidence that nicotine will be self-administered by rats and is, therefore, a "weak" reinforcing agent. But the manuscript itself states:

"that termination of prolonged access to nicotine under conditions in which it functions as a positive reinforcer does not result in physiological dependence." The manuscript thus did not conclude that nicotine is "addictive."

Moreover, by the time the Philip Morris researcher was ready to publish this information (1983), the "positive reinforcing" nature of nicotine had already been reported in other <u>published</u> literature.

Indeed, the 1988 Surgeon General's Report states that such nicotine reinforcement was "shown conclusively" as early as <u>1981</u>, based on <u>government</u>-supported research.

VI. CONSUMERS ARE NOT MISLED BY THE PUBLISHED NICOTINE DELIVERIES AS MEASURED BY THE FTC METHOD

Contrary to the impression given by Commissioner Kessler that the FTC has somehow adopted a test procedure that misleads the public as to the true levels of tar and nicotine they are inhaling, the routine Analytical Smoking Methods derived from the FTC method are nearly identical to those used throughout the world to measure tar and nicotine deliveries and accurately compare brand deliveries.

All of the tests are conducted on cigarettes obtained from the marketplace. They are, therefore, the

same cigarettes smoked by the consumer after all cigarette manufacturing processes have been completed.

As a result of this testing, the nicotine delivery of all commercial cigarettes is measured and disclosed to the tenth of a milligram, both in public releases by the FTC and, perhaps more importantly, in every cigarette advertisement.

Commissioner Kessler suggested that the FTC figures were misleading because smokers might "compensate" for lower tar and lower nicotine brands by smoking those cigarettes differently. In fact, the data indicates that, despite the dramatic reductions in tar and nicotine levels over the past decades, the number of cigarettes smoked by an individual has remained constant, and even declined slightly. More importantly, the data shows no difference in the number of cigarettes smoked by those who favor higher and lower yield brands.

Mr. Chairman, we at Philip Morris appreciate having the opportunity to respond to some of the claims made against us. We will be pleased to answer any questions you may have about these matters and to provide a more detailed written submission should that be appropriate.

Statement of R. J. Reynolds Tobacco Company

Before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health and the Environment

Concerning Whether the Food and Drug Administration Has Jurisdiction to Regulate And Therefore Ban Cigarettes

April 14, 1994

- R.J. Reynolds Tobacco Company ("Reynolds Tobacco") welcomes this opportunity to respond to the inaccurate and misleading attacks that have precipitated these hearings. For the past several weeks, Reynolds Tobacco and the rest of the tobacco industry have been bombarded with spurious and inflammatory claims. Our responses to these charges are simple and straightforward:
 - Does Reynolds Tobacco add nicotine to its products? No.
 - Does Reynolds Tobacco manipulate nicotine yields to create, maintain, or satisfy "addiction"? Again, the answer is no.
 - Does Reynolds Tobacco hold patents for technology that relates to modification of nicotine yields independent of "tar" yields? Yes. In fact, for years some governments, smoking and health critics, and international public health scientists have encouraged such developments in cigarette design.
 - Is Reynolds Tobacco using such technology commercially? No.
 - Is cigarette smoking an "addiction"? No, cigarette smoking is not an "addiction" under any meaningful definition of the term, including the new definition presented by Dr. Kessler before this Subcommittee.

There is no factual or policy basis to regulate or ban cigarettes as drugs simply because they contain nicotine or simply because cigarette manufacturers have the ability to reduce the nicotine yields of their products. This company is not engaged in some sinister plot to deceive the American smoker.

Progress or Prohibition

If this Subcommittee fairly and objectively evaluates the true facts about cigarette design, it must find that the efforts of Reynolds Tobacco and others in the industry demonstrate a remarkable record of achievement and progress. This company is justifiably proud of those accomplishments and of the dedicated and talented employees who have

contributed and now contribute to them. We regret that others seek to advance an agenda of prohibition over progress.

Today, we are here to discuss whether there is a basis for FDA regulation of cigarettes as drugs. Contrary to many reports, this issue is not novel. In fact, the question has been advanced and rejected many times before. For example, twenty-two years ago, the Commissioner of the Food and Drug Administration (FDA), Dr. Charles C. Edwards, testified at a hearing similar to this one before the Consumer Subcommittee of the Senate Committee on Commerce. Dr. Edwards stated, "Cigarettes and other tobacco products would be drugs subject to the Federal Food, Drug and Cosmetic Act if medical claims are made for the product However, cigarettes recommended for smoking pleasure are beyond the Federal Food, Drug, and Cosmetic Act." Dr. Edwards was echoing a conclusion that has been consistently reached -- both by FDA and the courts prior to and after his statement.²

Three weeks ago, FDA Commissioner Dr. David Kessler appeared before this Subcommittee and testified extensively concerning the "task facing the FDA," which he characterized as "to determine whether nicotine-containing cigarettes are 'drugs' within the

To Amend the Federal Cigarette Labeling and Advertising Act to Require The Federal Trade Commission to Establish Acceptable Levels of Tar and Nicotine Content of Cigarettes. 1972: Hearings on S.1454 Before the Consumer Subcomm. of the Senate Comm. on Commerce, 92nd Cong., 2d Sess. 239 (1972) (statement of Charles C. Edwards, Comm., FDA).

See, e.g., FTC v. Liggett and Myers Tobacco Co., 108 F.Supp. 573 (S.D.N.Y. 1952), aff'd on op. below, 203 F.2d 955 (2d Cir. 1953); Letter from Donald Kennedy, Commissioner of Food and Drugs, to John F. Banzhaf, III, Dkt. No. 77P-0185 (December 5, 1977); Action on Smoking & Health v. Harris, 655 F.2d 236 (D.C. Cir. 1980).

meaning of the Federal Food, Drug, and Cosmetic Act." All cigarettes sold are "nicotine-containing cigarettes," and indeed the tobacco plant is known as <u>nicotiana tabacum</u> in recognition of the fact that it naturally contains nicotine. Moreover, the facts relevant to whether FDA has jurisdiction over cigarettes today are substantially the same as when Dr. Edwards testified in 1972 and when the FDA rejected petitions to regulate cigarettes in 1977 and on other occasions. At those times, as is the case today, a variety of cigarette brands was available to consumers which yielded a variety of "tar" and nicotine levels. Through advances in cigarette design and in response to consumer preferences, however, the average cigarette sold today yields one-third less "tar" and nicotine than when Dr. Edwards testified.

Cigarette Design

How and why have these reductions in "tar" and nicotine yields come about? To evaluate these questions completely, it is imperative to consider the evolution in the design of cigarettes over the last forty years -- an evolution that, in its purpose and effect, differs significantly from the grossly inaccurate allegations and misrepresentations by our critics in these proceedings and recently in the press. In short, Reynolds Tobacco designs cigarettes to respond to consumer demand and to attempt to address the many scientific and other criticisms that have been leveled at our products for more than forty years. Today's cigarettes reflect the enormous efforts to respond directly to consumer demand and those criticisms and suggestions. A very brief discussion of the history of cigarette design will illustrate why these recent claims are misguided.

Early cigarettes were primarily cut tobacco (much like pipe tobacco) wrapped in paper, with flavorings such as the oil of citrus peels. The quality of a cigarette depended

primarily on the single type of tobacco it contained -- Turkish tobacco was used in premium cigarettes and domestic air-cured or flue-cured tobacco was used in less expensive cigarettes. The first American blend cigarette, which combined both Turkish and domestic tobacco, was Reynolds Tobacco's Camel brand, introduced in 1913. Although slightly different blends and different materials were used in cigarette manufacturing, cigarettes remained largely unchanged until the early 1950s.

At that time, most cigarettes produced in the United States were made from fluecured, burley and Turkish tobaccos. They were 70 mm long and unfiltered. When smoked, these cigarettes yielded an average of 40 mg of "tar" and 2.8 mg of nicotine by methods comparable to those used by the United States Federal Trade Commission (FTC). (The FTC methods became official in 1969).

A number of watershed developments in the early 1950s led to another evolution in cigarette design. Several epidemiologic studies published during the early 1950s reported that there was a statistical association between cigarette smoking and lung cancer. Also, in 1953, Dr. Ernst Wynder and others published the results of a mouse skin painting experiment in which the researchers observed skin tumors on the backs of mice exposed to cigarette smoke condensate. All these studies were widely publicized in the general media and the media coverage affected consumer demand. Reynolds Tobacco in turn has made extensive efforts to respond to these scientific theories and demands and the tastes of its consumers to produce a broad array of products.

Since the 1950s, Reynolds Tobacco, among many other lines of research, has pursued two basic lines of research and development in this area: (i) identification of individual

constituents in tobacco smoke and development of technology to attempt to reduce or remove those of potential concern, and (ii) development of new technologies to reduce yields of "tar" and nicotine generally. The first line of research has had limited success; the second line of research has been remarkably successful.

Selective Reduction

During the 1950s and early 1960s, many researchers focused on one chemical constituent of smoke (or a family of constituents) in the search for a "cancer-causing" agent that would explain the epidemiologic and skin painting results. This focus turned to disappointment, as reflected in the 1964 Report of the Advisory Committee to the Surgeon General ("Surgeon General's Report"). From the mid-1950s until today, a succession of constituents has been targeted by the biomedical community. Even today, however, the biomedical community has been unable to agree on which, if any, of those constituents is responsible for the reported association between cigarette smoking and lung cancer.

Cigarette manufacturers and others explored and published numerous methods to reduce or eliminate individual constituents (or a family of constituents) in cigarette smoke, e.g., reducing the temperature at which the cigarettes burned, breeding tobacco plants to change the chemical composition of the tobacco, and adding different types of filters or other filtration mechanisms to the cigarette. Unfortunately, manufacturers faced a moving target as the focus changed from constituent to constituent. Constituents of concern at one point in time were later determined by the scientific community to be of no significance. Moreover, techniques that might have selectively reduced a constituent in the laboratory

commonly increased another constituent. In general, efforts to reduce individual constituents have not been successful.

General Reduction

During the same period, Reynolds Tobacco and other cigarette manufacturers also directed their research to attempt to reduce levels of all constituents. This approach, also advocated by researchers such as Dr. Ernst Wynder, offered advantages over selective reduction because it led to the reduction of total smoke yields and the levels of individual compounds more or less proportionately.

To understand the concept of general reduction, it is essential to understand what smoke is. Smoke is a complex mixture -- it consists of a particulate or "tar" phase as well as a vapor or gas phase. Since the mid-1950s, cigarette manufacturers have devoted extensive resources to achieve a general reduction in "tar" and the vapor phase components of cigarette smoke. Techniques incorporated in cigarettes over the last 40 years which reduce "tar" include:

- Filtration
- Reconstituted tobacco
- Paper porosity
- Reduced tobacco
- Expanded tobacco
- Filter ventilation

Design changes such as the development of more porous cigarette paper, improved filtration, and the use of expanded (or "puffed") tobacco and reconstituted tobacco made

general reduction possible. By utilizing one or more of these techniques, cigarette manufacturers can offer smokers a variety of cigarettes with a range of "tar" and nicotine levels. Cigarette designers have been so successful in their efforts to respond to the demand for these reductions that today there are commercially available cigarettes that yield "tar" and nicotine at levels so low they cannot be measured reliably by the FTC's standard procedure.³ In 1979, the Surgeon General listed more than 25 different design techniques that reduce yields of "tar" and nicotine.⁴ Each of these techniques has been well-publicized and known to the government, public health, scientific and even lay communities. A brief analysis of these design achievements demonstrates the effectiveness of general reduction methods to achieve lower yields of "tar" and other smoke constituents.

The earliest developments included the cellulose acetate filter, use of porous paper, and use of reconstituted tobacco. Each of these developments was in place by 1965, and "tar" and nicotine yields had been reduced dramatically. After 1965, the principal design

³ See, e.g., Federal Trade Commission, "Tar," Nicotine and Carbon Monoxide in the Smoke of 207 Varieties of Domestic Cigarettes 2-3 (1985).

Public Health Service, U.S. Department of Health, Education, and Welfare, Smoking and Health: A Report of the Surgeon General 14:110 (1979) ("1979 Surgeon General's Report"). The techniques identified in the 1979 Surgeon General's Report were genetics and breeding of tobacco plants, planting density, nitrate fertilization, applying agricultural chemicals, topping the tobacco plant at different stages, altering the type of tobacco, altering the position of the stalk, changing the nitrate content, selecting tobacco with specific constituents (e.g., proteins, carbohydrates, resins), curing, homogenized leaf curing, grading, fermentation, solvent extraction, tobacco expansion (freeze-drying), additives, blending, changing the amount of tobacco, changing the amount of tobacco stems, utilizing varying amounts of reconstituted tobacco, using expanded tobacco, varying the tobacco cut, using porous cigarette paper, perforating the cigarette paper, smoke filtration, and perforating the filter tips. Id. at 14:108-14.

breakthroughs were expanded tobacco and air dilution through perforation of cigarette filters. Expanded tobacco resulted from the search for ways to reduce the volume of tobacco in each cigarette in order to reduce "tar" and nicotine yields. The tobacco is "puffed" or expanded in order to allow the same amount of tobacco to occupy more space, much like popping popcorn. As a result, each cigarette is filled with less tobacco, there is less tobacco available to be burned, and the yields of "tar" and nicotine are therefore reduced. Reynolds Tobacco developed expanded tobacco and was the first to introduce it commercially, in 1968. In fact, Reynolds Tobacco licensed this process to others in the industry for commercial use throughout the world.

In the late 1960s, scientists discovered that perforating the cigarette filter allows air to mix with the mainstream smoke, thereby diluting the smoke and reducing the total yields of "tar," and nicotine. Air dilution also reduces the burning temperature of tobacco and causes less tobacco to be burned per puff, thereby further reducing the "tar" and nicotine yields. Perforated filters were first sold commercially in about 1972. By 1981, approximately 50% of all cigarette brands sold had perforated filters.

By 1981, the tobacco content by weight of the average cigarette had declined by 23.8% through the use of expanded tobacco.⁶ In some ultra low-"tar" brands, expanded

Public Health Service, U.S. Department of Health and Human Services, The Health Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Consequences of Smoking: The Changing Cigarette. A Report of the Surgeon Cigarette Consequences of Consequence

Thus, as part of the design techniques to achieve lower yields of "tar" and other smoke constituents, the amount of tobacco in cigarettes has been reduced, with the corresponding result that the smoke nicotine has also been reduced dramatically.

The cigarette design efforts discussed above have been reviewed and commended by government and other scientists. For example, from 1966 through 1978, the National Cancer Institute supported a program to develop a "less hazardous cigarette". This effort involved government, tobacco industry, public health groups, and universities. Reynolds Tobacco and other cigarette manufacturers participated in this program. The NCI program evaluated over 100 different cigarette designs -- many of which had already been incorporated in commercial cigarettes by the major manufacturers. The results of this program indicated that the general reduction approach as described above was the best approach to respond to the scientific criticisms of cigarettes. Importantly, virtually every design variable that was evaluated by the NCI group had been developed by the United States tobacco industry and utilized in a commercial brand.

In 1979, scientists involved in the field of smoking and health came together at the Banbury conference. This conference reviewed virtually all work that had been done to modify cigarettes during the previous twenty-five years in response to the smoking and health controversy. All of the papers presented at the Banbury conference were published,

This point is especially significant because it addresses Dr. Kessler's "surprise" at finding that, for some brands in the ultra low-"tar" category, the percent nicotine in the tobacco itself might be the same or slightly higher than the percent nicotine in the tobacco used in higher-yield cigarettes. Reducing the amount of tobacco has a major influence on the nicotine yield to the smoker.

together with all the debate and discussions. The consensus among scientists participating in that program was that overall "tar" and nicotine reduction was the most effective and most appropriate approach. Several scientists, including Dr. Dietrich Hoffmann, acknowledged the responsiveness of the tobacco industry:

I do think the tobacco industry, voluntary or not, adjusts very well to the demands of the logical reasoning of the scientific community and that we should continue on this path.⁸

In Dr. Kessler's March 25, 1994 statement, he asked the cigarette companies to address the intent of cigarette design developments. The clear intent behind cigarette design developments has been and remains to manufacture and market a broad range of cigarette products in response to the demands and tastes of today's adult smokers and to ensure cigarette to cigarette and pack to pack consistency within a brand. Within the universe of cigarette products, there is a range of "tar" and nicotine levels. As noted earlier, reducing "tar" yields automatically results in roughly proportional reductions in nicotine yields. That is seen by the dramatic reduction in both "tar" and nicotine achieved by Reynolds Tobacco and other cigarette manufacturers since 1955.

In 1957, Dr. Ernst Wynder and others called for efforts to reduce "tar":

[F]or practical purposes, a filter-tip capable of filtering out 40 percent of the tar would be a step in the right direction....
"Such a filter-tip... placed on a regular-size cigarette which normally yields 30 milligrams of tar in its smoke, would reduce the smoker's tar exposure to about 18 milligrams. A reduction to that level, as shown both by animal experiments and human

Dietrich Hoffmann, Discussion in "Risk Reduction Achievements", Banbury Report
 3 - A Safe Cigarette?, pp. 155-178 at 174 (1980).

statistical studies would be a significant reduction in cancer risk."9

The tobacco industry has accomplished this objective -- and has gone much further. The vast majority of today's cigarettes are 85-100 mm long, have filters and yield an average of 11.5 mg of "tar" and 0.8 mg of nicotine. Some cigarettes now available yield less than 1.0 mg of "tar" as measured by the FTC method.

These "tar" and nicotine reductions have largely been achieved through innovations in cigarette design -- innovations pioneered by Reynolds Tobacco and other members of the tobacco industry. Since the complexity of smoke provides a cigarette with its taste and other sensory properties, many of these reductions in "tar" and nicotine have come at the expense of flavor. Some smokers are unwilling to sacrifice flavor for reduced "tar." This has prompted a continuing effort to develop new cigarette designs.

It is ironic that in the face of the overwhelming recommendations of just such an approach, certain public and private critics of cigarettes have decided once again to attack the industry -- and to seek to stop, if not to reverse, the extensive design innovations that other public and private critics have encouraged over the years.

"Tar"/Nicotine Ratios

Reynolds Tobacco does not manipulate the nicotine in its products to create, maintain, or satisfy "addiction". Claims to that effect are false. As "tar" yields have been reduced over the years, nicotine yields have also been reduced, roughly in proportion to the "tar." The fact that "tar" to nicotine ratios are not exactly the same for all cigarettes is not

Mattox, L. and Monahan, S., "Wanted -- And Available -- Filter-Tips That Really Filter", Readers Digest, pp. 43-49, 44 (August 1957) (quoting Dr. E.L. Wynder).

news to anyone familiar with tobacco products or to anyone who has reviewed the extensive "tar" and nicotine reports published by the FTC.

Reynolds Tobacco's cigarettes contain approximately one and one-half to two and one-half percent nicotine, depending upon the tobacco blend. When burned, these cigarettes yield varying amounts of "tar" and nicotine. "Tar" to nicotine ratios, while not constant, are very closely linked because both are found in the particulate phase of smoke. As "tar" yield is reduced, through filtration, paper porosity, expansion, and other design parameters, nicotine yield is also reduced. Filters, however, are slightly more efficient at reducing "tar" yield than nicotine yield. This is due to the fact that cellulose acetate, the primary filter material used by Reynolds Tobacco and others, was developed to reduce "tar" yield. The ability of these filters to reduce the gas phase constituents is somewhat limited. Since a small amount of nicotine (unlike "tar") is found in the gas phase of cigarette smoke, as well as in the particulate phase, slightly more "tar" is filtered out of the smoke, proportionately, than nicotine. Thus, as yields are reduced, the ratio of "tar" yield to nicotine yield is reduced slightly.

In response to the fact that "tar" and nicotine yields are so closely and naturally linked in cigarette smoke, many public health officials and others have suggested that the tobacco companies should attempt to develop cigarettes which break that link. In other words, we have been encouraged to develop cigarettes with reduced "tar" while maintaining nicotine yields. Notable among officials who have encouraged such development is the Independent Committee on Smoking and Health of the United Kingdom, which recommended in 1983 that "... there should be available to the public some brands with

low levels of tar and a proportionately higher nicotine yield."¹⁰ According to one recent publication cited by Dr. Kessler in his testimony:

One proposal has been to develop tobacco that is high in nicotine but low in tar. This is not easy to do naturally; nicotine and tar are highly correlated in the tobacco leaf. One method would be to add nicotine to a low tar, low nicotine cigarette.¹¹

The fact is many scientists, government and/or public health officials have suggested reducing "tar" to nicotine ratios as a way toward potential progress in cigarette design.¹²

Much as the industry responded to calls to reduce "tar" and nicotine yields in the 1950s and 1960s, Reynolds Tobacco has devoted research to responding to these calls to reduce the "tar" to nicotine ratios. Out of the hundreds of patents issued to Reynolds Tobacco personnel over the years, Dr. Kessler referred to nine Reynolds Tobacco patents during his recent testimony to this Subcommittee. These patents reflect work that Reynolds has done in this area. As Dr. Kessler recognized, however, patents do not necessarily reflect what is being used in practice. While Reynolds Tobacco has been able to develop a cigarette which disassociates "tar" and nicotine in the laboratory, it has not been able to achieve an acceptable commercial product. As stated above, this is not easy to do because

¹⁰ Third Report of the Independent Scientific Committee on Smoking and Health of the United Kingdom (1983).

Schelling, T.C., "Addictive Drugs: The Cigarette Experience." <u>Science Vol. 255:430-433 (1992)</u>.

See, e.g., "UICC Tobacco Control Fact Sheet 3," Tobacco and Cancer Programme, International Union Against Cancer (March 1993); Editorial, "Monsieur Nicot's Legacy," <u>Lancet II</u> (8249): 763 (1981); Russell, M.A.H., "Smoking and Society (There Is No Question)", <u>Rehabilitation</u>, 32 (1-4): 41-42 (1979).

"tar" and nicotine are so highly correlated. If we could develop such a cigarette acceptable to the consumer, it would apparently be welcomed and encouraged by European governments and public health officials, rather than being characterized as some sinister plot by tobacco companies, as Dr. Kessler appears to characterize it. In fact, none of the nine Reynolds Tobacco patents cited by Dr. Kessler has been used commercially.

Published FTC "Tar" and Nicotine Yields

The amount of nicotine present in a cigarette is in large part a result of the choice of tobaccos used in the cigarette blend, which are chosen because of their taste and other properties. It is not present as a result of a decision to "manipulate" nicotine levels to some carefully controlled "addictive level." The concept of an "addictive level", raised but not defined by Dr. Kessler, is not a concept known to or understood by Reynolds Tobacco. Neither that concept nor any similar concept is used by Reynolds Tobacco in the design of its cigarettes. We do not know what the concept means, and we are unaware of any data

In 1988, Reynolds Tobacco introduced Premier, a cigarette that heated rather than burned tobacco. That cigarette addressed many of the scientific criticisms that had been made against cigarettes for many years. It virtually eliminated "tar"; it vastly reduced environmental tobacco smoke; and it reduced cigarette ignition propensity. Despite these attributes, certain U.S. government officials, public health officials and, of course, anti-smoking activists launched a vigorous attack on the cigarette — in terms that sound strikingly similar to the anti-smoking rhetoric surrounding this current debate. European health officials, on the other hand, and some United States scientists recognized the attributes of Premier and, indeed, encouraged the development of similar cigarette technologies. See, e.g., "Smoking Pleasure Without the Danger of Fire and Risks To Health," Die Neu Aerztliche (December 19, 1988); Hoffmann, D., et al., "Cancer of the Upper Aerodigestive Tract: Environmental Factors and Prevention," Journal of Smoking-Related Diseases 3(2): 109-129 (1992).

A variety of agricultural factors and practices influence these properties, including, for example, tobacco type, stalk position of the leaf, curing practices, and crop year.

that give it meaning. Further, what is relevant is not what is present in the cigarette, but what is present in the smoke.

Dr. Kessler has made much of the fact that the FTC numbers do not necessarily reflect the precise "tar" and nicotine yields for every smoker. This is certainly true, just as EPA mileage estimates do not reflect the precise fuel economy that will be achieved by every automobile driver. The important point is that in spite of broad variations in how individual smokers may smoke any given cigarette, the fact remains that the lower the yield by FTC numbers, the lower the yield will be to any given smoker. The yield for any given smoker will probably be different from the FTC yield; for some smokers it will be higher, for some it will be lower, but overall, the FTC yields are generally predictive of the yield to smokers as a group. The statement, however, that "in reality" low yield cigarettes do not yield low "tar" and nicotine, is not true. In work published by members of the Swiss Federal Institute of Technology, lower yield cigarettes were associated with reduced smoke absorption.¹⁵

Another indication of Dr. Kessler's misunderstanding of cigarettes relates to his statements concerning low "tar" cigarettes. He stated that from 1967 to 1978 eighteen brands of filter cigarettes underwent increases in overwrap width, resulting in less tobacco being smoked by machine smoking in accordance with the FTC method. Since the FTC method specifies that the cigarette is smoked to within 3 millimeters of the tipping overwrap, and Dr. Kessler stated that the tobacco within the overwrap was still smokeable

¹⁵ Hofer, et al., "Nicotine Yield as Determinant of Smoke Exposure Indicators and Puffing Behavior." Pharmacology Biochemistry and Behavior, Vol. 40, 139-149 (1991).

(and would be smoked by the consumer), he concluded that these brands deviously "cheat" the FTC method. That is not true. First, Reynolds Tobacco uses standard tipping overwrap and has not increased the width because that would reduce puff count and the value to our consumers. But, more importantly, the tipping overwrap simply is not smokeable. No smoker would consciously smoke the overwrap more than once. The tipping paper, because it is not intended to be smoked, imparts a significant off-taste to the cigarette smoke.

Finally, in his testimony before this Subcommittee, Dr. Kessler used several charts (which have since been widely publicized) to support his contention that the nicotine/tar ratio for the lowest "tar" cigarettes has increased since 1982 on a sales weighted basis. This allegation surprised Reynolds Tobacco as much as it surprised Dr. Kessler. Company scientists immediately tried to duplicate Dr. Kessler's charts, using the identical FTC data and the only publicly-available brand sales data of which this company is aware. Despite applying the same data allegedly employed by Dr. Kessler's staff, our scientists cannot duplicate these findings. In fact, our results show exactly the opposite -- nicotine yields and nicotine/"tar" ratios in the lowest "tar" category decreased slightly between 1982 and 1991 -- the time period covered by Dr. Kessler's charts. We have, in fact, asked FDA staff members to provide its data and complete methodology. We would welcome the opportunity to review the data and methodology used by FDA staff to prepare these charts, so that we would have a full opportunity to understand and review the procedures used and evaluate the conclusions reached.

The "Addiction" Hypothesis

A major premise of the charges against the cigarette industry today is the claim that cigarettes are "addictive". Dr. Kessler and our other critics rely on selective and incomplete evidence to support this claim. They ignore significant and meaningful differences between cigarettes and truly "addictive" drugs. When long-established criteria for labeling a substance or activity as "addictive" do not permit our critics to fit cigarette smoking nicely within the existing criteria, these critics resort to a simple tactic to further their agenda—they attempt to lower the standards and change the definition of "addiction" and its alleged components.

In 1964, the Advisory Committee to the Surgeon General recognized that cigarette smoking did not meet well-established criteria for "addiction." In 1988, the Surgeon General altered the definition to fit the existing data on smoking. In essence, the Surgeon

The Report concluded that tobacco smoking was properly classified as a habituation. 1964 Surgeon General's Report, 351, 354.

The 1964 Advisory Committee Report to the Surgeon General defined "addiction" as follows:

[&]quot;a state of periodic or chronic intoxication produced by the repeated consumption of drug (natural or synthetic) whose characteristics include:

[&]quot;(1) An overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means;

[&]quot;(2) A tendency to increase the dose;

[&]quot;(3) A psychic (psychological) and generally a physical dependence on the effects of the drug;

[&]quot;(4) Detrimental effect on the individual and on society"

General moved the goalposts after he located the ball on the field. We categorically reject the claim that cigarettes are "addictive", and we know that an objective review of the facts and science supports our position.

Dr. Kessler defined "addiction" in terms of four elements:

- compulsive use
- psychoactive effect
- reinforcing behavior
- withdrawal symptoms

When each of these elements is carefully analyzed in an unbiased manner, it becomes clear that cigarette smoking is no more "addictive" than coffee, tea or Twinkies.¹⁷ Further, in spite of the efforts to expand the definition, it still does not properly encompass cigarette smoking.

1. <u>Compulsive use</u>. This concept of compulsive use, like the definition of "addiction" itself, has undergone a redefinition in an attempt to encompass cigarette smoking. The classic definition of "addiction", as used in the 1964 Surgeon General's Report, properly defines compulsive use seen with hard drug addiction as "an overpowering desire or need (compulsion) to continue taking the drug and obtain it by any means." This is precisely what is seen with truly "addicting" substances like cocaine and heroin. The

Using similarly vague definitions, researchers claim to have discovered addiction to love, jogging, television, credit cards and even eating carrots. See, e.g., Peele, S., Love and Addiction, 1976; Hailey and Bailey, "Negative Addiction in Runners," (1979); Winn, M., The Plug In Drug (1977); Parade Magazine, April 5, 1987, p. 28; Wright, M.R., "Surgical Addiction: A Complication of Modern Surgery?" Archives of Otolaryngology: Head and Neck Surgery, 112: 870-872 (1986); Cerny and Cerny, "Can Carrots Be Addictive? An Extraordinary Form of Drug Dependence," Br. J. Add. 87:1195 (1992).

desire is overpowering and leads to criminality and violence, if necessary, to satisfy the need for the drug.

In the 1988 Surgeon General's Report, the term "compulsive use" was expanded to include behaviors driven by "strong urges". ¹⁸ There is a world of difference between the irresistible need of the hard drug addict and a "strong urge" to engage in a pleasurable behavior or activity. People have strong urges to eat sweets, drink coffee and watch their favorite soap operas. It is misleading to label these types of "urges" as compulsions. Smokers are frequently in situations where they resist the urge to smoke. They are not in the throes of an overpowering desire to use and obtain cigarettes by any means. They do not remotely resemble cocaine addicts whose very real compulsion to take this highly intoxicating drug totally disrupts their lives, their families and their occupations.

Smokers are now constantly characterized as addicted and thus unable to quit. Common sense belies that conclusion. Since 1974, more than 40 million people have stopped smoking permanently without any outside intervention or assistance. As one exsmoker has candidly acknowledged: "To quit, you have to decide you want to quit. Then you quit."

The full definition states: "Highly controlled or compulsive drug use indicates that drug seeking and drug-taking behavior is driven by strong, often irresistible urges". It provides no criteria for determining when a strong urge becomes "irresistible". In fact, no such criteria exist, as admitted by the American Psychiatric Association. "The line between an irresistible impulse and an impulse not resisted is no sharper than that between twilight and dusk. . . ." See "American Psychiatric Association Statement on The Insanity Defense", Am. J. Psychiatry, 140(6), 681-688, 1983.

¹⁹ Leonard Larson, Scripp Howard News Service.

This is not to say that stopping smoking, or changing any well-liked, habitual behavior is easy. It takes effort and commitment. But, the process is not different from successfully losing several pounds and maintaining the weight loss or developing a regular exercise program. It is completely different from successfully recovering from hard drug addiction or alcoholism. The true addict must overcome severe physical withdrawal, rebuild every aspect of his life, learn new value systems, and approach life without being constantly intoxicated. None of these impediments is present in stopping smoking.

"psychoactive effect. Originally, the scientific community described the term "psychoactive" to include, as a necessary component, distortions or disruptions in cognitive and motor performance, i.e., intoxication. Those concepts were in effect for decades and were included in the 1964 Surgeon General's Report. Smoking/nicotine, however, does not produce intoxication. To eliminate this inconvenient truth, the 1988 Surgeon General's Report redefined "psychoactive" to mean anything that gets to and produces effects in the brain. Based on this imprecise and revised definition, nicotine is psychoactive. So too is the caffeine in chocolate, coffee and soft drinks. Sugar, warm milk, cheeses, and many other everyday substances and common pleasant experiences (such as watching sporting events or listening to music) also produce psychoactive effects similar to those from smoking. They are quite unlike the profound effects caused by hard drugs and alcohol. It is the intoxication of hard drugs and alcohol that sets them apart and causes muddled thinking and loss of self control.

Robinson, J.H. and Pritchard, W.S., "The Role of Nicotine in Tobacco Use." Psychopharmacology, 108, (4): 397-407, 1992.

Dr. Kessler testified that nicotine contained in cigarette smoke releases a certain chemical (dopamine) in the "pleasure centers" of the brain, resulting in similar effects as addicting drugs such as heroin and cocaine. Dr. Kessler failed to acknowledge that many different pleasurable and not so pleasurable experiences and activities also result in the release of dopamine in these "pleasure centers". Once again, the attempted analogy becomes meaningless when viewed objectively and without blinders. Dopamine release is one part of the neurochemical response to both pain and pleasure. It will occur if one receives an electric shock or slap in the face and also occurs in response to pleasant experiences of all kinds. Attempting to mystify a basic physical reaction and implying that it only occurs with addicting drugs is misleading at best.

- 3. Reinforcing behavior. Dr. Kessler's third criterion, reinforcing behavior, provides yet another example of the attempt to invest commonplace concepts with scientific mystique, combined with an erroneous implication that the condition only occurs with addicting drugs. Such is not the case. As presented in the 1988 Surgeon General's Report, reinforcing behavior merely refers to the fact that a pleasant experience will likely be repeated, whether it involves a chemical or activity.²¹ Dr. Kessler cites two lines of evidence as support for his claims regarding reinforcement from nicotine:
 - 1. That animals can be trained to self-administer nicotine; and
 - 2. The experiments which claim that nicotine causes activation of "pleasure centers" in the brain involving dopamine.

The report artificially attempts to separate reinforcement involving chemicals from those involving activities. In reality, it is the magnitude of the effect that is most important, not the source. Further, we reject the notion that the reinforcement, or pleasure, derived from cigarette smoking is solely the result of ingestion of nicotine.

Although it is true that animals will self-administer nicotine under certain very limited circumstances, this does not imply that the effects produced by or the motivation for ingesting nicotine are in any way similar to those of truly "addicting" drugs. Scientists at the Bowman Gray School of Medicine, in association with a Reynolds Tobacco scientist, recently published a peer-reviewed study demonstrating that nicotine and caffeine are very weak reinforcers when compared to cocaine and methylphenidate (Ritalin™).²² Their findings were in line with the overall weight of the scientific evidence, which has consistently found caffeine and nicotine are both weak reinforcers.²³ Animals can be trained to selfadminister a wide variety of substances. Animals have been trained to self-administer very painful electric shocks, and morphine addicted monkeys have been trained to self-administer opiate antagonists, precipitating very painful withdrawal symptoms. However, none of these self-administration behaviors proves the existence of an "addiction". Moreover, animals do not have to be extensively trained to self-administer cocaine or heroin. Once they start receiving either drug, they quickly become hooked and self-administer it to the exclusion of food and water and until death if not stopped.

4. <u>Withdrawal symptoms</u>. Although nicotine withdrawal was defined in 1987 by the American Psychiatric Association (DSM-III-R) as an element of tobacco dependence,

Dworkin, et al., "Comparing the Reinforcing Effects of Nicotine, Caffeine, Methylphenidate and Cocaine." Medical Chemistry Research, Vol. 2:593-602 (1993).

Griffiths, R.R., Brady, J.V., and Bigelow, G.E., "Predicting The Dependence Liability of Stimulant Drugs" in Thompson and Johansen Behavioral Pharmacology of Human Drug Dependence, NIDA Monograph 37, 1981, p. 92. This position has not changed. Griffiths, R., American Psychiatric Association Annual Meeting, San Francisco, CA, (1991).

the associated symptoms were identified in the 1964 Surgeon General's Report: restlessness, anxiety, trouble concentrating, and other "mild and variable symptoms". That report stated that these symptoms were the same as those seen when any well-liked behavior was suddenly stopped. Nothing new has been established in this area. Caffeine withdrawal is much more well-established and well-defined, including the physical symptom of the "caffeine headache." Under Dr. Kessler's definition, caffeine and heroin should be treated equally.

Smoking cessation never involves any of the severe physical and behavioral disruptions involved in withdrawal from truly addicting drugs such as heroin, cocaine, and amphetamines. In fact, the symptoms of hard drug withdrawal normally require medical treatment. With many drugs (e.g., barbiturates and alcohol), the addict can die from withdrawal if not medically treated. An addict undergoing withdrawal from hard drugs is unable to think clearly or control his actions while in the throes of withdrawal. This is never the case with cigarette smokers who quit. They continue to attend to their responsibilities and lead normal lives. The symptoms reported by cigarette smokers when they stop are of the same kind and magnitude reported by dieters and people changing sleep patterns (e.g., changing from the first to third shift at work).²⁵

²⁴ 1964 Surgeon General's Report, supra, at 352.

It should be noted that DSM-III-R states that there is no evidence that, even at its most severe level, tobacco withdrawal prevents a person from successfully stopping. The same can not be said for barbiturates, alcohol or crack cocaine. Diagnostic and Statistical Manual of Mental Disorders (Third Edition - Revised) American Psychiatric Association, (1987), 151.

Cigarette smoking is more like drinking coffee and eating chocolate than like using cocaine, heroin, or any truly addicting hard drug. Cigarettes, however, are unpopular, which is why our critics strain so mightily to demonstrate that smoking is "addictive". The plain truth is that, under any objective scientific (or common sense) measure, cigarette smoking should not be considered "addictive".

Dr. Kessler and others support their assertions by repeating a deluge of facts that, in their judgment, prove their conclusions. Let us examine just a few of these "facts":

- First, Dr. Kessler quotes a 1993 Gallup Survey reporting that 75% of smokers say they are addicted. What Dr. Kessler does not report is that the same survey found that 69% of the same smokers said they "could quit if I wanted to." Moreover, this survey was conducted after the well-publicized 1988 Surgeon General's Report, which equated cigarette smoking with cocaine and heroin addiction. Does Dr. Kessler not believe that such publicity could affect responses to this survey?
- Dr. Kessler states that "By some estimates, as many as 74 to 90 percent are addicted." He relies on a paper by Hughes, et al. This paper also included the comment, "In addition, the fact that this definition [referring to DSM-III-R] classified 90% of the tobacco users in this study as dependent suggests that it is over inclusive and thus may lack diagnostic discriminability".
- Dr. Kessler makes repeated references to how certain percentages of people "may" or "might" possibly behave in certain circumstances. In one example, he discusses patients who continue to smoke after surgery or a coronary event. Some continue to smoke; most quit. Some also follow their doctor's advice and eat less fat, exercise regularly and lose weight. Some don't. The fact that human behaviors run a wide gamut when faced with similar situations tells us something about human behavior and little about smoking or nicotine.
- Dr. Kessler's "experts" tell him that most smokers reach for their first cigarette within 30 minutes of waking. He concludes that this fact is "a meaningful measure of addiction". By this measure most coffee drinkers should be considered addicts.

Manufacturers of coffee makers have even developed machines which have coffee prepared by exact times to ensure that the coffee "addiction" can be satisfied immediately upon awakening.

It should be pointed out that Dr. Kessler's "definition" of addiction would classify most coffee, cola, and tea drinkers as caffeine addicts. Caffeine is psychoactive and the effects last longer than those of nicotine. Many people experience a "strong urge" for a cup of coffee each morning. There is a well-established physical withdrawal syndrome for 2-3 cups a day coffee drinkers who suddenly stop drinking coffee. Is caffeine similar to cocaine and heroin because of this? Neil Benowitz, one of the editors of the 1988 Surgeon General's Report, admitted that caffeine meets their new definition of addiction:

Many physicians have treated patients who continue to drink large quantities of caffeinated beverages in the face of information that caffeine is harmful to their health and advice to quit. Such behavior suggests that these people are addicted to caffeine. Addiction liability can be analyzed according to criteria recently presented by the United States Surgeon General. The three major criteria for addiction liability are psychoactivity, drug-reinforced behavior, and compulsive use. That caffeine is psychoactive and that some people consume caffeine compulsively is clear. That caffeine reinforces its consumption has recently been demonstrated in people, although reinforcement is highly dependent on the dose, with excess doses producing dysphoria. Minor criteria for addiction liability include the development of tolerance, physical dependence, and recurrent intense desire for the drug, all of which are characteristic of regular caffeine consumers. Thus, there is a group of coffee drinkers who appear to be addicted

See Jaffe, J. and Kantzer, M., "Nicotine: Tobacco Use, Abuse and Dependence, Subst. Abuse, 0(0): 256, 1981. See also Sawyer et al., "Caffeine and Human Behavior: Arousal, Anxiety and Performance Effects, J. of Behav. Med., 5(4): 415, 1982. "Caffeine is, without question, the most commonly used psychoactive drug in the World." Jaffe, J.H., Comprehensive Textbook of Psychiatry, Chapter 13, Psychoactive Substance Use Disorders, 1(0), page 683, 1989.

to caffeine, although the extent of caffeine addiction in the population is unknown.²⁷

If the same "standards" are applied to caffeine, should the FDA also be considering (or should you suggest that it begin) regulating coffee and soft drinks as drugs?

One final point is important. Essentially every claim made about manipulating nicotine in cigarettes by Dr. Kessler can be made about alcohol in beer, wine and spirits. Spirits manufacturers constantly monitor the alcohol content of their products throughout the fermentation process to precisely control the level of alcohol. Beers and wines are offered to the public with a wide range of alcohol content. Alcohol is added to fortified wines. High alcohol malt liquors are also available to the public. While no one will dispute that alcohol can be a truly "addicting" substance under any definition, there is no move to regulate alcohol as a drug, and we do not believe there should be.

Why People Choose to Smoke

Dr. Kessler dismisses the issue of why people smoke by concluding, as the antismoking supporters he relies upon conclude, that smoking is an "addiction" and smokers would quit if they could break this "addiction". In the current climate of social disapproval and "political correctness", it is unpopular for smokers to honestly state that they smoke for pleasure and enjoyment. Yet for hundreds of years smoking has been accepted as a social custom, providing a pleasurable, enjoyable break from normal activities. Smokers enjoy the taste and other sensory aspects of smoking. A few moments with a cigarette can be a break

²⁷ Benowitz, N.L., "Clinical Pharmacology of Caffeine." Ann. Rev. Med., 41(0) 277-288, 1990.

during boring or intensive tasks, or a nice complement to a meal. All of these highly subjective reasons for smoking have found support in scientific publications.

Dr. Kessler pejoratively refers to "top tobacco industry officials" when referencing internationally respected Reynolds Tobacco scientists who have published widely in peer-reviewed scientific journals because they do not believe that tobacco is addictive. He then goes on to mischaracterize their data. In the journal article referenced by Dr. Kessler, Drs. Robinson and Pritchard summed up the evidence concerning addiction and tobacco use:

We believe that Warburton (1990) has developed a balanced, functional theory of nicotine use that recognizes the beneficial psychological effects of nicotine. This "resource" or "psychological tool" hypothesis holds that people smoke cigarettes primarily for purposes of enjoyment, performance enhancement and/or anxiety reduction. This theory also passes the common sense test of why people smoke. They smoke, not because they are addicted to nicotine, but because they achieve some benefits from smoking, enjoy these benefits which are totally compatible with everyday tasks and stresses, and choose to continue to enjoy these benefits....

We believe the distinctions are clear and cannot be stated more clearly than what was said in the 1964 SGR [Surgeon General's Report]: "the practice [smoking] should be labeled <u>habituation</u> to distinguish it clearly from <u>addiction</u>, since the biological effects of tobacco, like coffee and other caffeine-containing beverages, . . . are not comparable to those produced by morphine, alcohol, barbiturates, and many other potent addicting drugs" (p. 350, emphasis in original). If we lose this common-sense perspective of the role of nicotine in tobacco use, those of us who enjoy the "lift" we receive from that first cup of coffee in the morning or that cola drink in the late afternoon may find that a few years from now a small group of researchers have equated our coffee/cola-drinking behavior to that of a hard-core crack or heroin addict.²⁸

²⁸ Robinson and Pritchard, supra, at 405-6.

No scientific breakthrough has occurred since the 1964 Surgeon General's Report to warrant classifying cigarette smoking as "addictive". All of the essential facts describing the behavior have been well known for years. The only thing that has changed is the political climate surrounding cigarette smoking, and with it the ability of anti-smoking critics to develop a new definition of "addiction" solely to include cigarette smoking within it.

Conclusion

The facts are clear:

- Reynolds Tobacco does not add nicotine to its cigarettes.
- Reynolds Tobacco does not manipulate nicotine yields in its cigarettes in order to create, maintain, or satisfy "addiction".
- Cigarette smoking is not an "addiction" under common sense and honest comparison with truly "addicting" drugs.

Simply put, there is no factual basis or policy reason for the FDA to regulate cigarettes as drugs. The result of FDA regulation, moreover, would be a ban, or prohibition, of cigarettes. Dr. Kessler made this point clear in his recent statement before the Subcommittee. Members of this Subcommittee have stated that a ban or prohibition is not their intent; the American public resoundingly rejects the prohibition of cigarettes as well. We encourage a dialogue that will lead to progress rather than prohibition.



Reynolds Building 4th & Main Street Winston-Salem, NC 27102

Contact: Maura Ellis

Public Relations (910) 741-6996

RJRT 94-05

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Anti-Smokers Seek Return to Prohibition Says RJR Chairman

Washington, D.C. -- The chairman and chief executive officer of R.J.

Reynolds Tobacco Company said today "the anti-smoking industry is seeking a return to prohibition in America."

Jim Johnston was among six tobacco industry CEO's who testified today before the House Energy and Commerce Committee's Subcommittee on Health and the Environment.

"My company and I must speak up for the 85 percent of Americans who oppose prohibition," Johnston said. "The real question before the American public is this: Should cigarettes be outlawed? Will adults be allowed to choose to smoke, to afford to smoke, to smoke outside their homes -- or is it time to say: No, the government knows better?

"The American public overwhelmingly opposes prohibition, regardless of whether it comes in through the front door or sneaks in through the back door. So let's be clear that back-door prohibition is prohibition nonetheless," Johnston noted.

Johnston cited six examples of what he considers back-door prohibition:

- Raising taxes to force smokers to quit.
- Banning smoking in all public places -- indoors and outdoors, including parks, workplaces and outdoor stadiums -- to further stigmatize smokers.
- Banning advertising so that new or better products can't be effectively introduced.
- Forcing manufacturers to produce products that smokers find unsatisfying or unacceptable.
- Attacking every attempt by the industry to respond to public and smoker concerns.
- Advocating that the FDA regulate cigarettes as a drug, which would effectively ban cigarettes from the market.

Johnston opened his testimony by denying claims that Reynolds Tobacco "spikes" cigarettes with nicotine. The points he emphasized were:

- Reynolds does not "spike" its products with nicotine -- in fact, the manufacturing process results in a loss of nicotine.
- The company does not add or otherwise manipulate nicotine to "addict" smokers.
- Finally, there is no justification for the FDA to regulate cigarettes as a drug.

If the tobacco industry stopped using current cigarette manufacturing techniques, Johnston explained, "tar" and nicotine levels would return to 1940 levels of 40 milligrams of "tar" and 2.8 milligrams of nicotine for the average cigarette — more than three times the current average for these substances.

Johnston also denied claims that nicotine is addictive, adding that under FDA Chairman Dr. David Kessler's definition, "most coffee, cola and tea drinkers" would have to be classified as "caffeine addicts.... no one should try to use the back door and force prohibition by saying that cigarettes are a drug because they contain tobacco, which contains nicotine," he noted.

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Statement of Andrew H. Tisch Chairman and Chief Operating Officer Lorillard Tobacco Company

before the Subcommittee on Health and Environment House Energy and Commerce Committee

April 14, 1994

Mr. Chairman and distinguished members of the Subcommittee: I am Andrew H. Tisch, Chairman and Chief Executive Officer of the Lorillard Tobacco Company. With me is Alexander W. Spears, Lorillard's Vice Chairman and Chief Operating Officer. Dr. Spears has senior responsibility for Lorillard's research and production operations. On behalf of the more than 3700 employees of Lorillard Tobacco Company, Dr. Spears and I are pleased to have this opportunity to address the issues you identified in your letter to Lorillard of March 31, 1994 announcing this hearing.

You will recall that Dr. Spears testified before this Subcommittee on March 25, 1994, with respect to the same subjects proposed for discussion here today. Inasmuch as Dr. Spears' and Lorillard's position on the questions raised has not changed in the past two weeks, and for the sake of brevity, I have attached to my statement a copy of Dr. Spears written submission of March 25th, and ask your permission that it, and his March 25 oral testimony, also be entered into the record of today's hearing.

At the outset, I want to reaffirm and emphasize what Dr. Spears said during his appearance on March 25th, and to make absolutely clear, to the Congress and to the public, that the level of nicotine in the products manufactured and sold by Lorillard is solely determined by the tobacco that we buy and the blending of the different tobaccos used in our manufacturing. The tar and nicotine yields of our products are determined by a combination of the tobacco blends and the physical characteristics which constitute the construction of the cigarette, namely, length, circumference, paper porosity, filter, tip ventilation and tobacco density.

Nicotine levels follow tar levels, and are not raised or reduced for particular brands. Dr. Spears previously advised you that in the course of manufacturing we use denatured alcohol, which the Bureau of Alcohol Tobacco and Firearms requires be made unpotable by the manufacturer of the alcohol through the addition of a minuscule amount of nicotine. We also use a number of flavors which incorporate a tobacco extract that contains some nicotine. But it is important to understand that the combined amount of nicotine from these sources is too small to be measured in the final products.

The manufacture of our brands of cigarettes also involves the use of reconstituted tobacco or tobacco sheet. One of the processes Lorillard utilizes in the production of reconstituted tobacco involves a temporary separation and subsequent reapplication of water-soluble components of tobacco, including

nicotine. However, and I invite your very specific attention to this important fact: this process, and others, all of which are well known in the published literature, results in a reduction of nicotine in the finished product.

Dr. Kessler's March 25th testimony referred to a 1980 Lorillard patent dealing with nicotine in reconstituted tobacco. I am advised that an early laboratory observation indicated a possible use for the process, and, following our usual business practice, and that of virtually every other company in America, we applied for, and obtained, the patent. However, so that there is no misunderstanding, the record should reflect that Lorillard has never practiced the patented process in any commercial manner. Moreover, even if it was to be used, the process would not result in any increase or decrease in the nicotine level.

In your March 31 letter we are asked to "address any studies of the physiological or psychological effects of nicotine and related compounds" which have been undertaken by Lorillard. I can respond succinctly: Lorillard has not undertaken any such research.

Finally Mr. Chairman, allow me to sum up and to state Lorillard's position on the principal issues raised in the Statement released by you when you scheduled today's hearing. In doing so, it is also my purpose to respond to Dr. Kessler's erroneous assertions, first made on February 25th, and then expanded upon at your March 25th hearing.

- Lorillard does not take any steps to assure a minimum level of nicotine in our products.
- Lorillard does not add nicotine to cigarette tobacco for the purpose of "manipulating" or "spiking" the amount of nicotine received by the smoker.
- Lorillard makes no effort to keep secret any information about the nicotine content of our products, and as you know, since 1971, every cigarette advertisement has carried a complete disclosure of tar and nicotine content.

Mr. Chairman, I respectfully suggest to you that Lorillard has acted, and will continue to act, in a completely responsible manner, in this, as well as in all of our business practices. Furthermore, I state unequivocally that our manufacturing processes neither violate the Federal Food Drug and Cosmetic Act, nor do they justify placing the manufacture of cigarettes under the jurisdiction of the FDA.

Thank you for your attention and for this opportunity to state Lorillard's position. At the appropriate time Dr. Spears and I will take any questions you or your colleagues may have.

Statement of Alexander W. Spears Vice Chairman and Chief Operating Officer Lorillard Tobacco Company

before the
Subcommittee on
Health and the Environment
of the
Committee on Energy and Commerce
U.S. House of Representatives
March 25, 1994

My name is Alexander W. Spears, and I am Vice Chairman and Chief Operating Officer for Lorillard Tobacco Company.

Within the last few weeks, ABC's <u>DAY ONE</u> show has featured two cigarette-related programs alleging that the tobacco industry adds nicotine to cigarette tobacco for the purpose of manipulating the dose of nicotine to the consumer. These statements are completely false.

David Kessler, Commissioner of the Food and Drug Administration, stated in a letter to Scott Ballin of the Coalition on Smoking or Health dated February 25, 1994, that manufacturers commonly add nicotine to cigarettes to deliver specific amounts of nicotine. This letter was released to the media, perpetuating its false assertions.

The level of nicotine in the tobacco of our products is solely determined by the tobacco that we buy and blending of the different tobaccos during manufacturing. The tar and

nicotine yields of our products are determined by a combination of the tobacco blends and the construction of the cigarette, i.e., length, circumference, filter, tip ventilation, tobacco density, etc. The Federal Trade Commission has reported the results of tar and nicotine analysis by brand for years.

We do not set nicotine levels for particular brands of cigarettes. Nicotine levels follow the tar levels. The easy proof that no nicotine manipulation has occurred may be found in the temporal tar and nicotine data from the 1950's to the 1990's. As shown in Chart I, both tar and nicotine on a sales weighted basis have decreased in a parallel fashion and by the same amount, (reference, U.S. Department of Health and Human Services, "Reducing the Health Consequences of Smoking: A Report of the Surgeon General," at 88; 1988-1990 numbers based on information similar to that used in the 1989 Surgeon General's Report.) Chart II presents the results of a longitudinal analysis for the latest tar and nicotine results on 483 brands to be reported by the Federal Trade Commission. The correlation coefficient of 0.975 is essentially perfect correlation between tar and nicotine and shows that there is no manipulation of nicotine.

We do not add nicotine to our products, except in two insignificant and incidental cases:

(1) through the use of denatured alcohol, which is required to contain small amounts of nicotine under regulation by the Bureau of Alcohol, Tobacco and Firearms; and (2) through the use of a few flavors which incorporate a tobacco extract that contains some nicotine. The combined amount of nicotine from these sources is too small to be measured in the final products.

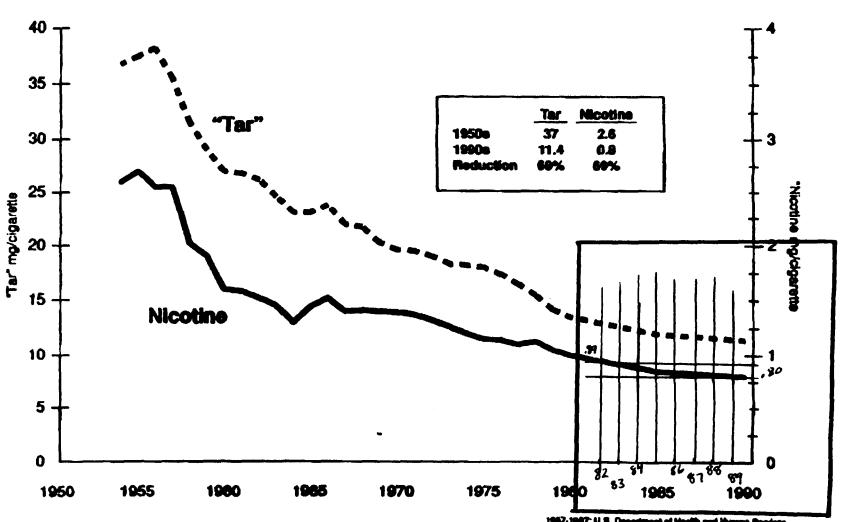
One of the processes for the production of reconstituted tobacco, which is used in the manufacture of cigarettes, involves temporary separation and reapplication of water-soluble components of tobacco, including nicotine. This process, which is well described in the published literature, including three Surgeon General's reports, results in a reduction of nicotine in the finished cigarette. Other processes which have been described in the literature result in similar products but do not involve the temporary separation of water soluble components of tobacco. Again, some nicotine is lost during the manufacture of reconstituted sheet with the sheet containing much less nicotine than leaf tobacco.

I repeat, the allegations of <u>DAY ONE</u> and David Kessler concerning nicotine manipulation are false and are inconsistent with reported tar and nicotine data on commercial cigarette brands.

Tar and Nicotine of the Smoke of Domestic Cigarettes

	.						mostro Organ		
	Value (CTASAP) Visa (CTASAP) No 100's 100'PASAP	148 148 148	0,97 0,95 1,05	HI-Lite 100FHP Hartzen KPSP Hartzen Menthal KPMSP	128 10.8	1.03 0.84	Pail Mail Red Filters 100's 100PSF "Parliament Lights KFH#	16 2 8.5	1 24 0.66
	, rep Lights (CFLBHP , sine Lights (CFLBHP)	8.8	0. 66 0.70	Hanzon 100FSP Hanzon Menthal 100FMSP	10.9	0.75 0. 42	Perfement Lights ICFSP *Perfement Lights 100's 100FSP	8.9 11.8	0.69
	Algino Lights 100°s 100°PMBP American Full Player XPSP	16.2	0.71 1.24	Kent Golden Lights KFHP Kent Golden Lights KFSB	11.5 7.7 40	0.84 0.86 0.80	Philip Morris International 100FHP Philip Morris International Menthol 100FMHP Phosyume RNFSP	15. 8 15.5	1.13
	American Full Flavor 100's 100FSP American Lights KFSP	16.9	1.29 0.91	Kent Golden Lights Menthal ICFMSP Kent Golden Lights 100s 100FMB	7.9	0.00 0.73	Proyume FONEHP Proyume KEHP	15.9 23.8	1.00
	American Lights 100's 100PSP American Lights 100Fs Manches 100PMSP Buildt 10FMSP	11.7	0.98	Kent Golden Lights 100s 100FSP Kent Golden Lights 100s Menthal 100FMSP Kent KFHP	4.9 6.5	0.79 0.76	Players Menthol KPMMP Players 100's 100FMP	11.7 11.3	0.85
	Salar 100's	9.8 8.4	0.98 0.73 0.61	Kent KFHP Kent KFSP	11.7 12.1	0.86 0.86	Players 100's Menthal 100FMHP Players Lights 25's KPSP	13.8 13.3	1.02
	Seler Low Price ICPMSP Seler Low Price 100's 100FMSP	14.3	1.13	Kent 100s 100FSP Kent 100s Menthel 100FMSP	13.1	0.98	Players Lights 25's Nonthal KFMSF Players Lights 25's 100's 100PSP	9.6 9.6 (1.1	0.74
	Seater Love Price Lights (107-1007-1007-1007-1007-1007-1007-1007-	8.9 9.0	0.78 0.80	Kent III Ultra Lights KFSP Kent III Ultra Lights 100s 100FHP	17	0.37	Players Lights 25's 100's Menthol 100FMSP Pyramel KNFSP	11.1 11.3 21.8	0.83 0.84 1.38
	Beneam & Hedges Delate (CPHP Beneam & Hedges 100's 100PHP	13.6 15.6	1.03 1.14	Kent III 100s Ulira Lights 100FSP Koot RNFMSP	4.6 20.2	0.46 1.23	Pyramid Full Playor KFSP Pyramid Full Playor Mengod KFMSP	14.2 14.0	1.05
	Senson & Hedges 100's Menthal 100FMHP Senson & Hedges 100's 100PSP	15.2 15.4	1.09 1.13	Kool KFMHP Kool KFMSP	15.4 16.5	1.02	Pyramid Full Player 100's 100FSP Pyramid Full Player 100's Manthel 100FMSP	15.4 15.0	1.21
	Barrison & Headyes 100's Meminat 100FMBP *Barrison & Headyes Colors Ultra Lights 100's 100 *Barrison & Headyes Colors Ultra Lights 100's Mon Barrison & Headyes Culptus 100's 100FMP Barrison & Headyes Lights 100's 100FMP Barrison & Headyes Lights 100's Maneaut 100FMMP Barrison & Headyes Lights 100's 100FMP Barrison & Headyes Lights 100's 100'	15.2 5.4	1.31 0.4 6	Kool Super Longs 100's 100FMSP Kool Lights KFMSP	15.8 7 6	1.13 0.62	Pyramid Lights KFSP Pyramid Lights 100's 100FSP	10.5 10.5	0.80
	Barrieri & Hedges Lights 100's 100FHP	10.5	0.45 0.78	Kool Lights 100's 100FMSP Kool Milds KFMHP	7. 8 11.4	0.64 0.82	Pyramid Lights 100's Menthol 100FMSP Pyramid Ultra Lights 100's 100FSP	10.7 5.2	0.87
	Bersen & Hodges Lights 100's 100PSP	10.4 10.2 9.7	0.78 0.79 0.75	Kool Mids KFMSP Kool Mids 100's 100FMSP	11.0 11.3	0.80 0.83	Releigh KNFSP Releigh KFSP Releigh 100's 100FSP	23.0 14.7	1.27
	Benean & Houses Lights 100's Mentiol 100FMSP 8 & H Mutellar KPSP 8 & H De-Nic KPHP	11.0 8.3	0.75 0.85 0.08	Kool Ultra Lighes KFMSP Kool Ultra Lighes 100's 100FMSP L & M KFHP	21 4.7	0.19 0.41	Raleich Lights KFSP	15.0 11.1	0.94 0.81
	5 & H De-Nie Menthel KFMHP 8 & H De-Nie 100's 100FHP	8.5 7.1	0.08	L&M KFSP L&M Super Kings 100FSP	126 126	0.95 0.95	Raleigh Lights 100's 100FSP Raleigh Extra KNFSP	12.4 24.7	0.8 4 1.35
	8 & H De-Nic 100's Maneral 100FMMP Bristol Non-Riter KNFSP	8.0 27.0	0.07	L & M Long Lights 100FSP Lark KFSP	10.9 7.2	0.86 0.70	Raiogh Extra KFSP Raiogh Extra 100's 100FSP	16.5 15.0	0.97 0.93
	Bristol Full Flavor KFSP Bristol Full Flavor 100's 100FSP	15.5	1.12	Lark 100FSP	14.5 14.4 11.4	1.10	Releigh Extra Lights KFSP Releigh Extra Lights Meninol KFMSP	10.3 9.3	0.7 0 0. 66
	Bristel Lights MFSP Bristel Lights Menthal ICFMSP	9.4	0.80 0.80	Lark Light 100's 100FSP	12.0	0.84 0.97 1.68	Releigh Extra Lights 100's 100FSP Releigh Extra Lights 100's Monthel 100FMSP Releigh Extra Ultra Lights KFSP	11.6 8.5	0.76
	Briefel Lights 100's 100PSP Briefel Lights 100's Menthal 100PMSP	9.9	0.84 0.83	Lucky Strike Filters KFSP Lucky Strike Filters 100's 100FSP	13.1 13.8	1.00	Raisign Extra Ulife Lights 100's 100PSP Richard 20's KPSP	5.9 5.6	0.43
	Briskii Lowest 100's 100PSP	0.9 1.9	0.14 0.22	Lucky State Lights KFSP Lucky State Lights 100's 100FSP	7.8 9.4	0.67 0.80	Pichland 20's Menthal KFMSP Pichland 20's 100's 100PSP	16.3 15.4 16.6	1.1.3
	Briefel Ultre Lights 100's 100PSP Buels KPSP	5.2 14.0	0.50 0.97	Magna KPHP Magna KPSP	14.4 14.8	1.01	Richland 20's 100's Manthul 100FMSP Richland 20's Lights KFSP	15.5 13.5	107
	"Budin Lights KPSP Bull Curham KPHP	10.7 14.2	0.7 8 1. 04	Megne Lites KPHO	107	A 75	100's 100FSP	12.4 16.6	0.91
	Bull Durham Lights ICFHF Cambridge Full Planer ICFSP	9.7 16.0	0.80 1.05	Maditu Filters Maditu Manri SSP Maditu 100:		1.22	25's 100's 1	15.6 17.2	1.00
	Cambridge Full Flevor 100's 100FSP Cambridge Lights KFSP Cambridge Lights Manthel KFMSP	16.1	1.09	Medite Mendant of 100		1.23	Sales	12.3	0.86
	Cambridge Lights 100's 100FSP Cambridge Lights 100's Membrid 100FMS	11.3	0.83	Malita Lights Malita Lights 1006			Salam HTMS Salam 100's	17.2 18.1	1.24 1.16
	Cantings Louist ICSP Cambridge Louist 107s 100FSP	10.6 0.9 1.5	0.20	Melburo KPHP Merboro KPHP Merboro Menthol Attack			Sales 100FMHP	9.9 [1.1	0.71 0.84
	Cambridge Utra Lety Tay 100's 100FSP Cashel RNFSP	5.7 21.2	0.48 1.40	Merboro KFSP Merboro Menthal KFMSP	15.3	1.06	Salem Sam Lights 100FMSP Salem Sam Lights 100's 100FMHP	8.5 8.9	0.71 0.70
_	Castel Filters KFHF Castel Filters KFSP	16.9	1.18	Marboro 100's 100PHP Marboro 100's 100PSP	15.2 15.4 15.6	1.02 1.11	Salam Ultra Lights (FMSP Salam Ultra Lights 100's 100FMSP	- 5.0	0.42
	"Sand Filters 90's 100FHP shall Filters 100's 100FSP	16.1	1.00 1.13 1.00	Mariboro 25's KPSP Mariboro Lights KFHP	1 <u>5.7</u> 10.4	1,13 1.00 0.78	Saratoga 120's 120FHP Saratoga 120's Menthal 120FMHP Sath 100FSP		1.08
	nel Lights KFHP mel Lights KFSP	9.2	0.66 0.76	"Mariboro Lights Menthel KFMHP Mariboro Lights KFSP	9.6 10.4	0.74 0.77	Satin Menthal 100FMSP	11.1	0.94 0.95 0.97
	James Lights 96's 100PHP Carest Lights 100's 100PSP Carest Utra Lights KPHP	9.1 9.9	0.70 0.72	Meritore Lights 100's 100FMP "Meritore Lights 100's Menthet 100FMMP	10.4 9.2	0.81 0.73	Silve Thins Filters 100FHP Silve Thins Menthal 100FMHP Spring 100's Menthal 100FMSP	11.6	0.95
		5.4 5.4	0. 50 0.51	Mariboro Lights 100's 100F5P Mariboro Lights 25's KFSP	10.6 10.4	0.82 0.78	Spring Lemon Lights Monthal KFMSP Spring Lemon Lights 100's Monthal 100FMSP	9.4	1 53 0.75 0.89
	Carri 100FHP	5.8 9.0	0.54 0.71	Marboro Medium KFHP Marboro Medium KFSP	11.6 11.9	0.84 0.87	Starting KFSP Starting Mangal KFMSP	14.2	100
	Capit Manthol 100FMHP Capit 120's Super Silms Lights 120FHP Capit 120's Super Silms Lights Manthol 120FMHP	9.1 13.6	0.70 1.01	Meritorio Ultra Lights IOFHP Meritorio Ultra Lights 100's 100FHP Max 120s 120FSP	5.8 5.7	0,48 0,48 1,28	Stering 100's100FSP Stering 100's Munitial 100FMSP	15.5	112
	Carlion Ultra KFNF	123	0.93	Max 120s Manenci 120FMSP	15.8 16.1	1.30	Stering Lights KFSP Stering Lights Menthal KFMSP	9.3	0.72
	Certon KFSP Certon Menthel KFMSP Certon 63 KFMF	1.2	0.1 5 0.1 4	Merk KFHP 'Meril KFSP	7.6 7.7	0. 60 0. 60	Storing Lights 100's 100FSP Storing Lights 100's Menthal 100FMSP	10 4 9 2	0.84
	Carten 100's 100FHP Carten 100's Menthal 100FMHP	1.0 1.1 1.0	0.14 0.14	Ment Menthal KFMSP Ment 100's 100FSP	7.6 8.9	0. 6 1 0.71	Staning Ulira Lights 100's 100PSP Staning Ulira Lights 100's Manthal 100PMSP	4.4	0.40 0.41
	Carten 100's 100FSP Carten 100's Menthal 100FMSP	21	0.13 0.23 0.22	Ment 100's Munthat 100FMSP Ment Ultre Lighes KFHP Ment Ultre Lighes KFSP	9.1 5.0	0.73 0.46	Starting Stim Lights 100's 100'FHP Starting Stim Lights Menthal 100's 100FMHP Style Lights 100FHP	8.2	0.67 0.66
	Carlton 120's 120FSP Carlton 120's Months! 120FMSP	5.0 4.6	0.46 0.48	Mont Ultra Lights Monthal KFMSP Mont Ultra Lights 100's 100PHP	4.8 4.8 5.7	0.44 0.44 0.51	Style Lights Menthal 100FMHP Style Lights 100's 100FSP	11 1	0.91
	Carder 10's 100FHP Carder 10's Manthol 100FMHP	7.6 5.3	0.67 0.71	"Ment Ultra Lights 100's 100FSP "Ment Ultra Lights 100's Menthal 100FMSP	5.6 5.6	0.50 0.46	Style Lights 100's Menthal 100FM3P Style Sime 100FHP	11 8 11 8 9.5	0 92 0 93 0 82
	Carder 20's 100FHP Carder 20's Manthol 100FMHP	8.6 8.1	0.71 0.68	Misty Slims Lights 100FHP Misty Slims 100's Lights Menthal 100FMHP	8.4 8.6	0.74 0.74	Style Slime 100's Menthal 100FMHP Tell 120s 120FSP	9.7	0.79
	Century 25's KFSP Century 25's 100's 1:00FSP	14 8 15.0	1.06	Montdar Full Flavor KFSP Montdar Full Flavor 100's 100FSP	15.7 15.7	1.17 1.14	Tall 120s Meneral 120FMSP Tereyton KFSP	16.8	1 41
Ì	Century 25's Lights (25) KFSP Century 25's Lights 100's 100FSP	10.5	0.68 0.88	Montdair Lights KFSP Montdair Lights Menthol KFMSP	11.1 11.3	0. 86 0.89	Tereyton 100s 100FSP Tereyton Listes KFSP	13.8	1 02
	Cardary 25's Lights 100's Moneral 100FMSP Chesterfield RNFSP Chesterfield KNFSP	11.0	0. 89 1.13	Montday Lights 100's 100FSP Montday Lights 100's Monthol 100FMSP	11.9 11.6	0.96 0.94	Taraytan Long Lights 100s 100FSP Trumph KFSP	8.0	0.71
l	Commender RNFSP Commender KNFSP	21.9 21.5 26.7	1.37 1.33	Mentdar Ulira Lights 100's 100FSP More 120s 120FSP More 120s Mentiol 120FMSP	5.9 15.8 16.1	0.52 1.21	Trumph Menthal KFMSP Triumph 100e 100FSP	39	0.39
	Dakota KFHP Dakota Lights KFHP	17.0 11.7	1.66 1.22 0.94	More Lights 100s 100FHP More Lights 100s Menthal 100FMHP	93 8.8	1.29 0.76 0.66	Triumph 100s Meninal 100FMSP True KPHP True KPSP	4.4	0 39 0 42
ŀ	Doral Full Player KFSP Doral Full Flavor Menthal KFMSP	15.4 15.5	1.14 1.13	More Lights 120s 120FSP More Lights 120s Menthal 120FMSP	11 4 11 8	0.92	True Menthal KFMSP True 100s 100FHP	4.4	043
1	Doral Full Player 100's 100FSP Doral Full Flayer 100's Menthol 100FMSP	147	1.12	More White Lights 120s 120FSP More White Lights 120s Menthol 120FMSP	120	0.93	True 100s 100FSP True 100s Menthal 100FMSP	6 2	0.59 0.58
	Doral Lights KFSP Doral Lights Menthol KFMSP	9.8 9.5	0.80 0.79	Newport KFMHP Newport KFMSP	16.4 17.5	1.30	Vantage KFSP Vantage Menengi KFMSP	8 1	0 57
1	Coral Lights 100's 100FSP Coral Lights 100's Menthal 100FMSP	9.6	0.93 0.80	Newport 100's 100FMHP Newport 100's 100FMSP	19.1 19.1	1 44	Ventage 100s 100FSP Vantage 100s Membrol 100FMSP	7.8	0 62 0 63
	Doral Ulira Lights KFSP Doral Ulira Lights 1005 10055P	5 2 4 8	0.4 8 0.4 6	Newport 10's KFMSP Newport 10's 100's 100FMSP	17.5 16.4	1 42	Vantaĝo Ultra Lights KFSP Vantaĝo Ultra Lights 100s 100FSP	5 3	048
l	English Ovels KNPHP Eve Ultra Lights Slim 100's 100FHP	24 7 5 5	1 65 0.53	Newport 25s KFMSP Newport 25s 100's 100FMSP	17.7 18.8	1 44	Viceray KFMP Viceray KFSP	15 8	1 05
	Eve Ultra Lights Stim 100's Meneral 100FMHP Eve Lights 120's 120FHP Eve Lights 120's Meneral 120FMHP	12.3	0.55 1 02	Newport Lights KFMHP Newport Lights KFMSP	8.5 8.5	0.73 0.72	Viceray Super Long 100's 100FHP Viceray Super Long 100's 100FSP	16.3	1 15
	Eve Ultra Lights Sim 120's Menthol 120FMHP Eve Ultra Lights Sim 120's Menthol 120FMHP	12.4 5.6	1 01 0 54 0 54	Newport Lights 100's 100FMHP Newport Lights 100's 100FMSP	8.0 8.4	0.73 0.76	Viceray Lights KFNP Viceray Lights KFSP		0.50
	Eve UPS Lights SIM 12US Meneral 12UPMHP GPC-Approved KNPSP GPC-Approved KNPSP	5 7 24 8	1 35	Newport Strone Lights 100FHP Newport Strone Lights 100FMHP	10.9 11.2	0.88 0.87	Viceroy Lights 100's 100FHP Viceroy Lights 100's 100FSP	11 5	0 30 3 86
+-	GPC-Approved NFSP TRC-Approved Manthal KFMSP	16.2 17.0 15.7	0.93 1.01	Newport Single Shine Lights 100FMHP New KFHP	9.4	0.75	Virginia Slima (ODFSP) Virginia Slima Manthal (ODFMSP) Virginia Slima Lighta (ODFMP)	14. 6 14. 8	1 06
	PC Approved 100's 100FSP PC Approved 100's Monthol 100FMSP	15.5	0.9 6 0.97 0.92	Now KESP Now Menting KEMSP Now 100s 100FHP	0.9 1.0	0.12 0.13	Yirginia Silma Lights Manthal 100FMHP	8.4	0.67 0.68
	.PC-Approved Lights KFHP GPC-Approved Lights KFSP	100	0.65 0.66	Now 100s 100FFP Now 100s Menthal 100FMSP	1.8 1.9	0.19 0.20	Vvijona Sima Lights 120's 120FHP Vvijona Sima Lights 120's Manthol 120FMHP Vvijona Sima Ulira Lights 100FHP	13 8	1 04
	GPC-Approved Lights Menthol KFMSP GPC-Approved Lights 100's 100FSP	92	0 67 0 77	Old Gold Streights KNFSP Old Gold Filters KFSP	26.9 17.5	1.85	Virginia Sima Ultra Lights Menthol 100FMHP Virginia Sima Supersima 100FHP	5 6	0 50 0 49 0 54
	GPC-Approved Lights Menthol 100's 100FMSP GPC-Approved Ultra Lights KFSP	8 8 5 9	0 72 0 44	Old Gold Filter 100's 100FSP Old Gold Lights KFSP	18.3 7.9	1 43 0 71	Virginia Slime Superminis Menthol 100FMMP Winston KFMP	5.8	0.54 0.55 1.19
	GPC-Approved Ultra Lights 100's 100FSP Harry Davidson KFSIP	5 6 10 2	0 46 0 77	Old Gold Lights 100s 100FSP Pail Mail KNFSP	11 5 25 9	0 93 1 76	Winston KFSP Winston 100's 100FSP	17.2	1 45
-	Harry Davideon Lights KFSP Harbert Tareyton KNFSP	8 I 25 5	0.71 1.67	Pall Mail 100's 100FSP Pall Mail Gold Lights 100's 100FSP	14.9	1 1 8 1 21	Winston Lights KFHP Winston Lights KFSP	9.5	0.71
	Hentage Lights KFSP Hentage Lights 100s 100FSP	105	Q 86 Q 88	Pall Mail Lights (00's 100FSP Pall Mail Red Filters KFSP	9.4 15.4	0.78 1.20	Winston Lights 100's 100FHP Winston Lights 100's 100FSP	90	0.71
					Tohacon Institut				

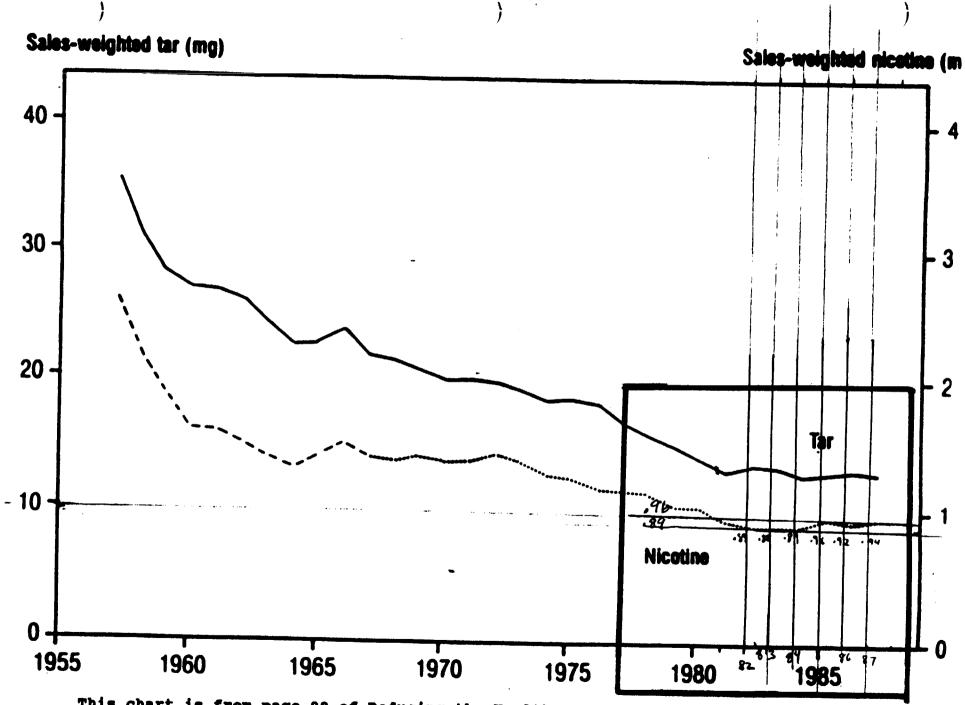
"Tar" and Nicotine Yields of U.S. Cigarettes Sales Weighted Average Basis, 1954-90



This chart was submitted to the Health and the Environment Subcommittee, as part of the March 25, 1994 testimony of Alexander W. Spears, Lorillard Tobacco Company.

1967-1967; U.S. Department of Health and Hamon Barrison, "Radwing the Health Consequences of Baseling: A Playest of the Burgeon General," at 89 (1969); 1964-1969 and 1989-1989 compiled from elimiter data.

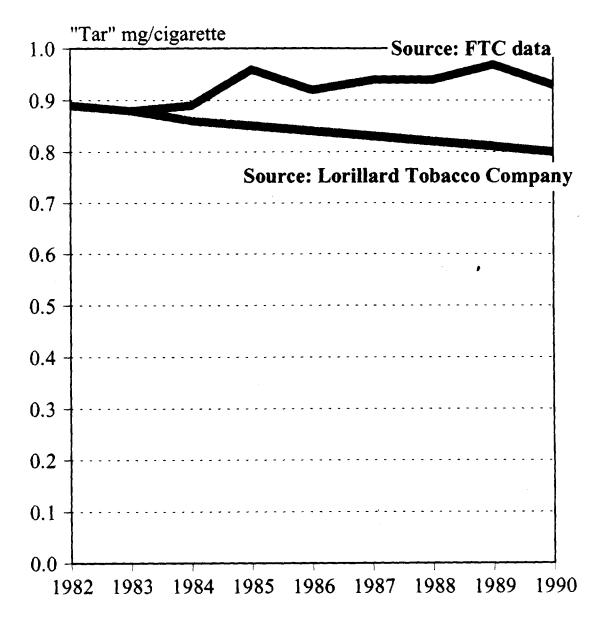
Note that trend since 1982 is down.



This chart is from page 88 of <u>Reducing the Health Consequences of Smoking</u>, Report of the Surgeon General (1989).

Note that the trend since 1982 is slightly up.

Average Nicotine Yields of U.S. Cigarette Sales Weighted Average Basis



^{*} Based on data furnished to the FDA by the FTC

STATEMENT

OF

JOSEPH R. TADDEO, PRESIDENT UNITED STATES TOBACCO COMPANY BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT APRIL 14, 1994

Good morning, Mr. Chairman. I am Joseph Taddeo, President of United States Tobacco Company, a position I have held since 1990.

- U.S. Tobacco is a leading producer and marketer of smokeless tobacco products, including moist snuff. U.S. Tobacco does not manufacture cigarettes.
- U.S. Tobacco's smokeless tobacco brands include Copenhagen, one of America's oldest registered brand names, introduced in 1822 and Skoal, introduced in 1934. Clearly, smokeless tobacco is not a new product.

The use of smokeless tobacco has been a tradition in the United States since the 18th century, predating branded cigarettes by over a hundred years. In fact, smokeless tobacco products dominated the American tobacco market until the early 20th century when cigarettes began to win wide public acceptance. While today smokeless tobacco products are consumed throughout the United States, per capita consumption of smokeless tobacco in the 1990s is less than 25 percent of what it was at the turn of the century.

As for U.S. Tobacco's products specifically, the makeup and manufacturing process for its smokeless tobacco brands is very similar to what it was at the turn of the century, regardless of flavor, cut of the tobacco, form or packaging.

I welcome, Mr. Chairman, this opportunity to set the record straight with regard to the baseless claims made before this Subcommittee on March 25th concerning U.S. Tobacco's marketing practices.

Before turning to those matters, however, I will comment on allegations of manipulation or control of nicotine in tobacco products.

U.S. Tobacco does not in any way manipulate the nicotine levels in its tobacco products. Nor does U.S. Tobacco take any action to control the nicotine content of its tobacco products before, during or after the manufacturing process.

In fact, an incidental effect of U.S. Tobacco's manufacturing process is that the nicotine content of our smokeless tobacco products is less than that which occurs naturally in tobacco.

Other than the tobacco itself, the only material used in the manufacture of U.S. Tobacco's smokeless tobacco products which contains nicotine is denatured alcohol, which is purchased from a supplier as a carrying agent for the application of certain flavorings that do not dissolve in water.

The denatured alcohol used by U.S. Tobacco has been denatured by its manufacturer with small amounts of nicotine. The use of nicotine as a denaturant for alcohol which is to be used in the processing and manufacturing of tobacco products is specifically approved by the Bureau of Alcohol, Tobacco and Firearms.

The amount of nicotine that might be contributed to our smokeless tobacco products through the use of denatured alcohol in the manufacturing process is so minuscule as to be unmeasurable by standard laboratory methodologies.

Mr. Chairman, three serious allegations were made before this Subcommittee on March 25th regarding U.S. Tobacco's marketing practices:

First, the allegation that U.S. Tobacco markets its smokeless tobacco products to persons under the age of 18;

Second, the allegation that U.S. Tobacco has conducted scientific research for the purpose of "creating and maintaining dependence" among smokeless tobacco consumers;

And third, the allegation that U.S. Tobacco's products are developed on the basis of "graduating" levels of nicotine.

As to the allegation that U.S. Tobacco markets its products to persons under the age of 18 - that allegation is false.

U.S. Tobacco strongly believes that those who enjoy its products should be adults. That is why U.S. Tobacco and other smokeless tobacco manufacturers have devoted substantial efforts and resources to discourage the sale of their products to minors.

Those efforts include support of state laws mandating 18 as the minimum purchase age of smokeless tobacco; programs to remind parents, retailers and other adults that smokeless tobacco is an adult custom not intended for youth; and a national campaign in publications such as <u>USA Today</u> and <u>U.S. News and World Report</u> to communicate our "adults only" policy.

I, too, am concerned about reports indicating that some individuals have tried tobacco products, including smokeless tobacco, before they are adults. Research conducted by others indicates that advertising plays little, if any, role in the decision to begin using smokeless tobacco. That research indicates that a variety of factors, including family and friends, appear to influence the decision to begin using various products, including smokeless tobacco.

It is noteworthy that according to a recent Department of Health and Human Services' report, use of smokeless tobacco by males under 18 years of age is low, decreasing and very close to HHS's "target" or goal for the year 2000. The 1992 Healthy People 2000 Review states that the reported use of smokeless tobacco defined as use on at least one occasion in the last 30 days - by 12 to 17 year old males decreased 20% from 6.6% in 1988 to 5.3% in 1991.

Moreover, a survey published in October 1993 by the Substance Abuse and Mental Health Services Administration reported that use of smokeless tobacco by 12 to 17 year old males had further declined in 1992 to 4.8%, which is very close to the 4.0% "target" for the year 2000 in <u>Healthy People 2000 Review</u>.

Even though these trends are encouraging, U.S. Tobacco will continue its efforts to discourage the sale of smokeless tobacco products to minors.

As to the allegation that U.S. Tobacco has conducted scientific research for the purpose of "creating and maintaining dependence" among consumers - that allegation is also false.

The research in question was funded by U.S. Tobacco and other tobacco manufacturers. However, it was neither intended nor used by U.S. Tobacco to develop or manufacture smokeless tobacco products. The research was conducted 15 years ago by a group of independent researchers in the Department of Pharmacology at Pennsylvania State University College of Medicine.

For a number of years, the Pennsylvania State researchers had been interested in measuring extremely low levels of blood nicotine in tobacco consumers, and later became interested in studying the absorption by humans of nicotine from snuff and chewing tobacco. The Pennsylvania State researchers submitted a research proposal for a three-year study to pursue this matter. Several tobacco companies, including U.S. Tobacco, funded this research during the period 1978 to 1981.

The document relied upon to support this allegation relates to the research conducted at Pennsylvania State and was prepared by those researchers. The results of that research are reflected in a 1983 publication by the Pennsylvania State researchers in the journal <u>Pharmacology</u>, and therefore available in the public domain.

This project was part of the smokeless tobacco industry's ongoing funding of research by independent investigators into questions relating to smokeless tobacco and health. Over the years, such funding has totaled more than twenty-five million dollars and has been acknowledged in nearly eight hundred scholarly articles and abstracts in a wide spectrum of scientific publications.

As to the allegation that U.S. Tobacco's products are developed based on "graduating" levels of nicotine - that allegation is false.

As indicated in my written statement, the assertions that U.S. Tobacco manipulates its consumers and dictates which of its smokeless tobacco products those consumers ultimately choose to use are totally false.

The key to our product development process is developing products which appeal to the taste preferences of our consumers. The taste characteristics of our smokeless tobacco products, as with all tobacco products, are inherently complex: a number of factors interacting with each other affect the ultimate taste, including the leaf blend, cut of the tobacco, moisture, pH, flavors and, undoubtedly, nicotine in the tobacco leaf.

U.S. Tobacco's success is based on its unique ability to develop a wide selection of flavored products incorporating blends of tobacco developed over one hundred years ago.

Let me tell you what I would say to anyone who would suggest that U.S. Tobacco employs a so-called "graduation strategy" enticing consumers to begin using low nicotine "starter" smokeless tobacco products and manipulate them - either through advertising or through nicotine dependence - to products with higher levels of nicotine.

I would tell them that our consumers do not conform to any so-called "graduation strategy". The oral tobacco market does not work that way - there is no set pattern of brand switching among smokeless tobacco consumers. Smokeless tobacco consumers remain loyal to a single brand or switch among a variety of brands according to their taste preference, cut of tobacco, form and packaging.

U.S. Tobacco's line of smokeless tobacco is based on the appreciation that we cannot make any part of the public like and use any one of our products if it does not appeal to their taste preferences.

Finally, Mr. Chairman, let me address the general concerns which have been raised about the ingredients added to tobacco products.

The identity of the ingredients in U.S. Tobacco's smokeless tobacco products is proprietary information.

I can assure you, however, that U.S. Tobacco has a procedure in place for the evaluation of all available scientific information regarding the ingredients added to tobacco in the manufacture of our smokeless tobacco products. As a result of these evaluations, U.S. Tobacco believes that no ingredient which it adds to tobacco in the manufacture of its smokeless tobacco products would result in adverse health consequences to a consumer of our products.

Without revealing proprietary information, I can tell you that every ingredient which U.S. Tobacco adds to tobacco in the manufacture of its products is a common food item or approved for use in food, with the single exception of SDA-4, which is approved by BATF for use in the manufacture of tobacco products.

Thank you, Mr. Chairman and may I ask that the Company's written statement, which was submitted to the Subcommittee on April 12th be incorporated in its entirety into the hearing record after my statement today.

Statement of United States Tobacco Company
Before the

House Energy and Commerce Committee

Subcommittee on Health and the Environment

April 14, 1994

United States Tobacco Company welcomes this opportunity to address a number of issues, as they relate to smokeless tobacco products, raised at the March 25, 1994 hearing before this Subcommittee concerning the possible jurisdiction of the Food and Drug Administration over the manufacture of tobacco products, and in Chairman Henry Waxman's March 31, 1994 letter inviting United States Tobacco Company to participate in today's hearing.

Further, United States Tobacco Company will set the record straight with regard to the baseless claims made by Dr. Gregory Connolly on March 25th concerning United States Tobacco Company's marketing practices.

To provide a context for this discussion, this statement will briefly address the history of smokeless tobacco, and the background of United States Tobacco Company, its products, and the process by which they are manufactured.

Smokeless Tobacco

Smokeless tobacco products -- snuff and chewing tobacco -are a variety of consumer products which, unlike cigarettes,
cigars, pipe tobacco or other smoking tobacco, are not
manufactured to be smoked but instead are placed in the mouth and
chewed or passively enjoyed. Consumers choose to use smokeless
tobacco products for a variety of reasons, particularly where
smoking is inconvenient.

Smokeless tobacco was introduced in Europe early in the 16th century by explorers who found the natives in the Western

Hemisphere using tobacco in several ways. Its use quickly grew in popularity throughout Europe and the British Isles. The use of smokeless tobacco has been a tradition in the United States since the 18th century, predating branded cigarettes by over a hundred years. Smokeless tobacco dominated the American tobacco market until the early 20th century when cigarettes and other lighted forms of the leaf began to win wide public acceptance.

Today, smokeless tobacco products are consumed throughout the United States, although per capita consumption of smokeless tobacco in the 1990s is less than 25 percent of what it was at the turn of the century.

United States Tobacco Company

United States Tobacco Company (U.S. Tobacco), founded as the Weyman-Bruton Company in 1911, is a leading producer and marketer of smokeless tobacco products, including moist snuff.

U.S. Tobacco's leading moist snuff brands include
Copenhagen, one of America's oldest registered brand names,
introduced in 1822; Skoal, another fine-cut smokeless tobacco
product introduced in 1934; Skoal Long Cut, consisting of
slightly larger particles of fine-cut tobacco, introduced in
1984; and Skoal Bandits, a portion-pack product developed for
ease of use introduced nationally in 1983.

U.S. Tobacco's Smokeless Tobacco Manufacturing Process

U.S. Tobacco's smokeless tobacco products are made up of a combination of aged tobaccos and flavorings. The tobaccos used in U.S. Tobacco's smokeless tobacco products are a historical blend which includes whole or threshed dark fired, dark air cured and burley tobaccos. The hallmark of U.S. Tobacco's basic manufacturing process is tradition. Thus, for example, the makeup of and manufacturing process for Copenhagen brand smokeless tobacco today is very similar to what it was in 1906, the earliest date for which records are available.

The process by which U.S. Tobacco's smokeless tobacco products are manufactured is illustrative. The process begins at U.S. Tobacco's facility with the arrival of the tobacco from farmers. It is then processed for aging in large containers known as hogsheads. After aging, the tobacco is removed from the hogshead and put into bulking bins where it is blended. Blended tobacco from the bulking bins is then cut to the final particle size. Once cut, the tobacco is then dried and sifted.

As the process continues, water and other ingredients are added. The product next goes into stainless steel cure bins where it is subjected to curing and mixing.

Once cured, the tobacco is sifted. Flavoring and other ingredients are added during the process. The product is then brought into the packing room where it is packed, labeled and wrapped. Finished rolls are packed into cartons for shipment.

Over the years, this process has remained substantially the same. Of course, as technology progressed with the times, the machinery used to perform the functions described has become more automated.

Throughout the entire manufacturing process, the product and process are carefully monitored to ensure adherence to U.S. Tobacco's high standards of manufacturing practices and product quality.

General Claims Regarding Addiction and Nicotine Manipulation

At the March 25th hearing, Dr. David Kessler and others charged that tobacco products are highly addictive, and that tobacco manufacturers may intentionally manipulate or control the amount of nicotine in their products for the purpose of creating and maintaining dependence on tobacco products among their consumers.

The Addiction Claim

The assertion that smokeless tobacco use can be addictive is without merit. In this day and age, people claim to be addicted to a wide variety of things — to work, to sweets, to video games — when in fact they are describing settled practices or habits. The fact of the matter is that tobacco use, like many other routinely repeated activities in life, involves a wide array of diverse psychological and physical factors that elude scientific explanation. When confronted with such a lack of understanding,

some have resorted to the charge that tobacco use is "addictive". Such charges ignore the scientific facts, including the fact that more than 50 million Americans have given up tobacco, including 8 million who have given up smokeless tobacco. While the use of smokeless tobacco may become a settled practice or habit, it is not addictive.

U.S. Tobacco is, of course, aware that the 1988 Surgeon General's Report on nicotine claims that tobacco is "addicting" and that "nicotine is the drug in tobacco that causes addiction."

Professor David M. Warburton, a British researcher who prepared a portion of the 1988 Surgeon General's Report, has published a critique of that Report. It is Professor Warburton's judgment that the Report's conclusions are "political pronouncements" rather than experimentally verified scientific claims.

Furthermore, Professor Warburton believes that the Surgeon General's "misleading comparisons" of tobacco and drugs may

¹Warburton, D.M., "Is Nicotine Use an Addiction?", <u>The Psychologist</u>, 4, 166-170, April 1989.

unintentionally encourage teenagers to experiment with heroin and cocaine:

"The problem is that putting tobacco, a legal product, in the same category with heroin and cocaine trivialises the illicit drug problem. Thus, statements that equate [tobacco use] with heroin use and cocaine use could promote hard drug experimentation with all its risks. Teenagers see the normality of friends and relatives who [use tobacco] and think that, if heroin and cocaine use are only like [tobacco], then there is no harm in trying these drugs. Nothing could be further from the truth. Heroin use in our society leads to gross physical, social and moral deterioration in the frequent user. Misleading comparisons of [tobacco] with other substances may unintentionally encourage hard drug use and its horrifying evils."

The concept of "addiction" cannot and should not be applied to a consumer product such as smokeless tobacco which has been widely used and accepted worldwide for hundreds of years.

The Nicotine Manipulation Claim

- U.S. Tobacco offers smokeless tobacco products suited to the taste of those consumers who choose to make tobacco a part of their lifestyle. U.S. Tobacco actively competes against more than 600 brands of other tobacco products and the variety of its products reflect the wide range of consumer preferences in flavor, cut of the tobacco, form and packaging.
- U.S. Tobacco does not in any way manipulate or "spike" the nicotine levels in its tobacco products. Nor does U.S. Tobacco take any action to control the nicotine content of its tobacco products before, during or after the manufacturing process. In fact, an incidental effect of U.S. Tobacco's manufacturing process is that the nicotine content of U.S. Tobacco's smokeless tobacco products is less than that which occurs naturally in tobacco.

The only material used in the manufacture of U.S. Tobacco's smokeless tobacco products, other than the tobacco itself, which contains nicotine, is denatured alcohol which is purchased from a supplier as a carrying agent for the application of certain flavorings that do not dissolve in water. The denatured alcohol (SDA-4) used by U.S. Tobacco has been denatured by its

manufacturer with small amounts of nicotine. The use of nicotine as a denaturant for alcohol which is to be used in the processing and manufacturing of tobacco products is specifically approved by the Bureau of Alcohol, Tobacco and Firearms (see 27 CFR 21.38). The amount of nicotine that might be contributed to a U.S. Tobacco smokeless tobacco product through the use of denatured alcohol in the manufacturing process is so minuscule as to be unmeasurable by standard laboratory methodologies.

Claims Regarding U.S. Tobacco

At the hearing held by this Subcommittee on March 25, 1994, Dr. Connolly made a series of claims regarding U.S. Tobacco that may be summarized as follows:

- 1. Allegation that U.S. Tobacco has conducted proprietary "in-house" scientific research on the pharmacological properties of nicotine, and has used that knowledge to create and maintain dependence on its smokeless tobacco products among consumers;
- Allegation that U.S. Tobacco developed Skoal
 Bandits to target cigarette smokers aged 15 to 35 years of age; and

3. Allegation that U.S. Tobacco employs a "graduation strategy" with the intent of moving new users from low nicotine brands up to higher nicotine brands as dependence occurs, and intentionally adjusts the nicotine dose in each brand to cause and maintain dependence.

Dr. Connolly's Agenda

Before addressing the substance of these allegations, it is important to understand the demonstrable bias of the individual who is making them. Although Dr. Connolly stated on March 25th that he was appearing on behalf of the American Public Health Association, his public statements on matters relating to U.S. Tobacco and the smokeless tobacco industry are not those of an objective public health official. Rather, they depict a vindictive individual whose personal crusade against U.S. Tobacco and the smokeless tobacco industry extends far beyond any responsible public health stand.

Two examples of Dr. Connolly's personal agenda will suffice. He was quoted in a 1986 <u>Business Week</u> article as stating, "I'm going to kill [U.S. Tobacco]." Dr. Connolly recently admitted the accuracy of this statement before the House Ways and Means Committee. And in 1985 Dr. Connolly was quoted as having the

self-proclaimed goal of "crippling the smokeless tobacco industry nationwide."

It should also be noted that the claims which Dr. Connolly made on March 25, 1994 were first put forth during the 1986 trial of a product liability lawsuit, <u>Marsee v. U.S. Tobacco</u>, in which Dr. Connolly attempted to testify on behalf of the plaintiff.

In the <u>Marsee</u> case, an Oklahoma jury rendered a unanimous verdict in favor of U.S. Tobacco, indicating that the jury did not believe U.S. Tobacco was responsible for a 19-year old's tongue cancer and subsequent death. The jury announced its verdict after approximately six hours of deliberation following a five-week trial during which the plaintiff called thirty-one witnesses and introduced 140 exhibits. The suit was brought by the mother of Sean Marsee after his death. She claimed his cancer was caused by his use of snuff and sought approximately \$147 million in damages, including punitive damages. The Tenth Circuit Court of Appeals in Denver, Colorado upheld the jury verdict in favor of U.S. Tobacco.

The Nicotine Research Allegations by Dr. Connolly

In support of his assertion that U.S. Tobacco "has conducted research on the pharmacological properties of nicotine

and has knowledge of its dependence producing properties," Dr. Connolly points to a single document which was made available by U.S. Tobacco to plaintiff's counsel prior to the Marsee trial. That document is entitled "Pharmacokinetics of Nicotine and its Major Metabolites in Naive and Habituated Snuff Takers." Dr. Connolly further asserts that "there is only one reason that this type of research would be conducted and that is to understand how the drug nicotine delivered from oral snuff effects the structure and function of the human user as compared to cigarette smokers and in turn assist [U.S. Tobacco] in creating and maintaining dependence on their products among consumers."

Dr. Connolly misstates the facts both as to who conducted the research, and the purpose for which it was conducted. Both Dr. Connolly's assertion that this research was conducted by U.S. Tobacco and his assertion that its purpose was to "assist [U.S. Tobacco] in creating and maintaining dependence on their products among consumers", are false.

The research in question was not conducted by U.S. Tobacco, and was neither intended nor used by U.S. Tobacco to develop or manufacture smokeless tobacco products. The research was conducted 15 years ago by a group of independent researchers in the Department of Pharmacology at Pennsylvania State University College of Medicine. For a number of years, the Pennsylvania

State researchers had been interested in measuring extremely low levels of blood nicotine in tobacco users, and later became interested in studying the absorption by humans of nicotine from snuff and chewing tobacco. The Pennsylvania State researchers submitted a research proposal for a three-year study to pursue this matter. Several tobacco companies, including U.S. Tobacco, funded this research during the period 1978 to 1981. The document relied upon by Dr. Connolly relates to the research conducted at Pennsylvania State and was prepared by those researchers. The results of that research are reflected in a 1983 publication by the Pennsylvania State researchers in the journal Pharmacology.

This project was part of the smokeless tobacco industry's ongoing funding of research by independent investigators into questions relating to smokeless tobacco and health which over the years has totaled more than twenty-five million dollars and has been acknowledged in nearly eight hundred scholarly articles and abstracts in a wide spectrum of scientific publications.

The Youth Allegations By Dr. Connolly

Again relying on allegations made in the <u>Marsee</u> case,
Dr. Connolly asserts that U.S. Tobacco's Skoal Bandit product was
targeted at "new users, mainly cigarette smokers, age 15-35."
That allegation is also false. The document relied upon by

Dr. Connolly to support his assertion was written over 20 years ago, does not mention Skoal Bandits, was not created by U.S. Tobacco and does not reflect U.S. Tobacco policy.

U.S. Tobacco strongly believes that those who enjoy its products should be adults. That is why U.S. Tobacco and other smokeless tobacco manufacturers have devoted substantial efforts and resources to discourage the sale of their products to minors. Those efforts include support of state laws mandating 18 as the minimum age for purchase of smokeless tobacco; programs to remind parents, retailers and other adults that smokeless tobacco is an adult custom not intended for youth; and a national campaign in publications such as <u>USA Today</u> and <u>U.S.News and World Report</u> to communicate our "adults only" policy.

In this regard, it is noteworthy that according to a recent HHS report, use of smokeless tobacco by males under 18 years of age is low, decreasing and very close to HHS's "target" or goal for the year 2000. The 1992 <u>Healthy People 2000 Review²</u> states

²The 1992 <u>Healthy People 2000 Review</u> was compiled by the National Center for Health Statistics (Centers for Disease Control and Prevention) and submitted by HHS Secretary Shalala to the President and Congress in compliance with the Health Services and Centers Amendments of 1978.

that the reported use of smokeless tobacco (defined as use on at least one occasion in the last 30 days) by 12-17 year old males decreased from 6.6% in 1988 to 5.3% in 1991.

Moreover, a survey published in October 1993 by the Substance Abuse and Mental Health Services Administration (SAMSHA)³ reported that use of smokeless tobacco by 12-17 year old males had further declined in 1992 to 4.8%, which is very close to the 4.0% "target" for the year 2000 in Healthy People 2000 Review.

Furthermore, the reported use of smokeless tobacco by the total 12-17 year old population (males and females) was only 2.6% in 1992 according to the SAMHSA survey.

Allegations Regarding A "Graduation Strategy"

Dr. Connolly has alleged that U.S. Tobacco "employs a 'graduation' strategy with the intent of moving new users from the low nicotine brands up to higher nicotine brands as dependence occurs." And Dr. Kessler has asserted that "there is evidence that smokeless tobacco products with lower amounts of nicotine are marketed as 'starter' products for new users, and

³National Household Survey on Drug Abuse: Population Estimates 1992 DHHS Pub. No. (SMA) 93-2053, Oct. 1993, p. 97.

that advertising is used to encourage users to 'graduate' to products with higher levels of nicotine."

The assertions of Drs. Connolly and Kessler suggest that U.S. Tobacco manipulates its consumers and dictates which of its smokeless tobacco products those consumers ultimately choose to use. Those assertions are totally false. U.S. Tobacco does not employ any marketing strategy based upon a theory that consumers can be enticed to begin using low-nicotine "starter" smokeless tobacco products, and subsequently caused to "graduate" through advertising (according to Dr. Kessler) or through nicotine dependence (according to Dr. Connolly) to products with higher levels of nicotine.

This fanciful concept was created by plaintiff's counsel in the 1986 Marsee litigation in an unsuccessful attempt to sway the jury against U.S. Tobacco. This fiction has been perpetuated by Dr. Connolly.

Furthermore, the inflammatory allegations of Drs. Connolly and Kessler regarding a so-called "graduation strategy" are not supported by the facts. Smokeless tobacco products, like all tobacco products, vary in nicotine content. Any suggestion that U.S. Tobacco's line of products is developed based on "graduating" levels of nicotine is not true.

Moreover, there is no set pattern of brand switching among smokeless tobacco consumers. In short, smokeless tobacco consumers remain loyal to a single brand or switch among a variety of brands according to their preference for flavor, cut of tobacco, form and packaging. They do not conform to any so-called "graduation strategy".

U.S. Tobacco offers smokeless tobacco products suited to the tastes of those consumers who choose to make tobacco a part of their lifestyle. The variety of different U.S. Tobacco products reflects the wide range of consumer preferences in flavor, cut of the tobacco, form and packaging.

Conclusion

U.S. Tobacco does not in any way manipulate the hicotine levels in its smokeless tobacco products, nor does it control the nicotine content of its tobacco products before, during or after the manufacturing process.

Furthermore, U.S. Tobacco does not employ any marketing strategy based upon a theory that consumers can be enticed to begin using low-nicotine "starter" smokeless tobacco products, and subsequently caused to "graduate" to products with higher levels of nicotine.

Statement of Edward A. Horrigan, Jr. Chairman and Chief Executive Officer Liggett Group Inc.

before the

House Energy and Commerce Committee Subcommittee on Health and the Environment

April 14, 1994

My name is Edward A. Horrigan, Jr. I am the Chairman and Chief Executive Officer of Liggett Group Inc. With me today is Gregory A. Sulin, Liggett's Vice President of Operations.

I am pleased to have this opportunity to address the Subcommittee on the matters that were discussed during the Subcommittee's earlier hearing on March 25.

At the outset, I would like to make it clear that Liggett does not increase the nicotine level of our cigarettes beyond the level of nicotine found naturally in the unprocessed tobacco that we use to make our cigarettes. Secondly, Liggett does not manipulate the level of nicotine in our cigarettes to "hook" or "addict" smokers. Third, Liggett does not use any of the patented technology that was referred to by Dr. David Keasler, in his testimony before this committee on March 25, 1994. Finally, I want to emphasize that we at Liggett are proud of the quality of the cigarettes that we produce for our customers. We are proud of the people who grow the tobacco that goes in our cigarettes and who help us make and distribute our cigarettes around the country.

With regard to the manufacture of cigarettes, I would like to emphasize that the manufacturing process results in a reduction in the amount of nicotine in cigarettes when compared to the nicotine in the unprocessed tobacco. Secondly, the essential components of cigarette manufacturing, and specifically the use of reconstituted tobacco, has been publicly documented for decades. None of it is new. Reconstituted tobacco is used to reduce waste and to achieve the most efficient use of the natural tobacco purchased for our cigarettes. Tobacco is the most expensive component of the cigarette and any loss of that tobacco would make the production of cigarettes more costly.

In brief, the reconstitution process involves the addition of water to the tobacco to separate water-soluble substances, including some nicotine, from the tobacco. The remaining tobacco cellulose can then be formed into sheets. Water-soluble substances originally removed from the tobacco are then once again returned to the tobacco sheet. No nicotine not

found naturally in the tobacco is added in the production of the reconstituted tobacco. It is also significant that the reconstituted tobacco contains less nicotine than the raw tobacco from which it was made, because a certain amount of the natural nicotine is inevitably lost in the process.

Denatured alcohol and tobacco flavorants are the only other sources of nicotine in our cigarettes. Nicotine occurs naturally in the water-soluble extracts of tobacco used in minuscule amounts as flavorants. The use of tobacco flavorants has been a matter of public record for decades. The Specially Denatured Alcohol No. 4 (SDA-4), used as a carrier for flavorants, is the only denatured alcohol that has been approved by the Bureau of Alcohol, Tobacco and Firearms for use in the cigarette manufacturing process. The BATF requires that the alcohol be denatured by the addition of a minuscule amount of nicotine to make it undrinkable; and it is denatured in accordance with the prescribed formula outlined in the BATF regulations. The amount of nicotine contributed to tobacco smoke by way of tobacco flavorants and denatured alcohol is so minuscule that it cannot be measured in tobacco smoke using the FTC standard test method. Moreover, as I noted, the nicotine content of cigarettes manufactured by Liggett is lower than the nicotine in the unprocessed tobacco that we use to make our cigarettes.

Thus, Liggett does not "manipulate" or "spike" the amount of nicotine during the manufacture of its cigarettes to achieve an alleged "addicting level" of nicotine. Specifically, Liggett does not (and has not) used any of the patented processes described in the patents referred to in Dr. Ressler's earlier testimony before this committee. Liggett does not believe there is any such thing as an "addicting level" of nicotine in cigarettes or that cigarettes are addictive like heroin or cocaine, as has been alleged. To equate cigarette smoking with actual hard drug addiction ignores the significant differences between them. It also blinks at reality. There are over 40 million Americans who have quit smoking. More than half of all adult smokers have quit; over 90% of them quit without the aid of nicotine substitutes or any other cessation aid. It is thus apparent that irrespective of the nicotine in cigarettes, consumers can and do choose to quit.

Consumers also express their personal preferences by choosing from a wide variety of cigarette brands and styles on the market that have different "tar" and nicotine yields. To meet the demands of the marketplace, Liggett produces a variety of cigarette brands with a variety of "tar" and nicotine yields. For more than 20 years, cigarette advertising has carried the nicotine yield of each cigarette brand and style as measured in accordance with FTC standard test methods. Over the years, consumers have expressed a growing preference for cigarettes with lower "tar" and nicotine yields. This

has resulted, on an industry-wide basis, in more than a 50% reduction in average nicotine yields over the past 40 years.

In conclusion, let me add that nicotine is just one of the naturally-occurring substances in tobacco, which is obviously an intrinsic characteristic of cigarettes. Liggett does not design or manufacture its cigarettes with the intent to manipulate or spike the amount of nicotine in cigarettes. There is no secret about the nicotine yields of Liggett's cigarettes, which I reiterate, have been publicly disclosed for years.

Thank you for this opportunity to set the record straight and I thank you for your attention.



Statement of Thomas E. Sandefur, Jr. Chairman and Chief Executive Officer Brown & Williamson Tobacco Corporation

before the

Subcommittee on Health and the Environment House Energy and Commerce Committee

April 14, 1994

Mr. Chairman and members of the Subcommittee, I appear today on behalf of Brown & Williamson Tobacco Corporation in response to the Chairman's letter of March 31, 1994, to address questions concerning nicotine in cigarettes that have been raised in recent weeks by FDA Commissioner David A. Kessler and others. This statement supplements the statement submitted by Brown & Williamson in connection with the Subcommittee's hearing on March 25, which is part of the record of that hearing.

Addiction

The premise of the questions raised by Commissioner Kessler is that nicotine is "addictive." The term "addiction" has been used to describe everything from an enslavement to hard drugs to an inability to lose weight or watch less television, and Surgeon General Koop himself proclaimed in 1982 that children were "addicted" to video games. In view of the radical differences between tobacco and hard drugs in their effects on behavior and the symptoms associated with quitting, and in view of the fact that more than half of all Americans alive who have ever smoked have quit — over 90 percent without professional help — equating cigarettes and hard drugs is nothing more than rhetoric.

Control

Initially, in his letter of February 25, 1994, Dr. Kessler suggested that cigarette manufacturers "commonly add nicotine to cigarettes to deliver specific amounts of nicotine." Brown & Williamson has never done that, as we demonstrated in our submission to this Subcommittee in connection with its March 25 hearing. Dr. Kessler mentioned a number of patents in his testimony on March 25, including some that have been secured by Brown & Williamson. I can state categorically that Brown & Williamson does not utilize, and has never utilized, any of these patents to control the amount of nicotine in cigarettes. As Brown & Williamson explained, moreover, "the nicotine content of B&W cigarettes is lower than the nicotine content of the tobacco used to produce them." According to the New England Journal of Medicine, the average nicotine delivery dropped from 2 milligrams to 0.9 milligrams between 1955 and 1987.

After the submissions by Brown & Williamson and the other manufacturers, Dr. Kessler, in his testimony on March 25, retreated to the suggestion that the cigarette manufacturers' failure to use the technology supposedly at their disposal to eliminate nicotine from cigarettes suggests that they may intend it to satisfy an addiction. This, too, is incorrect.

Without nicotine, you don't have tobacco. Without nicotine, cigarettes simply would not taste like cigarettes. The experience of another manufacturer indicates that consumers will not accept a cigarette without nicotine. Calls for legislation to eliminate nicotine amount to a call to ban cigarettes — not because the substance that allegedly satisfies an "addiction" would be removed, but because the resulting product would taste nothing like a cigarette. We offer a range of products with a range of nicotine deliveries and the consumer makes the choice.

FTC Ratings

We also vigorously dispute the suggestion of Dr. Kessler and Dr. Slade that the "tar" and nicotine ratings produced using the FTC test method are meaningless or misleading. The cigarette manufacturers have never suggested that these ratings reflect the precise amount of "tar" and nicotine that each individual smoker actually receives. But we do believe that smokers can expect to receive lower amounts of those constituents from lower-rated brands than from higher-rated brands, and that the FTC test method therefore reliably ranks cigarettes in terms of "tar" and nicotine deliveries. EPA's mileage figures may not reflect the actual experience of individual drivers, but EPA is correct that a Cadillac delivers fewer miles per gallon than a Honda.

Conclusion

Hopefully our testimony today will help to clear up some of the misconceptions that currently exist about nicotine in cigarettes.

On April 5, Dr. Kessler wrote me a letter asking to arrange a meeting between FDA representatives and members of our research, scientific, technical, and production staffs to review relevant information. I have responded to Dr. Kessler's request and anticipate that such a meeting will take place shortly.

Statement of Donald S. Johnston
President and Chief Executive Officer
The American Tobacco Company

before the

House Energy and Commerce Committee Subcommittee on Health and the Environment

April 14, 1994

Mr. Chairman and distinguished members of the Subcommittee, my name is Donald S. Johnston, and I am the President and Chief Executive Officer of The American Tobacco Company. With me today is Robert S. Sprinkle, Executive Vice President-Research and Quality Assurance. Thank you for giving me this opportunity to appear and, by my testimony, to address issues which have been raised before this Subcommittee.

Aside from tobacco itself and federally authorized use of alcohol denatured with minute amounts of nicotine, The American Tobacco Company does not use nicotine in the manufacture of its cigarettes. Contrary to the implications that have been aired before this Subcommittee and elsewhere, The American Tobacco Company does not spike its cigarettes with nicotine and does not use any of the patents that have been placed before this Subcommittee or any other like processes or devices.

The only source of nicotine other than that naturally occurring in tobacco is introduced from Specially Denatured Alcohol No. 4 used as a solvent for flavorings.

SDA No. 4 is authorized for tobacco use in accordance with 27 Code of Federal Regulations, Alcohol, Tobacco Products and Fire Arms, revised as of April 1, 1993, Section 21.118 and 21.38 and is denatured by the alcohol manufacturer in accordance with the prescribed formula outlined in the regulations. The quantity of nicotine indirectly added to tobacco from use of SDA No. 4 is on the order of 3 parts per million ("ppm") to 5 ppm, or 0.0003% to 0.0005% by weight, and is infinitesimal in comparison to naturally-occurring nicotine of tobacco blends that generally contain 2% to 2.5% by weight.

Further, The American Tobacco Company manufactures reconstituted tobacco by the Fourdrinier paper making process that involves separation of water-soluble components from tobacco, formation of a tobacco cellulosic sheet and reapplication of the water-soluble components to the sheet in a continuous process. American does not add nicotine to this process. The end product is tobacco material that contains only the quantity of water-soluble components including nicotine originally removed from the tobacco. In practice, the nicotine content of the finished reconstituted

tobacco material is approximately 4% less (owing to processing losses) than the nicotine content of the natural tobacco utilized in the reconstitution process.

The American Tobacco Company uses various types of natural tobaccos including reconstituted tobacco in the manufacture of its cigarettes. The percentages of natural tobacco types and reconstituted tobacco vary by cigarette brand; however, after processing of tobacco for cigarette manufacture, the nicotine content is on the order of 5% less than that of the various tobaccos entering the process.

Further, The American Tobacco Company has been issued two patents (U.S. Patents No. 3,428,049 and No. 4,505,282) which reference the addition of materials which could include tobacco extract and/or nicotine to cigarette filters and an innerliner wrap for a tobacco smoking article. As with any patent, the language is purposely broad in scope with an objective of covering a wide variety of conceptional applications which may or may not be reduced to practice. While The American Tobacco Company has been issued such patents, addition of tobacco extract and/or nicotine to cigarette filters and wrapper have never been employed in a commercial cigarette product by American.

In summary, nicotine involved in the federallyregulated and authorized use of SDA No. 4 denatured alcohol is negligible, and nothing is done in the tobacco processing or manufacture of cigarettes or filters by The American Tobacco Company to increase nicotine beyond that naturally occurring in tobacco.

I would now like to address questions that have been raised with respect to the intent of the design of our cigarettes in relation to nicotine. In 1966, the Federal Trade Commission amended its Cigarette Advertising Guides to encourage cigarette manufacturers to publish "the tar and nicotine content (expressed in milligrams) of the mainstream smoke from a cigarette" declaring that to be "information concerning cigarettes which may be material and desired by the consuming public." Time has proven the FTC to have been right, in that consumers have shown an interest in, and differing preferences for, different levels of "tar" and nicotine. Moreover, since 1971, American has been governed by, and has adhered to, an FTC Consent Order requiring American to publish in its advertisements for "low tar" cigarettes "tar" and nicotine data as determined "by the testing method employed by the Federal Trade Commission in its testing of the smoke of domestic cigarettes." Through tobacco blends, filtration, and ventilation, American has, on a sales weighted average, reduced "tar" and consequently nicotine levels (as determined by FTC method).

and nicotine data for each of American's products are published. American carefully monitors its finished cigarettes and published data to assure that "tar" and nicotine figures are accurate. Thus, American manufactures and sells cigarettes with different "tar" and nicotine content in response to consumer demand for different types of cigarettes, and provides correct information to consumers about those amounts. American has no desire or intent to "manipulate" nicotine. At no time has The American Tobacco Company attempted to market a cigarette based upon nicotine content, or more generally, has it ever designed or marketed a cigarette with the purpose or intent of selling "nicotine." Rather, American has always considered that it sells cigarettes, and that nicotine is one of several intrinsic properties characteristic of tobacco itself.

Thank you for your attention.

Johnston cited six examples of what he considers back-door prohibition:

- Raising taxes to force smokers to quit.
- Banning smoking in all public places indoors and outdoors, including parks, workplaces and outdoor stadiums — to further stigmatize smokers.
- Banning advertising so that new or better products can't be effectively introduced.
- Forcing manufacturers to produce products that smokers find unsatisfying or unacceptable.
- Attacking every attempt by the industry to respond to public and smoker concerns.
- Advocating that the FDA regulate cigarettes as a drug, which would effectively ban cigarettes from the market.

Johnston opened his testimony by denying claims that Reynolds Tobacco "spikes" cigarettes with nicotine. The points he emphasized were:

- Reynolds does not "spike" its products with nicotine -- in fact, the manufacturing process results in a loss of nicotine.
- The company does not add or otherwise manipulate nicotine to "addict" smokers.
- Finally, there is no justification for the FDA to regulate cigarettes as a drug.

If the tobacco industry stopped using current cigarette manufacturing techniques, Johnston explained, "tar" and nicotine levels would return to 1940 levels of 40 milligrams of "tar" and 2.8 milligrams of nicotine for the average cigarette — more than three times the current average for these substances.

Johnston also denied claims that nicotine is addictive, adding that under FDA Chairman Dr. David Kessler's definition, "most coffee, cola and tea drinkers" would have to be classified as "caffeine addicts.... no one should try to use the back door and force prohibition by saying that cigarettes are a drug because they contain tobacco, which contains nicotine," he noted.

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