

APPENDIX I

Glossary

The following is a listing and definition of many of the technical terms used most frequently in this Opinion. It would be impossible to include them all. Many of the terms identify extremely complex scientific phenomena which require many pages, if not books, to explain adequately. The definitions provided are intended to serve as a concise, useful, short-hand reference for the reader as she wades through a mass of what may well be unfamiliar, dense, and admittedly dry material.

Bias: Procedures or data which would affect the accuracy of the findings of an epidemiologic study. In epidemiologic research, there are three different kinds of bias: information bias, selection bias, and confounding.

Bioavailability: The amount and rate of entrance of a drug into the circulatory system.

Biomarkers: Compounds or other indicators can be measured in a body fluid, a tissue, and air breathed by people, that demonstrate exposure to a possible source of disease.

Brand Equity: The value built up in a brand, made up of a combination of 5 elements: product, packaging, positioning, promotion and price.

Cancer: Development of a tumor or mass of cells that have uncontrolled, unrestrained growth.

Carcinogen: An agent that causes cancer.

Case Control Studies: A backward-looking observational epidemiological study which examines people who have a disease and people who don't and determines who was exposed to a source of the disease and to what degree.

Cohort Studies: A forward-looking observational epidemiological study which examines people exposed and not exposed to substances for comparison and follows them over time to analyze the development of a disease.

Compensation: Smokers increase puff volume, puff frequency, and number of cigarettes smoked to compensate for the reduced yield of nicotine in low yield cigarettes.

Confidence Interval: The width around a statistic which describes where scientists think the "truth" lies. Typically, a 95 percent confidence interval is used, which means, for example, "we think with 95 % certainty, that the true increase in risk is in this interval."

Confounding: Bias that arises when the effect of one factor is mixed up with the effect of the factor being studied.

COPD: Chronic obstructive pulmonary disease, the irreversible damage of the lung that results in shortness of breath. Often, in the past, it has been referred to as "emphysema."

Cotinine: An alkaloid that is the principal metabolite of nicotine and is widely used as an indicator of recent exposure to nicotine.

Countertop Display: A free-standing display with a minimum height of 30 inches and a minimum width of 18 inches that is placed on the counter at retail shops within the line-of-sight of any customer who is standing in line for the register.

CPS-I: Cancer Prevention Study I, a study carried out by the American Cancer Society from 1960 to 1972 which followed over one million smokers, former smokers, and never smokers for twelve years.

CPS-II: Cancer Prevention Study II, a study begun by the American Cancer Society in 1982, which continues to follow and monitor one million smokers, former smokers, and never smokers.

Cross-Sectional Studies: An observational epidemiological study which looks at a population at one particular moment in time and records information about the disease of interest and other relevant factors or personal characteristics.

Direct Mail Marketing Database: A database within which Defendants maintain information about individuals to whom they have sent mail in the past or intend to send mail in the future. The information maintained includes, for example, name, age, mailings sent and dates of mailings, demographic information, smoking preference, and whether the individual has provided any proof of age, such as a signature or government issued identification. Any records of any individuals who are currently alive and are 21 years of age or older to whom Defendants have sent mail at any point in time shall be deemed to be included in this definition, even if Defendants have since moved those records to a second database, to an archive, or have in some other way designated them as not to receive additional mail.

Disaggregated Marketing Data: Data that has been broken down by type of marketing (including sales data), brand, geographical region (to the smallest level of geographic specificity maintained by each Defendant), type of promotion or marketing used, number of cigarettes sold, advertising in stores and any other category of data collected and/or maintained by or on behalf of each Defendant. This breakdown of marketing data is required by the FTC but kept confidential. The FTC only publishes only the aggregated data.

Dose-response relationship: The relationship between the amount of exposure and the degree of response.

Epidemiology: The science of conducting studies of health and disease in the population, describing how much disease there is, and identifying the causes of disease.

ETS: Environmental tobacco smoke, the combination of the sidestream smoke that is released from the cigarette's burning end and the mainstream smoke exhaled by the active smoker.

Free Nicotine: Free or unprotonated nicotine does not have a proton or positive chemical charge. It has an effect on sensory nerves, which contributes to the impact or strength of the cigarette. Free nicotine is absorbed more quickly than protonated nicotine across mucous membranes. Free nicotine transports across cells more rapidly. See also “unprotonated nicotine.”

FUBYAS: First user brand young adult smokers.

Full Flavor: An industry term used to indicate that the cigarette is not low tar. The FTC characterized the 15 mg. FTC tar divide as “the FTC’s official definition of low tar cigarettes” to distinguish full flavor from “light” cigarettes.

Header Display: The banner that is displayed by a retailer at the top of a cigarette display case, which may show a cigarette brand name, cigarette brand imagery, prices for cigarettes, or promotional offers to consumers.

Impact: Refers to the immediate sensory effect that the delivery of nicotine has on a smoker. This sensory response occurs through nicotine’s stimulation of the afferent nerves in the back of the throat when cigarette smoke is first inhaled, causing a peripheral nerve effect that is recognized by the brain. The impact of a cigarette is a characteristic distinct from taste.

Information bias: Bias created because the information obtained in the study may have some error, which leads to incorrect classification on exposure or outcome, referred to as misclassification.

Line Extension: Extension of an already existing product line into a new type of market (e.g., developing a “light” version of an existing full flavor cigarette).

Longitudinal Studies: A study in which the response for each experimental unit in the study is observed over time on two or more occasions. The defining feature of a longitudinal data set is repeated observations on experimental units.

Mainstream Smoke: Smoke exhaled by an active smoker.

Meta Analysis: A statistical approach which combines data from many different studies.

Metabolite: Products of metabolism.

Mutagenic: A term used to describe a substance that -- under some conditions in some systems -- can produce a change or mutation in DNA.

Nicotine Transfer Efficiency: The measurement of the amount of nicotine transferred from the original unsmoked tobacco rod to the cigarette smoke (where it is available for inhalation).

Observational Studies: Epidemiological studies which simply observe and report on natural occurrences in a population.

Package Onsert: A communication affixed to but separate from an individual cigarette pack and/or carton purchased at retail by consumers, such as a miniature brochure included beneath the outer cellophane wrapping or glued to the outside of the cigarette packaging.

Price Promotion: Marketing activity that directly or indirectly lowers the price of cigarettes to a customer or provides added value. Price promotion includes: retail value added (defined by the Federal Trade Commission (FTC) as “[a]ll expenditures and costs associated with the value added to the purchase of cigarettes, including buy one get one free and buy one get x (promotional item) free; promotional allowances (defined by the FTC as “promotional allowances paid to retailers and any other persons (other than full-time employees of the cigarette manufacturers) in order to facilitate the sale of any cigarette, excluding expenditures in connection with newspapers, magazines, outdoor, audio-visual, transit, and direct mail”); coupons (such as “cents off” type coupons that can apply to single pack, multi-pack, or carton purchases distributed in a variety of ways, including at the point of sale, in newspaper and magazine advertisements, via direct mail, at sponsored events, in product packaging, and on the Internet); sampling (distribution of free cigarettes to the public, including at events sponsored by cigarette companies, bar and club promotions, and other venues); and specialty item distribution (programs that provide gifts that reward brand loyalty).

Protonated: One of the two primary states of nicotine delivered in mainstream smoke, also referred to as “bound.” This form of nicotine is more stable and has a slower rate of absorption over certain biological membranes.

Pyrolysis: Decomposition or transformation of a chemical compound caused by heat.

Randomized Clinical Trials: An experimental epidemiological study which involves randomly assigning people to either the treatment group, where the drug or active agent is provided, or to the control group, for whom a different drug, placebo, or activity is prescribed.

Reference Cigarettes: Cigarettes used for research purposes and not actually sold in stores.

Relative Risk: The rate of disease in people who have some particular exposure relative to that of a group of people who do not have that exposure.

Satisfaction: Refers to the pharmacological attributes associated with a cigarette's level of nicotine delivery. As found in industry documents, the word describes the "hit" of nicotine an individual receives when smoking a cigarette and the effect produced by that nicotine when it reaches the brain. Satisfaction, as used in this context, does not refer to the taste characteristics of a particular cigarette.

Secondhand Smoke (also called environmental tobacco smoke): The smoke which is released by smoldering cigarettes (sidestream smoke) and that which is exhaled by smokers and then inhaled by nonsmokers (mainstream smoke).

Selection bias: Bias stemming from the manner in which people are selected to be in the study.

Sidestream Smoke: Smoke that is released from a cigarette's burning end.

Starters: New smokers.

Statistical Significance: Quality of a study whose results are unlikely to have occurred by chance. In this case, there was no consensus among testifying scientists on what minimum value represents statistical significance.

Tar: The solid material in tobacco smoke.

Tolerance: The changes in the brain, including addition of new receptors, as it attempts to adapt to the persistent presence of addictive drugs, e.g. nicotine. Over time, the brain becomes tolerant to the effects of nicotine and needs greater amounts of nicotine to produce the same effects on hormones as it once did before the development of tolerance.

Unprotonated: One of the two primary states of nicotine delivered in mainstream smoke. Unprotonated nicotine lacks a proton or positive chemical charge and can be more readily released from the tobacco rod of a cigarette and more readily absorbed into the body of the cigarette smoker. See also "free nicotine."

YAS: Young adult smokers.