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**Expert Witness Report**  
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**For**  
**Falise, et al. v The American tobacco**  
**Company**  
**August 15, 1999**

**The Medical State of the Art: Tobacco and Asbestos. A  
Comparison of Industry and Public Knowledge and  
Responses to Knowledge with Respect to the Health  
Effects of Tobacco Smoke and Asbestos.**

**“Ignorance is never random.”**  
**-Gunnar Myrdal**

**1. Demonstrative Exhibits that may be used include:**

1. Glass of water
2. Grapes, red and green
3. Onion (yellow)
4. Videotapes of Friability of Asbestos
5. Drawing of 3 Circles
6. Overheads made from any quotes, tables, diagrams or lists in the report
7. Time line of bad acts
8. CD from Hong Kong
9. Children's apparel with tobacco logos
10. Pictures of third world marketing
11. Audio and Videos of tobacco advertising
12. Pictures of Tobacco Advertisements
13. We Card Video
14. Pictures of the lung and other organs
15. 3-D Human model cut away
16. Chocolate syrup and rat poison box
17. Videos of Tobacco Advertisements
18. Time line of FTC complaints
19. Time line contrasting public and private views on the link between smoke and disease.\*
20. Time line contrasting public and private views of the effectiveness of TIRC/CTR and company research..\*
21. Time line contrasting public and private statements on addiction.\*
22. Time line contrasting statements on individual and corporate responsibility for the consequences of their actions. \*
23. Time line of public and private statements on nicotine manipulation.\*
24. Time line of corporate statements on marketing to children (From pages 37-39)

\*These are not complete and will be submitted at a later date. They will be a composite of statements included in this report and other information to be acquired during discovery.

## Index of attachments

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## 2. Background and Qualifications

I am a medical doctor and Clinical Associate Professor of Community Medicine at Brown University.

I am board certified in Internal Medicine, and Preventive Medicine, and Occupational Medicine.

My office address is 759 Granite Street, Braintree, Massachusetts, 02184.

My curriculum vitae is enclosed with this report at TAB 1

I received a Bachelor of Science from Brown University in Molecular Biology in 1974 and a medical degree from Brown University in 1978. I completed a three-year medical residency in Internal Medicine at Strong Memorial Hospital in Rochester, New York, in 1981.

I completed a three-year training program in epidemiology, called the National Institutes of Health Epidemiology Training Program, in 1984. As part of this program, I completed a Master's in Public Health at the Harvard School of Public Health. At Harvard, I studied industrial hygiene and toxicology, epidemiology, statistics, occupational medicine and law, and public policy with respect to occupational and environmental hazards including regulatory approaches to control, the tort system, environmental law, FDA and OSHA law, and the Consumer Products Safety Commission law, and areas that relate to the specialty of preventive medicine including education, product design changes and substitution. One course that I completed during the program relating to the various approaches to control of health hazards was a joint course offered by the Harvard Law School, the Harvard School of Public Health, and the MIT Business School. I completed a third residency in preventive medicine in 1994.

I served two years at the National Institute for Occupational Safety & Health (NIOSH), designing and conducting small and large epidemiological studies. I was responsible for interpreting and implementing aspects of the OSHA Act of 1971. While at NIOSH, the most important part of my responsibilities involved education of workers, employers and members of the public on health hazards. I provided this information through a variety of vehicles, including written reports, conferences, mass meetings and face-to-face conversation. NIOSH and the CDC provided training on the mechanisms of effective communication.

Since 1978, I have published a variety of letters and medical articles on the issues that relate to the manner in which cause-effect determinations are made in medicine (the epistemology of medicine).<sup>1</sup> I have discussed the normal, accepted process of causal determination in medicine in several peer-reviewed articles. In addition, these ideas were accepted for presentation and were presented at the American Public Health Association meetings in 1984. I have also studied, taught and published articles on the history of medical ethics, public health and corporate responsibilities for and public health approaches to, the education of populations and individuals on health hazards and the redesign of products. I have taught and done research on the history of the development of medical and corporate practices concerning the need to inform patients and product users of potential health hazards during the 20th century. I have, on two occasions, testified before congressional sub-committees on the issues relating to informed consent and corporate responsibility to inform members of the public about health hazards. My testimony concerned the history of informed consent. In addition, I have published two papers on the topic of the history of the development of informed consent.

For the past seven years, I have taught a course at Brown University, called the Development of Medical and Scientific Knowledge in the 20th Century. This course deals specifically with the issues outlined in this report: the history of the development of knowledge of the health effects of asbestos and tobacco including corporate knowledge, the history of the development of government regulations on occupational and environmental safety, and the history of the development of contemporaneous appropriate public health responses to information on the adverse health effects of products on users including education of product users and product redesign. I have also published on these topics. I have taught a two-year course for medical students that covered medical ethics, community approaches to public health and health education. I have in the past taught a course on public health approaches to health problems in developing countries.

I have organized and help run two non-profit organizations. One of these, The Training Exchange sends volunteer health personnel to Central American countries and utilizes a “train the trainer” approach to the improvement of health through education. The other, Braintree Health people 2000 focuses on the development of a community-professional partnership to provide health education for children and seniors and provides a vehicle for cross generational exchanges. Finally I serve on the board of directors of the Citizens for Responsible Care & Research. This organization focuses on issues of medical ethics with an emphasis on issues that relate to informed consent.

My qualifications and opinions are also based in part on my clinical experience and awareness of the ways that physicians in medical practice make decisions about causal relationships that affect patients’ lives every day. Over 30 hours per week of my time is devoted to direct patient care.

As a practitioner, I utilize the epistemological and medical decision making concepts described below as part of my regular medical practice, which includes determining cause-effect relationships, judging drug side-effects, judging therapeutic interventions, judging the presence of disease, providing forensic testimony and judging the causes of disability and death. The described methodology is consistent with the usual methods physicians use in the ordinary practice of medicine.

My opinions in this case are based on my training and experience in molecular biology, medicine, physics, chemistry, epidemiology, philosophy, ethics, public health, industrial hygiene, medical practice, review of corporate documents in this and other cases, review of depositions, trial testimony and deposition exhibits, discussions with researchers, and my review of various medical literature.

I first formed opinions on the corporate conduct of tobacco companies when I read and studied these materials in the early 1980’s as part of my academic research on epistemology. I regard tobacco in the same way as I consider and evaluate the public health issues of any manufactured product.

My review of materials, particularly corporate documents and depositions is ongoing. I will supplement this report at a later date if needed. I charge \$250 per hour for research and testimony and \$350 per hour for deposition time.

### **3. Introduction.**

In the early 1950’s, after sales declined as soon as some members of the public became aware of some of the health hazards of tobacco smoke, tobacco companies engaged in a well-organized and highly-financed industry-wide campaign to (1) generate false controversy to discredit medical evidence on the tobacco-related disease, (2) deceive the public about tobacco smoke’s harmful effects through public statements and the use of marketing, and (3) target children and minorities to preserve the financial health of the industry. Some companies colluded through the formation and activities of the Tobacco Industry Research Committee (TIRC), and its successor organizations, the Council on Tobacco Research (CTR) and the Tobacco Institute. Some tobacco companies acted outside of their membership activities with TIRC and successor organizations and conducted private, independent research. This private, internal research, largely performed within a framework of marketing research, and the development of new products to finely regulate tar and nicotine delivery, led the industry to develop a secret body of knowledge in five areas: (1) tobacco smoke’s carcinogenicity and carcinogenic mechanisms, (2) nicotine’s pharmacological effects on the human body, including modifications to up-regulate nicotine delivery, (3) the compensatory increases in smoking consumption among low-tar cigarette smokers, (4) increased tar and nicotine exposures from smokers’ behavioral adaptations to additives or product redesign (such as menthol, sugars, humectants and filter tips), and (5) cigarette consumption by children, women, and minorities.

In an effort to sustain controversy and doubt about the toxic effects of tobacco, the tobacco industry adopted an epistemological viewpoint on the types of medical evidence necessary to demonstrate causal associations that was – and remains to be – without historical precedent and in marked disagreement with the contemporaneous epistemological position of the medical community and, in fact, of its own scientists.

The tobacco industry categorically dismissed entire areas of scientific and medical knowledge as part of the industry's calculated effort to discredit mounting evidence that refuted the tobacco industry's position that tobacco does not cause human disease and could promote health. In an historical period where epidemiology, case reports, pathology, and experimental animal evidence held general acceptance for their ability to demonstrate causal associations, the tobacco industry fabricated a unique and self-serving epistemology that rendered this entire mountain of evidence medically irrelevant or anecdotal, per se.

The scientific community has never judged it reasonable to ignore entire classes of available, valid, precise scientific data, or, in an ad hoc manner, elevate one class of data as carrying the ultimate burden of proof. Such open-minded and even-handed judgment particularly applies to a product that is either suspected or demonstrated to injure or kill its users, especially when millions consume the product in question.

Even if the tobacco companies were correct when they stated their public views on the epistemology of cancer causation, they were expressing a minority view on the issue after the early 1950s. Therefore, according to the public health standards of the time, they had obligation to educate users about and take other appropriate public health actions to respond to the tobacco health hazards that were accepted by the majority of the medical community. During this century, public health actions have been taken long before the materialization of some platonic ideal of proof. In fact the tobacco company epistemologic criteria have never been met for any carcinogen, infectious agent, behavioral intervention, toxin or poison. We do not know the exact mechanism of action for any of these, but public health interventions have saved millions of lives nonetheless. In this report I respond to four questions.

1. Who knew what when about the health hazards of asbestos and tobacco, including a comparison of public and private knowledge?
2. What were the contemporaneous standards for interpretation of that data?
3. What were the historical public health responsibilities to test products for hazards and what measures were taken to reduce the adverse health effects of any hazards?
4. A comparison of industry's response to knowledge of the health hazards of their products and contemporaneous response of other companies, the government and public health agencies and professionals with respect to the discovery of hazards.

This report is divided into four sections as follows:

- Methodology: A description of the methods used to prepare this report.
- State of the Art: A description of who knew what and when they knew it with respect to tobacco and asbestos health related issues; including a comparison of what information was available to members of the medical and public health community and the public compared with the information available to the tobacco and asbestos companies.
- A review of the contemporaneous historical public health principles of the obligations incumbent on manufacturers to test their products for potential adverse health effects on consumers and others who may come in contact with their products, and a review of the historical public health principles that explicate the appropriate corporate response to information on potential adverse health effects produced by commercial products, including a review of the tobacco companies' views on these issues. This section will emphasize education, substitution of a less hazardous product for a more hazardous product and other appropriate responses suggested by Tobacco executives.
- A review of the actual response of the tobacco companies to the public health obligations enumerated in section 3. This section includes an evaluation of the tobacco industry's compliance with established historical standards for testing and educating about product hazards as well as their own public declarations on these issues.

#### 4. Methodology

##### A. Review of medical literature.

I reviewed each issue of Index Medicus from 1910 through 1964. Index Medicus was computerized from 1964 forward and was reviewed by computer search.

I obtained approximately 800 medical articles relating to asbestos and asbestos health effects through 1964, in addition to approximately 800 medical articles relating to tobacco and tobacco health effects that were published prior to 1955.

##### B. Review of corporate documents.

I have reviewed corporate documents from a variety of sources for approximately 15-20 companies that made and/or used asbestos insulation products and six tobacco manufacturers. Most of these documents were exhibits in tort litigation and were supplied as part of the discovery process. In addition, I have visited several corporate document repositories to review corporate documents that are provided as part of the discovery process.

##### C. Review of depositions.

I have reviewed depositions of many corporate personnel of asbestos and tobacco companies as well as users of their products. I have interviewed patients who use asbestos and tobacco products.

In the next section I explain my analysis of the historical criteria used to establish cause-effect relationships in science & medicine. I then explain my current view on medical epistemology and my method for evaluating cause-effect relationships in medicine. I have also interviewed many physicians who were alive and practiced medicine from 1930 forward.

##### D. Principles of general causation

In making such judgments regarding medical causation, doctors utilize epidemiological data as one tool among many. Although doctors consider epidemiological research to be an important facet of medical epistemology, it is not regarded as being the sole or the most important contributor to decision-making. The branch of medical science concerned with the causes and origins of disease is called etiology. Epidemiology is *not* a synonym for etiology. Rather, etiologists use epidemiological evidence *along with other evidence* to draw conclusions about causal connections. Medical knowledge is based on empirical tests. Empirical tests are those gained from observation or experience.<sup>2</sup> Epidemiology is but one form of empirical knowledge.

The evidence used to determine disease etiology may come from chemistry, physics, biochemistry, pathology, molecular biology, toxicology, clinical experience and other scientific disciplines. Types of data relied upon include observation, experiment, analogy, computer models, animal experiments, and bacteriologic experiments, as well as epidemiologic studies. Doctors consider the *whole* data set available to establish a causal nexus.

##### E. Probabilistic causal analysis

In determining the etiology of *infectious diseases* (caused by a microorganism), doctors have used Koch's postulates as a basis for deciding what experimental evidence is necessary to establish cause. Koch's postulates are: (1) the microorganism must be observed in every case of the disease; (2) it must be isolated and grown in pure culture; (3) the pure culture must, when inoculated into a susceptible animal, reproduce the disease; and (4) the microorganism must be observed in, and recovered from, the experimentally diseased animal.<sup>3</sup>

Although epidemiology plays absolutely no role in Koch's postulates, the medical community has completely accepted them as valid epistemological criteria for certain causal relationships.

However, doctors *do not* apply Koch's postulates directly or by analogy to determine causation for injuries and non-infectious diseases. Like infectious disease, the etiology of non-infectious diseases and injuries is multi-factorial, and most of the factors are unknown. However, in contrast to infectious diseases, no single factor is *always a sine qua non of non-infectious disease*. For example in the *infectious* disease tuberculosis, all patients with the disease have the TB bacillus in their bodies. But all non-infectious diseases have multiple causes and have no *sine qua non* causal factor. For example, smoking and asbestos are both independent causes of lung disease and lung disease occurs in non-smoking, non-asbestos exposed people. (Asbestos is the *sine qua non* cause of asbestosis.)

Both TB and lung cancer demonstrate the multi-factorial nature of disease etiology. Only a very small percentage of smokers, and a very small percentage of persons carrying the TB bacillus, ever get either lung cancer or tuberculosis. A combination of other known and unknown factors determine which smokers develop cancer or which individuals with the bacillus develop tuberculosis. Although doctors accept that asbestos and cigarette smoking cause cancer, cancer occurs in less than 20 percent of smokers and slightly over half of asbestos insulation workers.

Therefore, the reliance on microscopic evidence implicit in Koch's postulates is not a universal causal criterion for non-infectious diseases. Neither pathologists nor epidemiologists nor clinicians require the presence of microscopic evidence of previous smoking to attribute lung cancer to a person's smoking. Case reports and uncontrolled population data convinced most physicians that smoking was a cause of lung cancer, and that exposure to ionizing radiation caused certain cancers. Astute pathologists and readers of pathologic literature were the first to recognize that asbestos was a carcinogen; epidemiologists did not make this association until many years later.<sup>45</sup> Pathologists and pathologic evidence is still the most important type of evidence for most legal proceedings and is usually the arbiter of choice for the determination of the cause of death. Epidemiologists are not called to the morgue to determine cause of death for death certificates.

In non-infectious diseases, probability analyses can be used to determine disease etiology. It is possible to integrate different data sets into one causal probability through a model influenced by Bayesian decision-making (see TAB 15 Figures 2, 3, 7). This method integrates available information into one model for causation, representing the results of each study type on a continuous line from 0 to 100, with 0 representing no evidence for causation and 100 representing the certainty of evidence of causation. Then the study types are arranged hierarchically, and the overall probability of causality is sequentially modified by each study type in turn, until a final value between 0 and 100 is reached.

It is necessary to describe this model for causation because of misrepresentation of the scientific method in public discourse. Some researchers have attempted to elevate one entire class of data to the level of final arbiter of causal proof. For instance, scientists working for tobacco companies argued that cigarettes had not been proven to cause lung cancer because of the lack of animal studies establishing such a relationship, because the exact mechanism of cancer induction is unknown and the specific carcinogenic substance(s) is (are) unknown. The scientific community has never exclusively relied upon epidemiology as the accepted method of evaluating cause-effect relations for making normal medical decisions. It is reasonable for different people to assign a different priority to different classes of studies. However, it is not reasonable to ignore entire classes of data, or, in an ad hoc manner, to elevate one class of data as carrying the ultimate burden of proof, especially for making public policy decisions regarding potential health risks.

#### F. Importance of clinical experience

The textbook titled Medical Decision Making identifies the following information available to physicians making medical decisions: personal experience, published experience, and attributes of the patient.<sup>6</sup> A physician's opinion is "guided by personal experience with similar events or by the experiences of colleagues. Thus, a surgeon's estimate of the probability that a patient will survive an appendectomy is guided by personal experience with this operation in similar patients."<sup>7</sup> In addition, physicians rely upon published experience, in the form of reports quantifying the risk or success associated with a certain

procedure. For instance, the above-mentioned surgeon may rely on a report giving the rate of death after appendectomy in order to estimate the probability that a patient may die from the operation. Published experience is “particularly influential when the physician has **little personal experience.**”<sup>8</sup> [Emphasis added] Finally, attributes of the patient are important to alert the physician for “unusual characteristics of the patient that put him at higher or lower risk than the average.”<sup>9</sup>

These principles of making medical decisions are exactly analogous to making cause-effect evaluations. In the case of appendectomy and likelihood of dying, the appendectomy is a determinant and the outcome is risk of dying. As can be seen from the above, in making these decisions, physicians rely heavily on their prior experience. “Clinicians use their prior experience with similar events to estimate probability. Experienced clinicians have seen so many patients that they have a good intuitive understanding of which events occur commonly and which events are unusual. Personal experience is, and will continue to be, the principal factor influencing a physician’s probability estimates.”<sup>10</sup>

Doctors relying on clinical experience depend on an implicit control or comparison group -- all the other patients they have seen. A case report is essentially a small epidemiologic study. A case report is made because the case is unusual or informative with respect to all other cases the doctor has seen.

Clinical experience is considered particularly important in the diagnosis of occupational and environmental diseases because of the importance of the history. The history is the most important piece of information in determining if an individual case of disease or injury is related to exposure. For example possible causes of asthma include cold air, exercise, pollen, chemical exposures, and dust. Doctors determine general and specific individual causation and causal factors from the history of the time course of exposure and symptoms onset and relief of symptoms correlated with removal of exposure. Physical examination and laboratory tests are helpful, “but ultimately it is information obtained from an occupational history that determines the likelihood that a medical problem is work-related ...”<sup>11</sup> The history is also critical in determining whether or not SBI induced disease in an individual. The time course of exposure correlated with the onset and continuation of symptoms, the pattern of signs, symptoms, laboratory abnormalities, and the effect of smoking cessation on symptoms and cancer incidence are all considered in the physician determination of general and specific causation. This is the usual method used by physicians in determining disease causation and in selecting treatments. This is particularly true in dealing with specific criteria for causation, such as temporality (discussed in more detail below). With a well-taken history, the course of a patient’s complaint can provide evidence as to whether the complaint is caused by an exposure. Doctors ask questions like: “Do the symptoms begin after the start of the exposure? Do they disappear if the exposure is removed? Do laboratory abnormalities follow the exposure? Are local effects present? Is there a pattern of symptoms or signs?” A physician’s clinical experience, and the quality of their history, is especially important in cases where an injury or disease has multiple known causes.

## G. Examples from medical practice

### 1. *Injuries*

When someone is run over by a car and dies, their death can be attributed to the traumatic injury of being struck by an automobile, even in the absence of specific knowledge of the cause of death. The immediate cause of death may have been a heart attack, a broken neck, or suffocation. Furthermore, even if the exact mechanism whereby an injury is produced is unknown, causal conclusions may safely be drawn. An epidemiological study is not necessary to determine that the trauma from the car caused death. In addition, if an epidemiological study of Chevrolets indicated that Chevrolets could kill people hit in traffic it is not necessary to perform another study to establish that Fords can kill people. Normal medical practice is the application of inference, not the deductive process of mathematical proofs.

### 2. *Diseases*

A further example is that of diabetes. There were no epidemiologic studies done to show that insulin was related to diabetes. The causal connection was established through animal studies only. Treatment with

insulin began as soon as insulin was available, without controlled trials to demonstrate proof of its effectiveness. Clinical experience combined with animal experimentation was sufficient.

### 3. *Proposed Treatments*

Penicillin was used to treat infections as soon as it was available. No epidemiology was cited in support of the use of penicillin for the treatment of patients sick with pneumonia. The first epidemiologic studies on the effectiveness of penicillin and pneumonia were not published until the 1970's. The epidemiologic studies failed to find any reduction in short-term mortality from the use of penicillin. Doctors used penicillin because of laboratory studies and because they had a vague understanding of the mechanism of action (they knew it killed bacteria).

### 4. *Examples from medical literature*

The importance of case reports, or personal experience, in making medical decisions is reflected in assessments of causation relied upon every day by physicians. When physicians turn to textbooks for opinions on general causation, they find all sources of data presented, often with no distinction made between epidemiologic and other data.

To assess the importance of animal studies and human health, the US Congress' Office of Technology calculated the percentage of papers in journals that relied on animal, non-animal or human data. In all but one of the biomedical and behavioral journals reviewed, the majority of papers published were animal studies.<sup>12</sup> The same publication contained a diagram of the "steps in biomedical research that preceded successful coronary artery bypass graft surgery". The diagram illustrated the importance of and reliance upon various types of animal research for medical decision-making.

The Physician's Desk Reference, which includes sections on side effects and precautions for prescribed medications, is one example.<sup>13</sup> The information contained in this text is supported by case reports, animal studies, and epidemiologic literature. The entries are not separated according to the source of information. All of the sources are considered important in making decisions about whether a certain drug may cause a side effect in a specific patient. A physician will reduce dosage, or change medications, when a patient reports side effects consistent with those described in the PDR.

The textbook Principles of Surgery identifies the following causes of low back pain: Compression fracture, vertebral process fracture, sprain and strain, ruptured disc.<sup>14</sup> This list is derived from an article published in 1960. At the time of publication, these relationships were not supported by epidemiologic studies. The relationships were then and are now understood to be causal by virtue of case reports, and physicians' general understanding of biomechanics.

In texts devoted exclusively to occupational medicine, causal associations are frequently made without reference to epidemiology. The following diseases are attributed to occupational causes in the absence of epidemiologic data:

Hand infections: "Mycobacterium marinum infections are unusual infections related to puncture wounds suffered from handling fish, crab, shrimp, or coral."<sup>15</sup>  
"Sporotrichosis is caused by the fungi *Sporothrix schenckii* and usually presents with cutaneous cellulitis and lymphangitis after a puncture wound secondary to a contaminated thorn."<sup>16</sup>

Chronic Paronychia: "Repeated immersion of the finger tips with consequent paronychia affects, in particular, bar tenders, kitchen workers, and laundry workers. Prolonged immersion of the hands in water, particularly hot water that contains detergents, increases the risk of paronychia."<sup>17</sup>

Onycholysis: "Enzymes in laundry detergent have been reported to cause painful onycholysis with hemorrhage. Onycholysis has also been reported from hydrofluoric acid in a rust-removing agent and to sodium hypochlorite in an 18-

year-old lifeguard who added 16% sodium hypochlorite to the pool daily.”<sup>18</sup>  
[emphasis added]

Koilonychia: “Koilonychia has been reported in a woman who was employed as a wire coil winder. Koilonychia has been reported from organic solvents used to clean metal parts and accessories in an office furnishing factory.”<sup>19</sup> [emphasis added]

These examples show that physicians sometimes require only one case study in order to warn the medical community and patients that certain exposures may cause disease. Furthermore, case reports serve to establish other important causal connections, especially for diseases or injuries that have many possible causes. Thus, case reports can make a new link between an exposure and an established disease or injury. This is an example of the use of the causal criterion analogy (see below for further detail), in which, because exposures are similar in nature, a case report documents the existence of a new risk of disease for an exposed population.

**Table 1 Causal Relationships Established By Case Reports:**

Thalidomide and malformation.
Omniflox and liver failure
Isocyanates and asthma
Cold exposure and asthma
Allergen exposure and asthma
Vinyl chloride and cancer
Vinyl chloride and scleroderma
Adulterated rapeseed oil and scleroderma
Vaginal cancer and DES (early epidemiologic studies failed to confirm but did not impact on the acceptance of the causal relationship)
Silica dust and scleroderma
Solvents and scleroderma
Epoxy resins and scleroderma
L-Tryptophan and scleroderma
Bleomycin and scleroderma
Pentazocine and scleroderma
Specific side effects of hundreds of drugs e.g. Chloramphenicol and aplastic anemia

Case reports have also provided a basis for many treatment modalities.

Table 2 contains examples from the rheumatologic literature.

**Table 2 TREATMENT MODALITIES IN RHEUMATOID DISEASE BASED ON CASE REPORTS/SERIES**

<u>Hypertrophic osteoarthropathy:</u>
Steinfeld, A.D., and Munzenrider, J.E.: The response of hypertrophic pulmonary osteoarthropathy to radiotherapy. <i>Radiology</i> 113:709, 1974.
Lopez-Enriquez, E. Morales, A. R., and Robert F.: Effect of atropine sulfate in pulmonary hypertrophic osteoarthropathy. <i>Arthritis Rheum.</i> 23:822, 1980.
Lokich, J. J.: Pulmonary osteoarthropathy; association with mesenchymal tumor metastases to the lungs, <i>J.A.M.A.</i> 238:37, 1977.
Leung, F.W., Williams, A.J., and Fan, P.: Indomethacin therapy for hypertrophic pulmonary osteoarthropathy in patients with bronchogenic carcinoma, <i>West J. Med.</i> 142: 345, 1985.
<u>Primary and Secondary Hemochromatosis</u>
Angevine, C.D., and Jacox, R.F.: Unusual connective tissue manifestations of hemochromatosis. <i>Arthritis Rheum.</i> 17: 477, 1974.
McCarthy, J.T., Libertin, C.R., Mitchell, J.C., III, and Fairbands, V. F.: Hemosiderosis in a dialysis patient: Treatment with hemofiltration and deferoxamine chelation therapy. <i>Mayo Clin. Proc.</i> 57:439, 1982.
Cohen, A., Cohen, I.J., and Schwartz, E.: Scurvy and altered iron stores in thalassemia major. <i>N. Engl. J. Med.</i> 304:158, 1981.
<u>Sarcoidosis</u>
Kaplan, H.: Sarcoid arthritis with a response to colchicine. <i>N. Engl. J. Med.</i> 263:778, 1960.
Kaplan, H.: Further experience with colchicine in the treatment of sarcoid arthritis. <i>N. Engl. J. Med.</i> 268:761, 1963.
Harris, E. D., Jr., and Millis, M.: Treatment with colchicine of the periarticular inflammation associated with sarcoidosis: A need for continued appraisal. <i>Arthritis Rheum.</i> 14:130, 1971.
Neville, E., Carstairs, L.S., and James, D.G.: Bone sarcoidosis. <i>Ann. N.Y. Acad. Sci.</i> 278:475, 1976.
Franco-Saenz, R., Ludwig, G.D., and Henderson, L.W.: Sarcoidosis of the skull. <i>Ann. Intern. Med.</i> 72:929, 1970.
Baldwin, D.M., Roberts, J.G., and Croft, H.W.: Vertebral sarcoidosis. <i>J. Bone Joint Surg.</i> 56:629, 1974.
Perlman, S.G., Damergis, J., Witorsch, P., et al.: Vertebral sarcoidosis with paravertebral ossification, <i>Arthritis Rheum.</i> 21:271, 1978.
Watson, R.C., and Cahen, I.: Pathological fracture in long bone sarcoidosis. <i>J. Bone Joint Surg.</i> 55:613, 1973.
Marcove, R.C., Rooney, R. and Weis, L.D.: Osteosclerotic lesions in sarcoidosis. <i>Clin. Orthop. Rel. Res.</i> 129:248, 1977.
Schriber, R.A., and Firooznia, H.: Extensive phalangeal cystic lesions-limited sarcoidosis. <i>Arthritis Rheum.</i> 18:123, 1975.
<u>Amyloidosis</u>
Stone, M.J., and Frankel, E.P.: The clinical syndrome of light chain myeloma. A study of 35 patients with special reference to the occurrence of amyloidosis. <i>Am. J. Med.</i> 58:601, 1975.
Smith, M.E., and Bywaters, E.G.L.: Mortality and prognosis related to the amyloidosis of Still's disease. <i>Ann. rheum. Dis.</i> 27:137, 1968.
Goldfinger, W.E.: Colchicine for familial Mediterranean fever (letter). <i>N. Engl. J. Med.</i> 287:1302, 1972.
<u>Polychondritis</u>
Svenson, K.L.G., Holmdahl, R., Klareskog, L., Wibell, L., Sjoberg, O., Klintmalm, G.B.G., and Bostrom, H.: Cyclosporin A treatment in a case of relapsing polychondritis. <i>Scand. J. Rheumatol.</i> 13:229, 1984.
<u>Osteoarthritis (Drug therapies)</u>
Anderson, R.J., Potts, D.W., Gabow, P.A., et al.: Unrecognized adult salicylate intoxication. <i>Ann. Intern. Med.</i> 85:745, 1976.
Hodgkinson, R., and Woolf, D.: A five-year clinical trial of Indomethacin in Osteoarthritis of the hip. <i>Practitioner</i> 210:372, 1974.

Articles in the medical literature discuss the importance of evidence besides epidemiology.

Fleming et al. reviewed and evaluated whether the investigation of disease clusters continues to play an important role in establishing disease-toxin connections in the workplace.<sup>20</sup> They identified 87 original disease cluster reports that established disease-toxin connections in occupational medicine (from 1775 to 1990). They identified four advantages in using cluster reports from the workplace to identify new hazards: “natural denominator boundaries, shared exposures, the ability to form intermediate hypotheses, and the possibility of locating comparable populations in which to study these hypotheses.” They concluded that, “because new products, intermediate products, and procedures are introduced into working environments faster than epidemiologic and toxicological studies can be designed to evaluate their potential risks, disease cluster investigations will remain central to the understanding of disease, and to protecting workers.”<sup>21</sup>

### 5. *Hill's Criteria for determining causality*

As an overall model for determining causality, Hill's criteria are well accepted.<sup>22</sup> They are: temporality, biologic gradient (dose-response), consistency, biologic plausibility, strength of association, analogy, experimental evidence, coherence, and specificity. All of Hill's criteria are subject to criticism, and only temporality is necessary to prove causality. Of Hill's nine criteria epidemiologic data is only required for determination of strength of association.

Strength of association is a reflection of the strength of effect of a study. The relevance of strength of association is limited because the strength of an effect measured in a study is related in large part to the prevalence of other co-factors and not to the factor studied. Strength of association is not a measure of the importance of a particular factor in causation. While studies with large rate ratios are less likely to suffer from errors due to bias or confounding, it is important to note that weak causal associations are as likely to be causal and as important as are strong associations.<sup>23</sup> In addition, a rate ratio of two is not required to establish that a factor contributed to a disease in a particular individual. For example chronic smoking of less than a pack a day induces less than a two fold increase in the risk of heart disease, nonetheless all physician's would state that smoking contributed to an individual smokers heart disease if he/she smoked at this rate. Epidemiologic studies can, when evaluated together provide more confidence in an association even in the absence of a “statistically significant” finding in any individual study. Consider for example five different polls that all indicate that a particular candidate for office is ahead by between two and three points all of which are within the “sampling error” of each individual poll. It would be reasonable to conclude that the candidate was going to win on a more likely than not basis.

The temporality criterion requires that the cause precede the effect. While this is generally relevant, conformity with temporality does not mean every study must evaluate this issue. In addition, there will be some cases where strict temporality is not necessary in order to evaluate etiologic relationships. As Weed states, “It is interesting to note that, in general terms, causality need not require antecedence. Counter examples include simultaneous cause-effect relationships...”<sup>24</sup> Temporality is usually established through non-epidemiologic evidence. Tobacco companies argue correctly that the current body of epidemiology literature cannot distinguish temporality from a genetic link between the tendency to smoke and risk factors for cancer. Conclusive support for the temporal relation of smoking and cancer is derived from molecular and animal data.

Biologic gradient is the existence of a dose-response relationship for the proposed cause-effect combination. A dose-response relationship is not always necessary in order to establish causation. This is true for several reasons:

“First, it is possible for sufficient evidence to be amassed for an association to be considered causal without any form of dose-response relation being observed. As two notable examples, most epidemiologists found persuasive the early evidence of association between vinyl chloride and angiosarcoma of the liver, and between diethylstilbestrol and adenocarcinoma of the vagina, even though no dose-response relations were demonstrated. The acceptance of these two cancer-exposure relations was firmly established on case reports only. The

presence of a dose-response pattern in epidemiologic data is, after all, partly a function of the opportunity to study such a pattern. Second, the interpretation of an apparent dose-response relation in the data must include the possible non-causal reasons for its appearance, such as confounding and other sources of bias. Hence, one might expect to see a non-causal dose-response relation between alcohol consumption and lung cancer due to a correlation between alcohol and smoking. Third, a dose-response curve reflects complex biological mechanisms and may take any form. For instance, there may be a 'threshold' dose below which there is no effect or a flat portion along which all doses produce the same magnitude of effect ... Finally, estimates of effect made in relative terms (i.e., with the rate ratio) may obscure or present the misleading appearance of a relation of dose to the absolute magnitude of response, which is measured by the rate difference."<sup>25</sup>

Consistency requires that a proposed effect be observed repeatedly under different circumstances. This criterion is useful, and similar studies performed under different conditions and/or different types of study can fulfill it. However repetition of findings under similar conditions does not necessarily satisfy this criterion.

Specificity requires that each cause have a single effect. This is rarely a useful criterion because many causes have multiple effects. Asbestos causes asbestosis, lung cancer mesothelioma and other cancers. Smoking causes heart disease, lung cancer, oral cancer, etc. Trauma from a car accident can cause many different injuries.

Biological plausibility (mechanistic understanding) asks if the theory of causation (mechanistic) fits known mechanisms of injury causation. But usually, doctors do not require a specific understanding of the underlying mechanism of an injury or disease before assessing causation. For instance, doctors still do not understand exactly how smoking causes cancer, yet we routinely attribute cancers to smoking. In addition, when an exposure may result in many different intermediate causes of an outcome, it is not necessary to know which particular mechanism caused the outcome, within a reasonable degree of medical certainty. For example, a bullet wound in the chest may damage many different organs and cause the death of the person who is shot. Damage to the heart, lung or aorta may have caused the death. Despite the lack of knowledge of a specific causal mechanism, no doctor would hesitate to state that the bullet wound caused the death. This is true, even though the dead individual may have suffered a heart attack at the exact time that he/she was shot. This and other possible error is the reason doctors' opinions are given to a reasonable degree of medical certainty.

Coherence asks if the causal theory is not inconsistent with what is already known of the injury or disease.

Experimental evidence can consist of laboratory studies, animal studies, controlled clinical trials, or observational pathology studies. This includes articles discussing mechanisms of injury production, whose authors use experimental evidence and observation as the basis for their conclusions. Animal studies are relevant to human inference. Animal studies are performed for application to human health, not to animal health. Animal studies are not conducted to determine risks to mice, rats, dogs or cats. They are not conducted out of concern for mouse or rat health. They are done because it is generally felt that inferences can be drawn from animal studies about human risks. If inferences are not to be drawn, there should be a specific justification for failure to do so since many studies indicate that illnesses in humans are reproduced in animals. Animal studies comprise the major criteria for Koch's postulates and thus have been the fundamental basis for medical epistemology since the 19th century. If negative animal studies are relevant, positive studies must also be relevant. It is for this reason that regulatory agencies including the NIH, FDA, EPA, NIOSH and the National Toxicology Program rely on, conduct and fund animal studies. Eighteen of 21 agents found carcinogenic in animals have also been found to cause cancer in humans. Of 23 human carcinogens, 21 have produced some indication of cancer in animals.<sup>26</sup> Animal models are used to test causation and treatments for a variety of non-cancer effects including drug side effects, teratogenicity, asthma, heart disease, and medical device testing.

Analogy asks if epidemiological and other studies have established that an environmental exposure analogous to the exposure being considered may cause diseases similar to those reported for the exposure being considered.

Hill noted, "None of my nine view points can bring indisputable evidence for or against the cause and effect hypothesis, and none can be required as a sine qua non."<sup>27</sup>

Hill's final emphasis placed responsibility on scientists for making causal judgments with available known facts. He recognized that decisions have to be made in the absence of perfect data noting, "All scientific work is incomplete--whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time."<sup>28</sup>

## 5. Medical Knowledge of Health Risks

### A. Tobacco

#### 1. Lung Cancer

##### a) Pathologic Studies

As I stated in my paper on epistemology and public health, during the first half of this century pathologists were usually the first specialists to suggest cause effect relationships between exposures and disease.<sup>29</sup> Insurance companies usually soon followed suit – they had a financial incentive to know what was killing workers, and had access to mortality data from death certificates supplied by policy holders to collect on insurance. This historical pattern holds true for tobacco and cancer. According to a tobacco company report, a Commercial Union Insurance Monograph reported that a pathologist Tylecote first linked cigarette smoking with lung cancer in 1931.<sup>30</sup> He stated that, “I have no statistics with regard to tobacco, but I think that in almost every case I have seen and known of, the patient has been a regular smoker generally of cigarettes. To this there have been the following exceptions: (a) two ladies who succumbed to the disease unusually rapidly. In each case the lady lived ‘hard by’ a railroad station where trains frequently stopped, and where smoke from the engines must have at almost all times pervaded both house and garden. (b) A group of acute adolescent cases, all males in which I regard the condition as being usually mediastinal Hodgkin’s disease.”<sup>31</sup> In, 1929 Hoffman, a statistician who worked for the Prudential Insurance Company concluded:

1. Smoking habits unquestionably increase the liability to cancer of the mouth, the throat, the esophagus, the larynx and the lungs.
2. The change in the cancer death rate during recent years has not, however, been at all disproportionate to the enormous increase in cigarette.
3. The problem is complicated by other factors, particularly syphilis and defective dental conditions, in the absence of which smoking habits are much less likely to result in cancerous affections.
4. The increase in cancer of the lungs observed in this and many other countries is, in all probability, to a certain extent directly traceable to the more common practice of cigarette smoking and the inhalation of cigarette smoke. The latter practice unquestionably increases the danger of cancer development.
5. In the absence of other predisposing conditions, extreme moderation in smoking habits would certainly be advisable. Likewise attention requires to be given to the use of cigarette-holders of a high degree of conductivity which must needs increase the liability to cancerous affections.
6. Finally something should be said about as to the gross amount of air pollution as the result of almost universal smoking habits, which may in some cases injuriously affect non-smokers who are the victims of conditions over which they have little control. This observation applies particularly to the development of cancer of the lungs which occur among women, as well as among men, and frequently among those who are not smokers.

Even the most exhaustive study of the present state of knowledge regarding smoking habits in their relation to cancer leaves many of the most important questions unanswered. There is, therefore, the utmost urgency for qualified research into what is still a rather obscure aspect of the larger problem of cancer control, and it is to be hoped that the present study will be of some aid in this direction and stimulate more qualified research workers to subject the data and conclusions to a competent analysis.<sup>32</sup>

Rodgman of RJR interviewed Hoffman in 1958 and reported on this article. (Interestingly, Hoffman was the first American to publish on the health effects of asbestos in 1918.) A 1960 editorial in the *New England Journal of Medicine* credited Lombard Doering for first suggesting “an association between smoking and cancer” in 1928.<sup>33</sup>

In 1957, Auerbach published the results of a pathologic study of lungs that revealed, “a stepwise progression” towards cancer.<sup>34</sup> Rodgman’s 1962 report to RJR summarized the following pathologic evidence that indicated that smoke was a cause of lung cancer:(see TAB 09)

(a) Cigarette smokers’ lungs show profound cellular changes (squamous metaplasia, basal-cell hyperplasia, and other atypias) which are proportional to cigarette consumption, these changes decrease progressively [sic] in the lungs of ex-cigarette smokers in proportion to the time interval between cessation of smoking and death, and similar changes develop in the lungs of mice exposed to cigarette smoke

(b) Fluorescent constituents of cigarette smoke are absorbed into respiratory tract cells of man and experimental animals. However, fluorescence and carcinogenic activity are not synonymous. Carcinogenic polycyclic hydrocarbons (benzo[a]pyrenes, dibenz[a,h]anthracene) and noncarcinogenic polycyclic hydrocarbons (anthracene, phenanthrene) are highly fluorescent; carcinogens like urethrene, p-benzo-quinone, and  $\beta$ -naphthylamine exhibit little or no fluorescence.

(c) Whole cigarette smoke and some of its constituents (phenols, fatty acids) cause ciliary paralysis

(d) Cigarette smoke collects at cilia-free areas and at areas of paralyzed cilia.

#### b) Epidemiological Studies

In 1941, Dr. Altori Ochsner and Dr. Michael DeBakey published an article evaluating the relationship between smoking and lung cancer. This paper, which was remarkably complete in its analysis of the body of previous literature, concluded that the increase in lung cancer could be largely explained by the increase in smoking twenty years before.<sup>35</sup>

In 1950, Dr. Ernest Wynder and Dr. Evarts Graham published an epidemiological study proving conclusively that smoking could cause lung cancer.<sup>36</sup> The *British Medical Journal* called these results ‘striking’ and said that ‘If they are confirmed, it would still remain to trace the carcinogenic agent and to apply the lesson.’<sup>37</sup> The study was confirmed shortly thereafter when the *British Medical Journal* published an independent study by Sir Richard Doll and Bradford Hill. Two other 1950s epidemiological studies, one by Mills and Porter<sup>38</sup> and one by Levin and Goldstein<sup>39</sup>, independently concluded from studies of lung cancer patients that cigarette smoking doubled the risk of cancer. As the *British Medical Journal* had indicated, it was time to ‘apply the lesson’ – the prevailing scientific and medical view was that sufficient evidence had been published to take public health action to eliminate cigarette smoke as a cause of lung cancer.

In his 1962 report on the health risks of tobacco for the industry, Rodgman stated that “It has been shown in thirty retrospective studies and in four prospective statistical studies that the incidence in lung cancer is low in nonsmokers, proportional to cigarette consumption, greater in cigarette smokers than in cigar or in pipe smokers (who show a higher incidence of oral cancer than do cigarette smokers), greater in cigarette smokers who inhale than in those who do not inhale, greater in cigarette smokers continuing the habit than in ex-cigarette smokers, and comparable in male and female cigarette smokers when smoking duration, amount, and tumor type are considered.”<sup>40</sup> He concluded that “criticism of these studies has been reduced to the dictum A statistical study cannot prove a cause-and-effect relationship between two factors [emphasis in original]” – all other attempts to discredit the studies having failed.<sup>41</sup>

In 1958 the Quebec Asbestos Mining Association (QAMA) published a cohort study of its workforce.<sup>42</sup> The study included 4,673 smokers and 1,265 non-smokers and included mortality data from 1950 to 1955. The Metropolitan Life Insurance Company provided data for this study as they did for the cohort study performed by the American Tobacco Company. All twelve lung cancers occurred in smokers. The smoking “data was so striking” that the authors further verified the findings by stratifying the cohorts by degree of exposure, age, and length of employment. None of these factors explained the smoking effect. The cohort study controlled for socio-economic status and the “urban factor” because the internal control group worked side by side with the smokers.

The authors also found a statistically significant increase in cancer rates due to asbestos exposure. They manipulated the data to fool the public and doctors about this phenomenon. Interestingly, they also struck part of the conclusion that emphasized the smoking effect. It is unclear why they did so.

Others published studies supported additional or other explanations for the smoke-cancer association. Rodgman found six, as opposed to the thirty-four supporting the hypothesis that smoking caused lung cancer. He commented on the six studies in his report:

Contrary data have been provided by statistical studies, which suggest that smoking habits (and possibly lung cancer) are linked to a constitutional factor. The twin studies of Friberg et al., Fisher, and Raascho-Nielsen indicated a greater concordance of smoking habits between identical twins than between fraternal twins. These studies, however, fall in the same category as some retrospective lung cancer-smoking studies, i.e. careful but limited. The Seventh Day Adventist study of Wynder et al. provides serious argument for the constitutional hypothesis. Other contradictory data were provided by the immigration (and also retrospective) studies of Eastcott in New Zealand and Dean in South Africa. To validate his findings, Dean obtained smoking data on his sample by questionnaires addressed to the next of kin, a practice decried in several of the retrospective lung cancer-smoking studies. Nevertheless, the results of these studies can account for only a small fraction of the lung cancer incidence observed between smokers and nonsmokers.<sup>43</sup>

c) Animal Studies

In 1953, Teague prepared a summary of the research relating tobacco to cancer for RJR. He consolidated the results of animal studies dating back to 1900 in a table:

Year	Author	Result
1900	Broach	Proliferation
1911	Wacker and Schmineke	Proliferation
1923	Schreus and Zurhelle	Probable Cancer Probable Cancer (2 studies)
1929	Lickint	Epithelial Overgrowth
1930	Roffo	Leukoplatia Carcinoma
1931	Chickmatsu	Canceroid
1931	Roffo	Carcinoma
1931	Cooper, Lamb, and Sanders	Carcinoma
1932	McNally	Too Toxic No Effect
1932	Roffo	Ear Tumor
1932	Bogen and Loomis	No Effect
1934	Lu-Fu-Rua	Cancer
1935	Schurch and Winterstein	No Activity
1936	Roffo	Tumors
1937	Schurch and Winterstein	Carcinoma
1937	Taki	Cancer
1939	Campbell	Carcinoma
1939	Roffo	Cancer
1939	Roffo	Cancer
1940	Roffo	Carcinoma Carcinoma (2 studies)
1941	Flory	Papillomas Carcinomatod Tumors
1941	Martene	Metaplasia, Ulcers
1941	Roffo	Gastric Lesions
1942	Roffo	Carcinomas

These results – certainly known to the tobacco industry by 1953 – overwhelmingly support the conclusion that tobacco causes or contributes to cancer. Of the 28 studies Teague found, only three indicated no effect from tobacco. Eighteen studies showed tumors, cancer, or carcinoma; one additional study found tobacco tar to be too toxic to give meaningful cancer research results.

Wynder and Graham also published a mouse study in 1953. Based on the fact that 44% of mice exposed to tobacco developed tumors, they concluded, “tobacco contains specific carcinogen(s).<sup>44</sup> Rodgman’s report confirmed this result, and noted that inhalation studies had produced adenomas in mice.<sup>45</sup> The tobacco companies accepted the link between air pollution and lung cancer, and argued that air pollution – not tobacco – was responsible for the rise in lung cancer. Ironically, Rodgman pointed out that the carcinogenicity of tobacco was established by the same methods that had been used to establish the carcinogenicity of air pollution – and that all of the arguments the tobacco industry used against the case for tobacco causing lung cancer applied equally to air pollution.

In another secret memo Rodgman confirmed the relevance of animal data to man.

“There is no evidence that any of these compounds will produce cancer in man, nonetheless, there is a distinct possibility that these substances could have a carcinogenic effect on the human respiratory system.

“Medical experience has shown that man responds to various chemical substances in the same manner as experimental animals. It follows therefore that it would be better for the consumer of cigarette smoke were devoid of such compounds”.

Rodgman goes on to note that smoke should contain as little as possible (preferably at the zero level) of a polycyclic hydrocarbons... and should contain sufficient nicotine to supply the necessary requirements of the smoker with respect to this compound”. Thus we see that the tobacco companies also understood that animal studies were relevant and that their public statements on this issue were contrary to their private views.<sup>46</sup>

d) Identification of Carcinogens

Rodgman listed seventeen specific carcinogens that the tobacco industry knew were found in cigarette smoke: benz[a]anthracene, benzo[ghi]perylene, benzo[a]pyrene, benzo[e]pyrene, chrysene, dibenz[a,h]anthracene, 1-methylpyrene, cholanthrene, dibenzo[a,h]pyrene, dibenzo[a,l]pyrene, dibenzo[a,l]pyrene, 2,3-dihydro-1H-benzo[a]cyclopent[h]anthracene, 10,11-dihydro-9H-benzo[a]cyclopent[1]anthracene, benz[e]acephenanthrylene, 7H-dibenzo[c,5]carbazole, dibenz[a,h]acridine, and dibenz[a,j]acridine. Additionally, he notes that cigarette smoke contains ‘various’ promoting agents that can synergistically cause cancer. Like other contemporary scientists, Rodgman based the conclusion that these substances were carcinogenic on the results of animal studies - the same kind of studies that the tobacco industry was claiming could not determine that tobacco was carcinogenic. Rodgman also pointed out that animal studies were not required to prove that a substance was carcinogenic - “asbestos and sodium arsenite, recognized industrial carcinogens, have not been shown to be carcinogenic in animals.”<sup>47</sup> Interestingly, the article by Boyland that he cites to show that these are ‘recognized industrial carcinogens’ also recognizes tobacco smoke as a carcinogen in the same sentence.<sup>48</sup>

In 1775, a year before the Declaration of Independence was signed, Percival Pott documented an increased incidence of scrotal cancer in chimney sweeps and concluded that soot exposure caused the cancer. This relationship was uncontroverted and generally accepted on the basis of a single epidemiological study with historical controls.

In his report, Rodgman summarized the evidence as of 1962:

“After reviewing this evidence, many governmental health agencies and medical societies throughout the world have concluded that it was sufficient to establish a cause-and-effect relationship between cigarette smoking and cancer of the lung. None stated that cigarette smoke was the cause, the only cause, etc., and many acknowledged the role of air pollutants in the increased incidence of lung cancer. None suggested that research on all other factors be dropped in favor of a concerted study of cigarette smoke. These agencies included the American College of Chest Physicians, the British Ministry of Health, the British Medical Research Council, the Danish Joint Committee of the Danish National Health Service, Danish Cancer Society, and the Danish Medical Association, the National Cancer Institute of Canada, the Netherlands Ministry of Social Affairs and Public Health, the Royal College of Physicians (St. Britain), the United States Study Group on Smoking and Health 1957, the United States Public Health Service, the World Health Organization, etc.

Commenting on such pronouncements, Little, Scientific Director, TIRC, said:

‘We will not find out from over-simplified and perhaps superficial conclusions as to causation. Such an attitude would only stifle or delay needed research to find the basic origins of lung cancer and cardiovascular diseases, which are most powerful, diversified, and deadly enemies to our well-being. Nor will they be solved by resolutions or by review committees that concern themselves solely with suggestive or incomplete data.’

At present in the United States, this evidence is under review by two groups, the Surgeon General's Advisory Committee on Smoking and Health and by a special committee of the American Medical Association. It will be very surprising if their conclusions differ substantially from those of other groups cited.

It has been repeatedly stated that some scientists discount the cigarette smoke-lung cancer theory. This is true. But it should be noted that many of those quoted in this regard are on record with contrasting views. Scientists in the category include, among others, Arkin, Berkson, Dean, Eastcott, Fisher, Hueper, Little, Macdonald, Passey, Rigdon, and Rosenblatt.

Berkson is repeatedly quoted as one of the statisticians disagreeing with the cigarette smoke-lung cancer data. However Berkson's considered opinion is illustrated by his statement:

'... the definitive important finding of these prospective statistical studies is not that there is an association between smoking and lung cancer, but that there is an association between smoking and deaths from all causes generally...'

The thesis that cigarette smoking was statistically associated with a shortened life span was advanced almost a quarter of a century ago.

The statistical studies by Dean in South Africa and Eastcott in New Zealand and the United Kingdom cannot carry the weight ascribed to them. Eastcott's study did not compare immigrant and nonimmigrant lung cancer victims with respect to their individual smoking habits but with the yearly per capita consumption in New Zealand and the United Kingdom. Since the per capita tobacco consumption was greater in New Zealand than in the United Kingdom and since the number of immigrant lung cancer victims was greater than the number of nonimmigrant lung cancer victims in New Zealand, Eastcott concluded that smoking did not contribute to his findings. Similarly Dean did not compare individual smoking habits. Later, he ascertained the smoking habits of the lung cancer victims by questionnaires addressed to the victim's next of kin, a procedure criticized previously by reviewers of the retrospective lung cancer-smoking studies.

Kotin, member of the Scientific Advisory Committee, TIRC, recently commented on the conclusions of the 1957 U. S. Study Group on Smoking and Health:

"The statement...to the effect that 'The sum total of scientific evidence establishes beyond reasonable doubt that cigarette smoke is a causal factor in the rapidly increasing incidence of human epidermoid cancer of the lung' represents a view with which we concur."

Little, Scientific Director, TIRC, stated in 1947 [note – this is what Little said before he went to work for TIRC]:

"Although no definitive evidence exists concerning the relation between the use of tobacco in the instance of lung cancer, it would seem unwise to fill the lungs repeatedly with the suspension of fine particles of tobacco products of which smoke consists. It is difficult to see how such particles can be prevented from becoming lodged in the walls of the lungs, and when so located, how they can avoid producing a certain amount of irritation. One might also question the

ultimate results of continued inhalation of the type of atmosphere which characterizes the lower levels of city streets. Experimental work with animals involving these matters is still inconclusive, but it seems probably that the lung as an organ is not immune to the effect of chronic irritation and that it will in this respect resemble the other organs of the body. Such being the case, wisdom in avoiding unnecessary lung irritation seems to be established [emphasis added].”

and more recently:

‘.....in the first place we don’t criticize the statistical findings. We believe that they were honestly obtained and that they show, under the conditions that they were collected, a strong correlation which is suspicious enough to make it imperative that further research be carried on.....’

Hueper, long a proponent of the lung cancer-air pollutant proposition, noted:

‘A definite amount of reservation is indicated in accepting the claims advanced by some parties concerning the role of cigarette smoking as a direct or indirect factor in the causation of lung cancer. Nevertheless the type and amount of evidence on this matter on hand justifies the conclusion that cigarette smoking has contributed to or aggravated the action of the other carcinogenic respiratory pollutants by producing especially functional disturbances in the bronchial mucosa.....It would be most unwise, on the other hand, if, through an exaggerated emphasis placed on the significance of cigarette smoking, the study....of air pollutants would be impaired and neglected. The available evidence rather definitely assigns to these factors an important role as human respiratory carcinogens.’

And Passey, who does not believe that lung cancer results from the action of carcinogens, says:

‘I do not belittle the important part which smoking plays [in lung cancer causation]. My aim is to suggest its mode of action. In fact, I would say that it is dangerous to smoke.’

Additional citations could be given but these few suffice for now.<sup>49</sup>

Rodgman summarized the evidence at the time, “Obviously the amount of evidence to accumulate to indict cigarette smoke as a health hazard is overwhelming.” I agree.

As noted above, Hill’s criteria are well accepted for non-infectious diseases. They are: temporality, biologic gradient (dose-response), consistency, biologic plausibility, strength of association, analogy, experimental evidence, coherence, and specificity. All of Hill’s criteria are subject to criticism, and only temporality is individually necessary to prove causality.

- Temporality is required and met since causation was only inferred because smoke exposure predated the effect.
- Biologic gradient has been established by multiple studies. In 1950, Wynder and Graham determined that “It appears that the less a person smokes the less are the chances of cancer of the lung developing and the more heavily a person smokes the greater are his chances of becoming affected with this disease.”<sup>50</sup>
- Biologic plausibility was established by the industry’s own studies which showed that tobacco smoke contained many carcinogens. Teague’s report in 1953 showed that the industry knew that smoke contained specific carcinogens.<sup>51</sup> The cancers most strongly associated with tobacco smoking are oral, laryngeal, and lung cancer; tobacco smoke is a

plausible cause of all three because the smoke reaches all three areas of the body, exposing these tissues to carcinogens. The incidence of lung cancer is greater in the upper bronchial tubes and at branching points, where more smoke collects, lending further plausibility to the premise.

- The strength of association was large in a number of epidemiological studies. The tobacco industry had publicly acknowledged this association by 1957, though medical science had known of the link earlier.<sup>52</sup> Mills and Porter<sup>53</sup> and Levin and Goldstein<sup>54</sup> independently determined that heavy smokers were twice as likely to get lung cancer. In their study of physicians, Doll and Hill found a death rate from lung cancer almost nine times higher in smokers than in nonsmokers.<sup>55</sup>
- Consistency of effect. All kinds of studies – epidemiological, pathological, and animal - have consistently linked tobacco with lung cancer (see above). In his 1962 report on the health risks of tobacco for the industry, Rodgman stated that “It has been shown in thirty retrospective studies and in four prospective statistical studies that the incidence in lung cancer is low in nonsmokers, proportional to cigarette consumption, greater in cigarette smokers than in cigar or in pipe smokers (who show a higher incidence of oral cancer than do cigarette smokers), greater in cigarette smokers who inhale than in those who do not inhale, greater in cigarette smokers continuing the habit than in ex-cigarette smokers, and comparable in male and female cigarette smokers when smoking duration, amount, and tumor type are considered.”<sup>56</sup> He found only six contradictory studies, five of which he considered flawed.<sup>57</sup> The epidemiologic results were consistent, regardless of the sample group – almost all of the epidemiological studies, on widely diverse groups, in several different countries, have had the same result. The animal studies were repeated and Teague found that 25 of the 28 studies showed health effects from tobacco.<sup>58</sup> Indeed, the tobacco industry found animal testing so reliable that it used mouse-painting studies to determine the effectiveness of its filters.
- The premise is coherent – the idea that filling one’s lungs with smoke is bad and could lead to cancer does not seem inconsistent with science’s general picture of how cancer works. Indeed, Abbe reported the idea that irritation – such as could be caused by the fine, superheated suspension of particles in the lungs acquired through smoking – could cause cancer in a 1915 article linking smoking with oral cancer, where it is described as “universally accepted.”<sup>59</sup>
- There were plenty of experimental studies – Teague’s table of animal experiments (see above) shows many of them.
- Air pollution, as Rodgman realized, provided a perfect analogy for lung cancer caused by cigarette smoke – both relationships were proven in the same way, and it was widely accepted that air pollution could cause lung cancer.<sup>60</sup>
- Only the specificity criterion has not been met, and this is the least important and least necessary of the nine.

## 2. *Other Tobacco-Related Diseases*

Lung cancer is not the only cancer caused by tobacco. As early 1915, physicians reported that tobacco caused oral cancer. Dr. Robert Abbe discussed the link as known, commenting that, “For more than a century ‘smoker’s tongue’ has been pictured and taught by medical men.”<sup>61</sup> Of ninety oral cancer patients he had investigated, eighty-nine, or 99%, were heavy smokers.<sup>62</sup> He also reported on a woman whose tongue cancer case demonstrated beyond reasonable doubt that tobacco caused cancer. The woman had the habit, all her life, of brushing tobacco on her tongue, mostly on the left side.<sup>63</sup> The entire left side of her tongue was cancerous, but only half of the right.<sup>64</sup> This was meaningful because the control – the right side of her tongue – had the same predispositions towards cancer as the left; and the applied tobacco constituted the only unique exposure, environmental agent or genetic factor. The cell type was the same as that developed by mice painted with tobacco smoke residue.

A 1921 article on cancer of the tongue by Dr. Bloodgood confirmed Dr. Abbe's conclusions; he reported that, of 160 tongue cancer cases, only two involved non-smokers.<sup>65</sup> He said that, "The evidence, therefore, is **overwhelming** that the continuous and prolonged irritation from tobacco in some form is the chief factor in producing a lesion which may later develop into cancer."<sup>66</sup> [Emphasis added]

In 1954, Greene and Berkowitz linked 'inhaled' smoke and bronchitis.<sup>67</sup>

In the early 1950's, studies by Hammond<sup>68</sup> and Doll and Hill<sup>69</sup> concluded that cigarette smoking also caused coronary thrombosis. Hammond concluded that, "All of the evidence we have seen seems to be consistent with the hypothesis that the association between smoking habits and death rates from lung cancer and diseases of the coronary arteries results from a cause-and-effect relationship. We know of no alternative hypothesis that is consistent with all of the known facts."<sup>70</sup>

A 1979 tobacco industry report listed a number of health problems that had been associated with cigarette smoking, and their rebuttals to the literature. The problems included:<sup>71</sup>

- Lung cancer
- Heart disease
- Emphysema
- Low infant birth weight
- Cancer of the pancreas
- Early menopause
- Birth defects
- Increased risk of disease with oral contraceptives
- Oral cancer
- Esophageal cancer
- Laryngeal cancer
- Bladder cancer
- Strokes
- Chronic bronchitis

Other known health problems associated with smoking include<sup>1</sup>:

- Tobacco amblyopia
- Aortic aneurisms
- Harm to non-smoking spouses
- Gastric ulcers
- Exacerbation of Asthma
- Otitis Media in children
- Fetal malformations

A bibliography of smoke related health literature is at TAB 16.

### 3. *German Literature*

Again, in parallel with asbestos health information, German scientists first established a causal link between smoke and disease in this century. In his book, The Nazi War on Cancer, Robert Proctor describes this history of discovery:

"By the 1930s, the specter of cancer had also begun to figure in antitobacco [sic] rhetoric. Tobacco had been suggested as a cause of cancer as early of the eighteenth century: the English physician John Hill in 1761 had tied smoking to cancer of the nasal passages, and Samuel T. von Soemmerring in Germany

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<sup>1</sup> This not meant to be an exhaustive list.

three decades later identified pipe smoking as a cause of cancer of the lip. (Thomas Harriot, the English naturalist who brought pipe smoking to England from America, died of cancer of the lip in 1621; his is the first known cancer death thought to have been caused by smoking, though tobacco was not suspected at the time of his death.) These early insights were confirmed in the 1850s, when a French physician by the name of Etienne-Frederic Bouisson in Montpellier found that sixty-three of his sixty-eight patients with cancer of the mouth (cancer des fumeurs) were pipe smokers. (Extirpation of the afflicted organ was one of the most common operations at his hospital.) The famous German pathologist Rudolph Virchow corroborated the connection in the 1860s, by which time the tobacco historian Friedrich Tiedemann had reported several cancers of the tongue brought on by smoking.

Smoking remained a relative luxury throughout the nineteenth century, however, and the cancer contribution cannot have been substantial. As recently as the First World War, lung cancer was still a rarity in Germany as elsewhere in the world. A turn-of-the-century review put the entire number of cases known to medicine at only 140. In 1912, when Isacc Adler produced the first book-length review of the anatomy and pathology of lung cancer, he felt he had to apologize for writing on such a rare and insignificant disease. Medical professors when they did find a patient with the disease took special care to show it to their students, since they were not expected ever to see another case. Today, of course, it is the world's most common cause of cancer death, claiming more than 150,000 victims a year in the United States alone. China is soon going to have close to a million lung cancer deaths every year- thanks almost entirely, again, to cigarettes."<sup>72</sup>

German physician Fritz Licking published evidence linking cigarette smoking and cancer in 1929. His study was a "case-series" concluding that people with lung cancer were likely to be smokers. German physicians were also aware that smoking could lead to heart disease. Furthermore, they realized that smoking was dangerous for pregnant women. <sup>73</sup>

Many tobacco companies sold cigarettes in Germany and had access to this information. In fact, Phillip Morris situated its research facilities in Cologne, Germany.

Unlike the United States:

"The Nazi regime launched an ambitious anti-smoking campaign, involving extensive public health education, bans on certain forms of advertising, and restrictions on smoking in many public spaces."<sup>74</sup> (See TAB 16 for examples of these ads)

The Nazis were expert at propaganda, and these advertisements reflect their expertise and were only surpassed in vehemence by anti-Jewish propaganda. BAT was aware of these advertisements and the Nazi campaign. The Nazi regime banned an advertisement for their GOLD DOLLAR brand in 1937. (See TAB-16) They also established an advertising code to prevent misleading advertisements in 1941. This code was designed to protect public health and indicates that companies should have been aware of the fact that tobacco advertising could be misleading:

"1. The Content of Tobacco Advertising

Tobacco advertisements should be reserved and tasteful in both images and text. They must not run counter to efforts to maintain and promote public health (Volksgesundheit), and must not violate the following principles:

- a. Smoking may not be portrayed as health-promoting or as harmless.

- b. Images that create the impression that smoking is a sign of masculinity are barred, as are images depicting men engaged in activities attractive to youthful males (athletes or pilots, for example).
  - c. Advocates of tobacco abstinence or temperance must not be mocked.
  - d. Tobacco advertising cannot be directed at women, and may not involve women in any manner.
  - e. Tobacco advertising may not be directed at sportsmen or automobile drivers, and may not depict such activities.
  - f. Attention may not be drawn to the low nicotine content of a tobacco product, if accompanied by a suggestion that the smoker may thereby safely increase his tobacco use.
2. Limits on Advertising Methods
- Advertising for tobacco products may not be conducted:
- a. In films.
  - b. Using billboards or posters, especially on gables but also along railway lines, in rural areas, at sports fields and racetracks.
  - c. On posters in post offices.
  - d. On billboards in or on public or private transportation, at bus stops or similar facilities.
  - e. On posters (*Bogenanschlage*) on walls, fences, at sports arenas or racetracks, or by removable tags on commercial products or adhesive posters on storefronts and doors of shops.
  - f. By loudspeaker (on top of cars, for example).
  - g. By mail.
  - h. By ads in the text sections of journals and newspapers.

As described by Proctor, in 1994, "PM identified smokers with Jews" and antismoking groups with Nazi's.  
<sup>75</sup> (See attached)

## B. Asbestos

### 1. *Asbestos Company's Knowledge and Conduct*

(See TAB 14 for annotated bibliography and additional information on several specific asbestos companies and the Metropolitan Life Insurance Company<sup>76</sup>)

A review of the historical literature, including, case reports, animal studies, pathological reports, epidemiological studies and the use of inference in medicine pertaining to asbestos-related diseases reveals the following concerning defendants' actual or constructive knowledge of the dangers of asbestos:

1. The first reported case in the modern literature linking asbestos and disease occurred in 1899.
2. The first documented death due to asbestos exposure occurred in 1907.
3. The knowledge that exposure to asbestos could cause a serious chronic pulmonary disease, called asbestosis, was irrefutably and universally accepted by 1928.
4. It was first known in 1929 that asbestos could affect individuals in the community who were not occupationally exposed to asbestos.
5. Asbestos exposure was first associated with cancer during the 1930's; asbestos was recognized as a compensable cause of lung cancer in Germany by 1943; a probable relationship between asbestos and lung cancer was recognized in textbooks by 1942, and was generally accepted by 1949.

The early historical literature did not necessarily distinguish between lung cancer and mesothelioma cancer. Medical articles associating asbestos exposure and mesothelioma appeared beginning in the 1940's. By the early to mid-1950s, the relationship between asbestos exposure and mesothelioma was generally accepted.

By 1960, it was generally known that even individuals not occupationally exposed to asbestos developed mesothelioma.

Through the years numerous articles appeared mentioning that workers occupationally exposed to asbestos containing products were at risk of developing asbestos related disease. The medical literature regarding asbestos associated diseases was widely known and commented on, easily accessible, and available to railroads, miners, manufacturers, and suppliers of asbestos and asbestos-containing products. This medical information was in such quantity and of such nature as to constitute clear knowledge that asbestos was a hazardous product to those exposed to it.

It is my opinion, based on a reasonable degree of medical certainty, that if a user of asbestos-containing products had performed a cursory review of the medical literature, it would have found that asbestos was a cause of asbestosis, pneumoconiosis and lung cancer in product users. It would have also found reports in the medical literature linking mesothelioma with exposure to asbestos. Furthermore, it is my opinion that there is nothing in the literature that indicates that asbestos loses any of its hazardous potential when incorporated into a product. No safe level of exposure to asbestos has ever been demonstrated.

It is my understanding that other insulation products, not containing asbestos, were available in the 1920's. It is apparent that Johns Manville was aware of the general medical literature concerning asbestos through its co-sponsorship of a group of studies conducted at the Saranac laboratories in Saranac Lake, New York in the 1930's and 1940's (Gardner studies) as well as through its corporate medical office.

In addition, Johns Manville and other asbestos manufacturing companies possessed knowledge on the hazards of exposure to asbestos beyond, that which was published in the medical literature. Johns Manville and other asbestos manufacturing companies kept this information secret. They acted in concert to withhold important information concerning the dangers of asbestos exposure from product users.

During the 1930's, 40's and 50's several asbestos manufacturing and mining corporations, including Johns Manville and other asbestos manufacturing companies, conducted research on asbestos health effects. These corporate sponsors suppressed and/or adulterated some of these studies. For example, Johns Manville and other asbestos manufacturing companies sponsored Gardner's studies. Gardner's studies determined that asbestos caused cancer in animals.

In 1948, Dr. Gardner's studies and determined that the findings of the studies should be published. He did not criticize the cancer findings. Despite this fact, the sponsoring companies (including Johns Manville and other asbestos manufacturing companies) had Dr. Gardner's findings on cancer struck from the final publication. Many asbestos companies worked in concert with Johns Manville to alter or suppress findings of other studies including:

- The suppression of cancer studies performed by Drs. Gardner and Vorwald at the Saranac Laboratories. These studies included mouse and cat experiments, which indicated that asbestos was a carcinogen. The suppression of repeat animal studies done by QAMA and IHF in 1954.
- The suppression of criticism of the "safe exposure level" from the 1951 paper summarizing Dr. Gardner's findings.
- The publication of misinformation on the health effects of asbestos by Dr. Kenneth Smith in 1955.
- The deliberate, manipulation and publication of incorrect information on the relationship between cancer and asbestos exposure in Canadian miners in a 1958 IHF and QAMA study by Truan and Braun.
- Hemeon 1947 report to IHF including criticism of the TLV that was not published.

- Incomplete publication of the findings of Dr. Enterline's AIA sponsored state of the art report in 1978 and again in 1991.
- The suppression and/or adulteration of asbestos medical research (corruption of medical research).
- Allowed the asbestos industry to buttress and influence the minority scientific position that asbestos was not a human carcinogen.
- Caused the delay in the recognition by some that the TLV was unreliable.

It should be recognized that the asbestos companies recognized their obligation to test their products for potential health hazards and commenced serious research on the health problems related to their products in the late 1920's after the first case reports were published. Ironically, almost as much as anything else that has occurred with respect to corporate response to potential health hazards from products they made, the asbestos companies actions reflect the contemporaneous importance of epidemiologic and toxicologic data. In fact, these studies were so important that, after they completed them, they found it necessary to suppress their positive results. The asbestos companies recognized that the publication of positive epidemiologic and animal studies that indicated that their products could cause cancer in product users would establish that asbestos caused cancer and reduce sales as a result of user education.

### C. Comparison of Asbestos Company and Tobacco Company Conduct.

#### 1. *Education of users:*

Some asbestos product manufacturers began to caution users of potential risks in 1962 (US Mineral). Johns Manville and several other insulation manufacturers began to caution users of potential risks and recommend some controls in 1964. These cautions were all voluntary. Many other asbestos product-manufacturing companies, like WR Grace, never put warnings on products that contained asbestos (as late as 1986).

Tobacco companies never voluntarily educated users of product risks.

Because asbestos companies never developed any program like the "gentleman's agreement", often the warnings given by asbestos companies differed company to company even on identical products. Some asbestos companies specifically addressed the issue of cancer while others did not. Some asbestos companies went beyond the requirements of the OSHA standard to provide more adequate warnings, cautions, brochures and lecture programs to educate users about asbestos health hazards and ways of avoiding them. The asbestos companies did not limit warning language to "federally mandated" minimums. On the other hand, the tobacco companies have arranged for immunity from tort law in exchange for placing inadequate caution labels on their products. Tobacco companies have sent videos to educate convenience store employees about the "We Card" program. They send salesmen to each merchant to maintain product supplies and construct sales stands. They have never distributed videos to educate convenience store employees on tobacco health issues, nor have they distributed brochures along with their products to educate users. (See response to knowledge section for a more detailed discussion of tobacco company responses.)

The tobacco and asbestos companies frequently failed to apply US education programs in other countries.

#### 2. *Government influence:*

Like the tobacco companies, the asbestos product manufacturers exerted considerable influence over governmental agencies. Asbestos product manufacturers wrote government specifications for the use of asbestos containing products. It was recognized that this specification process aided their marketing in the general market as well as providing them with governmental customers.

Asbestos companies opposed government regulations of asbestos (similar to the opposition given by tobacco companies). Most of the asbestos company opposition was done through public lobbying and testimony beginning at the Goldberg OSHA hearings in 1972. This has continued to at least 1994. In these cases, asbestos product manufacturers exerted considerable influence over the consumer product safety commission, OSHA and the EPA. In 1972, the AIA took credit for having changed nine and a half of eleven government regulations related to asbestos that they considered unfavorable to them. The most important of these was the removal of the word "cancer" from the warning proposed by NIOSH and OSHA and the delay of reduction of exposure limits.

### 3. *Product usefulness:*

In contrast to tobacco, which is deadly when used as intended, many asbestos products can be used safely. Asbestos can still be and is used for certain operations and is not unreasonably dangerous as long as accompanied by appropriate warnings and instructions. This is to be contrasted with tobacco.

### 4. *Marketing and Design:*

Both the tobacco companies and asbestos product manufacturers frequently distributed misleading marketing materials (like those showing workers working without respirators or commercials that claimed health benefits). Asbestos companies never targeted marketing materials at children. By the early 1970's, asbestos companies developed substitutes for asbestos for most asbestos containing products and stopped selling asbestos containing products. Again, in contrast to the tobacco industry, there was no agreement amongst companies to share health and safety information with respect to product development and there was active competition amongst companies to market their products as "safer". This is an excellent example of how a competitive market can result in health improvements for consumers. In contrast, the tobacco companies agreed to share health and safety information, and thus eliminated any market incentives for the development of safer cigarettes. Some tobacco companies intimidated other companies to prevent the marketing of safer cigarettes ( See XA story below).

Tobacco documents indicate that they intentionally marketed to children and did not believe their own claims about "low tar" cigarettes. This memo describes the classification system for the tobacco documents maintained by Brown & Williamson. It includes a detailed breakdown of marketing strategies for different target populations. It is interesting to note that they have an entire category devoted to documents on children. In addition, they place quotation marks around the words low tar. Apparently the author and readers from Brown & Williamson are skeptical about in the actual amount of tar that is delivered to users from smoking "low tar" cigarettes:

ABEG            Youth: Documents concerning advertising, market strategies, or market research (i.e., studies of brand awareness, message recall, or usage behavior) focusing on smokers 18 years of age or younger. ...[Emphasis added]

ABEP            "**Low Tar**": Documents concerning advertising, market strategies, or market research (i.e., studies of brand awareness, message recall, or usage behavior) focusing on smokers of "low tar" cigarettes.<sup>77</sup> [Emphasis added]

They targeted minorities with misleading health claims

ADA MAJOR KOOL ADVERTISING THEMES: Documents concerning themes of advertising campaigns. ***Examples are the throat comfort theme***, the Willie -the penguin campaigns, "Switch from 'Hots' to KOOLS," "Come Up to KOOL," "Problem-Solution/Slice of Life," "Menthol Mist," "Lady Be Kool", the waterfalls theme and the biker campaign. [Emphasis added].

ABEQ Menthol/Nonmenthol [sic]: Documents concerning advertising, market strategies, or market research (i.e., studies of brand awareness, message recall, or usage behavior) focusing on smokers of menthol or nonmenthol [sic] cigarettes.

ABEC Health Conscious: Documents concerning advertising, market strategies, or market research (i.e., studies of brand awareness, message recall, or usage behavior) focusing on the "health conscious" smokers.

ABED Hispanic: Documents concerning advertising, market strategies, or market research (i.e., studies of brand awareness, message recall, or usage behavior) focusing on Hispanic smokers.

ABEE Black: Documents concerning advertising, market strategies, or market research (i.e., studies of brand awareness, message recall, or usage behavior) focusing on black smokers. :<sup>78</sup>

They engaged in a concerted effort to mislead the public about smoking and health issues. Sometimes they were successful at getting their misleading message out and sometimes they were not:

AJ PROJECT TRUTH/PROJECT A/PROJECT B: Documents relating to any of these public issue campaigns involving the tobacco companies and TI. 'Project A,' developed, in 1970, consisted of three TV spots on smoking and health that would be substituted for some regular TV commercials for which time had already been contracted. The spots were rejected by the network. Ruder & Finn proposed 'Project B,' which called for TV and print advertising that might position tobacco beside liquor in terms of public tolerance. In the fall of 1970, TI distributed two public service TV spots, produced by Ted Bates, to counteract the anti-smoking spot announcements. This activity was called 'Project Truth.'

The asbestos companies had no similar campaign.

##### 5. *Addiction:*

Users of asbestos products were always free to stop that use when they found out about adverse health effects. Users of tobacco products frequently could not stop use due to addiction. (See below)

## **6. Public Health Obligations: The tobacco industry's public health obligations to safeguard the health of consumers and the public**

### **A. Public Health Obligations**

Public health decisions do not, should not, and cannot wait for a complete consensus in the scientific community. There is never complete consensus. As knowledge accumulates, scientists will shift their positions, and a general position may emerge. This general position does not represent a consensus, but corporate officials must still respond to it. A conservative scientist may hold on to the null hypothesis to his deathbed. A conservative public health official or concerned corporation takes action when there is reasonable suspicion that a public health problem is imminent. Reasonable suspicion for the asbestos-cancer and smoking-cancer relationship was available by the early 1940s. In the early 1950s, it was established beyond any reasonable doubt that smoking caused lung cancer. (See State of the Art section)

In addition, public health actions are not all-or-nothing propositions. There is a spectrum of actions that can be implemented to protect workers or consumers, including substitution of a less hazardous for a more hazardous ingredient, education (including but not limited to warnings), environmental controls, personnel protective devices or product removal. The various levels of the actions taken subdivide this spectrum further. Education programs and/or labels, for example, can identify a suspect carcinogen, a probable carcinogen, or a definite carcinogen. Even if the tobacco-disease link was "not proven" by unidentified industry criteria it was incumbent upon the industry to take some action to educate consumers of potential hazards and do whatever they could to reduce exposure to harmful components. Instead the industry engaged in a campaign of deception designed to undermine the warnings coming from the public health community. Tobacco companies actually told consumers the use of their product was safe. (See section on advertising above). Medicine and public health never attains final "proof". We take public health action when there is a reasonable basis to do so.

The force of the public health intervention should be determined by five variables:

- 1. The strength of the association between the product and certain health effects.*

Prior to 1954, studies indicated that tobacco use was strongly associated with adverse health effects. By 1954 the issue was scientifically settled.

- 2. The severity of the health effects.*

By 1954 tobacco health effects included the most severe of health effects:

- Death and injury from burning;
- Chronic lung disease which frequently resulted in disability and death;
- Cancer, which almost always resulted in death;
- Cardiovascular disease, which frequently resulted in disability and death.

- 3. The importance of the product or ingredient to commerce.*

Tobacco provided no economic benefit to the user.

- 4. Use by children*

Children are unable to make adult choices about health risks from product use. Products that may directly or indirectly effect children's health or addict children to use have a higher burden of responsibility to educate children and parents of product hazards. This is especially applicable to children's hazards since parents will often take actions or make sacrifices, to protect their children that they might not make for themselves.

#### 5. *Effects on bystanders especially children and the unborn*

This is particularly important since people will frequently do things for their children that they might not do for themselves. In addition, it is relatively easy for smokers to segregate themselves from their children and other bystanders while they smoke.

The interaction of these variables will determine the appropriate response to health risks.

Based on these criteria I have no reason to dispute Parker McComas' guidance,

"If the industry leaders really believed that cigarettes caused cancer, they would stop making them."<sup>79</sup>

While tobacco company representatives argue to information available that their customers should have known about health hazards of tobacco in the public domain, in 1939 the Manufacturing Chemist Association recognized that public information could not be substituted for a warning that the manufacturer should have placed on her product.

"The name of the product alone may be sufficient warning, if its nature is very widely known or if its sale is restricted to those who are presumed to know its nature, but even in such cases the advisability of a specific warning is indicated."<sup>80</sup>

These public health concepts existed at the time decisions were made about tobacco. Tobacco product manufacturing companies chose not to adequately educate customers or test their tobacco-containing products despite overwhelming evidence that the products were hazardous. This behavior is not justified by reliance on a scientific unanimity or the establishment of mechanistic understanding.

The sources of information available to any company for determining the health effects of products they use included: medical journal articles, medical meetings, medical textbooks, trade publications, general publications, trade associations, product and ingredient suppliers, company meetings and correspondence, and insurance company information.

#### B. Historical recognition of manufacturer's public health obligations to test their products and take appropriate public health actions

"The manufacturer or one who holds himself out to be the manufacturer must know the qualities of his product and he cannot escape liability on the ground that he did not know it to be dangerous."<sup>81</sup>

National Paint, Varnish and Lacquer Association, Inc. July 18, 1939.

"We accept an interest in peoples health as a basic responsibility, paramount to every other consideration in our business."

A Frank Statement to Cigarette Smokers  
January 4, 1954.

Our one all-consuming ambition is to create wealth for the owners of Philip Morris.

Philip Morris CEO Geoffrey Bible, Letter to shareholders February 1995.

"If the industry leaders really believed that cigarettes caused cancer, they would stop making them."<sup>82</sup>

Parker McComas, chief executive of Phillip Morris, temporary chairman of TIRC July 1, 1954

"We were not driving this car. We were not steering the ship. It was out of our hands. It was in the hands of people who were responsible for public health, who wanted to deal with this issue because it was so big and so important.

The industry sought to preserve itself. That can't be a shocker. It sought to preserve the rights of smokers who choose to continue to smoke."<sup>2</sup>

Opening statement of David Bernick representing B&W, January 27, 1998<sup>83</sup>

I agree with Mr. Bernick's statement assessing the role of the tobacco industry with respect to the health hazards of the products they sold and sell. The tobacco industry wasn't "steering the ship". They did however play a major role in the development, dissemination and acceptance of medical research on tobacco health hazards. To continue Mr. Bernick's analogy, the tobacco companies hid the ship's maps, put sand in the engine and held their hands over the eyes of the captain so he could not see. However they had public health obligations to behave otherwise.

Mr. Bernick correctly notes that the medical community recognized and publicized information on the health hazards of smoke. When the captain determined that smoking caused cancer the Industry did not accept her findings. Every major and minor medical organization has concluded that smoking causes lung cancer. The Industry may have relied on public health authorities to do the research, but they certainly failed to rely on the public health authorities interpretation of the research results. Until the Industry intervened, the public did begin to rely on these results. The tobacco sales decline that followed the dissemination of this health information in 1953 is a measure of the efficacy of the medical conclusions on smoking and cancer. The tobacco companies recognized that this trend would have continued if they failed to rebut or obfuscate the medical information. It was this perfidious rejoinder, described in the next two sections, which effectively blunted the public health response to the smoke problem. Had the tobacco companies remained silent the public health community would have taken care of the problem as it did with nickel carbonyl and food and cosmetic additives (Delaney clause). The tobacco companies violated the first rule of medicine and public health, primum non nocere: FIRST DO NO HARM.

### C. Contemporaneous corporate view of their public health responsibilities

Faced with a product that was suspected of causing lung disease in 1941, Owens Corning Fiberglass articulated these principles of corporate conduct towards employees and product users:

- 1) From a humanitarian point of view, no company can afford to subject its employees to an unknown hazard.

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<sup>2</sup> Mr. Bernick argues that the Tobacco companies were not responsible for any problems that have occurred as a result of their sale their product. This abdication of "responsibility" for the consequences of Industry conduct contradicts the Industry's view of the responsibility smokers have for the consequences of their "choice" to smoke. This inconsistency can be explained. Perhaps "responsibility" for actions only pertains to individuals and not corporations. If so, it is inconsistent with my understanding of corporate public health responsibilities.

- 2) From a cold business point of view, no company can afford to jeopardize its own existence by subjecting itself to the liability of unknown hazards that may be encountered by those to whom it supplies the material.”

Internal document of OCF, Draft letter for “Health Aspects of Fiberglass Brochure”  
ECA/6/12/41<sup>3</sup> (See TAB 5)

OCF described the specific actions a company should take in response to a potential product hazard. (See TAB 5)

- 1) Find out the facts.
- 2) Get the facts into medical literature.
- 3) Take the mystery out of the subject by making the facts available to members of our own organization and to the general public.
- 4) Handle inquiries promptly and fully.
- 5) Concentrate on professional and technical influence centers.

Dating to the 1930s, manufacturers of hazardous products set explicit standards that created affirmative public health obligations to safeguard the public against exposures to hazardous substances. These public health obligations placed the onus squarely on product manufacturers to (1) develop a base of scientific and technical knowledge on the hazardous properties of their commercial products, and (2) demonstrate the safety or safe uses of commercial products through the use of both product labeling and education of end-users. These principles – as a product of the permissive atmosphere of self-regulation that governed US markets for the early and mid-twentieth century – saw a minimal if non-existent role for the government, the public health, and the medical communities in assisting with these responsibilities. The set of principles developed by the National Paint, Varnish and Lacquer Association in 1939 (the predecessor to the National Paint Coating Association (NPCA)), for instance, charged manufacturers of all hazardous products with the responsibility to develop information about the hazardous nature of the product:

“The manufacturer or one who holds himself out to be the manufacturer must know the qualities of his product and he cannot escape liability on the ground that he did not know it to be dangerous.”<sup>84</sup>

Another example of a principle accepted by industry in the 1930s is the public health obligations of a hazardous product manufacturer to communicate the nature of the hazard and the precautionary measures necessary to prevent disease throughout the entire chain of commerce from product distributors and salesmen to the intended users of the product:

“Labeling — Each manufacturer can ably cope with the toxic material situation by constantly safeguarding the public through the products he manufactures and by the repetition of instructions to salesmen, service men and others who can intelligently instruct the consumer of the advantages of providing adequate ventilation and of maintaining personal hygiene.”<sup>85</sup> [Emphasis added]

#### D. Health education through sales people.

The tobacco institute, beginning in 1958 (as one of their first actions) developed a plan to send a publication Tobacco and Health to their distributors. This booklet contained information that rebutted or attempted to rebut the view that tobacco was a health hazard. This would have been an excellent vehicle through which the tobacco companies could have provided information on health hazards of tobacco which subsequently could have been passed on by salesmen to end customers and through them to end users.<sup>86</sup>

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<sup>3</sup> OCF served as a consultant to Lorillard in the 1950’s

In 1945, the Manufacturing Chemists' Association (MCA) published a manual that reaffirmed the public health obligations borne exclusively by the manufacturers of hazardous substances. The MCA stated that manufacturers must effectively educate about product hazards by communicating information to "every person using, transporting, or storing [hazardous] chemicals."<sup>87</sup> According to a submission by the MCA to OSHA in 1972, the principles advanced by their 1945 Manual "have been accepted by the chemical industry in general, and by various agencies of government, for a period of over 28 years [i.e., since 1944]."<sup>88</sup> Again reflecting the public health obligations established by industry in the 1930s, the 1945 MCA manual identifies the use of product labels as the most practical means to communicate information on health hazards through the entire chain of commerce:

"The most practical means for the seller to disseminate this information appears to be by labels affixed to containers of hazardous chemicals; bearing appropriate precautionary statements and instructions stated as simply and briefly as circumstances permit."<sup>89</sup>

The chemical industry identified these basic considerations in the drafting of an appropriate warning label:

"Determination of the hazards present in the particular chemical product...  
Selection of appropriate statements for each significant hazard inherent in the product...  
Arrangement of statements in the order of emphasis desired."

In the event that a manufacturer did not fully understand or investigate the potential health hazards of its, the MCA recommended a cautionary statement entreating the product user to exercise due care:

FOR EXPERIMENTAL USE ONLY

"CAUTION! The chemical physical and toxicological properties of this product have not been fully investigated and its handling or use may be hazardous. Exercise due care."

This statement not only discloses the Public health obligations of manufacturers to preemptively educate about the reasonably anticipated health hazards of their products, but also documents the epistemological importance of toxicological data in the determination of those health hazards. In addition, MCA recommendations for precautionary labeling also concerned foreseen misuses of their products beyond what was intended by their design, manufacture, and marketing:

"Efforts should be directed toward naming the serious hazards and warning against such abuses and accidents as are likely to be encountered under normal conditions."

#### E. Obligations and Promises: In Their Own Words

Tobacco Company views on public health obligations of product manufacturers parallel the generally accepted views on these issues.

In December 1970, the Tobacco Institute ran a statement that declared that, ... "from the beginning, the tobacco industry has believed that the American people deserve objective scientific answers." ... "in the interest of absolute objectivity, the tobacco industry has supported totally independent research with completely non-restricted funding" and "the findings are not secret."<sup>90</sup>

In 1971, the Tobacco Institute stated "keys" which might unlock the door between statistical evidence and causation:

Any organization in a position to apply resources in the search for those keys . and which fails to do so .will continue to be guilty of cruel neglect of those whom it pretends to serve.<sup>91</sup>

In a 1972 Wall Street Journal article, James Bowling, of Philip Morris, stated:

If our product is harmful. .we'll stop making it. We now know enough that we can take anything out of our product, but we don't know what ingredients to take out.<sup>92</sup>

In 1982, the Tobacco Institute published a pamphlet in which it wrote:

Since the first questions were raised about smoking as a possible health factor, the tobacco industry has believed that the American people deserve objective, scientific answers. The industry has committed itself to this task.<sup>93</sup>

F. Additional obligations incumbent upon manufacturers due to the nature of the product, children's use, and previous misleading health representations.

Cigarettes result in disease and death when used by the consumer or product end-user as intended in their design and manufacture, affirmatively creating an additional public health obligations to educate. Tobacco companies accrue additional obligations to educate the public due to the nature of the product, specific actions they have taken and misinformation they have provided to users during this century.

1. They have marketed their products to children.
2. The addictive nature of the product
3. They have designed products to fool users about the health aspects of use.
4. They made specific claims to users about the health fullness of their products.
5. They have engaged in a campaign of deceit to undermine medical researchers, public health authorities efforts at informing the public about the health hazards of their products.

#### 1. *Marketing to children.*

It is understood and uncontroverted that children are not able to make informed decisions about their conduct with respect to hazardous products. Nonetheless the tobacco industry has engaged in a 100-year campaign to promote their products to children. This marketing to children increases the burden on the industry to adequately educate the public about the health hazards of their products. Instead the tobacco industry has chosen to design marketing campaigns aimed at encouraging children to smoke.

Nearly one million teens each year, or about 3000 teens each day, begin to smoke cigarettes in the U.S. The first major conclusion of the 1994 Surgeon General's Report is that "nearly all first use of tobacco occurs before high school graduation ...."<sup>94</sup> According to the 1991 National Household Surveys on Drug Abuse, among all persons who had ever tried a cigarette, 88.2% had done so by age 18. Among all persons who had ever smoked daily, 71.2% of those had begun smoking daily by age 18. John Schwartz of the Washington Post, detailed the tobacco companies' response to these issues when he publicized the contents of previously secret memos:

A 1972 memo from consultants to Brown & Williamson recommended that the company consider Coca-Cola, apple or some other "sweet flavor cigarette. . . . It's a well known fact that teenagers like sweet products. Honey might be considered."

A 1973 memo talks about marketing KOOL menthol cigarettes to African Americans. Noting that black smokers make up 30 percent of the market for the brand, the memo states that "KOOL has shown little or no growth in share of users in the 26+ age group. Growth is from 16-25 year olds . . . at the present rate, a smoker in the 16-25 year age group will soon be three times as important to KOOL as a prospect in any other broad age category."

A 1975 report from outside marketing consultants to the company's ad agency, Ted Bates Advertising, suggested that efforts to attract beginning smokers should "(s)tart out with the basic assumption that cigarette smoking is dangerous to your health -- try to go around it in an elegant manner but don't try to fix it -- it's a losing war."

Instead, the report suggests, the company should play to the smoker's understanding that smoking is "part of the illicit pleasure category" and "falls into the same category with wine, beer, shaving, wearing a bra (or purposefully not wearing one) . . . to the best of your ability (considering some legal constraints) relate the cigarette to 'pot,' wine, beer, sex, etc."

A 1982 document for Brown & Williamson's Canadian sister company, Imperial Tobacco Limited, describes a "Project 16" and noted that many young people begin smoking "in the 14-16 age range" to experiment and don't believe they will become addicted. "Once addiction does take place, it becomes necessary for the smoker to make peace with the accepted hazards. This is done by a wide range of rationalizations," the memo stated.<sup>95</sup>

Tobacco companies were well aware of and studied the age of onset of cigarette smoking. They analyzed and utilized data on the incidence and prevalence of smoking by those less than 18 years of age. The industry studied and examined the prevalence of smoking for underage youths because childhood smoking was viewed as critical to the future of the industry. Tobacco companies view adolescents as the major source of replacement smokers for their business. This is particularly important since their product kills its users when used as intended. Replacements for older smokers who quit smoking or die must be found. Industry documents point out that because most people begin to smoke by age 18, the absolute number of future customers, depends on how many children begin to smoke. Industry documents cite decreasing smoking onset rates among those under age 18 as a negative trend for the tobacco industry, because the future of their industry depends on the absolute numbers of those at age 18 who are regular smokers. For example, an R.J. Reynolds Tobacco Company (RJR) document states:

"The loss of younger adult males and teenagers is more important in the long term, drying up the supply of new smokers to replace the old. This is not a fixed loss to the industry: its importance increases with time."<sup>96</sup>

A decline in teenage smokers was likewise discussed in a Philip Morris document: "Because of our high share of the market among the youngest smokers, Philip Morris will suffer more than other companies from the decline in the number of teenage smokers."<sup>97</sup> Philip Morris, with its "Marlboro Cowboy" advertising campaign, has long been the leading cigarette brand among youth under age 18. Philip Morris' successful exploitation of the children's market has made it the largest cigarette company in the U.S.

Cigarettes are among the most brand loyal product in the U.S. Therefore future sales for particular companies depend on teens beginning to smoke its brands. As one document discusses, the greatest revenues for the tobacco industry in the long-term are from those who begin smoking before age 18.<sup>98</sup> The

top brands of the 20th century, in terms of revenue generated for particular companies, according to industry documents, were those that appealed to beginning smokers.<sup>99</sup>

a) Tobacco Companies' Marketing to Children: In Their Own Words

In 1974 RJR recognized the need to sell to children:

"This young adult market, the 14-24 group...represent[s] tomorrow's cigarette business. As this 14-24 age group matures, they will account for a key share of the total cigarette volume - for at least the next 25 years."<sup>100</sup>

RJR targeted children and discussed the need to design a cigarette brand for this market.

"Evidence is now available to indicate that the 14-18 year old group is an increasing segment of the smoking population. RJR-T must soon establish a successful new brand in this market if our position in the industry is to be maintained in the long term."<sup>101</sup>

1957:

A Philip Morris executive wrote:

"Hitting the youth can be more efficient even though the cost to reach them is higher, because they are willing to experiment, they have more influence over others in their age group than they are far more loyal to their starting branding."<sup>102</sup>

1965:

Robert Wald, Counsel for Lorillard's stated Marlboro's campaign proceeded with a:

"Great campaign with probably the greatest appeal to kids: the gnarled, weather beaten cowboys- the hottest virility, sexual symbol going."<sup>103</sup>

1971:

An internal RJR Reynolds document stated:

"The lower age limit for the profile of smokers is to remain at 14."<sup>104</sup>

1972:

B&W document stated:

"It's a well know fact that teen-agers like sweet products. Honey might be considered."<sup>105</sup>

1975:

Marketing and Research Counselors statement on how to introduce "young starters" to Viceroy:

"For the young smoker, the cigarette is not yet an integral part of life, of day-to-day life, in spite of the fact that they try to project the image of a regular run-of-the-mill smoker. For them, a cigarette, and the whole smoking process, is part of the illicit pleasure category... In the young smoker's mind a cigarette falls into the same category with wine, beer, shaving, wearing a bra (or purposely not wearing one), declaration of independence and striving for self-identity. For the young started, a cigarette is associated with introduction to sex life, with courtship, with smoking 'pot' and keeping late studying hours."<sup>106</sup>

1976:

Document giving suggestions on how young starters can be attracted to Viceroy:

“Present the cigarette as one of few initiations into the adult world.

Present the cigarette as part of the illicit pleasure category of products and activities.

In your ads create a situation taken from the day-to-day life of a young smoker but in an elegant manner have this situation touch on the basic symbols of the growing up, maturity process.

To the best of your ability (considering some legal constraints) relate the cigarette to ‘pot’, wine, beer, and sex.

Don’t communicate health or related health points.”

...“Start out from the basic assumption that cigarette smoking is dangerous to your health- try to go around it in an elegant manner but don’t try to fight it- it’s a losing war.”<sup>107,</sup>

1977:

A working paper prepared for Imperial Tobacco stated:

“Rationale

By younger smokers, we mean people ranging from starters of the smoking habit up to and through the seeking and setting of their independent adult life style.

Relevant lifestyle is the key to the brand’s positioning, and the youthful emphasis is a psychological not a chronologic [sic] one.

At a younger age, taste requirements and satisfaction in a cigarette are thought to play a secondary role to the social requirements. Therefore, taste, until a certain nicotine dependence has been developed, is somewhat less important than other things.”<sup>108,</sup>

1977:

Philip Morris memo, Myron E. Johnson to Robert B. Seligman:

“It is important to know as much as possible about teenage smoking patterns and attitudes. Today’s teenager is tomorrow’s potential regular customer, and the overwhelming majority of smokers first begin to smoke while in their teens... it is during the teenage years that the initial brand choice is made: At least part of the success of Marlboro Red during the rapid growth period was because it became the brand of choice among teenagers who then stuck with it as they grew older... We will no longer be able to rely on a rapidly increasing pool of teenagers from which to replace smokers though lost normal attrition... Because of our high share of market among the youngest smokers, Philip Morris will suffer more than the other companies from the decline in the number of teenage smokers.”<sup>109,</sup>

1986:

An advertising report by McCann-Erickson Advertising of Canada for RJR Macdonald stated:

“Advertising Implications. Export should continue to appeal to younger males who

Are sports oriented

Drink Beer

Enjoy popular music

Are most comfortable in blue jeans and T-Shirt

... Export's masculine, rugged image needs to place in a more social/socially acceptable context communicating that it's alright to smoke, especially Export<sup>110</sup>,

1993:

An ex Philip Morris executive stated:

"You don't have to be a brain surgeon to work what's going on. Just look at the ads. Its ludicrous for them to deny that a cartoon character like Joe Camel is attractive to kids<sup>111</sup>

Marketing to children increase the obligation on the tobacco companies to provide proper education on the health hazards of its products.

## 2. *The addictive nature of the product*

The fact that the use of tobacco is addictive increases the burden on the tobacco industry to educate about general health effects in the specific effect of addiction. This is particularly true in view of the fact that most smokers began smoking while they are children.

Nicotine is an addictive drug. Smoking cigarettes effectively delivers nicotine to the blood for rapid onset of "highs". Addiction to nicotine is the sole or a substantial contributing cause of continued smoking in most smokers. Nicotine addiction impairs the ability of most smokers to control their smoking behavior. The American Psychiatric Association's Diagnostic and Statistical Manual, IV (DSM-IV) criteria is the accepted standard for substance dependence (addiction) and can be used to define any substance of dependence. DSM-IV defines substance dependence as a maladaptive pattern of substance use leading to clinically significant impairment or distress as manifested by at least three of the following seven criteria occurring at any time in the same 12 month period;

Cigarette smoking satisfies this criterion for dependence, as it is a maladaptive pattern of substance use that frequently leads to significant medical problems. It is the most lethal of all addictive drugs. Smoking is a contributing cause of death for than 400,000 US citizens every year. In contrast, heroin use results in fewer than 10,000 deaths per year. Only 1 in 20 smokers have a one-year cessation success rate when trying to stop on their own. More than half of heroin and cocaine addicts and alcoholics rate smoking cigarettes as harder to give up than other drugs. Moreover, relapse patterns for nicotine addiction closely follow those for heroin and alcohol.

DSM-IV in fact includes specific sections defining nicotine dependence and nicotine withdrawal. Some examples of how the seven DSM-IV criteria are fulfilled include:

**Tolerance:** When a virgin non-smoker initially smokes a cigarette, he experiences nausea, lightheadedness and other symptoms of nicotine toxicity. These symptoms lessen over time with continued smoking. Smokers become tolerant to these natural responses to tobacco smoke. Tolerance to nicotine is present in the majority of smokers. As with people using other drugs such as alcohol or cocaine, most smokers reach a limiting dose that they can self-administer on a daily basis.

**Withdrawal:** Psychological and/or physiological changes occur in the majority of smokers who try to stop smoking. Patients who stop or reduce their smoking frequently experience irritability, frustration, anger, anxiety, difficulty concentrating, insomnia, dysphoria (depressed mood), and restlessness. Physiological changes that may occur include a decrease in heart rate and an increase in appetite.

**Increasing dose:** Smokers regularly smoke larger amounts or over a longer period of time than originally intended.

**Inability to control use:** The desire to cut down or control substance use also occurs regularly in smokers. Over 80% of American smokers express a desire to quit, but on an annual basis, only 5% of the total are

able to stop. Loss of control over the use of a drug is a fundamental issue in defining an addictive disorder and is present in the majority of smokers.

Drug seeking behavior occupies significant time: Since cigarettes are readily available in so many different outlets and at all times of the day, they are easily accessible. Nonetheless, most smokers expend a lot of time to be sure that they do not run out of cigarettes by keeping a complete supply in multiple locations. Children may spend considerable time in drug seeking behavior.

Important social, occupational or recreational activities given up or reduced because of substance use: Many smokers give up or reduce their social, occupational or recreational activities because of smoking. Smoking has become less socially acceptable, and there are more restrictions on smoking indoors leading many smokers to avoid places where smoking is not possible

The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to be caused or exacerbated by the substance: Continued use of cigarettes despite knowledge of having a physical or psychological problem often occurs. Common scenarios include a person continuing to use cigarettes despite having had a heart attack, emphysema, peripheral vascular disease, lung cancer or laryngeal cancer. In fact, smokers who survive a heart attack are just as likely to continue to smoke, as they are to stop smoking.

The Surgeon General of the United States has found that nicotine is addictive. The 1988 Surgeon General's Report entitled, *The Health Consequences of Smoking -- Nicotine Addiction*, concluded that:

- 1) Cigarettes and other forms of tobacco are addicting.
- 2) Nicotine is the drug in tobacco that causes addiction.

The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.

The 1964 Surgeon General's Report concluded that smokers smoke due to the psychoactive effects of smoking but concluded that tobacco use was a habituation rather than an addiction. Internal documents of the tobacco industry, however, demonstrate that the tobacco companies acknowledged internally that cigarettes were addictive even before the 1964 Surgeon General's report. Indeed, industry documents demonstrate that in this area, as in many others, the tobacco companies knew more about smoking health effects like those of nicotine than was available in the general medical literature.<sup>112</sup>

Secret tobacco company documents indicate a long term awareness that nicotine, is addictive:

In 1962, Sir Charles Ellis, a scientific adviser to BAT stated:

What we need to know above all things is what constitutes the hold of smoking, that is, to understand addiction.<sup>113</sup>

He went on to say:

As a result of these various researches, we now possess knowledge of the effects of nicotine far more extensive than exists in published scientific literature. ... We believe that we have found possible reasons for addiction in two other phenomena that accompany steady absorption of nicotine. Experiments have so far only been carried out with rats, but with these it is found that certain rats become tolerant to repeated doses and after a while show the usual nicotine reactions but only on a very diminished scale...Supposing the tranquilizing action of nicotine can be tracked down in this way, then these reactions will be compared in the case of rats who have never had nicotine, or alternatively have

become addicted to it. Subsequent similar measurements will be made on human nonsmokers and on addicted smokers.<sup>114</sup>

A 1962 BAT document states that:

“...smoking is a habit of addiction that is pleasurable.”<sup>115</sup>

One R.J. Reynolds document concedes:

...“This hazard [posed by cigarettes] can be cut down by reducing or limiting smoking, but most smokers find this extremely difficult and it is generally accepted that this difficulty is caused by nicotine dependence.”<sup>116</sup>

One B&W document from 1978 states that:

“...very few consumers are aware of the effects of nicotine, i.e. Its addictive nature and that nicotine is a poison.”<sup>117</sup>

A report of discussions with industry research directors in the 1950s records among their opinions:

“...it's fortunate for us that cigarettes are a habit they can't break.”<sup>118</sup>

Secret tobacco company documents admit that the addictiveness of nicotine and its presence in cigarettes is in large part responsible for the revenues and profits that are produced by the sale of cigarettes:

One BAT document contemplates that:

“...high profits additionally associated with the tobacco industry are directly related to the fact that the customer is dependent on the product.”<sup>119</sup>

One RJR document, which discusses how nicotine levels could be maintained or increased as tar levels were reduced, also lists as one objective:

“...define optimum levels of additives compatible with smoker satisfaction and profitability.”<sup>120</sup>

One BAT document states that the addictiveness of nicotine made smokers placed cigarette manufacturers in the position where:

“...all we would want then is a larger bag to carry the money to the bank.”<sup>121</sup>

One B&W document describes how there is a preferred level of nicotine and that:

“...any company that deviated seriously from this level experienced sales difficulty.”<sup>122</sup>

Another document shows that, as early as 1963, B&W discussed “optimum levels” of nicotine, and correlated sales figures with nicotine levels, stating that “the nicotine level of B&W cigarettes...was not obtained by accident,” and recognizing that “even now...we can regulate, fairly precisely, the nicotine and sugar levels to almost any desired level management might require.”

In 1962 BAT analyzed nicotine content in a variety of cigarettes from each of the six major manufacturers. They concluded, “certainly the nicotine level of B&W Cigarettes given in the above table was not obtained by accident. It may be well to remind you, however, that we have a research program in progress to obtain, by genetic means, any level of nicotine desired. Neil has smoked very low nicotine Burley Cigarettes (0.2% level) and was surprised at how well the smoked.”<sup>123 124</sup>

This is proof that without question tobacco companies manipulated nicotine levels to “optimally addict” customers. The nicotine levels were lowered to keep them in an “optimum range”.

### 3. *Misleading Statements*

- (a) Semantic arguments
  - i. Associations, Risk Factors and causes

The tobacco companies have utilized semantic arguments in an effort to mislead the public on issues of smoking and health. I present two examples below. (Unfortunately some doctors have unwittingly walked the same path.) The argument attempts to distinguish between “association and causation” and is stated as follows: smoking is a “risk factor” but not a cause of cancer or other disease. This argument conflates the concepts of association, risk factor and causation.

Association may or may not be causal. For example, most people who wear dresses are women and roosters tend to crow before the sun rises. Dresses do not cause people to be a female, nor do roosters cause the sun to rise. Historically, the British philosopher Hume first raised this problem with inductive reasoning and it is referred to as Hume’s problem. However, physicians do not generally solely rely on post hoc ergo propter hoc arguments for making a cause effect determination. As can be seen in the methodology section, a variety of criteria are consciously or subconsciously are considered before physicians make cause effect determinations.

On the other hand, as far as common understanding is concerned, there is no difference between a risk factor as used in medicine and science and something that causes an effect. For example, driving drunk is a risk factor for getting in an accident. Most drunk drivers do not get into accidents. However, drunk driving causes or contributes to many accidents. Therefore, drunk driving is a risk factor for getting into an accident, but when the drunk driver has an accident, the drunkenness is usually a contributing cause of the accident. It is not merely associated with the accident; it actually contributes to or causes it. We do not make this causal connection merely because we have studied many accidents and find that the proportion of drunk drivers compared to sober drivers in accidents is quite high compared to their respective numbers in the population. We know other things about drunk driving, just as we know other things about smoking and cancer. Drunks have slower reaction times, they tend to fall asleep more readily and they tend to get confused, all of which are independent factors that contribute to accidents. Smoke is an irritant (see Clarence Little comments in 1947) and contained carcinogens (similar to those that caused cancer in chimney sweeps). It is these things, among others, in addition to the statistical association, that caused physicians to believe that drunk driving causes or contributes to accidents and that smoke caused lung cancer.

- ii. Necessary and sufficient causes

Even though drunk driving leads to accidents it is not a necessary or sufficient cause of accidents. Most accidents do not involve drunkenness and not all drunk drivers have accidents. A causal factor does not always have to be present to be a cause of some effects. Sober drivers also get into accidents and some people develop lung cancer in the absence of smoking (or even any other exposure). The cause does not always result in the effect. Drunk driving or smoking does not always result in the adverse outcome that it may cause under some circumstances (accident or cancer). When a cause precedes the effect it may be considered a cause even if it doesn’t always result in the effect or is not present in all cases. In other words, a cause does not have to be a sole cause nor does it have to be present in every case (necessary cause) to be a cause.

Koch’s postulates have been accepted with respect to the determination of the cause of infectious diseases like tuberculosis (TB). While it is true that the TB bacillus is present in every case of TB, it is a necessary cause but not a sufficient cause.<sup>125</sup> As Kass showed, over crowding, malnutrition and other byproducts of poverty are also necessary causes for TB infections. Virchow first argued for the multiple cause theory of

disease in the 1880's. For example TB rates decline precipitously prior to the introduction of antibiotics as the result of improvements in general living standards, social conditions and advances in sanitation. Similarly, in the 1980s TB rates increased along with and in large measure because of increases in homelessness.<sup>126</sup>

iii. Habituation versus Addiction

In 1962, the Surgeon General's Advisory Committee on Smoking and Health (SGAC) gathered to begin deliberations about the health effects of tobacco. Several members of the committee were suggested by the tobacco industry, including Maurice H. Seevers. Seevers, chairman of the pharmacology department at the University of Michigan, was an expert on habit-forming drugs and willingly agreed to the tobacco companies' request to serve on the committee. Seevers was also a smoker. He refused to identify the use of tobacco as an addictive behavior; the fault, Seevers insisted, lay with the user, not the substance.<sup>127</sup> In a secret meeting with tobacco executives, Seevers urged the Director of Research of the American Tobacco Company to keep up the nicotine content of the tobacco smoke. He even suggested that they add more nicotine to the tobacco.<sup>128</sup> Seevers also served at various times on the TIRC/CTR's SAB and the chairman of the AMA/ERF committee.<sup>129</sup>

In the subsequent 1964 report to the Surgeon General, the SGAC drew a fine distinction between addiction and habituation, categorizing smoking as a habituating behavior based on Seevers' recommendation. Leonard Schuman, another member of the SGAC, commented, "None of us [on the committee] were well versed enough in the field to pass judgment on his judgment."<sup>130</sup> The report defined addiction and habituation as:

Drug Addiction	Drug Habituation
Drug addiction is a state of periodic or chronic intoxication produced by the repeated consumption of a drug 'natural or synthetic.' Its characteristics include:	Drug habituation 'habit' is a condition resulting from the repeated consumption of a drug. Its characteristics include:
1) An overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means	1) A desire (but not a compulsion) to continue taking the drug for the sense of improved well being which it engenders
2) A tendency to increase the dose	2) Little or no tendency to increase the dose
3) A psychic (psychological) and generally a physical dependence on the effects of the drug	3) Some degree of psychic dependence on the effect of the drug, but absence of physical dependence and hence of an abstinence syndrome
4) Detrimental effect on the individual and on society	4) Detrimental effects, is any, primarily on the individual <sup>131</sup>

It is important to note that this definition, established by the World Health Organization, at about the same time, classified nicotine as a habituating drug. Cocaine and amphetamines, however, were also classified as habituating rather than addicting drugs.<sup>132</sup> Semantics aside, clearly from a current or a historical perspective, if an individual were told that something she was smoking had the same characteristics as cocaine and amphetamines, she would be concerned about her ability to stop using the drug. Although smoking was classified as a habituating behavior, several of the addiction criteria clearly apply to smoking and don't usually apply to drugs that were accepted as addicting. Some smokers experience an overpowering desire to continue smoking. Adult smokers may not resort to extreme measures to obtain cigarettes, but cigarettes are legal and easily obtained; not all users of cocaine, heroin, or marijuana are

driven to extreme measures to obtain their drug either. In addition, smokers exhibit a tendency to increase their dosage of nicotine throughout their lifetime. Smokers begin by consuming 1 or 2 cigarettes per day, but over time many progress to several packs of cigarettes per day and few maintain their initial consumption levels. I have never seen a patient who began by smoking 2 packs per day, but I have often seen a pattern of increased consumption that peaks at 1 to 3 packs of cigarettes per day.

As it is with all drugs, the spectrum of dependence with smokers is varied. Tobacco companies argue that because some smokers are able to quit smoking, smoking is not addictive. This claim conflicts with information about other addictive drugs, such as cocaine or marijuana. Many users are able to stop their consumption of these drugs.

The issue of psychological dependence was never disputed. In the May 8, 1971 issue of the *British Medical Journal*, M. A. H. Russell of the Addiction Research Unit at London's Institute of Psychiatry described five types of smokers:

1) Psychosocial:	use smoking as a prop in social situations
2) Indulgent:	smoke for the sensory rewards
3) Tranquilization:	use smoking for oral gratification and to occupy hands on order to relieve anxiety and tension
4) Stimulation:	use smoking to enhance alertness and perseverance
5) Addictive:	smoke to avoid the symptoms of withdrawal <sup>133</sup>

Some smokers experience the physical dependency characteristic of addiction. For example many of my patients find that without their drug (nicotine), they experience withdrawal symptoms that include edginess, irritability, hostility, depression, mood swings, oral fixation, craving, headache, constipation, and weight gain.

Finally, smoking causes detrimental effects to society as well as to the individual. Smoking is annoying for nonsmokers and also yields serious detrimental health effects to nonsmokers as well as smokers. Public funds directly and indirectly pay for smoking related illnesses.

Director William Pollin of the National Institute on Drug Abuse asserted that once an individual chooses to smoke, he experiences "a decided loss of control, with dire health consequences."<sup>134</sup> Smoking does not continue to be a freely chosen behavior, as the term habituation suggests. Rather, smoking becomes an addictive behavior that the smoker can no longer control. The tobacco industry, seeing the implications of the branding of their product as addictive, continues today to deny that smoking is addictive.

This is misleading to potential and current smokers and places an additional burden on these companies to educate the public about the addictive nature of smoking.

In addition the tobacco industry intentionally designed products to mislead users about potential health effects. These misleading statements increase the Public health obligations of the companies to properly inform consumers of the health effects of their products.

#### 4. *Design issues*

##### a) Intentional Control of Nicotine Levels

The recognition of the importance of addiction was so clear to tobacco companies that they developed an entire program designed to:

- Determine the dose needed to effectively attract and addict users.
- Develop methods to control the dose of nicotine delivered to the user.

Secret Tobacco company research showed them that, to sell product, they had to restrict nicotine levels in tobacco and thus in blood to a narrow range of concentration. Give the user too much drug and she will overdose and not use cigarettes. Give the user too low a dose and he will not become addicted.

While nicotine is a naturally occurring alkaloid in the tobacco plant, nicotine is not a necessary constituent of the modern cigarette. The technological ability exists to remove virtually all nicotine from cigarettes. The tobacco companies have, however, decided not to do so because sufficient quantities of nicotine are necessary for most smokers to continue smoking. Nicotine is not left in cigarettes primarily because of its taste. In fact, tobacco company internal documents recognize that nicotine tastes bad.

Secret tobacco company documents acknowledge that there is a threshold dose of nicotine needed to produce a “kick”. For example:

One Philip Morris study suggested that:

“...a threshold exists somewhere between 0.1 and 0.3 mgs of nicotine.”<sup>135</sup>

One BAT document states that for a smoker to be “satisfied,” cigarettes had to:

“...allow achievement of a required daily level of nicotine intake in an appropriate manner.”<sup>136</sup>

One RJ Reynolds document terms this threshold level the:

“...habituating level of nicotine.”<sup>137</sup>

A RJR document recognizes that if the company reduced or eliminated nicotine from its cigarettes:

“...then we shall eventually eliminate our business.”<sup>138</sup>

Secret tobacco documents also reveal research on a variety of ways to control nicotine received by smokers. This included research on the addition of nicotine to tobacco. As early as 1960, Philip Morris studied the addition of nicotine maleate to blended leaf to increase the nicotine content of cigarettes.<sup>139</sup> Secret documents also reveal research on the control of nicotine by altering the pH levels of smoke produced by cigarettes. These secret documents indicate that the tobacco companies knew more about the effect of pH on the absorption of nicotine by the smoker than did members of the medical and scientific community. However, this information is supported by current medical knowledge on the effect of pH on the absorption of nicotine. The documents describe how increasing the pH level has the effect of increasing the amount of “free” or “free base” nicotine, as opposed to “bound” nicotine thus increasing the nicotine effective dose to the user. The smoker than bound nicotine absorbs free nicotine more rapidly.<sup>140</sup> By increasing the amount of free nicotine, the tobacco companies can keep nicotine levels in the optimum

range for addiction while maintaining or even lowering the total amount of nicotine in cigarettes (as measured by the FTC method). R.J. Reynolds, for example, understood that, "...any desired additional nicotine 'kick' could easily be obtained through pH regulation" and discussed the importance of "kick" in the design of a cigarette for "new RJR youth appeal brand."<sup>141</sup>

One way to control the pH and affect the transfer of nicotine to the smoker is through the addition of ammonia compounds. Philip Morris introduced the use of added ammonia compounds in its cigarettes at least as early as 1965, and very rapidly Philip Morris brands, especially Marlboro, began growing in sales. The addition of ammonia compounds to cigarettes became standard practice in the industry.

Nonetheless the tobacco companies cynically argued and argue that there was some important distinction between "habituation" and "addiction."<sup>142</sup> The tobacco companies knew that this semantic difference was not relevant to drug dependence and it is for this reason that they were compelled to research nicotine effects, dose response relationships and then incorporate that information into product design. The intentional secret manipulation of nicotine levels increase the obligation of the tobacco companies to educate users of the effects of cigarettes and nicotine.

#### b) Toxic constituents of Tobacco Smoke

##### i. Particulates

The tobacco companies were aware that particulate levels in smoke were above ambient air quality standards.<sup>143</sup> They state, "There is a paper by Repace in Science May 2, 1980 that indicates that the amount of respirable particles suspended in the air frequently exceeds the National Ambient Air Quality Standards, NAAQS."

##### ii. Asbestos in Cigarettes

The joint impact of asbestos exposure and smoking was first noted in the medical literature in 1958.<sup>144</sup> Studies performed in the 1960s conferred further credence to the causal nature of this association. Synergy as used in this report means that the joint effects of exposure to asbestos and tobacco smoke increases the incidence of cancer in those exposed geometrically rather than in an additive manner. Asbestos and tobacco smoke are each independent and sufficient causes to the development of lung cancer. Neither is required for the development of lung cancer. For example, both a lit cigarette and a gasoline soaked rag are sufficient causes to set a newspaper on fire. (As with smoking and asbestos there are many other causes for fire that require neither. The fact that a cause is not always necessary is not a reason that it is not an actual cause in many or even most cases of fire or lung cancer.) The combined effect of throwing a lit cigarette on a gasoline soaked rag, onto newspaper makes it far more likely that the paper will catch on fire than if only the cigarette or rag was present. This geometric increased likelihood of effect occurrence is called synergy. To continue the analogy, there are other factors that make it more or less likely that a lit cigarette, gasoline soaked rag, or the combination will cause a fire. (For example is the newspaper wet or dry, is there a sufficient supply of oxygen, etcetera). The same is true for asbestos and/or smoke and lung cancer or lung disease. The other factors (genetic, other exposures, gender) may be considered other necessary causes for the development of cancer. This helps explain why all smokers do not get cancer or lung disease. Another reason is that they may die from a car accident or another tobacco related disease (heart attack, stroke etcetera. (See TAB 15, figures 5, 6)

Several asbestos companies utilized asbestos in their cigarettes. Kent cigarettes Micronite Filter contained asbestos from 1952 to 1956. In addition, other companies took out patents for the use of asbestos in the making of tobacco sheets for reconstituted tobacco. The Micronite filter was designed to appeal to health conscious smokers. It was specifically advertised in medical magazines and promoted to doctors to leave the impression a cigarette that was "safer". The joint program between Lorillard and Owens Corning fiberglass was initiated in the 1950s to try to develop a fiberglass filter to appeal to health conscious smokers. The filter released significant quantities of fiber.<sup>145</sup>

Information on the synergistic effects of asbestos and tobacco were known in the medical literature in the 1960s and was not well known amongst either the medical community or users of cigarettes who had been exposed to asbestos.<sup>146</sup> The tobacco manufacturers should have performed specific educational programs informing potential users of this phenomenon.

This type of information would still be of value since asbestos remains in the lung for many years after exposure. Thus even workers who were exposed to asbestos during World War II who continue to smoke today, continue to expose themselves to both the lit cigarette and the gasoline soaked rag.

Instead Industry representatives repeatedly stated that no tobacco additive had been found to cause cancer in people. This additive misinformation appeared in a Philip Morris paid advertisement in the New York Times April 15, 1994:

## **Smokers and Nonsmokers, Facts you can note**

### **FACT**

**None of the ingredients added in the manufacturer of cigarettes is harmful as used. Cigarette ingredients have been scrutinized by the Department of Health and Human Services since 1986. In addition, an independent safety assessment was conducted by six renowned scientists. Their report concluded: “the ingredients added to tobacco and a manufacturer of cigarettes by the six major US manufacturers are not hazardous under conditions of use”.**

- c) Toxic constituents of Tobacco Smoke that Mask Its Warning Properties  
Blocking the Smoker’s Natural Senses
  - i. Additives

#### **a) Sweets**

Nonsmokers who begin to smoke frequently experience a variety of symptoms including cough, upper respiratory tract irritation, and phlegm production. In fact one of the reasons that it is difficult to induce lung cancer in animals is their natural aversion to the inhalation of smoke. The animals run away from and try not to inhale smoke. This is a natural protective mechanism and humans have the same mechanism. Upper respiratory tract irritation and other symptoms are warning signs that smoke is bad for you. Cigarette smoke produces these symptoms and thus provides a natural warning to the user to stop smoking. In other words, cigarette smoke has onion like warning properties that signal the user to stop smoking.

Tobacco companies recognized that the natural warning properties of the inhalation of their product would inhibit its use. They developed a variety of chemicals that were added to cigarettes to remove or mask the natural “onion” properties of the smoke.

Additives render tobacco products more tolerable to users. They make the smoke milder and easier to inhale (sugars, cocoa and humectants), add flavor and aroma (masking).

#### **b) Anesthetics**

- (i) Menthol

Some additives anesthetize the throat (menthol and eugenol).<sup>147</sup> Menthol cigarettes mask the harmful effects of tobacco that users otherwise would have noticed.

(ii) Eugenol

Eugenol was also known to induce chromosomal aberrations in some testing.<sup>148</sup> Eugenol caused pulmonary edema in dogs. This information was not divulged to product users; the companies kept and keep this information to themselves.

d) Toxic Properties of Smoke that Mask its Warning Properties

i. Phenol

The tobacco companies were also that phenol in cigarettes impaired cilia function and acted as an anesthetic. They also developed technology to remove the phenol.<sup>149</sup> In fact they marketed Kent cigarettes expressly as a cigarette that would filter harmful smoke components.<sup>150</sup> It seems clear that cigarette companies were willing to utilize information on the health effects of tobacco smoke for marketing purposes when it suited their marketing objectives.<sup>151</sup>

Yeaman, a lawyer at Brown & Williamson summarized the effects of phenol:<sup>152</sup>

- “1. The uninhibited movement of the cilia tends to eject from the lung, (or impede entering to the lung) particulate matter.
2. It is known that phenol inhibits the action of the cilia.
3. It is known that phenol occurs in the inhaled smoke.
4. It is now known that phenol content of the smoke can, by use of certain additives in the filter, be very substantially reduced: In this state of knowledge, is it negligence on the part of the cigarette manufacturer either:
  - (A) To fail to remove phenols, or,
  - (B) To fail to educate consumers of the product of its potential danger.”<sup>153</sup>

This document, which is a summary of a 1962 research conference proceedings, also goes on to show that phenol concentrations were 900-1000 mg per cubic meter while the maximal allowable concentration was 19 for a working atmosphere and the odor threshold was 1.5. These BAT researchers recognized that phenol anesthetized the tissues and blunted the sense of smell and blocked the warning properties of the product. By masking the warning properties of the product, phenol duped the user's senses.

Other manufacturers inform phenol users of these risks on MSDS sheets that accompany or are attached to the phenol containers:

“Potential Health Effects  
-----

The major hazard of phenol is its ability to penetrate the skin rapidly, particularly when liquid, causing severe injury which can be fatal. Phenol also has a strong corrosive effect on body tissue causing severe chemical burns. Due to its local anesthetizing properties, skin burns may be painless. [Emphasis added]

Inhalation:

Breathing vapor, dust or mist results in digestive disturbances (vomiting, difficulty in swallowing, diarrhea, loss of appetite). Will irritate, possibly burn respiratory tract. Other symptoms listed under ingestion may also occur.

Ingestion:

Poison. Symptoms may include burning pain in mouth and throat, abdominal pain, nausea, vomiting, headache, dizziness, muscular weakness, central nervous system effects, increase in heart rate, irregular breathing, coma, and

possibly death. Acute exposure is also associated with kidney and liver damage. Ingestion of 1 gram has been lethal to humans.

Skin Contact:

Corrosive. Rapidly absorbed through the skin with systemic poisoning effects to follow. Discoloration and severe burns may occur, but may be disguised by a loss in pain sensation.

Eye Contact:

Corrosive. Eye burns with redness, pain, blurred vision may occur. May cause severe damage and blindness.

Chronic Exposure:

Repeated exposure may cause symptoms described for acute poisoning as well as eye and skin discoloration.

Aggravation of Pre-existing Conditions:

Persons with pre-existing skin, eye or central nervous system disorders, or impaired liver, kidney, or pulmonary function may be more susceptible to the effects of this substance.<sup>154</sup>

I agree with Mr. Yeomen's inference, that it is, "negligence on the part of the cigarette manufacturer" to "either (A) To fail to remove phenols, or, (B) To fail to educate consumers of the product of its potential danger."<sup>155</sup> It is clear that the tobacco companies considered the need to educate about or remove phenol from their products, and they intentionally did not do so. This was contrary to good public health practice. Other manufacturers of phenol, who do not intend that users inhale the material, inform users of the risks of inhalation, including the anesthetic property that may mask its toxic effects.

Therefore the tobacco companies, quite literally, sold sugar and chocolate covered cyanide gas, arsenic, and rat poison in "clean white" paper. This increases the public health obligation to educate users of the risks of exposure.

e) "Low Tar" cigarettes, compensation and false reassurance

Tobacco company documents indicate that they created "low tar" brands to "assuage smokers" health fears of cigarettes and to "maintain faith and confidence in the smoking habit".<sup>156</sup> Tobacco companies viewed these brands as a method to combat attempts by concerned smokers to stop smoking. Tobacco companies explain, "...quitting rates will not increase as existing smokers become increasingly reassured by the growth of Low Tar brands..."<sup>157</sup> Some internal tobacco company documents specifically call these "health reassurance" products.<sup>158</sup> But the tobacco companies knew this was false reassurance.

The tobacco companies knew that "low tar" cigarettes are smoked in a way that results in tar and nicotine absorption that is greater than that indicated by the "low tar" design or the measures of tar and nicotine levels that might register for such cigarettes according to the testing method of the Federal Trade Commission (FTC). The FTC method of measuring tar and nicotine was developed as a standardized method for assessing delivery of nicotine and tar. This method relies on smoking machines that draw smoke from a cigarette the same way each time. FTC machines do not reproduce actual smoking methods. Smokers "compensate" for the diluted nicotine and tar delivered by these types of cigarettes. Compensation methods include increasing inspiratory volume, holding their breath longer and occlusion of the ventilation holes in the cigarette, all of which result in blood nicotine and tar levels that are comparable to regular cigarettes. A BAT document states that this behavior is subconscious, "...a similar mechanism to Pavlov's dogs."<sup>159</sup>

The tobacco companies have failed to educate about any of the issues related to nicotine or warning properties. This failure increases the burden on them to educate users of the potential health effects of smoke. These design changes designed to mask the warning properties of smoke and the failure to remove "natural" anesthetics like phenol were neither the tobacco companies' first nor the only efforts to mislead customers about the health effects of their products

5. *Tobacco industry's recognition of the obligations to test and to educate, misleading statements, and the obligation to cease marketing.*

Obligations to test and inform the public

After Reader's Digest's "Cancer by the Carton" article publicized the link between smoking and lung cancer in 1952, tobacco sales went into marked decline. In addition, Dr. Wynder had recently published mouse-painting experiments that showed tumor formation on mouse skin exposed to tar distillate. In early 1954, the tobacco industry therefore announced the formation of the Tobacco Industry Research Committee (TIRC) through the publication of a full-page "Frank Statement to Cigarette Smokers" that ran in 448 newspapers nation-wide.<sup>160</sup> This statement, orchestrated by top tobacco company executives with the assistance of public-relations firm, Hill & Knowlton, marked the inauguration of the industry's concerted effort to divert the attention of the public, the government, and the public health and medical communities away from the existence of tobacco-related disease by creating, exaggerating, and repeatedly resurrecting an otherwise nonexistent scientific controversy.

The Frank Statement, presented as the formal doctrine of the tobacco industry's public health obligations, conveyed two essential positions of the tobacco industry to the public: (1) that the industry is charged with a public health obligation that comports with the standard principles of safeguarding the public's health already expressed and generally accepted by the manufacturers of hazardous substances, or that protecting the health of the public and the consumer is "of paramount importance to every other consideration," and (2) the industry therefore has the further commonplace public health obligations of investigating the nature of any potential hazards and engaging in the "disinterested" presentation of scientific facts.

Given the obligations established in the statement, the statement further served to cast doubt upon the epidemiological and animal evidence supporting the "theory that cigarette smoke is in some way related to lung cancer." The statement served to discredit this theory on broad epistemological grounds, or that experiments with mice bare no relation to human health and that statistics and epidemiology are not valid methods for the determination the causes of human disease. The tobacco industry's explicit statements of public health obligations and the self-professed candor of this statement directly appealed to the public's trust and established self-imposed public health obligations for the tobacco industry to safeguard the public by publicizing scientific findings (and any repudiations) in good faith. For instance, Timothy V. Hartnett, former Brown & Williamson president who was named the first full-time member of TIRC, emphasized the Industry's pledge of disinterestedness and objectivity by stating, "The millions of people who derive pleasure and satisfaction from smoking can be reassured that every scientific means will be used to get all the fact as soon as possible."<sup>161</sup> Further statements made by TIRC or tobacco industry executives whose companies were members of TIRC explicitly reaffirmed these public health obligations to safeguard the public's health, usually within the context of denying the hazardous effects of tobacco. Parker McComas, chief executive of Phillip Morris, stated for instance in his capacity of temporary chairman of TIRC, "If the industry leaders really believed that cigarettes caused cancer, they would stop making them."<sup>162</sup>

The tobacco industry's continued its public reassurances that the Industry would stick to its stated pledge of safeguarding the health and safety of tobacco consumers and the public through its supposed investigations into the hazards of tobacco smoke. Statements made after the Industry re-branded TIRC as the Council on Tobacco Research (CTR) and spun off its overt public relations activities into a sister industry group in 1958, the Tobacco Institute (TI), reiterate the industry's fundamental public commitment: to not sell a product known to be hazardous. The Industry used this commitment as *de facto* evidence of the safety of cigarettes, given their continued marketing of cigarettes in light of making these upstanding pledges. In 1963 for instance, James Chandler Bowling, executive assistant to Phillip Morris CEO Joseph Cullman, told Thomas Whiteside, reporter for *The New Yorker*:

"We believe there is no connection [between smoking and disease], or we wouldn't be in the business."<sup>163</sup>

Privately, the industry was aware of its standing public health obligations to discover and evaluate the scientific facts, and relate those facts truthfully to the public. For instance, in a November 30, 1970 memo

to the TRC executive committee, Henry Ramm, RJ Reynolds' general council, acknowledged, "When the products of an industry are being accused of causing harm to others, certainly it is the obligation of that industry to determine whether such facts are true or false."

#### G. Affirmative misrepresentations on the health benefits of smoking: The litigation and sales campaign

The fact that cigarette manufacturers never voluntarily educated users about the adverse health effects of tobacco on cigarettes sold in the US markets does not imply the tobacco industry was unconcerned about health; the tobacco industry was very concerned about making health representations as they applied to marketing and advertising. Dating back to at least the 1920's, the industry made direct and explicit claims in product advertisements about the healthfulness of cigarettes. (See TAB 13)

#### H. Marketing Public relations disinformation campaign - some examples:

##### 1. *Health claims*

RJR developed a campaign designed to "recruit physicians to support advertising campaigns communicating medical endorsements of smoking."<sup>164</sup> Grant Clarke who was an employee of Hill and Knowlton funded by RJR ran this campaign. In addition, Mr. Clarke was instrumental in creating the original TIRC scientific advisory board".<sup>165</sup> Clarke ran the Camel "Medical Relations Division" (CMRD) for Reynolds between 1942 and 1953. The medical relations division "appears to be nothing more than an address through which the add agency (ESTY) could mail out articles in the smoking and health area."<sup>166</sup> Reynolds ran Camel adds in medical journals claiming beneficial aspects of smoking Camels, including suggesting that less nicotine was beneficial.<sup>167</sup> In addition they developed support for an add campaign that stated that "more doctors smoke CAMEL". In 1953, this CMRD program was moved in-house at Reynolds.

Grant Clarke was a member of the original industry technical committee of the TIRC. The committee was formed in 1954 and consisted of research directors of member companies. In addition to Clarke, the committee was composed of seven directors of research of tobacco companies, a vice-president of research and a vice-president of manufacturing. The research directors "screened those people who were being considered for membership in the scientific advisory board."<sup>168</sup> Clarke was also involved in gathering expert witnesses for tobacco litigation.<sup>169</sup>

Clarke is a window into tobacco company efforts to influence the medical community, selectively provide them with literature and control the membership and output of the allegedly independent Scientific Advisory Board.

An advertisement prepared by The Tobacco Industry Research Committee was published in over 50 newspapers across the country. The "Frank Statement to Cigarette Smokers" was the beginning of the plan to disseminate misinformation about the health effects of tobacco. Here and elsewhere the tobacco companies made explicit representations about the health effects of tobacco and their response to the allegations of product related disease. Many if not all of these were false and misleading and thus ran contrary their obligations to test and inform users of the health consequences of tobacco use.

##### 2. *Kent Micronite filter*

From 1952 to 1956, Kent used crocidolite asbestos in its filters. This was during a time when it was well known that asbestos was a carcinogen. At the same time, Kent made health claims for its cigarettes. "Only Kent goes to the extra expense to protect you with microscopic filtering". "Kent's Micronite Filter takes out more nicotine and tar ... protects you as no other filter can".<sup>170</sup>

At around the same time Lorillard began a joint project with Owens Corning Fiberglass (OCF) to develop a fiberglass filter. This was done specifically to address the smoking cancer concerns that were evident in the medical literature.<sup>171</sup> The tobacco companies again showed concern over public perceptions of smoking health hazards. OCF personnel noted:

"One of the basic decisions they [Lorillard] still have to reach is whether they will or will not face the psychological hazard connected in the public's mind with the word glass as far as their innards are concerned."<sup>172</sup>

At the time that Lorillard placed asbestos in its filters between 1952 and 1956, medical literature had already established that asbestos was a carcinogen. (See Asbestos State of Art at TAB 14)

Because, like all other aspects of its products, Lorillard kept the constituents of its filter secret, consumers and physicians had no way of knowing that Lorillard was adding a known lung carcinogen to its cigarettes (in addition to the components of cigarette smoke that were established carcinogens). More ironically, this combination was marketed as a health advantage. There is no evidence that Lorillard tested their product to see if it did, in fact, "protect as no other filter can".

### 3. *Other misleading statements and conduct*

The Frank statement announced that the cigarette industry:

"We accept an interest in peoples health as a basic responsibility, paramount to every other consideration in our business.

We believe the products we make are not injurious to health.

We always have and always will cooperate with those whose task it is to safeguard the public health."<sup>173</sup>

The Frank statement acknowledged that it was the responsibility of the tobacco companies to protect the health of the people who used its products. I agree.

The Frank statement misleads users that its products were not injurious to health. This statement is contrary to the medical consensus that had developed by 1954 that tobacco smoking caused cancer and nonmalignant respiratory disease. The tobacco companies had not produced any evidence that indicated that their products were not injurious to health. More importantly they did not then, nor do they now state or explain what evidence would be sufficient for them to say that cigarettes were or are hazardous to health. This statement to smokers is thus false and misleading. Since it initially appeared in magazine and newspaper ads all over the country, the Frank statement and similar statements have been repeatedly made directly to consumers and public officials for over 30 years.

The Frank statement indicates that the tobacco companies will always cooperate with public health officials. On the contrary, the tobacco companies have engaged in a 100-year war with public health officials. At every opportunity they have attempted to block public health actions that would protect the public against the use of their harmful products.

They have co-opted professional organizations like the AMA and the Surgeon General's Committee.

The production and dissemination of misleading statements increases the public health obligations on the tobacco companies to take corrective action to inform the public of the real health hazards associated with their products.

In 1958, the industry continued to publicly deny the published science, speaking through the Tobacco Industry Research Committee's medical director, the industry claimed:

No convincing clinical or experimental evidence has yet been brought forward that cigarette smoking is the positive cause of lung cancer.

There have been and will continue to be speculations and opinions on the causes, but it is a matter of scientific fact that, in our present state of knowledge, no one knows the answers.<sup>174</sup>

In 1964 Bowman Gray, chairman of Reynolds stated, before a congressional subcommittee, that “[many] distinguished scientists are of the opinion that it has not been established that smoking causes disease,” and claimed a “lack of clinical and laboratory scientific evidence of the relationship between smoking and health.” He failed however to explain what would have constituted sufficient evidence of causation and did not explain how his company planned to carry out such testing.

In 1982 Edward Horrigan, CEO of R.J. Reynolds, stated “science to date after much research including over \$100 million funded by our industry, indicates that no causal link [between smoking and human disease] has been shown,” and that “there is absolutely no proof that cigarettes are addictive.”

One manufacturer conducted a national campaign in 1984, defiantly stating that the “studies which conclude that smoking causes disease have regularly ignored significant evidence to the contrary.” There was never any “significant evidence to the contrary.”<sup>175</sup>

These claims and the fact that the tobacco industry never formally refuted or withdrew them created a standing public health obligation not only to disprove the hazards of cigarette smoke, but also to affirmatively prove their health benefits. The tobacco industry's public response to evidence of smoking-related disease, however, has included (1) an openly defiant stance toward studies that revealed the hazards of their products; (2) a policy of generating a false sense of controversy to make it appear that a consensus on the dangers of smoking were not generally accepted within the general public and medical community, (3) repeated misrepresentations about the safety of its products, (4) marketing to children, (5) marketing an addictive drug, and (6) adulteration of the product to mislead users of the hazards of its use. These actions all contradict the principles historically adopted by the manufacturers of hazardous products for safeguarding the public from hazards inherent in the use of their products. These misrepresentations place an additional burden on the tobacco companies to educate consumers of the hazards of use of its products.

With respect to the public health obligations to test, to educate, to redesign (to make safe or safer) and to cease to market a product that is known to cause cancer, I agree with the statements made by industry representatives.

“We accept an interest in peoples health as a basic responsibility, paramount to every other consideration in our business.”

A Frank Statement to Cigarette Smokers- January 4, 1954.

“If the industry leaders really believed that cigarettes caused cancer, they would stop making them.”

Parker McComas, chief executive of Phillip Morris, temporary chairman of TIRC  
<sup>176</sup>

“We believe there is no connection [between smoking and disease], or we wouldn't be in the business.”<sup>177</sup>

Phillip Morris CEO Joseph Cullman, 1963

Unfortunately another industry executive described the motives of the industry that explain its response to its knowledge of its corporate responsibilities to protect the health of product users.

“Our one all-consuming ambition is to create wealth for the owners of Philip Morris.”

Philip Morris CEO Geoffrey Bible, Letter to shareholders February 1995.

I. Tobacco Company awareness of the importance of, and ways to, disseminate information on smoking and health.

The tobacco companies deny that they had an obligation to place educate users about the hazards of their products, offering contradictory arguments that range from a complete rejection of the health hazards associated with cigarettes to the claim that any health hazards should be common knowledge, should have been known by the user, and therefore did not trigger any obligation to educate users of potential health hazards. While many studies indicate that users are not aware of the risks of smoking, an examination of the knowledge of tobacco industry executives is the best evidence for the speciousness of this argument.

A 1954 Gallop poll indicated that 90 % of Americans “knew” about the “controversy over the health effects of cigarettes” however only 41 % in the very same poll, said they believed that cigarettes was a cause of cancer.<sup>178</sup> This is a measure of the effectiveness of the Industries’ disinformation campaign. Smokers were less likely to believe the effect was real (denial). The impact of the changes in the label is evident from the changes in 1966 and 1990.

Year	% Of Americans <sup>179</sup> Who Believed Smoking was a cause of cancer	Smokers only response	% Of Americans Who Believed Smoking was a cause of heart disease
1954	41	30	
1957	47	35	38
1958	44	33	
1966	40		
1969	70		
1977	81		
1981	83		
1990	94 <sup>180</sup>		

Tobacco executives should be experts on the health hazards of their own products and should be aware of any health risks associated with their products. Yet, in depositions industry officials have stated that they were ignorant of the dangers of their products. Robert K. Heimann of the American Tobacco Company, for example, asserted that he was not aware that smoking was related to two diseases that were expressly listed on the government mandated warning labels.<sup>181</sup> Heimann demonstrated his ignorance of smoking-related health issues in a deposition for a tobacco trial in the mid 1980s. He testified:

- The board of directors never discussed the substance of smoking-related health issues

- The idea that industry researchers would eventually establish the health hazards of smoking had never occurred to him
- Although he had never studied medicine, Heimann believed that he was more qualified than the Surgeon General to determine the hazards of smoking
- He did not know of any senior executives who ever consulted with a professional medical association.<sup>182</sup>

The lawyers from Jones, Day, Reavis, and Pogue realized that the tobacco companies' expressions of ignorance on issues of smoking and health limited their ability to blame the victim for ignoring health information that had escaped the notice of tobacco executives. They wrote:

"If a major American tobacco company could not in 1963 have foreseen that its product might cause disease, and if well-educated and highly-compensated [sic] executives were not aware of specific allegations, how can they criticize someone far less sophisticated?"<sup>183</sup>

The fact that tobacco executives were uninformed about smoking and health issues emphasizes the inadequacy of the dissemination of public health information on smoking and health.

The Jones, Day, Reavis, and Pogue document also indicates that tobacco executives and their legal counsel were aware of the effectiveness of education programs on smoking and health issues. They realized that education programs designed to train tobacco executives and other witnesses on smoking and health issues could be done effectively. They developed a training manual to assist in this process.<sup>184</sup> The training manual was designed to train lawyers to train tobacco executives and witnesses on smoking health issues. This is an excellent and efficient way to disseminate health information. (For example the nonprofit organization that I established, The Training Exchange, utilizes the same method (train the trainers) to disseminate health information in developing countries.)

The tobacco lawyers described the lack of awareness of witnesses on smoking and health issues and the need for an education program. They wrote:

It is abundantly clear that the defense has not adequately addressed the issue of corporate awareness. To overcome the problems identified above, care must be taken in the preparation of witnesses [company executives] to assure their familiarity with certain facts.<sup>185</sup>

The lawyers even went so far as to provide a list for the fact witnesses of ways in which the witnesses could become more familiar with the issues of which they already allegedly knew. This training manual included a detailed list of, "popularized epithets' ... (e.g. coffin nails, cancer sticks, nicotine fit, little white slavers, etc.)". These epithets were apparently unknown to the executives and appropriately (from a public health perspective) the lawyers listed them in detail. This is an excellent educational scheme. In fact the epithets are not well known. Other suggested mechanisms executives could mention to show that they had been kept informed and which would have provided them with information on the smoking and health issue included:

1. Infolog, published by TI
2. Current digests published by CTR.
3. Discussions at company board or committee meetings.
4. Discussions at TI board or committee meetings.
5. Discussions at CTR board or committee meetings.
6. Discussions with counsel with respect to pending litigation.
7. Discussions with counsel and others with respect to proposed litigation.

Periodic reporting, such as monthly, quarterly or annual Research and Development Department reports.<sup>186</sup>

These are and were excellent sources of information on smoking and health. Unfortunately (except for number 2) they were not available to the public. I agree with the Jones, Day, Reavis, and Pogue lawyers, this information should have been made available to the public.

(Ironically, the lawyer-training program for witnesses was designed to show that the witnesses and tobacco companies did not rely on lawyers for smoking-related health advice. In other words the lawyers planned to train the witnesses to prove that the witnesses did not rely on lawyers. This reference list that the lawyers provided was designed to “greatly diminish the apparent impact of reliance on lawyers for smoking and health advice.”)<sup>187</sup>

One of the main purposes of this “training manual” was to develop some of the responses for fact witnesses (see paragraphs 1-3 in particular below).

1. Industry witnesses should be able to identify each major disease process with which smoking has been associated, including particularly those listed on the rotating labels
2. Industry witnesses should also have a modicum of familiarity with the principles underlying the “Open Controversy” position with respect to the major disease processes, or be able to defer to someone in the company with knowledge.
3. Witnesses should be aware that while CTR has some warts, it not only has accomplished its fundamental goal but also has contributed more money to cancer research than ACS (and perhaps all voluntary health agencies combined).
4. The witnesses who are designated as Rule 30 (b) (6) witnesses must be knowledgeable with respect to the basic information in the documents which plaintiffs have selected and should be able to present concise, knowledgeable and credible responses to the questions which plaintiffs will ask them. **This report attempts to develop some of these responses.** The witnesses need not volunteer, but denying too much creates as much difficulty as admitting too much; and

The industry witnesses should be given positive benchmarks or reference points for all of their testimony, including the following:

- Cigarettes are a legal product with many benefits which people voluntarily choose to smoke;
- Everyone has known the allegations of risks associated with smoking for many years, long before the statutory warnings;
- The companies are under no duty to warn of that which is already known;
- Cigarettes have been heavily taxed and regulated by the FTC and Congress;
- The industry has imposed many aspects of regulation on itself which is unprecedented with any other product and unique to cigarettes;
- The companies and industry have conducted health research and product research to develop and market better cigarettes that satisfy consumer demand; and
- Many people including notable scientists assert a strong association between smoking and lung cancer, but if they can't tell us what causes

lung cancer in non-smokers, how can they tell us what causes lung cancer in smokers?<sup>188</sup>

It is important to note that the training program for executives was recognized to be effective. The lawyers from Jones, Day, Reavis, and Pogue characterized Robert Heimann as:

“...an excellent witness on personal and corporate awareness relating to smoking and lung cancer but is weak on other diseases associated with smoking. Thus, he was aware of the smoking and health controversy in the 1920s, and 'as a growing lad' had heard both the phrase 'coffin nails' and the claim that cigarettes caused tuberculosis.” In a recent deposition, Heimann claimed to be aware of historical smoking-related health issues and smoking studies, and has “tried to secure through the TIRC staff or through other means copies of everything of significance published in the area of smoking and health.”<sup>189</sup>

Restating the need for an education program:

“If a major American tobacco company could not in 1963 have foreseen that its product might cause disease, and if well-educated and highly-compensated [sic] executives were not aware of specific allegations, how can they criticize someone far less sophisticated?”<sup>190</sup>

I agree. Moreover if in 1986, these executives needed to be educated on tobacco health issues then so did and do product users. No better argument can be made for the need for public health education on the health risks of smoking and the companies' competence in the design and implementation of such a program.

## 7. Tobacco companies' response to knowledge

In this section I analyze the tobacco industry's response to the public health information it had available from the general medical literature and its own secret research. In other words, I answer the question, did the tobacco industry fulfill the contemporaneous, generally accepted public health standards that required companies to test their products for harmful effects, redesign them to make them safe and educate users if those effects were found? More importantly, did tobacco companies fulfill the promises they made to the public into Frank Statement To Cigarette Smokers and in other public statements?

"We accept an interest in peoples health as a basic responsibility, paramount to every other consideration in our business.

...We always have and always will cooperate with those whose task it is to safeguard the public health."<sup>191</sup>

A Frank Statement to Cigarette Smokers- January 4, 1954.

"If the industry leaders really believed that cigarettes caused cancer, they would stop making them."

Parker McComas, chief executive of Phillip Morris, temporary chairman of TIRC<sup>192</sup>

Unfortunately the tobacco companies did not make an appropriate Public Health response to the information they had available to them. The tobacco companies' response was and is characterized by deceit, deception and delay. They:

- Created a false scientific controversy (by confusing the epistemology of causation) and corrupted medical literature, (including suppression and misrepresentation of research findings):
- Acted improperly towards scientists, previous employees and others who wanted to tell the truth about the health effects of tobacco use and,
- Promoted the views of scientists whose views although, out of the mainstream of scientific discourse supported the industry's position on "Open Controversy".
- Sought and gained influenced government and private health organizations and successfully impeded public health actions,
- Targeted marketing at children,
- Masked the health effects of smoking through the addition of additives,
- Failed to fulfill their promise to stop selling products when the evidence for adverse health effects is overwhelming and admitted.
- Created a false scientific controversy (by confusing the epistemology of causation) and corrupted medical literature, (including suppression and misrepresentation of research findings)

### A. TIRC/CTR Creation of the "Open Question"

Following Wynder's mouse-painting experiments and the Reader's Digest article, the tobacco companies established three overlapping organizations to respond to the medical evidence of cancer causation:

The President's group, an organization of the presidents of the major tobacco companies. This group established the "Gentleman's Agreement".

The Committee of Council: A committee of outside counsel, who coordinated the tobacco companies' concerted response to smoking and health issues.<sup>4 193</sup>

The TIRC later split into the CTR and the Tobacco Institute. (Liggett did not join because it believed the group was not serious about research and might violate anti-trust law.)

Hartnett described the reason for starting the TIRC

Memo to Members of the Planning Committee on the TIRC<sup>194</sup>

This memo explains the purpose of the TIRC. There is only one problem-- confidence in how to establish: public assurance and how to create it--and a perhaps long interim on scientific doubts must remain and, most important, how to free millions of Americans from their guilty fear that it is going to rise deeper than biological tests--regardless of any logic--every time they light a cigarette. No resort to mere logic ever cured panic, whether on Madison Avenue, Main Street, or in a psychologist office and no mere recitation of arguments pro, or ignoring of arguments con, or careful balancing of the two together, is going to deal with such fear now.

That, gentleman, is the nature of the unexampled challenge to this office.

TIRC was designed to provide prophylaxis, not research for the industry.

Timothy Hartnett, in a memo to other industry executives, called for an industry-wide response to counter the medical evidence so as to "get the industry out of this hole", which entailed the "unstinted assistance of scientific research" on the question of "how to handle significantly negative research results if, as and when they develop."<sup>195</sup> This memo led the Industry to retain Hill & Knowlton's and form the TIRC months later, of which Timothy Hartnett would be the first chairman. In conjunction with the TIRC's lobbying and public relations activities, TIRC created a Scientific Advisory Board (SAB) to direct research objectives and publicize as a matter of science, the industry's denials of tobacco-related health effects. For example in April of 1954, soon after the Frank Statement's release, TIRC with the assistance of Hill & Knowlton published a pamphlet entitled "The Scientific Perspective on the Cigarette Controversy" that was sent to 176,800 doctors, members of Congress, and 15,000 members of the press and emphasized the existence of a controversy and lack of consensus on the health charges against cigarettes.<sup>196</sup> Additional examples of the Industry's unsubstantiated attempts to controvert scientific findings, and therefore sustain a controversy, came in the wake of the June 1954 Hammond and Horn study revealing higher mortality figures for smokers. Hartnett immediately dismissed the evidence as "biased, unscientific, and filled with shortcomings."<sup>197</sup>

The TIRC and the CTR were set up with three purposes in mind:

- To develop a cadre of "experts" whose statements and research could be used to confuse the public about tobacco health effects.
- To give the public and customers a false sense of security that the Industry was trying to do something about determining the health effects of tobacco. This was per se misleading; it gave the

<sup>4</sup> Throughout this document I rely on documents produced by in house and outside legal counsel for the tobacco companies, the TIRC/CTR, TI and others for the purpose of explaining the tobacco companies response to knowledge of tobacco health hazards. This is because these lawyers were actual participants in these actions. The lawyers controlled many of the activities undertaken by the tobacco companies like selecting and directing research projects, decisions on marketing and product design, and education programs for consumers. Therefore in this report I refer to all three entities as the Tobacco Industry.

misimpression that more research needed to be done before tobacco use could be related causally to disease induction.

- To allow Tobacco lawyers to argue in tort actions that the tobacco companies responded appropriately to the adverse health information published by others.

Dorothea Cohen a twenty-four year employee of the CTR, who wrote many of its research summaries describes the purpose of the CTR in 1993, “When CTR researchers found out that cigarettes were bad and it was better not to smoke, we didn’t publicize that. The CTR is just a lobbying thing. We were lobbying for cigarettes.”<sup>198</sup>

In my view it is not enough to criticize the “scientific” arguments put forth by tobacco company executives, consultants or grantees merely on the basis that they are self-serving or economically driven. In this section I evaluate and analyze these arguments and establish that they are not based on contemporaneous views of epistemology of medical causation. This analysis has two key components.

Many if not all of the tobacco company public statements on science and causation are contradicted by private statements on the same topics or by secret actions taken by the tobacco companies.

Other arguments on the epistemology of causation put forth by the tobacco companies and their supporters will be compared with the historical views on epistemology of the establishment of cause-effect relationships between exposures in the development of cancer.

a) The tobacco industry used the TIRC/CTR, a massive public relations campaign and political influence to engineer a “scientific controversy” that claimed the relationship between lung cancer and smoking was an “Open Question”.

Many if not all of the tobacco company public statements on science and causation are contradicted by private statements on the same topics or by secret actions taken by the tobacco companies. (See [Table 3](#))

Table 3 Tobacco company epistemology: Public statements vs. Private actions

Type of Evidence	Public Response	Actual View
Tobacco smoke causes cancer on mouse skin	Mouse data not relevant to humans because skin cancer is different from human lung cancer	Liggett uses mouse skin model to eliminate carcinogens from tobacco smoke
Tobacco smoke causes cancer on mouse skin	You have not identified the carcinogen	Liggett uses mouse skin model to eliminate carcinogens from tobacco smoke
Carcinogen identified	You don’t know mechanism of cancer induction	Companies’ duplicate and advance findings. (Find more carcinogens). Companies try to remove carcinogens from smoke
Epidemiologic studies show smoking causes cancer	Epidemiologic studies are not relevant to cause effect relationships	ATC touts its own epidemiologic study as evidence that smoking does not cause cancer
Smoke related human cell type duplicated in animal study	Animal studies are not relevant at all to cancer cause determination in humans.	Companies had secretly completed similar studies 15 years earlier with negative results and again in 1982 with positive results. <sup>199</sup>

In 1971, Brown and Williamson executives criticized the ‘Open Question’ and some of the industry actions used to perpetuate it:

"In defending the industry's interest, The Tobacco Institute has adopted a stance and used some methods which have led us to wonder if we are being realistic and constructive."<sup>200</sup>

Attorneys for the tobacco companies outlined and assessed documents corporate documents that describe and explain the "Open Question" strategy. I agree with their evaluation that this document (a 1972 review of the industry strategy)<sup>201</sup>, "contains damaging admissions, provides plaintiffs with a roadmap of the Open Question strategy and reveals that the purpose of "Open Question" strategy was to manipulate judges, juries, politicians and public opinion."<sup>202</sup>

I will, as the tobacco attorney's did, cite this document in "some detail."

"For nearly twenty years, this industry has employed a single strategy to defend itself on three major fronts -- litigation, politics, and public opinion.

While the strategy was brilliantly conceived and executed over the years helping us win important battles, it is only fair to say that it is not - nor was it intended to be - a vehicle for victory. On the contrary, it has always been a holding strategy, consisting of:

- creating doubt about the health charge without actually denying it
- advocating the public's right to smoke, without actually urging them to take up the practice
- encouraging objective scientific research as the only way to resolve the question of health hazard

On the litigation front for which the strategy was designed, it has been successful. While we have not lost a liability case, this is not because juries have rejected the anti-smoking arguments.

On the political front, the strategy has helped make possible an orderly retreat. But it is fair to say that it has not stemmed the pressure for new legislation despite the major concessions we have made.

On the public opinion front, however, our situation has deteriorated and will continue to worsen. This erosion will have an adverse effect on the other fronts because here is where the beliefs, attitudes and actions of judges, juries, elected officials and government employees are formed.

#### THE STRATEGIC IMPASSE

As an industry, therefore, we are committed to an ill-defined middle ground which is articulated by variations on the theme that, "the case is not proved." As the recent history of U.S. involvement in Vietnam demonstrated, it is impossible to hold the public on a middle course for any length of time. There seems to be no way that mass public opinion can engage in a controversy and choose an answer that goes beyond the range of either/or.

In the cigarette controversy, the public -- especially those who are present and potential supporters (e.g. tobacco state congressmen and heavy smokers) -- must perceive, understand, and believe in evidence to sustain their opinions that smoking may not be the causal factor.

As things stand, we supply them with too little in the way of ready-made credible alternatives.

#### THE ALTERNATIVES

Two such credible alternatives exist:

#### The Constitutional Hypothesis

i.e. people who smoke tend to differ importantly from people who do not, in their heredity, in constitutional makeup, in patterns of life, and in the pressure under which they live.

#### The Multi-factorial Hypothesis

i.e. as science advances, more and more factors come under suspicion as contributing to the illnesses for which smoking is blamed -- air pollution, viruses, food additives, occupational hazards and stresses.

Our 1970 public opinion survey showed that a majority (52%) believed that cigarettes are only one of the many causes of smokers having more illnesses. It also showed that half of the people who believed that smokers have more illness than non-smokers accepted the constitutional hypothesis as the explanation.

Thus, there are millions of people who would be receptive to a new message, stating:

Cigarette smoking may not be the health hazard that the anti-smoking people say it is because other alternatives are at least as probable.

The Roper Proposal would be [sic] persuasive (if not strictly scientific) medium for this message which we have done little to develop in a systematic or comprehensive way."

Attorneys for the tobacco companies correctly noted the parallelisms between Panzer's analysis of the Tobacco companies "Open Question" strategy and the "defense strategy at trial". Both involve:

" (1)Creating doubt about the health charge without actually denying it;  
(2)Suggesting alternative causes."<sup>203</sup>

This should not be surprising since the "Open Question" strategy was in large part designed to provide a defense in lawsuits. It was not, as these documents clearly show, designed by scientists or developed with any reference to scientific methods or based on scientific research.

Attorneys for the tobacco companies correctly noted the purpose of the strategy as outlined in the Panzer memo, "Jurors are likely to resent the expressly-recognized tobacco industry intent to manipulate them."<sup>204</sup>

#### B. Historical comparisons of the tobacco industry's epistemology on the causation of human cancer in relation to the epistemological stance of the medical community and other industrial producers of carcinogenic substances

Because smokers deny and rationalize their smoking behavior it was important to create an aura of doubt about smoking health effects. This was also necessary to influence public perceptions of the smoking-disease relationship in order to influence public policy and policy makers.

The tobacco industry's campaign to foment controversy and deceive the public, its customers, potential jurors, elected officials, insurance companies and others, is based on their distorted (and ever shifting) assessment of the appropriate epistemology for determination of a cause-effect relationship between tobacco use and certain forms of cancer. The tobacco companies have ignored and remained silent on the

epistemology of some tobacco related diseases like tongue and lip cancer (until the 1970's), amblyopia, and thrombo-angiitis obliterans.

Table 4 demonstrates the Tobacco Institute's initial position on the types of evidence required to establish causation. In this model, each type of experimental evidence is evaluated in a vacuum. Initially, the tobacco industry besmirched human epidemiologic studies in favor of animal experimental studies. In response to adverse animal studies the tobacco companies shifted epistemologic arguments:

Table 4 Initial Tobacco Epistemologic Position

TOBACCO INSTITUTE POSITION		
0%	Human experimental data	100%
****	0% Animal experimental data = Human causal theory	100%
0%	Bacteriologic data	100%
0%	Computer models	100%
0%	Molecular understanding	100%

Epidemiologic studies cannot prove anything about human cause-effect relationships. You cannot say smoking causes cancer in humans until you reproduce the effect in animals. When animal studies appeared the argument shifted to, "You can't say smoking causes cancer in humans until you prove what it is in the smoke that causes cancer." After carcinogens were identified, the argument shifted to, "You can't say smoking causes cancer in humans until you prove the exact mechanism of the offending agent." This line of reasoning continues ad infinitum.<sup>205</sup>

Alan Rodgman (RJR) described this shifting sands approach quite nicely in his 1962 review. Apparently, the only "proof" that would satisfy the tobacco industry is substantiation that lies one step beyond the existing evidence: (see TAB 09)

Any criticism leveled at the lung cancer-cigarette smoke proposition, e.g., statistical studies cannot prove cause-and-effect relationship between two factors (a criticism of the epidemiology), mice are not men (a criticism of the biological evidence); metaplasia and hyperplasia do not become cancerous (a criticism of the pathological evidence); and no experimental evidence exists to show that any cigarette smoke constituent is carcinogenic to human lung tissue at the level present in cigarette smoke (a criticism of the chemical evidence), is equally applicable to the lung cancer-air pollution proposition.

Rodgman realized that the 20<sup>th</sup> century lung cancer epidemic had to be caused by either smoke or air pollution or both. He recognized that the tobacco companies' epistemologic arguments were inconsistent. On the one hand they argued that "air pollutants" caused lung cancer. As Rogeman noted, the tobacco companies relied on the same types of evidence to make this point that they derided with respect to the epistemology of the smoking-cancer relationship. Of course after reviewing the literature Rogeman also concluded:

"Obviously the amount of evidence accumulated to indict cigarette smoke as a health hazard is overwhelming. The evidence challenging such an indictment is scant."<sup>206</sup>

The tobacco industry, for instance, argued in the early 50s that cigarettes were not proven to cause lung cancer because of the lack of animal studies establishing such a relationship. This emphasis on the importance of animal studies in establishing causal relationships historically reflects the industry's

epistemological stance which initially elevated animal evidence to the ultimate bearer of causal proof. Later, once cancer was successfully induced in experimental animals, the tobacco industry began shifting its epistemological stance, or the burden of proof, toward the need to identify the exact biochemical and molecular mechanism of cancer induction and the specific carcinogens in tobacco smoke.

The scientific community, however, did not exclusively rely on one class of medical evidence or one branch of medical knowledge to the exclusion of other areas of knowledge when evaluating cause and effect relationship, drawing inferences and conclusions, or making any other decisions.

Two important points need to be made here. First, even if the tobacco companies were correct when they stated their public views on the epistemology of cancer causation, they were expressing a minority view on the issue after the early 1950s. Therefore, according to the public health standards of the time, they had obligation to educate and take other appropriate public health actions to responds to the tobacco health hazards that were accepted by the majority of the medical community. During this century, public health actions have been taken long before the materialization of some Platonic ideal of proof. In fact the tobacco company epistemologic criteria have never been met for any carcinogen, infectious agent, behavioral intervention, toxin or poison. We do not know the exact mechanism of action for any of these, but public health interventions have saved millions of lives nonetheless. Secondly, the fact that the tobacco companies' public epistemologic arguments were self-serving, cynical and disingenuous does not mean they were wrong. In the following section I examine the views on epistemology held by medical doctors and other scientists during this century.

Epistemological issues are complex. One view of epistemological perspectives on cause-effect relationships in occupational and environmental health as they have developed over time is sketched in Figure 1. (See TAB 15) At different points in time, different types of information are more relevant and/or more available to medical scientists. Despite this fact, important information of a single type could establish a likely cause-effect relationship, even if other kinds of information were not available. This remains true today. Many substances are regulated on the basis of toxicologic data alone.

The scientific community has never judged it reasonable to ignore entire classes of available, valid, legitimate scientific data, or, in an ad hoc manner, elevate one class of data as carrying the ultimate burden of proof. Such open-minded and even-handed judgment particularly applies to a product that is either suspected or demonstrated to cause death, especially when millions consume the product in question. Figure 2 (See TAB 15). In general most physicians utilize a Bayesian approach to medical decision making. Figure 3 (See TAB 15)

In an effort to sustain controversy and doubt about the toxic effects of tobacco, the tobacco industry adopted an epistemological viewpoint on the types of medical evidence necessary to demonstrate causal associations that was – and remains to be – without historical precedent and in marked disagreement with the contemporaneous epistemological positions of the medical community. The tobacco industry categorically dismissed entire areas of scientific and medical knowledge as part of the industry's calculated effort to discredit mounting evidence that refuted the tobacco industry's position that tobacco does not cause human disease and can, in fact, promote health. In an historical period where epidemiology, case reports, pathology, and experimental animal evidence held general acceptance for their ability to demonstrate causal associations, the tobacco industry fabricated a unique and self-serving epistemology that rendered this entire mountain of evidence medically irrelevant or anecdotal, per se. Figure 4. (See TAB 15)

Tobacco company documents indicate an awareness of the fact that many smokers seek to justify their smoking, and will cling to any rationalization of their conduct. Smokers will also deny to themselves and others, even in the face of serious medical problems caused by smoking, that cigarettes are harmful or addictive. Tobacco documents indicate that tobacco companies have "created doubt" about the health charge so that smokers will "... perceive, understand, and believe in evidence to sustain their opinions that smoking may not be the causal factor."<sup>207</sup> Another secret tobacco company document states, "Smokers are more ready to deny the validity of the evidence, or to consciously suppress their awareness of overt propaganda."<sup>208</sup> Thus, public statements by tobacco companies denying the health consequences of

smoking and “creating doubt” about the causal link between smoking and disease are a substantial contributing factor to continuing smoking behavior.

### 1. *The disparagement of epidemiology*

The types of medical evidence the tobacco industry has disputed for their ability to provide evidence of cancer etiology historically conflicts with the ordinal weight given to this same class of medical evidence by both the scientific community and industrial producers of other carcinogens, for purposes of evaluating identical questions on cancer etiology. For much of the early half of the 20th century, the scientific community and most industries – including the chemical and asbestos industries – recognized pathology and case reports as the two classes of medical evidence that provided the most definitive proof of the causes and mechanisms of disease.<sup>209</sup> The epistemological acceptance of pathology grew from technological advances in microscopy and radiography – namely high-powered light microscopy and x-ray imaging – in the latter part of the 19th and early part of the 20th century. The case report became the established format for medical practitioners to common as well as rare or unusual clinical findings in individual patients and could in itself, constitute enough evidence to establish a causal link between an exposure and an effect. The coining of the word ‘asbestosis’, a term that describes the unique scarring of the lung caused by the inhalation of asbestos dust, resulted from the post-mortem case report of one individual, Nellie Kershaw.<sup>210</sup>

In the 1920s, the development and refinement of statistical techniques and bio-statistics led to the first theoretical advances in epidemiology. These advancements allowed statistical comparisons to be made between groups on the basis of disease or exposure status. The tobacco industry’s opposition to epidemiologic data sought to overturn the validity of any cause and effect relationship predicated on statistical associations. Beginning in the 1930s and through the 1950s, the use of epidemiological evidence gained increasing acceptance within the medical community as a valid means for discerning the causation of cancer and other diseases. In 1938, the ILO encyclopedia stated epistemologic criteria for cancer causation:

“(1)...that the incidence rate in the occupation under review should exceed that in the general population to a significant extent, and  
(2) that in the occupation concerned there should be sufficient association of a worker with a substance proved experimentally to have carcinogenic properties.”<sup>211</sup>

These criteria reveal the early acceptance of epidemiology as a causal criterion. Epidemiological evidence became more important coincident with the publication of several large epidemiological studies in the 1940 and 1950s relating cigarette smoke and asbestos exposures to lung cancer. For instance in 1957, Surgeon General Leroy R. Burney issued a draft statement supporting the validity of the mounting epidemiological evidence against smoking. He stated that while this evidence still remained “largely epidemiological in nature”, many important public health advances had been based largely on statistical data in the past, and that such evidence indicated that smoking is “one of the causative factors in lung cancer.”<sup>212</sup> The tobacco industry responded against the mounting epidemiological evidence of Doll and Hill and Hammond and Horn through repeated denials of the health hazards of tobacco smoke within the framework of a larger campaign that struck at the validity of drawing scientific inferences from epidemiological evidence. For instance as one public relations document emphasized in arguing against the applicability of statistics to causal relationships,

Yet a common mistake made in the interpretation of epidemiological data is the identification of a statistical association as a causal association. Statistics can never prove a cause and effect relationship; as the AMA official noted, “Statistics pose questions, they don’t answer them.”<sup>213</sup>

Tobacco companies, however, conducted their own epidemiological studies during this period in an attempt to seed the literature with negative studies to counter the rising tide of epidemiological evidence. In 1952, one year before Doll published his epidemiologic study on lung cancer and smoking, the American

Tobacco Company (ATC) initiated an epidemiologic study of its 11,000 employees to determine if they were at increased risk for the development of cancer of the lung or larynx.<sup>214</sup> They stated that their interest in this question was stimulated by the 1936 publication of Kennaway and Kennaway.<sup>215</sup> The Metropolitan Life Insurance Company, their group life insurance carrier, collected data for the study from 1946 to 1952. (Metropolitan Life was also the insurance carrier for many asbestos companies and beginning in the 1920's had similarly assisted them in the conduct of workforce epidemiologic studies to determine health risks from asbestos exposure.)

In 1963 American Tobacco (ATC) published their results, and compared their worker's mortality rates to the age-sex matched mortality rates of the nation. The authors concluded that the total mortality of this workforce (about eighty percent of males were smokers compared to about forty-five percent of the general male population) was better than age-sex matched controls from the general population. Total mortality was twenty-nine percent lower than expected. ATC spokesman Robert Heimann cited these figures in his dismissal of the health charge during his 1963 address to the New York Society of Security Analysts.<sup>216</sup>

Results of the ATC study were published in four papers.<sup>217</sup> However while total mortality was twenty-nine percent lower than expected, cause specific mortality for lung and laryngeal cancer, was the same as the expected rate for the general population. There was, therefore, a forty-five percent increase above expected, in lung and laryngeal cancer rates in this population of heavy smokers (crude PMR).

More importantly, the authors never published a comparison of lung and laryngeal cancer rates between their smoking and nonsmoking workers. It strains credulity to believe this comparison was not done. At about the same time, the asbestos companies published a similar study of their workers in Canada.<sup>218</sup> This study was stratified by both smoking and asbestos exposure. All twelve lung cancer cases smoked.

Without question, lung cancer mortality among American Tobacco Company employees who smoked was higher than expected when compared with the mortality rate in nonsmoking employees. The American Tobacco Company has never published a comparison between smoking and non-smoking employee cancer rates. Many of the tobacco companies' criticisms of epidemiologic studies were or could have been answered by this study. For example worker alcohol consumption rates, marital status, and even psychological status could have been determined and compared. The workers lived in the same area and thus had similar exposures to air pollution and other environmental factors and were from the same socio-economic class. Finally even the "constitutional hypothesis" might have been tested because the ATC may have employed members of the same family who had differential smoking rates.

## 2. *The disparagement of animal experimental evidence*

The tobacco industry contended that statistical evidence was largely speculative due the general lack of any experimental animal data (or as one 1958 public relations document notes, "inhalation animal studies have been conducted for 30 years with uniformly negative results"). When animal studies failed to produce evidence that tobacco smoke was carcinogenic the industry accepted the negative animal studies as proof that cigarettes were safe. This means that they found that valid inferences could be drawn from animal studies and applied to human cause-effect relationships. The industry further argued animal studies not performed on the lungs of animals could not be extrapolated to human lungs, and offered an explanation for Wynder's mouse-painting findings:

"In mouse-painting, smoke condensates are painted or dropped on the backs of mice, and cancerous skin tumors have been produced in this manner. However, these condensates are artificially produced under laboratory conditions and, as such, have little, if any, relation to cigarette smoke as it reaches the smoker. Rather, the results obtained on the skin of mice should not be extrapolated to the lung tissue of the mouse, or to any other animal species. Certainly such results should not be extrapolated to the human lung."<sup>219</sup>

Over a decade later when Auerbach and Hammond successfully induced lung cancer in a cohort of beagle dogs, the Tobacco Institute's shifted the epistemologic sand. They branded all experimental animal evidence as an errant attempt to compile causal evidence, inconsistent with what the Institute alleged was the scientific community's epistemological acceptance of cancer data from experimental animal models: "there is no satisfactory animal model for smoking experiments [within the scientific community]."<sup>220</sup> Such a wholesale dismissal of experimental animal evidence serves not only to misrepresent the state of contemporaneous scientific thought on the validity of experimental smoking models, but also contradicts the industry's own historical use and acceptance of experimental smoking models.

From the 1920s through the 1940s, tobacco companies turned to the commonly-used study designs and the preferred evidence of the day to substantiate *their claims* that genuine differences existed among their products, particularly those that related to advertised health claims such as the anti-irritant properties of a particular brand's tobacco smoke on the throat and lungs. These studies – while largely plagued by substantive flaws in methodology – affirmed the tobacco industry's general acceptance of case reports and animal evidence as relevant to human cause-effect relationships. When the study results were helpful to them, tobacco companies found them to be "valid," and readily made inferences from animal studies to human health. These inferences and the studies that supported them were directly marketed to the public.

For instance, Philip Morris' introduction of a glycol humectant (diethylene glycol) as a substitute for glycerin prompted the company's commissioning of academic physicians and researchers that led to the publication of data favorable to Philip Morris' modified cigarette in the medical literature. One study performed by Michael Mulinos and published in the 1934 Proceedings of the Society for Experimental Biology tested the effects of glycol and glycerin humectants on rabbit eyelid tissue. This data formed the basis of Philip Morris' advertising claims in late-1930 medical journals that "Our research files contain exhaustive data from authoritative sources" that the use of glycol humectants markedly reduces irritation.

It appears then, that both with respect to human epidemiology and animal studies, it is not the study type, design or methodology that matters. Instead, the key question of relevance is based on the answer to this question: Will the results enhance the economic interests of the industry? If the answer is yes then the tobacco industry deems the study type (animal, epidemiological or vegetable for that matter) and the study methodologies "valid"; if not, the study is critiqued in any number of ways.

The shifting of the tobacco industry's viewpoint further toward an unparalleled and unprecedented epistemological position on cancer causation occurred by dint of the industry's departure from its reliance on campaign to discredit. Though advances within the scientific community's knowledge of biostatistics and theoretical epidemiology as well as other forms of medical evidence led to a degree of usurpation in the importance of pathology by the 1980s, these temporal changes in no way supported the tobacco industry's increasingly solipsistic and isolated epistemological views. For instance the chairman of the CTR, Clarence Little, engaged in broad dismissals of evidence demonstrating that inhaled smoke caused tissue changes in the lung by citing a non-existent controversy within the scientific community as to the meaning of these pathological changes. The meaning of changes in tissue and cellular appearance formed part of the basis of the pathological inference of disease, and the histological changes involved in cancer induction and tumor formation gained documentation and general acceptance during the ascendancy of pathology during the early part of the 20<sup>th</sup> century.

By the late 1930s, the scientific community recognized that the metamorphous in the histology of normal cells turned malignant followed the distinctive stages of hyperplasia, metaplasia, neoplasia, and metastasis. At this time the scientific community also understood the location of the cancer's origin at the anatomical site that corresponds to a high degree of insult or exposure to pathogen to be valid and revealing evidence of a causal relationship. For instance, the preliminary findings of Auerbach et. al.'s 1957 report on the pathological changes in the lungs of heavy smokers constituted generally acceptable pathological evidence of a causal relationship.<sup>221</sup> His findings included hyperplastic, metaplastic, and tumorous lesions that Auerbach referred to as "pre-invasive" and a higher incidence of tumors at the bifurcation point of the human bronchial airway, where inhaled smoke concentrations are heaviest. Following the initial presentation of Auerbach et. al.'s findings, TIRC and Liggett & Myers commissioned similar studies examining tissue changes in experimental animals. Individual tobacco companies performed secret studies

on the effectiveness of modified cigarette prototypes and used pathological findings as an outcome for measuring the biological hazards of their products (XA project).

The scientific, public and political acceptance of the legitimacy of experimental animal evidence gained formal codification in law with the passage of the Delaney clause in 1958. This obligated the FDA to ban any food or **cosmetic** additive found to cause cancer in “man or other animal”.<sup>222</sup> Carcinogens were different from other substances in that cancer-causing agents were believed to induce cancer even with extremely small doses. Scientists and Congress accepted the theory that even a single molecule of a carcinogen could cause cancer in some people. Secretary Flemming, the Cabinet Secretary responsible for FDA, explained the scientific justification for concurrence with the provision:

No one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being. ...The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for man a safe tolerance for a cancer-producing agent. Until cancer research makes a breakthrough at this point, there simply is no scientific basis on which judgment or discretion could be exercised in tolerating a small amount of a known carcinogenic color or food additive.<sup>223</sup>

The Delaney clause established the legal principle that animal test results for carcinogenicity were by law applicable to man. There is no better example of corporate interest superceding science than the Delaney clause. After passage, animal carcinogens could be inhaled but not used as eye shadow. Tobacco companies could legally sell tobacco if it was to be smoked; it was illegal to sell it if it was to rub on the skin as a cosmetic.

The NEJM summarized the contemporaneous epistemologic view of causation and the parallel contemporaneous public health response that the evidence demanded:

“It is true that much remains to be learned about the pathogenesis of lung cancer and that smoking is certainly not the only cause. Pulmonary neoplasms have not been produced in laboratory animals by cigarette smoke. Despite this, it may prove that observations on human beings will be as “definitive” as experiments on animals. Although the search should continue for a carcinogen in cigarette smoke, there is already sufficient evidence on hand to implicate smoking as “the principal etiologic factor in the increased incidence of lung cancer,”<sup>2</sup> and lives can be saved if these facts are made known to the medical profession and to the smoking public.

It is not necessary to have precise information on etiology to prevent disease. Vaccination protected against smallpox more than a hundred years before the virus was identified, and the cholera vibrio was unsuspected at the time that John Snow had the foresight and courage to take the handle off the Broad Street pump.

Lives will continue to be lost if control measures must await definitive studies. Lives will be saved if physicians can now persuade their patients to stop smoking.”<sup>224</sup>

In 1965, Bradford Hill developed a list of criteria for demonstrating causal associations that draw upon a broad universe of scientific evidence for its potential to satisfy the criteria. These criteria stem from Hill’s observation that diseases that are causally linked to environmental factors exhibit a collection of observable associations and empirical traits. Hill’s criteria became a generally accepted paradigm that defined the traits of causal associations, including etiological associations with cancer.<sup>225</sup> Hill grouped the criteria into the following categories: temporality, biologic gradient, consistency, biologic plausibility, strength of association, analogy, experimental evidence, coherence, and specificity. The adoption and scientific acceptance of these criteria as a framework for evaluating causal plausibility is contingent upon their

application in good faith. Bradford Hill emphasized, for example, the responsibility of scientists making causal judgments to follow the available scientific evidence when applying the criteria, and not to withhold judgment in anticipation of the potential discovery of evidence at a later date. In the publication of his criteria, he recognized causal decision-making must be made in the absence of perfect data by cautioning that:

All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.<sup>226</sup>

The evolution of the tobacco industry's epistemological bias lies not only out of proportion to the epistemological considerations of the scientific community throughout time, but does not approximate the epistemological development of other manufacturers of carcinogenic substances (see table 1). The asbestos industry, for instance, gave early historical weight to animal and pathological evidence, and later, epidemiological evidence to argue myriad positions on the intricacies of causation, as it related to dose-response, asbestos fiber type distinctions, and mechanisms of asbestos-related disease. Though the asbestos industry worked to gather self-serving evidence to support the same a priori position as the tobacco industry (i.e. non-causality), this evidence differed according to the type of medical evidence represented.

Most industry personnel accepted the relationship between cancer and cigarette smoking. However some industry scientists felt that their job was, in part, to maintain or create a smoking and health controversy. However even these scientists could not bring themselves to question the relationship between smoking and emphysema.<sup>227</sup>

### 3. *Industry acceptance of tests for mutagenicity.*

The tobacco companies clearly relied on tests of mutagenicity. For example, the following memo excerpts indicate that BAT conducted Ames testing and relied on the results to determine whether or not an additive should be used as a tobacco adulterant. In addition this memo shows that potentially carcinogenic substances were secretly added to cigarettes.

"Mutagenic Activity of Flavor Compounds: Some 270 compounds have been assayed for mutagenic activity in Ames test ... In these experiments a number of flavor compounds have been shown to be positive mutagens.... If these agents are to be added to tobacco, it would appear prudent to review the levels of addition in the light of the above evidence. For maltol and o-methoxycinnamaldehyde, the evidence indicates a possible carcinogenic potential of these agents. This would again suggest reviewing the use of such agents for human use."<sup>228</sup>

### 4. *Other lung carcinogens of the 1950's, nickel carbonyl, chromate, and asbestos.*

It is instructive to look at the epistemologic criteria applied to determination of carcinogenicity for substances other than tobacco. By 1955, several substances were recognized lung carcinogens, including asbestos, chromates and nickel carbonyl.<sup>229</sup>

The American Conference of Governmental Hygienists (ACGIH) recognized nickel carbonyl as a "suspect" carcinogen in 1955 and established specific exposure guidelines designed to protect users from the development of lung cancer after exposure. Nickel carbonyl was the first substance that was treated as a carcinogen by the ACGIH and therefore is illustrative of contemporaneous epistemologic views and public

health principles. First, health experts treated nickel carbonyl as though it were a carcinogen even though they only "suspected," but had no definitive "proof" of its carcinogenicity. Therefore, even suspected carcinogens were treated with extreme caution (by responsible industries, government, and scientists) and public health actions were taken to protect and safeguard the public's health before it was compromised. This is, of course, required since scientists can never achieve complete "proof" of any cause-effect relationship; we are always somewhere between zero and 100 per cent sure of a relationship.<sup>230</sup> More importantly, nickel carbonyl illustrates the type, quantity and quality of information that was relied on during the 1950's to establish cause-effect relationships of lung carcinogens. The ACGIH based their decision on two animal studies and one epidemiologic study and maintained this position even though they received correspondence from Germany that indicated that one very prominent scientist did not think it was a carcinogen.<sup>231</sup> More importantly, nickel carbonyl was not a major product or profit center for any manufacturer. Unlike asbestos, chromates and smoke, corporations that manufactured nickel carbonyl did not try to influence the medical literature or the standard setting process. Left to their own devices and scientific principles the public health authorities took appropriate action to protect worker health.

Scientific criteria for the determination of cause-effect relationships were made on scant, and incomplete data. Nonetheless the public health authorities did not wait for "perfect proof" prior to taking public health action and found this information sufficient to warrant public health intervention.

In the mid 1950's Smyth, who was with the Mellon Institute and Union Carbide Corporation, explained the public health response to dealing with carcinogens in an article. The article was a republication of the Donald E. Cummings Memorial Lecture presented at the 17<sup>th</sup> Annual Meeting of the American Industrial Hygiene Association. Dr. Smyth wrote:

"Cancer.

One substance is reasonably well established as a cause of respiratory tract cancer. This is nickel carbonyl. It appears probable that the minimal cancerigenic exposure will never be defined. At this time, it is prudent to set the standard for a cancerigenic substance substantially at zero as has already been done for nickel carbonyl and no considerations can justify allowing the inhalation of any concentration which is avoidable."<sup>232</sup>

This same issue of the American Industrial Hygiene Association Journal presented a variety of discussions on exposure recommendations (threshold limits) and toxicity. Dr. James Sterner, medical director of Eastman Kodak Company noted that data available for establishing threshold limits were frequently lacking. Nonetheless, threshold limits were, "recommended as a guide for 'industry' in the control of exposures and as a measure for action by governmental agencies."<sup>233</sup>

Dr. Sterner also recognized that the establishment of exposure guidelines was dependent upon animal and human data and he emphasized the importance of "clinical evaluation of exposed workman".<sup>234</sup>

By the mid-1950s, asbestos and chromates were also recognized to be lung carcinogens, but regulatory action was slow to develop after this initial recognition. Like the tobacco industry, asbestos and chromate manufacturers engaged in a successful campaign to forestall effective public health actions to protect the safety of end-users and the general public. Unlike the tobacco companies, these industries did not need to engage in a campaign to deceive the public, or convince the public that their products were safe when scientific evidence indicated otherwise.

Companies that sold and manufactured asbestos and chromate products, like the tobacco companies, engaged in a successful campaign to forestall public health interventions. Unlike the tobacco companies, these industries did not need to engage in campaign to deceive the public. Efforts were limited to the scientific community and regulatory agencies.<sup>235</sup>

Table 5 Types of medical evidence historically used in the scientific and medical acceptance of non-tobacco related carcinogens by 1955

Substances Recognized to be Carcinogenic to the lung by 1955	Types of medical evidence used to establish causation				
	Cohort Epidemiology	Case Reports	Pathology	Toxicology (Animal studies)	Ames testing
Asbestos <sup>236</sup>	?	?	?	?	?
Nickel Carbonyl	?	?	?	?	?
Tobacco	?	?	?	?	?

? = heavily relied upon; ? = moderately to slightly relied upon; ? = not relied upon

##### 5. *Industry views of the “Open Question”.*

A review of Industry reliance reveals that the results not the study type determined the industry’s response to epistemology. While the tobacco companies currently claim that epidemiologic studies are not anything but statistics, they have relied on them in the past when they found their results to be helpful to them. Kluger describes the following examples of industries’ selective reliance on epidemiology for “proof”. In the early 1950’s Liggett cited a six-month study of smokers who used between ten and forty cigarettes a day.

“The subjects underwent “thorough examinations” before and after smoking. An examination of their “nose, throat and all accessory organs” was performed in all of the participants and they were found to be “not adversely effected”.

Liggett quickly capitalized on this small short-term epidemiologic study. Arthur Godfrey on his show “Arthur Godfrey and His Friends” broadcast this news to his adoring audience:

‘Now the [six-month test results] ought to make you feel better if you have any worries at all about it. I never did. I smoke two to three packs of these things everyday. – I feel pretty good. I don’t know. I never did believe that they did you any harm. – We’ve got the **proof**. ‘ [Emphasis added]

Apparently a six-month study of a few smokers constituted “proof” of no harm. The FTC was not quite as pleased. They asked the federal courts to issue an injunction against Liggett’s health claims in 1952.

Although the tobacco companies dismissed animal studies in the 1950’s, they previously and subsequently relied on them when the results were favorable to them. In 1934, Mulinos published a rabbit skin study.<sup>237</sup> In this study, he applied a variety of irritants to rabbit’s eyelids and then measured swelling. He compared the effect of glycerine with smoke, to glycol and smoke and used smoke without humectants as a control. He found that the glycol caused much less edema than did the glycerine or plain smoke. There were no control solutions used and the humectants were of different strengths.

Philip Morris then contracted with Frederick Flinn. Flinn was a throat specialist who got some of his friends to examine patients who smoked an average of twelve years. At the time of the study, they smoked an average of twenty-eight cigarettes a day. Three quarters had evidence of a “congestive larynx or pharynx.” Two-thirds had coughs and seven had irritated tongues. All were switched to a glycol humectant. According to Flynn in three to four weeks the symptoms or irritation had disappeared in two-thirds of cases while all of them enjoyed a “considerable improvement”. Three-quarters lost their cough and every case of irritated tongue resolved. They then crossed over and 80% of the subjects displayed renewed irritation when they returned to the glycerine humectant cigarette.<sup>238</sup>

Philip Morris apparently found these animal studies and short-term epidemiologic studies quite convincing. The company hired publicists to roam the country to distribute reprints of the Mulinos and Flinn studies to

doctors throughout the country. They went to doctor's conventions, sent out mass mailings and placed ads in forty national and state medical journals arguing that their cigarettes were less irritating. Philip Morris advertised, "diethylene glycol [used as antifreeze] has the greatest achievement in cigarette manufacture since the introduction of cigarette themselves". Flynn's study was said to have "*proved conclusively* that on changing to Philip Morris, every case of irritation due to smoking cleared completely or definitely improved." The advertisement stated that "these facts have been accepted by eminent medical authorities". In 1938 the company advertisement in medical journals said that "our research files contain exhaustive data from authoritative sources". There was no data besides the Mulinos and Flinn studies.<sup>239</sup>

When the results of animal or epidemiologic studies, no matter how poorly designed or conducted, are helpful to the tobacco companies, they accept them as "proof" or "disproof" of an effect. It is clear that the tobacco companies are concerned about study results and not scientific methodology.

## 6. Secret views of the "Open Question"

Even industry executives found the "Open Question" position to be a mere public relations gambit without scientific justification. The president of Brown & Williamson wrote the president of Reynolds on 10/16/62:

"Let me make my position perfectly clear. If we were able to make, strong, affirmative, well documented statements, which might tend to convince the public that the charges against our industry are invalid and insupportable, I would subscribe wholeheartedly to a series of paid advertisements in which we could tell our story. But, since we cannot take such a position, I think it far better to continue to let the public make its own judgments which since 1953 it has done with results not wholly unfavorable to the tobacco industry".<sup>240</sup>

The chairman of the board of Lorillard agreed and in addition stated:

"I believe that paid advertisements which would satisfy all of us, including our respective legal counsel and litigation counsel (in which would still remain firm and positive rather than negative and defensive) would be almost impossible to arrive at."<sup>241</sup> Some members of the SAB or the TIRC had "mixed feelings about the industry's position."<sup>242</sup> James Bowling, a Philip Morris employee developed a chronology of significant events with respect to smoking and health and called the document a "chronology of confusion".<sup>243</sup>

In 1967, TI's public relations agency tried to start a program that "reestablishes the cigarette controversy".<sup>244</sup> William Kloepfer in 1968 stated, "Our basic position in the cigarette controversy is subject the charge and may be subject to a finding, that we are making false or misleading statements to promote the sale of cigarettes."<sup>245</sup>

In 1958, British scientists visited top officials and scientists in the U.S. tobacco industry, "the extent in which it is accepted that cigarette smoke 'causes' lung cancer." The British scientists reported widespread acceptance of causation:

With one exception (H.S.N. Greene) the individuals with whom we met believed that smoking causes lung cancer if by "causation" we mean any chain of events which leads finally to lung cancer and which involves smoking as an indispensable link. In the U.S.A. only Berkson, apparently, is prepared now to doubt the statistical evidence and his reasoning is nowhere thought to be sound.

The authors concluded that there was no serious dispute that statistical associations established a "cause and effect" relationship:

Although there remains some doubt as to the proportion of the total lung cancer mortality which can be fairly attributed to smoking, scientific opinion in the U.S.A. does not now seriously doubt that the statistical correlation is real and reflects a cause and effect relationship.<sup>246</sup>

In 1964, Philip Morris scientist Wakeham examined the first Surgeon General's Report and found that "little basis for disputing the findings at this time has appeared."<sup>247</sup>

In 1967, G.F. Todd of the Tobacco Research Council noted the inconsistency of the Industry's position on causation in a letter to Mr. Addison Yeaman:

The only real difficulties that we encountered arose out of the unavoidable paradox at the centre of our operations .namely that, on the one hand the manufacturers control TRC's operations and do not accept that smoking has been proved to cause lung cancer while, on the other hand, TRC's research program is based on the working hypothesis that this has been sufficiently proved for research purposes. In addition, the Council senior scientists accept that causation theory. .We have not yet found the best way of handling this paradox.<sup>248</sup>

In 1976, BAT scientist S.J. Green criticized the industry's public position on causation:

The problem of causality has been inflated to enormous proportions. The industry has retreated behind impossible demands for 'scientific proof whereas such proof has never been required as a basis for action in the legal and political fields. Indeed if the doctrine were widely adopted the results would be disastrous. ...It may therefore be concluded that for certain groups of people smoking causes the incidence of certain diseases to be higher than it would otherwise be.

In 1979, Lee of BAT commented on the "misleading" TI publication, "The Continuing Controversy":

"Discussion of the role of other factors can be particularly misleading when no discussion is made of relative magnitudes of effects. For example, heavy smokers are observed to have 20 or more times the lung cancer rates of non-smokers. Sure, this does not prove smoking causes lung cancer, but what it does mean, and TA73 never considers this, is that for any other factor to explain this association, it must have at least as strong an association with lung cancer as the observed association for smoking (and be highly correlated with the smoking habit).

TA73 seems ready to accept evidence implicating factors other than smoking in the etiology of smoking associated disease without requiring the same stringent standards of proof that it requires to accept evidence implicating smoking. This is blatantly unscientific."<sup>249</sup>

In 1980 BAT considered admitting that smoking causes disease because BAT acknowledged that the "no causation" position was not credible:

The company's position on causation is simply not believed by the overwhelming majority of independent observers, scientists and doctors. The industry is unable to argue satisfactorily for its own continued existence because all the arguments eventually lead back to the primary issue of causation, and on this point, our position is unacceptable.<sup>250</sup>

The "severe constraint of the American legal position" prevented them from telling the truth to the public.<sup>251</sup>

In 1982, BAT consultant, Francis Roe, found the industry position on causation “short of credibility,” noting that “. . . it is not really true, as the American Tobacco industry would like to believe, that there is a raging worldwide controversy about the causal link between smoking and certain disease.”<sup>252</sup>

## 7. *Constitutional Hypothesis*

The tobacco companies have made two mutually contradictory arguments to defend their position that cigarette use has not been “proven” to cause lung cancer and that cigarette use is not “addictive”.

This argument states that epidemiologic studies cannot distinguish between smoking as a cause of lung cancer and a genetic linkage between the tendency to smoke and the tendency to develop lung cancer. (This is because it would be unethical to perform a randomized trial today and because the tobacco companies failed to conduct such a trial in the early 1920’s when it should have been performed and would have proper to do.)

### Cancer rates and genetics

If there were a genetic link between the tendency to smoke and the tendency to get lung cancer then one would expect that age specific rates lung cancer in the population would have remained constant over the past several centuries. Certainly it is not reasonable to posit that during this century mutations have occurred in the human population that resulted in increases in age-specific cancer rates. In fact, age-specific lung cancer rates in the US have dramatically increased in this century in corresponding to increases in smoking rates. This increase cannot be due to genetic mutation and must be due to differences in environmental exposure(s). In addition, if a genetic linkage between the tendency to smoke and the tendency to get lung cancer existed, one would expect that people who stopped smoking would have the same cancer rates as people who continue to smoke. This is not so. People who stop smoking have lower rates of lung cancer than people who continue to smoke.

#### b. Smoking cessation and cancer rates

To account for cancer rate decreases in quitters, the tobacco companies argue that people who were “able to stop smoking” had a different genetic predisposition to smoke and get lung cancer than those who were “unable to stop smoking”. If this were true then the genetic link between smoking and the tendency to get lung cancer would include a “non-voluntary” inability to stop smoking. In other words, people who are unable to stop smoking are addicted. The Industry however argues that smoking is not addictive. Both facts cannot be true.

If people are addicted, then they do not have “free choice” to stop smoking and the tobacco companies are under considerable obligation to educate them about this phenomena.

Finally the constitutional hypothesis predicts that lung cancer rates are independent of smoking rates and therefore should not change for the population as a whole over time. However, contrary to this prediction cancer rates have declined in parallel with declines in smoking rates.

#### c. Synergy and genetics

The phenomenon of synergy, which was known in the medical literature at least since 1958 with the publication of Braun and Truan and specifically acknowledged in medical literature from 1964 onward (after the publication of articles by Selikoff) completely rebuts the constitutional hypothesis. People are not genetically inclined to be exposed to asbestos. However, people who smoke and are exposed to asbestos have a synergist 50-100 fold increased risk for the development of lung cancer. This cannot reflect underlying genetic hyper-susceptibility that links cancer with a tendency to smoke and be exposed to asbestos.

Therefore the awareness that smoking and asbestos were synergistic completely rebutted any constitutional hypothesis related to tobacco and cancer causation.

More importantly, the Industry sponsored twin studies in Sweden to test the hypothesis of the genetic linkage between the tendency to smoke and the tendency to develop lung cancer. After long delays the results of this study were published in 1988.<sup>253</sup> This study conclusively showed that identical twins and fraternal twins had different rates of cancer and heart disease. Those differences were determined by whether or not they smoked cigarettes. I reproduce the abstract here:

Data on smoking and mortality from the Swedish Twin Registry were analyzed as a prospective cohort study and as a co-twin control study. The twin method involves control of genetic and early environmental factors and thereby a general control of the nested factors that may act as confounders, adjustments not obtainable in ordinary study designs. In the cohort analyses the following relative risks for cigarette smokers were found for men and women, respectively: death all causes 1.4 (90% CI 1.3; 1.5), 1.4 (1.3; 1.5), CHD death 1.4 (1.3; 1.7), 1.6 (1.3; 2.0), lung cancer 19.7 (9.1; 42.7), 5.1 (3.0; 8.7), and other cancers 1.2 (1.0; 1.4), 1.2 (1.0- 1.4). The comparison of deaths in cigarette-smoking twins and their non-smoking co-twins gave the following risk estimates for monozygotic (MZ) men: death all causes 1.6 (35 versus 22 first deaths), CHD death 2.8 (11 versus 4). The results for dizygotic (DZ) males and for females were in agreement. Four lung-cancer deaths occurred in MZ and 17 in DZ smoker twins while the non-smoker co-twins showed two such cases (DZ women). Other cancer deaths did not occur more often in the smoker than in the non-smoker twin. The impact of smoking on mortality, CHD death and lung cancer is also valid among smoking discordant twins.

This study, funded by the tobacco companies, invalidates the constitutional hypothesis. There is no reasonable basis to argue that anything but smoking causes an increased rate of occurrence of these diseases in people who smoke. The tobacco companies published voluminous documents that promoted the "constitutional hypothesis" to doctors, politicians and the public. Some of this cant cited the twin studies. The companies have never directly provided any information on the final findings of the twin studies to anyone.

#### 8. *Loews and the CNA close the "Open Question"*

If there is any doubt about whether or not tobacco companies really believe that there is an "Open Question" on the health effects of smoking, Loews Corporation, owner of both CNA insurance and Lorillard removed it when they offered nonsmoker discounts on life insurance.<sup>254</sup> Thus Loews has specifically recognized the validity of the relationship between tobacco and health when it is profitable to do so, but refuses to admit or recognize the validity in the cigarette context.

Loews has financial motives for both arguing that there is an "Open Question" and providing nonsmokers a discount on life insurance. However the non-smoker discounts only helps profits accrue if nonsmokers actually live longer. If smokers did not live longer or if they were destined to get lung cancer anyway (the "constitutional hypothesis") the discount would not make Loews more money; they would lose money by attracting smokers who are destined to get lung cancer whether or not they smoked. The discount is only profitable if nonsmokers live longer due to the mere fact that they don't smoke.

American Brands owns both the ATC and Franklin Life Insurance.

TIRC/CTR: Creation of a false impression that the industry was concerned about health issues

In 1953, concerned that the publicity on the health effects of cigarettes were hurting sales, the entire tobacco industry met in secret to formulate a concerted strategy to maintain profits. This program, which is still in effect, had the following key elements:

- To publicly deny the evidence proving that cigarettes caused disease.
- To create a false impression the industry was concerned about health issues.
- To use semantics to confuse the public and scientists.

The tobacco companies failed to adequately investigate possible adverse health effects of cigarette smoking. The tobacco companies never employed, epidemiologists, medical doctors, or other specially trained to investigate health issues. In response to the early 1950's evidence that cigarettes were carcinogenic, in early 1954 five Cigarette manufacturers formed the Tobacco Industry Research Committee (TIRC later the CTR and referred here as the CTR).<sup>255</sup> The CTR posed as a research institution engaged in finding out the "truth" about cigarette smoke. The TI utilized the CTR to promote the views of scientists whose views although, out of the mainstream of scientific discourse supported the industry's position on "controversy."

Addison Yeaman, a former Brown & Williamson Co. lawyer and ex-chairman of the Council, says the passage of time hasn't altered his faith in this view expressed at a Council meeting in 1975: "The CTR is the best and cheapest insurance the tobacco industry can buy, and without it, the industry would have to invent CTR or would be dead."

Michael Pertschuk, a former chairman of the Federal Trade Commission, finds the industry's defense extraordinary: "There never has been a health hazard so perfectly proven as smoking, and it is a measure of the Council's success that it is able to create the illusion of controversy in what is so elegantly a closed scientific case."

The TIRC/CTR established an "independent" Scientific Advisory Board (SAB). Unfortunately the TIRC/CTR was merely a front for the tobacco companies' public relations program. Its real purpose was to lend support to the "Open Question." They hired the previous head of the American Cancer Society, who had been unseated from that organization, Dr. Clarence Little to head the organization.<sup>256</sup> Kluger reports the, "His departure from the ACS was understood to have been prompted in large measure by Mary Lasker's deep disapproval of both his professional conduct within the organization and an attitude towards women said to be alternately patronizing and predatory."<sup>257</sup> A 1958 memo reveals much about Dr. Little's "objectivity". He wrote to the head of the TIRC with concerns that their research programs might adversely impact on the public's views about the safety of cigarettes. He advised industry on their public relations campaign, with regard to, how to convince the public that cigarettes were not dangerous. An objective researcher would not be concerned about the consequences of research. An objective researcher would be concerned about the quality of the result.<sup>258</sup> (This is particularly true if an adverse inference means users are getting sick as a result of smoke inhalation).

Of course the objectivity of the TIRC should have been immediately questioned when prior to awarding even a single grant, its first chairman Timothy Hartnett announced that:

"There is no conclusive scientific proof of a link between smoking and cancer.

Medical research points to many possible causes of cancer. Statistics indicating a relationship between smoking and disease could apply with equal force to many other aspects of modern life...

...The billions of people who derive pleasure and satisfaction from smoking can be reassured that every scientific means will be used to get all the facts as soon as possible."<sup>259</sup>

Mr. Hartnett was not a scientist; he was the retired President of Brown & Williamson. He knew the answer to the tobacco-health question prior to the conduct of any research or literature review and was ready to

reassure and did reassure the public about the safety of cigarettes. The TIRC, therefore, even before it was formally organized, became mouthpiece for the public relations campaign designed to confuse the public about the real scientific issues that underlined the smoking and cancer relationship.

Dr. Little advised that TIRC's membership about the SAB's real views, which conflicted with the public views he expressed before he was hired by the TIRC (See State of Art Section as quoted by Rodgman):

"He declared that both he and the members of the board were aware of the attacks which have been made on Tobacco for over 200 years and wished to build a foundation of research sufficiently strong to arrest continuing or future attacks."<sup>260</sup>

Of course, the TIRC had an explicit public relations function. Its executive secretary, Hoyt, described, "The two major purposes for which the committee was organized has the public relations phase and the research program".<sup>261</sup>

Mr. Hoyt repeated and elaborated on the purposes of the organization 04/28/55.

"Our job is to maintain a balance between the two, and to continue to build soundly so that at all times research and public relations complement each other. In that way we intend to assume the mantle of leadership and, ultimately, to create a condition where the public will look to the TIRC for answers rather than to others."<sup>262</sup>

Hill & Knowlton served as TIRC's public relations advisor from 1954 to 1964. Hill & Knowlton representatives attended all meetings of the SAB along with industry lawyers. Hill & Knowlton presented a written public relations report at each meeting.

Dr. Little made false statements about the presence of carcinogens in cigarettes. He told Edward R. Murrow on 06/07/55 on the "See It Now" television show that there were "no carcinogens in any product of smoking."<sup>263</sup> However, he was aware of the fact that BAP had been demonstrated to be present in cigarettes a year earlier. Little was so concerned about this report that he had a SAB member Dr. Kotin contact Rand to suppress the findings.<sup>264</sup> Dr. Little published a reassuring article in the Atlantic and made many other reassuring statements about cigarettes and health.<sup>265</sup>

The efforts of manipulating public opinion (public relations functions) caused the tobacco companies to influence the direction of the allegedly independent SAB's choice of research projects. During a SAB meeting in 1957, "it was suggested ... that consideration should be given to a broadening of studies to determine other factors which might be expected to have a role in the pathogenesis of lung cancer and perhaps the enlistment of other industries, thus involved..."<sup>266</sup>

The SAB felt that it was a priority to develop information concerning tobacco and health so that they could be more adequately fortified to rebut "undue emphasis ... frequently placed on statements concerning tobacco and health"... "They expressed the opinion that the information policy of the advisory board should be amended from one of avoiding public utterances to one of issuing positive information".<sup>267</sup> Clearly the SAB was in the business primarily of collecting and disseminating a subset of selected "scientific information" that would be of assistance in confusing the public about the real facts on smoking and cancer.

The SAB met with foreign scientist to seek help in rebutting the smoke-cancer relationship. This effort failed since the Europeans were scientists just like the Americans, and they felt that the facts were clear, smoking caused lung cancer.<sup>268</sup>

Several members of the SAB complained about the public relations function and threatened to resign over it in 1958.<sup>269</sup> As a result of this dissension amongst the ranks, the tobacco companies set up The Tobacco Institute allegedly to separate the public relations functions from the "research functions". Nonetheless,

Hill & Knowlton remained as a public relations consultant to both organizations. The chairman of the TIRC reported to members of the industry:

“The staff of TIRC is constantly in touch with Hill & Knowlton and consults on every phase of activity relating to health matters. For example, it provides speakers for platforms, helps analyze both scientific papers and charges against smoking which appear in the public press and consults on statements which are issued to inform the public.”<sup>270</sup>

TIRC deception continued when on 04/28/60, Dr. Little told the Monroe County Cancer Association of New York that no substance known to be carcinogenic to man had been found in cigarette smoke.<sup>271</sup> This statement was made despite the fact that Dr. Little himself tried to suppress these results by influencing the Rand Report (see above).

The ACS contemporaneously criticized the TIRC:

“Dr. Little ... is executing an ordered delaying action in a cigarette lung cancer ‘controversy’. This tactical maneuver which is apparently agreeable to other members of the scientific advisory board is to deny repeatedly ... to mislead the public ... and to convince the trusting tobacco consuming public of the industries eleemosynary [sic], ‘lasting interest in peoples health’.”<sup>272</sup>

Clearly, the tobacco research counsel and its grants program was designed to delay regulatory action, develop data that might be useful in litigation, and confuse the public and its legislative leaders about the truth about smoking and disease. As such, it was the pivot man for the tobacco industries perfidious campaign fool the public.

### C. Failure to Test

#### 1. TIRC/CTR’s “research”

##### (a) SAB review mechanism.

This documented indicate that the “independent scientific research effort” was anything but that:

#### **“SUGGESTED GUIDELINES FOR INDUSTRY COMMITTEE FOR THE REVIEW OF INDUSTRIES OVER ALL INDEPENDENT SCIENTIFIC RESEARCH EFFORT”.**

To determine the Industries short and long term objective for its independent scientific research, and to establish priorities with respect to that research. The thrust of such deliberations should probably be consideration of the impact of that research upon, among other things:

Legislative and regulatory matters. The impact of our research on congress, legislatures, and regulatory agencies.

Advancement of the state of scientific knowledge, for use in both positive and defensive situations.

Public relations:

- (a.) Establishing credibility for the Industry and its products with consumers, and re-enforcing consumers with respect to the smoking and health controversy.
- (b.) Emphasizing to scientific and medical communities the sincerity and magnitude of our commitment to advancing the state of scientific knowledge.”

Real research is not designed to advance political influence, assist in litigation, public relations, enhance Industry credibility or support a spurious "health controversy". **Real research is designed to answer scientific questions about disease causation, prevention and treatment.**

Media relations. Furnishing the mass and scientific media with results of tangible and significant independent research that demonstrates the sincerity and magnitude of the industry's commitment to support of independent research which will assist in closing gaps and knowledge in the area of smoking and health.

Relationships with members of the scientific and medical communities relating to litigation. Establishing credibility for the Industry with these communities for practical application in litigation and other adversary proceedings such as congressional and regulatory hearings.

Real research is not designed to demonstrate sincerity or develop medical witnesses for litigation of to influence Congress. **Real research is designed to answer scientific questions about disease causation, prevention and treatment.**

...

\* \* \* \*

It is suggested that answers to the following questions, and such other as the committee or other interested parties might pose, may provide the committee with information that will enable it to recommend the establishment of criteria, as well as administrative structures or procedures, as will most effectively and economically accomplish the objectives to be established by the Industry for its independent scientific research efforts.

#### **A Overall objectives**

1. What are the industries overall objectives for independent research.
2. Can a uniform standard (or standards) of performance be developed against which research projects can be measured.
3. Can criteria be established to define how each of the Industry's research projects contribute to the objectives and priorities to be established for the overall effort.
4. Can the five subject areas referred to in Section I above (legislative and regulatory matters, advancement of scientific knowledge, public relations, media relations and relationships with medical and scientific communities) be rated in terms of priority of importance. What are the criteria for such a rating. Are short term goals different than long range goals?
5. Is there merit, where possible, in attempting to spread budgeted amounts for specific research projects over extended periods of time, rather than expedite the completion of a project.
6. Can a practical, workable system be developed to efficiently monitor both the scientific and fiscal aspects of each project or effort.
7. Should the research be limited to strict smoking and health projects.
8. Is the focus of CTR's research direction where it should.

#### **B. Capital Organization**

1. Should any of the research projects (Harvard, Washington, and UCLA) be merged into or coordinated through CTR.
2. Would it be desirable for all independent research to be funded through and coordinated under the aegis of the CTR.
3. How does (or should) CTR as it presently exists (or in any revised form) fit into the Industry's goals and priorities. Is CTR responsive to the Industry's needs in the mid-1970's.

4. Is there efficient coordination of the various Industry pr resources as they relate to independent scientific research. Should there be a single PR outlet for the Industry with respect to scientific research activities.
5. Is there sufficient and effective communication between TI and CTR.
6. Should the name of CTR be changed. If so, to what.

### **C. Fiscal**

1. Should maximum expenditure levels be established for research.
2. Can (or should) the Industry in approving a research budget or project, specifically negate and implied commitment for renewal.
3. Should maximum durations be established for various projects.
4. Is the fiscal administration of CTR in need of any revision.
5. How could or should the handling of the CTR budget process be improved, including but limited to time of preparation, presentation and approval, and details of backup support for proposed items.

### **D. Deriving maximum return on investment and research.**

1. What specific public relations activity should normally accompany new research projects. Should they be widely and locally publicized--and if so, to whom and by whom.
2. How can the accomplishments of CTR and other research organizations or institutions funded by the Industry be utilized by the Industry and the TI. Should an effort be made to change the public image of CTR.
3. Does the Industry derive the same, better or poorer public relations and political benefits from research which is conducted by institutions and investigated outside of CTR, than it does from that which is identified with CTR. If so, why.
4. Are there particular scientific journals which are of higher priority for publication than others.
5. Are letters to the editor of scientific journals useful.
6. Are verbal presentations of papers at scientific meetings useful.
7. Is the Industry effectively publicizing research findings in other areas which are favorable to the smoking and health controversy--e.g., air pollution, genetically-inherited enzyme deficiencies, diet, hypertension, intake of soft water, stress, and the like.

This document lays bare the fact that the Industry's research efforts were not geared towards the determination of the health effects of smoke or how to eliminate the adverse health effects of smoke but rather served as a vehicle, through which, the Industry impacted on government, public and medical perceptions of tobacco hazards. The "research" was designed to minimize the public perception of the adverse health effects of cigarette smoke, establish credibility with the public and the medical and scientific community, and impact on litigation and regulation of their product. This was "anti-research".

Lawyers were the main source of health information for most tobacco industry executives.<sup>273</sup> K.V. Dey, in charge of all tobacco operations at the Liggett Tobacco Company, testified that this was how he became aware of any health issues related to tobacco.<sup>274</sup> The industry has failed to employ either physicians or epidemiologists to evaluate health issues. Although the industry executives should be knowledgeable experts of tobacco related health issues, most of them gave "stock answers" when examined in court.<sup>275</sup>

The TIRC never conducted studies of tobacco smoke and never conducted animal studies or epidemiologic studies. The one tobacco company that would not joint it, Liggett, criticized CTR research. They felt that a directed program would be more effective than small individual grants.<sup>276</sup> Even Dr. Little criticized the CTR grant system in 1968.<sup>277</sup> Even Yeaman counsel to Brown & Williamson and CTR complained:

"Over the years the CTR's grants have produced some 'good science, but science which has not provided us with either much material useful on the offensive, nor much that was very meaningful on the defensive.'"<sup>278</sup>

In addition to criticizing their research focus, it is clear that CTR research was aimed at producing specific results that would be helpful to the tobacco industry and not the truth. Things did not improve. In 1977, Heimann of American Tobacco wrote a scathing letter to Mr. Yeaman, counsel to CTR:

“Following our discussion of December 5<sup>th</sup>, I should like to summarize our companies position with respect to the Council For Tobacco Research. For many years after the TIRC was established in 1954 we were able to say that ‘all grants are made upon recommendation of an advisory board of independent doctors, scientists and educators. Recipients of grants are assured complete scientific freedom in conducting their investigations.’ Indeed, this point was made a part of our pledge to the public in full-page advertisements, headlines, ‘Frank Statement to Cigarette Smokers’ and ‘nine important facts about smoking and your health.’ The later ad specifically said: ‘a scientific advisory board of outstanding doctors, scientists and educators has complete and free rein in directing the research program and awarding the money for grants.’

This we can no longer say since what is called, ‘direct’ or ‘contract’ research has been brought into the picture. As I remarked at the September 1976 meeting, the original concept of TIRC did not embrace the idea of contract research but envisioned industry support of research on a pro bono publico, arms<sup>1</sup>-length basis. I believe the current movement toward contract research is a violation of our advertised pledges to the public and I also believe industry support of objective and independent scientific research is of cardinal importance in maintaining [sic] a statesman-like stance. I do not think that it would be an exaggeration to say that the current shift to contract research bastardizes a fine concept of objectivity which many good people in past years worked long and hard to establish.<sup>279</sup>

Mr. Yeaman told Mr. Heimann that he was “completely mistaken.”<sup>280</sup>

The SAB was not an independent board of course. The tobacco companies’ directors of research chose the board. No scientist who believed in the smoking-cancer relationship ever sat on the board. It can hardly be said that it was “objective” or “representative” of the general medical community. It is interesting to note that, probably because of Hill & Knowlton contacts the SAB membership overlaps with consultants used by the asbestos industry for the same purposes. For example, Drs Lynch, Kotin, and Craighead were and/or are all asbestos industry consultants.

#### (b) Legal Control

Industry lawyers attended all TIRC/CTR, SAB meetings and TI meetings. Some of the research funding was directly controlled by Tobacco lawyers and specifically directed at developing witnesses to testify in lawsuits. The tobacco companies needed to bolster their litigation defenses that association was not equal to causation and that you can’t extrapolate from animals to man. Thus, “special projects” were born. These special projects were publicly projects of the CTR, but were not approved by SAB; they were granted to consultants like Rosenblatt who were friendly to TIRC and SAB.<sup>281</sup> In addition, although the underlying purpose of special projects was to develop witnesses, special project grantees have “full freedom of publication” with attribution the CTR funding being required. Grantees have included Sterling, Fisher, Eysenck and MacDonald.” All have been vigorous defenders of tobacco.<sup>282</sup> Lawyers reviewed all grant applications and approved or rejected them.<sup>283</sup>

Many documents indicate that for years, the Tobacco companies acted together to suppress or eliminate internal research on smoking and health, in contrast with their public representations to conduct research into “all phases of tobacco use and health and report all facts to the public.”<sup>284</sup>

In 1968, Wakeham described a “gentleman’s agreement” that barred the companies from conducting in-house biological experiments on tobacco smoke:

We have reason to believe that in spite of gentleman’s agreement from the tobacco industry in previous years that at least some of the major companies have been increasing biological studies within their own facilities.<sup>285</sup>

A 1970 memo by D.G. Felton, a BAT senior scientist, referred to this “tacit agreement” not to conduct in-house biological research.<sup>286</sup> This memo further described how this “tacit agreement” led Philip Morris to direct RJR to shut down its in-house biological work. After learning that RJR was conducting biological studies, Philip Morris president Cullman lodged a complaint with RJR president Galloway. The result was a “sudden reorganization at Reynolds, resulting in the closure of the biological section.”<sup>287</sup> This later became known as the “mouse house” incident.

A 1980 letter from Robert Seligman to Alexander Spears, a senior scientist at Lorillard, listed potential areas of scientific research for the industry. Seligman included a list of “subjects which I feel should be avoided.”<sup>288</sup> The list of “Subjects To Be Avoided” included:

1. Developing new tests for carcinogenicity.
2. Attempt to relate human disease to smoking.<sup>289</sup>

In 1978, Sheldon Sommers, M.D., who was then Chairman of the CTR Scientific Advisory Board, complained to William Gardner, who was then the Scientific Director for CTR, that he was unable to understand the legal counsel he was being given. Sommers’ complained that CTR lawyers were controlling tobacco research legal considerations.<sup>290</sup>

I think CTR should be renamed Council for Legally Permitted Tobacco Research, CLIPT for short.<sup>291</sup>

A hand-written memorandum dated April 21, 1978, produced by Lorillard, complained that:

We have again abdicated the scientific research directional management of the Industry to the “Lawyers” with virtually no involvement on the part of the scientific or business management side of the business.<sup>292</sup>

In 1976, S.J. Green, also discussed “legal considerations” which determined the direction of research:

The public position of tobacco companies with respect to causal explanations of the association of cigarette smoking and diseases is dominated by legal considerations...By repudiation of a causal role for cigarette smoking in general they hope to avoid liability in particular cases. This domination by legal consideration thus leads the industry into a public rejection in total of any causal relationship between smoking and disease and puts the industry in a peculiar position with respect to product safety discussions, safety evaluations, collaborative research etc.<sup>293</sup>

A 1964 trip report by English scientists described how a committee of U.S. lawyers dominated the smoking and health arena:

This Committee is extremely powerful; it determines the high policy of the industry on all smoking and health matters - research and public relations

matters, for example, as well as legal matters - and it reports directly to the presidents.

The lawyers were described as the most powerful group in the smoking and health situation.<sup>294</sup> This Committee, later known as the Committee of Counsel, also was involved in “clearing papers (e.g. Dr. Little’s annual report).”<sup>295</sup>

Attorneys created “privileges” to control research. In 1979, the corporate counsel for B&W, Wells, wrote a memo to Ernest Pepples, B&W’s vice president of law.<sup>296</sup> Wells outlined a plan to conceal scientific information in attorney-client privilege. Mr. Wells’ proposal specifically provided that “...in the operational context BAT would send documents without attempting to distinguish which were and which were not litigation documents.”<sup>297</sup>

Acted improperly towards scientists, previous employees and others who wanted to tell the truth about the health effects of tobacco use and,

## 2. *Discrediting of the Auerbach Beagle Experiment*

Corporate lawyers and researchers recognized that their approach to epistemology of tobacco causation twisted the truth to suit the particular need of the day.<sup>298</sup> Twisting the truth was an accepted method in the industry in explaining this to the TIRC Hartnett suggested alternative solutions to the smoke-health problem:

Memo to Members of the Planning Committee on the TIRC<sup>299</sup>

...“In the past, industry has given little **twists** of the facts of science, to coerce them into sales propaganda, without much risk. Cigarette industry has indeed been doing this for years. We can therefore readily understand its assumptions that the same technique will work now in devising propaganda. But it is highly important to note that the deep issues of life and death that are now involved make highly doubtful as to whether the familiar techniques can be relied on. The stakes are too large; the penalties for losing could be too great). [Emphasis added]

Hartnett described other approaches:

...a)Smearing and belittling opponents. b.) Trying to overwhelm them with mass publication of the opposed viewpoints of other specialists. c.) Debating them in the public arena or d.) we can determine to raise the issue far above them so that they are hardly even mentioned and then we can make our real case.

The industry implemented steps a-d to combat Dr. Auerbach.

In the 1950's the cigarette industry claimed tobacco did not cause lung cancer because no substance carcinogenic to humans had been detected in cigarette smoke.<sup>300</sup> After the discovery of PAHs in tobacco smoke that position became indefensible, the industry epistemologic positions metamorphosed to, ‘no one has ever produced squamous cell cancer of the lungs in any experimental animal using whole smoke.’<sup>301</sup>

The last epistemologic argument left to the tobacco industry was that animal smoke inhalation experiments failed to cause human lung cell type tumors. But in 1970, Dr. Oscar Auerbach reported that cigarette smoke induced invasive squamous cell carcinoma in beagles. Auerbach’s study conclusively met the last element of “proof” that the tobacco company claimed was required. Therefore, when Oscar Auerbach

reported that he had found squamous cell cancers in animals that had smoked in 1970, the tobacco industry arguments again became untenable.

The industry could not accept the findings, but the beagle study was unimpeachable. The industry then initiated a massive cynical campaign to personally discredit Dr. Auerbach.<sup>302</sup>

Joseph Cullman, Chairman and CEO of Philip Morris and chairman of the Tobacco Institute executive committee wrote the American Cancer Society:

"Since the American Cancer Society asserts that the present study is of considerable import to smokers, I believe that the industry is entitled to have a full understanding of the nature and significance of the findings as quickly as possible. In the interest of accomplishing this aim, I request that the society permit a thorough evaluation of the experiment and its results by a panel of independent scientists with wide experience in areas relevant to the data".<sup>303</sup>

This letter by Cullman was nothing more or less than an attempt to set Auerbach and the American Cancer Society up.<sup>304</sup> Unfortunately, the American Cancer Society responded by saying that they would not submit the study to any committee chosen by the tobacco institute.<sup>305</sup> The tobacco industry then executed a \$500,000.00 advertising campaign to discredit Auerbach. One such advertisement was titled,

"The Tobacco Institute believes the American public is entitled to complete, authenticated information about cigarette smoking and health.

The American Cancer Society does not seem to agree."<sup>306</sup>

The Tobacco Institute then sent letters to members of Congress stating,

"This letter is being sent to you to reveal the facts about what may be one of the great scientific hoaxes of our time".

"Eight months ago -- just as House and Senate conferences were about to meet and resolve different versions of the 1970 cigarette bill -- the American Cancer Society called a news conference at the Waldorf-Astoria Hotel in New York City. It announced that two researchers had "for the first time" produced lung cancer in dogs as a result of heavy cigarette smoking.

It was, in the Cancer Society's view, a "significant achievement" which should have a "significant impact" on cigarette smoking, lead to a "reassessment" of cigarette advertising and "effectively refute" cigarette industry's contention that previous charges were "only statistical". The mass media accepted the unevaluated and unverified findings at face value, duly displayed the story on front pages and exposed it on prime time television. The Cancer Society did not reveal that the experiment was as yet unpublished in any professional journal and had not been evaluated by any independent scientific reviewers. Walter Cronkite broadcasted the society's claim that "this is the first such direct cause-effect link between cigarettes and higher animals made to inhale.

One of the researchers who conducted the experiment was quoted in newspapers as declaring: "... we have snapped the last link in the chain. There is no question that there is a cancer causing agent in cigarette smoke."

Today, long after the initial publicity, we can report that:

-- The research is still unpublished in any professional medical journal.

-- Two prestigious medical journals have declined to publish the study.

-- One of the researchers has now publicly retreated from claims (a) as to the number of lung cancers produced, and (b) as to the significance of the study in humans.

It now appears likely that none of the dogs developed cancers and that once again the American public has been seriously misled on the vital issue of smoking and health.

The tobacco institute believes that the "case of the smoking dogs" is a misuse of science.<sup>307</sup>

The TI selectively published its correspondence with the ACS concerning the beagle study. TI did not publish or otherwise reveal to the public the ACS 07/02/70 letter to Mr. Cullman or the enclosure to that letter which contradicted the TI assertions to the public and Congress. In its letter to Mr. Cullman, the ACS stated:

"I have read with care your most recent letters... I note that you as a spokesman for a part of the tobacco industry continue to question the Auerbach-Hammond findings which have been reviewed and accepted by distinguished pathologists. Your recent views are much the same as those the cigarette industry has expressed since 1954 when the first American Cancer Society report on the risk of cigarette smoking was made.

As you know, in response to your newspaper advertising campaign, we wrote the Surgeon General asking that he appoint a committee of scientists to review the Auerbach-Hammond work. His answer is enclosed. While this was sent to you at the time we made it public, I am inclined to believe from your statements that you have not had a chance to read it carefully."

In response to the ACS, the Surgeon General stated:

"... It is contrary to fact that scientists have been prevented from reviewing the Auerbach-Hammond study or that any data have been withheld. Among the qualified persons who have already made themselves familiar with the data and who have been given opportunity to review the laboratory material are Dr. John W. Berg, a pathologist from the National Cancer Institute and Dr. Raymond Yesner, a pathologist from the Veterans Administration. We understand that a number of scientists outside the government have also gone over the study in detail, and that the opportunity continues for review by other persons, including scientists representing the tobacco industry...

The procedures they [Auerbach and Hammond] have followed have been fully described in the literature; they have issued what appears to be an adequate report of their study and they have opened their data to the inspection of other scientists. We do not know what more can be expected of investigators, especially those with the reputations for excellence and probity enjoyed by Drs. Auerbach and Hammond.

Dr. Berg has told us that he has no doubt but that the progressive changes in the bronchial tissues in the animals studied where [sic] as Dr. Auerbach has described them, and that among other conditions found were early invasive squamous cell carcinoma in the bronchial tubes in two of the dogs. If the question at issue is whether human-type lung cancer has been discovered in the

lungs of dogs exposed to cigarette smoke, then the answer is yes, in the view of a public health service pathologist with special competence in cancer. This is also the view, we understand of Dr. Yesner and of the other pathologists who have reviewed the material.

It is not necessary to go to this study to support the conclusion that cigarette smoking causes lung cancer in human beings. There was enough evidence six years ago to cause the Surgeon General's Advisory Committee On Smoking And Health to come to this conclusion, and this evidence has been strengthened in the years since. The Auerbach-Hammond study adds one more element of certainty to a conclusion which the world's medical and health authorities already consider certain.<sup>308</sup>

After receiving this letter, the industry continued its assault upon the ACS and the Auerbach study. The public relations campaign only stopped after the study was published. JDRP lawyers noted,

"To this day the industry scientific witnesses repeat the 15-year-old allegations that Auerbach refused to permit independent pathologists to examine his data and in particular his slides. Curtis Judge testified he was not advised that Dr. Sommers was invited by Dr. Auerbach to examine the data. He said that he would be surprised to find out if this had really happened. On 05/07/70, the American Cancer Society wrote all of the editors of the publications, which carried the TI ad. The ACS acknowledged that it refused the TI request that TI be allowed to appoint a committee to review the findings of the Auerbach study."

The ACS, however, stated:

'There has never been any restriction against individual scientists visiting the Veterans Administration Hospital ...and reviewing the research with Drs. Auerbach and Hammond. A number of distinguished scientists have already reviewed the findings.'

The ACS also requested that the Surgeon General appoint a scientific body to review the Auerbach data. The TI was aware of this offer on 06/01/70. <sup>309</sup>

They also failed to mention that their researchers had already viewed the slides and agreed with Auerbach. In a February 25, 1970 memo, Fagin told Wakeham that she had reviewed Auerbach's slides and agreed that they were carcinomas. This indicates that the tobacco companies had reviewed the study and that their representative Fagin, concluded that "the study is the crude but effective in that carcinoma in dogs has been produced".<sup>310</sup> Their June 23, 1970 press release "chronology of events" was a complete perfidious misrepresentation of the events.<sup>311</sup>

Dr. Sheldon Sommers, scientific director of CTR repeated the accusations on December 18, 1985, even though he personally had been invited to review the slides by Dr. Auerbach. He claimed he didn't remember the invitation, even though Dr. Auerbach was able to produce telegrams back and forth between him and Dr. Sommers, that indicated that Sommers was invited to review the slides and failed to do so.

The JDRP lawyers note:

"The circumstances surrounding Dr. Sommers' apparent ignorance of his opportunity to review the Auerbach slides needs investigation. It appears either Dr. Sommers was incorrect in his deposition testimony, or that someone at TI or CTR prevented Dr. Sommers from seeing the slides. It is difficult to judge which scenario is worse. In any case, the real hoax appears to be one by TI on the public. A forthright confession of the facts is probably the best response."<sup>312</sup>

Both could be true, in either case the testimony is clearly wrong. I agree that TI perpetrated a hoax on the public and members of Congress. I also agree that a "forthright confession is called for." My review of materials is continuing, I have thus far failed to discover any "confession", acknowledgement of wrongdoing or apology."

a) Attempt to embarrass Dr. Hammond

Tobacco Industry lawyers note that the tobacco companies tried to "embarrass" Dr. Hammond.

"A 1971 note from C. B. Wade (RJRT) notes that "Dr. Sterling is the man Shinn and Hardy are working with on this project to embarrass Hammond and raise questions in the scientific community. Correspondence between Dr. Sterling and Dr. Hammond indicates the project was at least partially implemented".<sup>313314</sup>

This episode supports the inference that the Open Question was without scientific merit since if there was a scientific basis for the Open Question, the Tobacco Industry wouldn't have to have its paid researchers conspire to "embarrass" some of the best-respected researchers in the 20th century.

b) The Homberger Affair

Liggett & Myers consulted closely with Wynder in 1955 and successfully replicated his tumor induction experiments in its commissioned use of the Arthur D. Little Laboratories. Liggett & Myers then suppressed the public release of these results until 1962, at a time when the Industry maintained mouse-painting experiments to be irrelevant. If the results were irrelevant why suppress them? Later examples of tobacco industry involvement in experimental animal evidence include the 1970 attempt of the CTR to quash its own funded study performed by Freddy Homburger at the Bio-Research Institute, a commercial laboratory. The experiment, a one-hundred week inhalation study of 200 Syrian hamsters, resulted in findings of hyperplastic or neoplastic cell changes in the epithelium of the larynx in 90 percent of exposed hamsters. 47 percent of the exposed animal showed cancer or what Homburger termed legions "known to precede cancer." The CTR attempted to manipulate the results of this research by insisting that the cancers were of viral origin, and then insisted the term "cancer" be removed from the paper and replaced with a term denoting a lesser degree of pathology, or "pseudoeitheliomatous hyperplasia".<sup>315</sup> The CTR corrupted the 1974 publication of the paper in the Journal of the National Cancer Institute by inserting the word "microinvasive cancer" into the final manuscript, suggesting that the nature of the induced cancer was different than "regular" cancer.

Latter the council contracted with Microbiological Associates of Bethesda, Maryland to do the world's largest inhalation study, involving more than 10,000 mice.

The Wall Street journal reported:

"To do it, the Council spent hundreds of thousands of dollars in a quest for the perfect smoking machine, one that prevented mice from either holding their breath or overdosing on carbon monoxide. The lab initially had considerable freedom, says Carol Henry, who was its director of inhalation toxicology. But after nine years of work and \$12 million, the team was told in 1982 that it could no longer meet with Council staffers unless a lawyer was present. "We had never done science through lawyers before, and we told them it was unacceptable," says Dr. Henry. She says a Jacob Medinger lawyer told her, "That's the way it is."

The scientists knuckled under. If the Council had canceled before all phases of the first experiment were done, 40 staffers might lose their jobs and nine years' worth of data would never come to light. In the first experiment, in which mice inhaled the equivalent of five cigarettes a day, five days a week, for 110 weeks,

19 out of 978 mice got cancer -- versus seven out of 651 controls. However, the tumors weren't squamous-cell carcinomas, the kind usually seen in human lung cancer. And there was a 10% possibility the results were due to chance, whereas scientists prefer no more than 5%. Even so, Dr. Henry says the study built a "very strong case" that cigarettes can induce cancers in animals. This was to be the first of several experiments. But lawyers from Jacob Medinger told Microbiological the project would go no further. "When a contract is canceled given these kinds of results," Dr. Henry says, "reasonable scientists might conclude the liability issue must have suddenly become apparent to this group." In fact, says Dr. Kreisher, the Council's former associate scientific director, Council lawyers "worried like hell" about it. Microbiological and the Council parted ways, but the tobacco industry got plenty of mileage out of the Microbiological mice. In 1984, the Council issued a news release noting the absence of squamous-cell lung cancer in the lab's study. The timing wasn't coincidental: That year, lawyers from Liggett, Philip Morris and Lorillard began taking depositions in the landmark case of Mrs. Cipollone, a New Jersey woman whose family claimed she had died of smoking-related squamous-cell lung cancer. And at the federal trial four years later, a witness for the defense said the fact that the smoking mice didn't get squamous-cell carcinoma (although some did get cancer) showed that "cigarette smoke has not been shown to be a cause of lung cancer."

The witness also put Dr. Homberger's Syrian hamsters to good use. Smoking hadn't produced any more than "microinvasive" tumors in the hamsters, noted the witness, toxicologist Arthur Furst. Dr. Homberger, regretting he had agreed under pressure to use this milder wording, calls this use of his report "baloney," adding: "It was cancer beyond any question, not only in our opinion but in the view of the experts who looked at the slides." And at the federal trial four years later, a witness for the defense said the fact that the smoking mice didn't get squamous-cell carcinoma (although some did get cancer) showed that "cigarette smoke has not been shown to be a cause of lung cancer."

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"The tobacco companies succeeded in planting doubt in some jurors. "I didn't think it was proven scientifically that smoking caused her lung cancer," says juror Barbara Reilly. She says that under pressure from other jurors, she and two other holdouts went along with a finding in favor of the Cipollones, but managed to hold the damages to \$400,000 instead of the \$20 million some wanted to give."<sup>317</sup>

This corruption of literature was put into operation to influence the public, the medical community, and judges.

#### c) Censorship of Ernst Wynder

The TI funding of Dr. Frank Horsfall, the director of the Slone-Kettering Institute was more dangerous and cynical.<sup>318</sup> Horsfall was Ernst Wynder's supervisor. Tobacco companies recognized that Horsfall had influence and control over Wynder and noted that Slone-Kettering officials, including public relations vice president, Carl Cameron along with Horsfall, had responded to the funding by "subjecting Wynder to more

rigorous screening procedure before letting him speak in the name of the [Sloan-Kettering] Institute. This has had a proper and pleasing effect”.

Contemporary Examples:

In the 1990's this pattern has continued with the disparagement and harassment of Jeffrey Wigand, Alan Feingold, William Ferrone, and Ann Cohen.

### 3. *Supporting biased and irrelevant research*

Gary Huber

The Tobacco industry promoted the views of scientists whose views although, out of the mainstream of scientific discourse supported the industry's position on "controversy". Tobacco companies funded very little outside research directly. One of the researchers they funded was Gary Huber of Harvard. Dr. Huber solicited money from the tobacco companies with letters that indicated that his mind had already been made up about the fact that smoking was not likely to be a significant cause of cancer.<sup>319</sup>

In 1981 Dr. Huber was investigated for possible misuse of University of Kentucky funds and falsification of research data.<sup>320</sup> Former Surgeon General Terry called him a, "prejudiced researcher who never should have been hired by the University"<sup>321</sup> Nonetheless, Dr. Huber made a presentation at the American College of Chest Physicians Meeting in 1979 and claimed that tobacco smoke may improve the lung's ability to kill bacteria.

#### f) Fixing the Results-UCLA

In another example they funded the UCLA Medical School, which essentially guaranteed the Tobacco Institute negative results on smoking and health causation in their application:

"Although one cannot with certainty predict the outcome of such experiments, our preliminary results suggest that we are not likely to find any significant impairment of defense cell function in the smoker lung. On the contrary, smokers cells appear to be activated."<sup>322</sup>

These examples show how nefarious the tobacco companies were in their selection of researchers. They sought to fund people who could advance their position and who were going to guarantee results. In addition, they tried to and to some extent were successful in silencing, scientists whose research indicated that smoking was hazardous.

Ironically the industry lawyers use examples like these, the funding of the AMA/ERF, and TIRC/CTR research projects as evidence of good will and a serious commitment to the determination of the relationship between smoking and health.<sup>323</sup>

#### g) The Gentleman's Agreement

The tobacco companies sent in a gentleman's agreement in which they all informally agreed to share smoking and health related research and to not conduct any smoking and health research themselves.<sup>324</sup>

Documents describe the agreement and its purpose:

"Jones, Day, has uncovered some documents of Reynolds that refer to an agreement among cigarette companies scientists (and perhaps others) consisting of two points: 1. That the companies would not conduct any in house animal research (sometimes this is described as no in house smoking and health research), and 2. That the companies agree to share any "breakthroughs" in the

smoking and health area (this is sometimes referred to as any breakthroughs on a “safer” cigarette).<sup>325</sup>

Cudd stated, “R&D for international operations is totally separate from domestic efforts and engages in activities apparently not found in domestic research.” In addition, various witnesses for tobacco companies agreed that health research was not conducted in house, but was left to TIRC.<sup>326</sup>

The agreement to share safety and health information removed the competitive incentives that companies would have to market “safer cigarettes.” Why develop a safer cigarette if you have to share the results with the other companies anyway?

Company representatives have frequently testified that they did not do research on smoking and health. The CTR / TIRC representatives state that their research was “independent” and free from tobacco company control. Therefore, the tobacco companies failed to fulfill their obligation to test their products.<sup>327</sup> If the CTR was independent then the CTR was not doing research directed at smoking and health for the industry. If the CTR was not independent then all of its public pronouncements about independence were a sham. In fact, the TIRC/CTR was not independent and its research program was a sham, but was successful. It was designed to blunt the public’s response to the adverse health information on tobacco and it has been an unmitigated success. It was designed specifically to assist the tobacco companies in their public deception, to develop witnesses to assist in litigation and to influence the public, and the medical and scientific community by putting forth spurious statements on the relationship between smoking and health. It has worked as designed. Even the blind squirrel occasionally finds an acorn and along the way. The TIRC/CTR and other industry sponsored “research” (AMA/ERF) has produced some useful results. The most important of these were corrupted (Homburger) and/or stopped (Leo Abood’s CNS research, RJR mouse house, Leuchtenbergers) due to the intervention of lawyers who were concerned that the result would adversely impact on the defense of personnel injury lawsuits.<sup>328</sup> The amount of spending on “research” alone (although dwarfed by advertising expenditures) gave the appearance of a response to the problem. More importantly, it planted a seed of doubt in the public’s mind, by giving the appearance that there was some important information that needed to be discovered before the smoking and health question was settled. It thus reinforced the public’s natural tendency to deny unpleasant facts and continue to smoke. In other words the research program was part of a marketing strategy.

One telling episode is the SAB contract with Tennessee Eastman Company for a chemical analysis of cigarette smoke. This was done with the specific idea that the results would not be published. The results were going to be shared secretly with SAB members.

The CTR also took over industry functions for collecting research. This research was allegedly done for tobacco company lawyers to prepare defenses in litigation. Lawyers for the tobacco companies state:

“All possible effort should be taken to preserve LS Inc. [the original research company whose legal research functions were turned over to the CTR] entitlement to work product protection. Contingency planning should also be made in the event that the protection is breached, so that alternative mechanisms are available”.<sup>329</sup>

Alternative mechanisms to production of discoverable evidence are not described in this document. However, tobacco company employees have described a systematic program to physically hide important research findings, not publish studies that supported litigation related scientific issues unfavorable to the tobacco company positions, delay product improvements that would reduce the health impacts of smoking, and to physically destroy some research results.<sup>330</sup>

Company researchers also explained that the tobacco companies had agreed not to do any animal testing in the United States:

“The basic philosophy that was explained to me was that these tests were being done under the aegis of a different company, I think it was Philip Morris Europe

and therefore Philip Morris U.S.A., where we were located, wouldn't have those records in their files if they were sued."<sup>331</sup>

There is evidence the tobacco companies, the TIRC/CTR, TI, and outside legal counsel worked together to:

- not educate the public about tobacco health hazards unless the government forced them to,
- not compete through the sale of "safe" cigarettes,
- not compete using comparative claims that explicitly relied on the link between smoking and disease
- to restrict certain kinds of research,
- to disseminate public information that undermined the scientific evidence that showed that smoking and health hazards and,
- to suppress information that supported the fact that smoking had adverse physiologic effects including death.

### Company Research

As stated above, the tobacco companies have admitted that they did no health and safety research related to their products, but delegated this to the TIRC.<sup>332</sup> Industry witnesses say that they relied on the CTR to conduct research. But if the CTR was conducting research for the company, rather than as they stated independently, then there was no company research program. The industry can't have it both ways. Either the CTR was doing what they said, that is funding independent scientific research or they were working for the tobacco companies. Their public statements indicate that they were independent. The secret reality is that they were working under the direction and control of the tobacco companies. But that direction and control was not aimed at getting at the truth of cigarette smoking health connection, it was aimed at supporting the industry public relations campaign to fool the public about the health hazards of cigarette smoke.

While Tobacco Company executives generally deny that their companies performed smoking-health research, some companies actually did significant research on smoking and health. Unfortunately, they failed to utilize the results to make their products safer, and the most significant results were kept secret.

#### 4. *Liggett*

Liggett contracted with ADL to repeat the Wynder studies and after Rand Development Corporation found polycyclic aromatic hydrocarbons, including benzo(A)pyrene (BAP) in cigarette in addition recognized that this could be removed. ADL and Liggett indicated that Rand had made a "strong case ... for the presence of 3-4 benzpyrene, one of the most active carcinogens yet discovered."<sup>333</sup> More importantly Liggett concluded that:

"If benzpyrene is produced by regular cigarette paper, even under Rand's conditions, it may be important to (a) modify the paper as to eliminate the production of the polynuclear substances, or (b) eliminate paper from the cigarette...The results obtained and knowledge of the work should be restricted to the smallest possible group of individuals within the ADL organization. The entire program and associated exchange of knowledge between L&M and ADL should be held in strictest confidence."<sup>334</sup>

Shortly thereafter, ADL's Liggett study confirmed the presence of benzpyrene.<sup>335</sup> ADL also repeated Wynder's mouse painting study and confirmed them. This work was kept secret.<sup>336</sup> An undated Liggett document indicated the following:

“In addition to 3,4-benzpyrene, the group at Arthur D. Little, Inc. has identified the following compounds from paper smoke paste on ultraviolet difference spectra:

Phenanthrene.  
Pyrene  
Anthracene.  
1,2-benzpyrene.

The same work by Arthur D. Little indicates the probable presence of, but does not identify, the following:

Acenaphthalene.  
Naphthalene.  
Naphthacene.  
Benz(o)anthracene.  
Chrysene.  
Fluorene.

Work done in this laboratory identified the following compounds in addition to 3,4-benzpyrene:

Anthracene.  
1,2-benzpyrene<sup>337</sup>.”

In 1961, ADL summarized the results of its research for Liggett in a memo to Liggett.

“There are biologically active materials present in cigarette tobacco. These are:

Cancer causing.  
Cancer promoting.  
Poisonous.  
Stimulating, pleasurable and flavorful.

There is no reason why the poisonous group, CO, HCN, NO<sub>2</sub>, etc., cannot be reduced, even though they are not seen as a primary health hazard. Methods for removal are:

Filtration (treated carbon, etc.)  
Elimination treatment for removing precursors, CN elimination.  
Addition as a reactant (urea for NOs).

Cancer promoting materials, esters, phenols, amines, can possibly be reduced by some treatment extraction, etc.

The cancer-causing materials apparently are in many substances that are pyrolyzed but seem to be associated with tobacco in greater concentration than for primarily cellulose.

...There are many forces which continue to emphasize that L&M is in the tobacco business, not the pleasure business [sic] will have to be accomplished by avoiding these major pressures. A means is emerging -- is it correct? Can it be accelerated?”<sup>338</sup>

Some of this information was secretly given to the advisory committee to the Surgeon General. Dr. Darkis refused to allow the author Mold, to publish the information.<sup>339</sup> These documents were specifically kept from the AMA. Dr. Mold testified that the study results were suppressed because “the natural assumption would be that they wouldn’t want to give information out that would support this public medical opinion” (that their product is hazardous or cancerous).<sup>340</sup>

Based on this work, Liggett developed the XA palladium cigarette. Unfortunately, this safer cigarette was not marketed due to legal department's interference.

5. *Reynolds:*

Reynolds confirmed the presence of many constituents of smoker, which are reported in scientific literature and others it has not.<sup>341</sup> Rodgman and Cook confirmed the presence in BAP in cigarettes in 1956. They also discovered that cholanthrene a potent carcinogen had not been reported by others.<sup>342</sup>

Reynolds identified BAP in cigarettes three years prior to it being published in the medical literature. Of course the real basis of Reynolds research was described in a 1978 memo which listed the objectives of its research department to "provide the research and services necessary to protect the corporation against the smoking health claims of professed enemies of the tobacco industry".<sup>343</sup>

A 1968 Reynolds research report, from the director of the mouse house to the Murray Senkus, Reynolds' research director, states:

Smoking Rats

The chronic exposure of rats to smoke is continuing. The number of exposures was increased to two a day on July 16, 1968. Three rats were lost after bleeding tissues were taken for histology. No gross pathology was noted.

The histology of the tissues from the rat which had smoked TEMPO cigarettes via an indwelling tracheal cannula has been completed with the results given on the following page.

A diffuse, marked emphysema throughout the lungs...<sup>344</sup>

In 1970, RJR stopped this revealing research, shut down the Biological Research Division and fired 26 scientists:

We are here today to inform you about a significant reorganization of the Research Department and a reorientation of research programs... In-house biological testing in the smoking health area such as work we have been doing for the Scientific Advisory Board of the Council for Tobacco Research has been terminated. Any further biological testing that may be needed in further developing smoking machines, etc. will be referred to qualified independent research organizations...

The Biological division is being dissolved...

Altogether, 26 staff people are being terminated.<sup>345</sup>

6. *Philip Morris:*

Dr. Dupuis of PM gave television viewers a reassuring message about their research.

"Using these instruments, we have isolated and identified some three dozen components of smoke, many more will be identified. As we find these

components, we publish the results of our work in technical journals, which are available to any scientist in any part of the world.

So far, we have found none that give us any cause for concern. If we do find any that we consider harmful, and so far we have not, we will remove these from smoke and still retain the pleasure of your favorite cigarette".<sup>346</sup>

Later Philip Morris identified BAPs in cigarette smoke.<sup>347</sup> There is no evidence that they fulfilled their public promises, to either publish this finding or to remove the BAP from the cigarette.

Philip Morris had a program to systematically destroy important scientific findings. A 1977 memorandum from Robert Seligman, described the elimination of written contact between INBIFO (their German research center) and Philip Morris:

We have gone to great pains to eliminate any written contact with INBIFO, and I would like to maintain this structure.<sup>348</sup>

Handwritten notes from Thomas Osdene, another Philip Morris scientist, described the document destruction program:

1. Ship all documents to Cologne...
2. Keep in Cologne
3. OK to phone & telex (these will be destroyed)
4. Please make available file cabinet. Jim will put into shape by end of August or beginning Sept.
5. We will monitor in person every 2-3 months.
6. If important letters have to be sent please send to home .I will act on them & destroy.<sup>349</sup>

It is generally accepted that research reports that reveal important information about smoke and health should not routinely be destroyed. This is a poor research practice.

7. *Lorillard:*

Lorillard did work on the BAP and the removal of BAP. They also developed a filtration system, which removed some of the phenols in Kent cigarettes.

A 1978 memo written by Curtis Judge, CEO of Lorillard, indicated that lawyers controlled scientific research:

"We have again 'abdicated' the scientific research directional management of the Industry to the "Lawyers" with virtually no involvement on the part of scientific or business management side of the business."<sup>350</sup>

Experts in research control real research. Generally these experts have technical training in science or a related field. The law is not considered a related field for scientific expertise. In general, it is a poor practice to have lawyers control scientific research. This organizational matrix is not likely to generate optimum scientific results. I am unaware of any other industry that placed lawyers in positions of authority over scientific and medical decision making.

8. *American:*

American conducted an epidemiologic study of its own employees. This study failed to compare smoking employees with nonsmoking employees, no doubt because it would have shown that smoking, no doubt, because it showed that smoking employees had higher mortality than nonsmoking employees. Instead, it compared all of its employees to the general population. However, these studies are confounded by age stratification bias. Heiman, president of American said that it was their policy to "leave medical research to institutions other than the company".<sup>351</sup> Thus Heiman admitted that American failed to fulfill its obligation to test its products.

Influencing the public, planting of favorable magazine articles.

9. *True Magazine*

In late 1967, the tobacco industry hired Stanley Frank to write an article titled, To Smoke Or Not To Smoke - That Is Still The Question. The article was published in the 07/68 issue of True Magazine. In addition the industry ran an add in 72 markets announcing the article. A revised version of the article was published in a second tabloid, the National Inquirer under an alias, Charles Golden and under a different title, Most Medical Experts Say: Cigarette-Cancer Link Is Bunk - - 70 Million Smokers Falsely Alarmed. Finally the Tobacco Institute, through its public relations agency, Tiderock, mailed reprints of the True article to doctors and other "opinion leaders" throughout the country. The tobacco institute did not identify itself as the distributor of the article. This was all exposed in a Wall Street Journal Article.<sup>352</sup>

A total of 414,820 copies were distributed to physicians, dentists, media personals, scientists, educators, government figures, security analysis, lawyers, insurance companies and other executives.<sup>353</sup>

10. *The Morris Fishbein Affair*

Dr. Morris Fishbein was Editor of the JAMA from 1924 until 1949. During this time, JAMA published editorials that concluded that asbestos caused lung cancer. In 1953, Lorillard retained him as a consultant after he left his post. The agreement is describes below. The president's full time salary year was 100,000.

"We then mutually agreed on a total of \$50,000, to include all of the research work on the above ten projects that can be performed during the remaining ten months of this year – this to include such personal fee as you dictate but to not exceed \$25,000. As I understand, your fee covers your personal direction of all of this research work, your analysis and interpretation of the findings. It covers the collection and study of all important literature on the subject of cigarette smoking and keeping it up to date. It covers your offer to personally write and endeavor to place any articles resulting from such research in consumer publications (such as "Reader's Digest and "Good Housekeeping"), your direction, guidance and counsel in preparing and placing any articles, resulting from this research in professional medical journals, and your counsel and guidance as required on advertising claims which are based on this research.

I believe it was also mutually agreed at the time we originally discussed this work that we shall have the right to see and approve all manuscripts prior to release to any publication. Also, that all results from these research projects and manuscripts are the exclusive property of P. Lorillard Company and, at the conclusion of this work, all equipment paid for by P. Lorillard Company shall become its property."<sup>354</sup>

During the 1950's Lorillard produced Kent cigarettes with asbestos filters. These were advertised for their health advantages in advertisements that were placed in medical journals. (See TAB-13) Dr. Fishbein served as consultant on advertising; therefore Lorillard had access to this information on asbestos and cancer. Their advertisements even cited JAMA articles.

More importantly they used Fishbein to secretly vet witnesses for lawsuits, and tried to use him to plant favorable articles in popular magazines.

#### 11. *Other examples*

The Wall Street Journal exposed the methods used by the TIRC to influence the public:

But the Council's role was never just research. It was largely a creature of Hill & Knowlton, the public-relations firm, which cigarette merchants retained when the mouse research came out. Hill & Knowlton installed the Council in the Empire State Building in New York one floor beneath its own offices, with one of the PR firm's staffers as the supposedly independent research council's executive director. Hill & Knowlton also began publishing a newsletter that reported such news items as "Lung Cancer Found in Non-Smoking Nuns," and it helped authors generate books with titles like "Smoke Without Fear" and "Go Ahead and Smoke."

"Cigarette smoke condensate is a weak mouse skin carcinogen," said a Council-financed study completed in that year. Ensuing Council-financed research found more links to disease. In 1961, a study of 140 autopsies at a Veterans hospital in Iowa City, Iowa, said "a history of cigarette smoking is significantly related to the incidence of carcinoma." In 1963, researchers at Philadelphia General Hospital and the University of Pennsylvania linked chronic smoking to earlier coronary artery disease and a higher incidence of coronary occlusion. The Council summarized such results in its annual reports, but it often chose other research to stress to the public.

Ms. Cohen, who wrote the summaries, cites a 1965 study that said pregnant women who smoked had smaller babies and were more likely to give birth prematurely. But the industry in 1982 submitted to Congress a study the Council hadn't financed, saying that smokers had no greater risk of premature babies and that low birth weight wasn't a problem.

"In the '60s," says Ms. Cohen, "there was so much bad news about smoking that there really wasn't much the CTR could put out, but anything they could find they would use."

By 1964, keeping the case open was no longer just shrewd public relations; it had become a legal imperative. As more Americans came to believe smoking could kill, the number of tobacco liability suits jumped to 17 from seven the year before. And in that year, the Surgeon General labeled smoking a health hazard. It "was a serious, stunning shock," says Mr. Bowling, the former Philip Morris director. "That's the stage at which the lawyers became a lot more involved."

Needing a defense from science as never before, yet dreading the legal exposure that adverse research would bring, the industry created within the Council a Special Projects division -- with lawyers, not scientists, at the helm. Much of what it did was shrouded in mystery. "Everything was cloak-and-dagger," recalls John Kreisher, a former associate scientific director of the Council. "We weren't allowed on their floor." The core of the lawyers' operation

was a vast database, storing the world's literature on tobacco and health, data on foes and strategy documents. The lawyers began shuttling the globe, looking for research and expert witnesses. They sought out studies supporting causation of lung cancer by factors other than smoking and research suggesting the complex origin of all diseases linked to tobacco. Overtures to scientists usually were handled by outside law firms, especially Jacob, Medinger, and Finnegan & Hart in New York. It also served as counsel to the Council, and its Edwin Jacob took the lead role at the Special Projects unit. This arrangement offered crucial advantages. Notes Roy Morse, a former research chief at R.J. Reynolds:

"As soon as Mr. Jacob funded" a scientific study, "it was a privileged relationship and it couldn't come into court" **because of legal rules protecting attorney-client communications. "So they could do projects that they could bury if they chose."**<sup>355</sup>[Emphasis added]

## 12. *Misleading public statements on causation*

In 1962, the Tobacco Institute issued a press release stating that:

The causes of cancer are not now known to science. Many factors are being studied along with tobacco. The case against tobacco is based largely on statistical associations, the meanings of which are in dispute.<sup>356</sup>

In 1969, a CTR press release stated:

There is no demonstrated causal relationship between smoking and any disease.. ..If anything, the pure biological evidence is pointing away from, not toward, the causal hypothesis.<sup>357</sup>

In 1970, a CTR press release said:

The deficiencies of the tobacco causation hypothesis and the need of much more research are becoming clearer to increasing numbers of research scientists.<sup>358</sup>

In 1970, a Tobacco Institute advertisement stated:

After millions of dollars and over 20 years of research: The question about smoking and health is still a question.<sup>359</sup>

In 1972, a Tobacco Institute press release, stated:

The 1972 report of the Surgeon General... 'insults the scientific community'...[T]he number one health problem is not cigarette smoking, but is the extent to which public health officials may knowingly mislead the American public."<sup>360</sup>

In 1977, a Tobacco Institute pamphlet stated:

Has the Surgeon General's report established that smoking causes cancer or other disease? No.<sup>361</sup>

In 1978, a Tobacco Institute pamphlet stated:

The flat assertion that smoking causes lung cancer and heart disease and that the case is proved is not supported by many of the world's leading scientists.<sup>362</sup>

In 1979, the Tobacco Institute circulated a report titled "Smoking and Health 1964-1979: The Continuing Controversy" in an attempt to rebut the 1979 Surgeon General's Report:

The American public would be better served if high government health officials and private interest groups which encourage them abandoned the myth of waging war against diseases and their alleged causes.... Indeed, many scientists are becoming concerned that preoccupation with smoking may be both unfounded and dangerous. Unfounded because evidence on many critical points is conflicting. Dangerous because it diverts attention from other suspected hazards.<sup>363</sup>

In 1983, an RJR advertisement said:

It has been stated so often that smoking causes cancer, it's no wonder most people believe this is an established fact. But, in fact, it is nothing of the kind. The truth is that almost three decades of research have failed to produce scientific proof for this claim. ..in our opinion, the issue of smoking and lung cancer is not a closed case. It's an open controversy.<sup>364</sup>

### 13. *Misleading statements on addiction*

In 1988 the Tobacco Institute stated:

Claims that cigarettes are addictive contradict common sense. ...The claim that cigarette smoking causes physical dependence is simply an unproven attempt to find some way to differentiate smoking from other behaviors. ... The claims that smokers are 'addicts' defy common sense and contradict the fact that people quit smoking every day.<sup>365</sup>

In another 1988 press release, the Tobacco Institute stated that the Surgeon General's conclusion that smoking is an addiction was:

... "An escalation of antismoking rhetoric...without medical or scientific foundation."<sup>366</sup>

In a 1989 interview on ABC's Good Morning America, the Tobacco Institute spokesperson stated:

"I can't allow the claim that smoking is addictive to go unchallenged...."<sup>367</sup>

In a 1990 interview on CNN Larry King live, the Tobacco Institute spokesperson stated:

"About 95 percent of those people have quit cold turkey. They've walked away from cigarettes and they've not gone through formal treatment centers or anything else. It's not like alcoholism or drug abuse. It's not an addiction."<sup>368</sup>

In a 1992 pamphlet, Philip Morris stated: "Those who term smoking an addiction do so for ideological -- not scientific -- reasons."<sup>369</sup>

In a 1994 published statement, Philip Morris stated: "Philip Morris does not believe cigarette smoking is addictive."<sup>370</sup>

Finally, in congressional testimony in 1994, the chief executive officers of the tobacco companies each testified under oath that cigarettes are not addictive:

- William Campbell, Philip Morris: "I believe that nicotine is not addictive, yes."
- James Johnston, Reynolds: "Mr. Congressman, cigarettes and nicotine clearly do not meet the classic definition of addiction."
- Andrew Tisch, Lorillard: "I believe that nicotine is not addictive."
- Ed Horrigan, Liggett: "I believe that nicotine is not addictive."
- Thomas Sandefur, B&W: "I believe that nicotine is not addictive."
- Donald Johnston, American: "And I, too, believe that nicotine is not addictive."

14. *Sought and gained influenced government and private agencies and successfully impeded public health actions*

Insurance Industry

"HL INSURANCE INDUSTRY: Documents suggesting that the tobacco companies were concerned that the insurance industry, by offering lower rates to nonsmokers, was providing the message that smoking was harmful. TI contended that the' rate reduction was a sales gimmick based on faulty actuarial tables. TI lobbied the insurance companies with fairly successful results."<sup>371</sup>

h) Governmental agencies

The tobacco industry helped select members of the Surgeon General's Task force in 1962. This significantly impacted on the results of that study. (See habituation vs. addiction section.)

The industry has successfully lobbied against a variety of anti-smoking measures.

Documents indicate the companies used their influence to block disclosure of their additives, which, because of their toxicity, would result in "restrictions against use".

"Of note, "support for mandatory "additive" disclosure may lead to restrictions against use of some flavoring substances in cigarettes... The BMW strategy for dealing with the smoking and health issue environment should include the following elements:

1. Increasing funding of independent basic scientific research; 2. Increasing contributions to an effective industry lobbying program and development with independent relationships with key congressmen; and 3. Urging all tobacco companies to take a low public profile."<sup>372</sup>

Because of their influence some congressmen actually did the bidding of the industry. One document indicates that Congressman Jones of North Carolina called Kenneth Moser to pressure him to release the raw data of a study that was unfavorable to industry."<sup>373</sup>

i) AMA

AMA/ERF Studies

In late 1963, shortly before the first Surgeon General's Report was issued, the industry and AMA agreed to fund research concerning smoking and health. This grant bought the silence of the AMA, which, in addition, was concerned about alienating Senators from tobacco states who could help them block the

Medicare bill. It bought more than silence; the AMA opposed the Federal Cigarette Labeling and Advertising Act. The "research program" falsely reassured the public and Congress. If more research was needed maybe there was no proof of causation.

The AMA/ERF program was to be financed entirely by the U.S. tobacco industry, pursuant to an agreement entered into in February 1964. The AMA was not slow in expressing its gratitude. On February 28, 1964 its Executive Vice President, Dr. Blasingame, wrote the FTC: urging it not to require warning labels on cigarette packages:

With respect to cigarettes, cautionary labeling cannot be anticipated to serve the public interest with any particular degree of success.- The health hazards of excessive smoking have been well publicized for more than ten years and are common knowledge. The answer which will do the most to protect the public health lies not in labeling (which is likely to be ignored), but in research.<sup>374</sup>

Adding additional support to the "Open Question", in September 1967, the AMA issued a press release concerning the AMA/ERF that began with the question "is smoking a psychological addiction with deadly overtones or more in the nature of a bad habit?"<sup>375</sup> Hill & Knowlton distributed copies of the press release under cover of an "Information Memorandum" dated two days latter in which it took succor from the release: "the best estimate of clinicians and scientists in the field is that cigarettes are a health hazard. But they admit they don't have the scientific data yet to establish why and how."

The AMA withdrew from the project in 1971 but still wanted to placate the Tobacco lobby. The AMA's executive vice president advised the Tobacco Institute that:

... he regards the program as a great liability -- that from AMA's view it has only caused further blackening of AMA's image. He said from the industry's standpoint the research has produced no evidence to clear cigarettes from the generally accepted conclusion that they cause "lung carcinoma" and other maladies. He said he thought the latter point would be widely reported as the reason the industry decided to terminate the program, regardless of what is said by either party about it. (He) also made these points:

1. He is most anxious to avoid any incident which will create displeasure with AMA among tobacco area Congressmen--he said AMA needs their support urgently.
2. "He is told that 85% of the ERF research with tobacco funds has been "useful basic research" but that through neglect by all concerned no effort has really been made to impress anyone in or out of AMA with this."<sup>376</sup>

The industry was critical over the direction of AMA/ERF research. In 1965, early enough to cause a change in direction of the program, Philip Morris concluded that "only 2% of the effort has been allotted to carcinogenesis, and this single project involves research for agents which will stimulate immunological responses in the host." "Approximately one-half the grant money has been allotted to the five universities with which the committee members are directly associated."<sup>377</sup> Philip Morris sent a copy of this study to Mr. R. P. Roper, with the observation that:

"While we recognize that in spite of the very extensive studies which have been made in the past there may still be gaps in our knowledge of the pharmacology of nicotine which the AMA Committee might feel it desirable and necessary to close, we are wondering if this area of effort should receive as much attention as they are giving to it to the almost total exclusion of carcinogenesis which we thought was the major smoking and health problem. We suspect that one reason for this is merely that of simple expediency. It is relatively easy for an investigator

carrying out a simple line of pharmacological investigation with various chemical compounds to add nicotine to his list and thereby qualify for an AMA grant." <sup>378</sup>

A second Philip Morris document reports that industry scientists attending an AMA/ERF program in Scottsdale, Arizona on May 68, 1970 concluded that "not more than 50% of the program was relevant to smoking" and that "little of scientific significance will emerge from this program in the foreseeable future." <sup>379</sup> Liggett's Dr. Mold attended this same meeting and was equally critical. <sup>380</sup>

The money was wasted. Half of the grant money was allotted to the five universities with which AMA were directly associated. After a decade, the AMA terminated the AMA/ERF project, and stated that the relationship had "blackened" the AMA's image.

The AMA/ERF's final report on the project was issued on May 27, 1977. Having lost the fights over Medicare and Medicaid, embarrassed by their connections to Tobacco and aware that they could no longer profit from the relationship, the final report was unfavorable to Tobacco.

"Valuable information has been obtained relating to distribution, metabolism, excretion and toxicity of nicotine absorbed by the human body via cigarette smoking. In the area of carcinogenesis, the Committee restricted the number of awards because cancer research was being generously financed by the National Institutes of Health and other agencies. Nevertheless, the demonstration of potent co-carcinogens in tobacco and the potential value of the measure of inducibility of aryl hydroxalase [sic] as a determinant of susceptibility to lung cancer represent some of the more significant contributions in this area. Emphasis was placed on the impact of cigarette smoking of the physiology of the cardiovascular, respiratory and central autonomic nervous systems. The Committee believes; that the bulk of research sponsored by this project supports the contention that cigarette smoking plays an important role in the development of chronic obstructive pulmonary diseases and constitutes a grave danger to individuals with preexisting diseases of the coronary arteries." <sup>381</sup>

Even though they funded and in large measure, controlled the research, the industry did not admit its product caused cancer after the final report was issued.

The industry has successfully allied itself with a variety of non-profit groups, and other influence centers to enhance the general acceptance of its product

Minority groups

ACLU

Labor Unions

Entertainment concerns

Sports leagues

Front groups: The National Smokers Alliance

Notes from a meeting of counsel, February 7, 1968: "two football leagues called on Earl today-concerned-25% of revenues for football come from tobacco. Maggie wants put team in Seattle. They can help in our legislature problems, can get media help." <sup>382</sup>

Design defects

Instead of making their cigarettes safer, the industry engaged in a variety of product changes that actually made them more hazardous.

15. *Low Tar and nicotine Cigarettes, Compensation and Dissuading Smokers From Quitting*

Tobacco companies developed low tar and nicotine cigarettes. They were aware that smokers would "compensate" for this deficiency and smoke more cigarettes or cover the holes in the filter to increase the dose per cigarette. The tobacco companies specifically discussed these "compensatable filters". Although there were concerns about lost taste, the priority was to ensure that smokers could continue to receive enough nicotine.

"Compensatable Filters.

Strategic Objective:

To make it easier for smokers to take what they require from a cigarette. This means in effect that the filter will be compensatable and implies a high taste to tar rates.

Constraints:

Is this the ethical thing to do?"<sup>383</sup>

The cigarette was designed to allow smokers to take a much higher level of tar and nicotine from the cigarette than is registered on official machines. Thus again the tobacco companies specifically designed a cigarette that would deceive users. They never educated about this. I agree with the inference that this conduct was unethical. In addition it is contrary to good public health practice and the practice of all other manufacturers who sell products meant for human consumption in the United States.

16. *Low gas cigarettes.*

Brown & Williamson developed and marketed a cigarette that filtered carbon monoxide. After the cigarette (called Fact) failed in test markets, their advertising agency developed a campaign to educate the public about the health hazards of carbon monoxide in cigarettes. Brown & Williamson termed this campaign "appalling" and decided not to market the cigarette. Brown & Williamson clearly failed to market the cigarette that might have produced some health benefit because it would have been an acknowledgement for the dangers of carbon monoxide.

17. *Palladium cigarettes (XA).*

Liggett developed and patented a palladium cigarette, which removed "biologic activity", code word for carcinogens. Liggett utilized mouse painting studies to determine "biologic activity" i.e. carcinogenicity. Thus Liggett acknowledged that mouse studies were relevant to humans.<sup>384</sup> Liggett went to the White House to try to get relief from the FTC prohibition against health claims in advertising.<sup>385</sup> The power of the cigarette industry was perhaps best revealed when President Carter's staff leaked word of Liggett's their advance to other tobacco companies. As a result Philip Morris pressured Liggett to stop development of this safer cigarette.<sup>386</sup> Finally lawyers from Liggett killed the project.<sup>387</sup> Liggett still holds the patent and this prevents any other company from marketing a similar product. Ironically instead of advancing safety, Liggett's research, PM's intimidation and the "Gentleman's agreement" have blocked sale of safer cigarettes. Safer cigarettes have been available and in the tobacco industries patented possession for the last twenty years, but none have been marketed.

18. *Lower tar and nicotine cigarettes.*

While the tobacco industry capitalized on the alleged health benefits of lower tar and nicotine cigarettes as a marketing strategy, they nonetheless continued to market high tar and nicotine cigarettes. Since the technology to manufacture low tar products was available before the 1950's clearly these could have been developed and sold long before the "tar derby" broke out in the 1950's.

Charcoal filters:

Liggett realization that there were carcinogens in cigarette smoke led to the development of the charcoal filter:

"During 1957, [the Liggett Research Program] was expanded to include a general study of the pharmacologic effects of cigarette smoke and its components. In the succeeding years, this experimental program clearly demonstrated a number of undesirable effects arising from the presence of volatile and irritating vapors in the smoke stream. Many of these effects could be accounted for by the presence of hydrogen cyanide in small but detectable quantities in cigarette smoke. One of the primary and potentially most significant effects was the discovery that cigarette smoke, and its hydrogen cyanide component, inhibited, and in excessive quantities destroyed, the ciliary action of mammalian trachea."<sup>388</sup>

Liggett went on to test hydrogen cyanide produced by cigarettes and realized that this component inhibited cilia function. Liggett's director of research, Dr. Darkis, requested that his laboratory search for a "cigarette filter which would reduce the cyanide content of the smoke stream".<sup>389</sup>

Therefore, it is clear that Liggett knew that hydrogen cyanide was in cigarettes and specifically designed this program to eliminate this poison. Unfortunately, they never told any smokers that there was cyanide gas in the material they were smoking. This research led to the development of charcoal filters, which were first marketed as Lark in 1963. In addition, American and Reynolds marketed Taryton and Tempo on the same premise.

As a result, Liggett developed a medical public relations program. They sent letters to doctors in the United States that emphasized the fact that the charcoal would reduce the effects of "certain gases which inhibit the activity of mammalian respiratory cilia."<sup>390</sup> They did not mention the fact that the gas reduced was cyanide. In this case, they were more than willing to publish their findings and did so in the prestigious New England Journal of Medicine.<sup>391</sup> They neglected to mention that Liggett had funded this research.

Liggett sought to place an article in Esquire Magazine to promote the health aspects of their cigarettes.<sup>392</sup> Liggett then tried to have Reader's Digest publish a favorable article on the charcoal filter.<sup>393</sup>

Liggett engaged in a campaign to influence the medical literature by writing to Dr. Moore of the Roswell Park Memorial Institute criticizing him for failing to publish the benefits of the charcoal filter in his article, which reviewed tar and nicotine content from different brands of cigarettes.<sup>394</sup> Dr. Moore of RPMI wrote back to Liggett stating:

"Personally, I have grave reservations about their work [Kensler] since it represents selective publication of research. In other words, there workers contract work performed for commercial purposes and they publish only that information which they wish to release. For example, we are quite aware of the fact that they have confirmed the carcinogenicity of tobacco smoke, but if not published this information.

I have no objection to work performed from such laboratories, but I think it should be clearly indicated in a footnote that it was done under contract.

It is regrettable that much of this information is not available to us. In my opinion, those of us who feel that a safer cigarette can be designed are probably the ones most likely to help the Tobacco Industry in producing a safer product, and thus not only protect the smoking public, but also provide information which is actually in the interest in the industry.<sup>395</sup>

Kensler replied to Moore stating that he had published articles confirming the carcinogenicity of cigarette smoke.<sup>396</sup>

Moore, however, replied, “You are correct that you did publish some experiments in a monograph which I overlooked. I do not believe that this work was done while you were on the staff of Arthur D. Little, Inc. I also believe that you have not published any data on the carcinogenicity of tobacco as independent research in a scientific journal since that time.”<sup>397</sup>

A TIRC grantee, Dr. Bock, also wrote to Dr. Bates and suggested that since it was recognized that:

“...Hammond has shown that ‘smokers cough’ is a sensitive indicator of a reduction in the exposure of cigarette ‘tar’. A well financed long term study of the smokers of specific types of cigarettes – taking into consideration such effects as cough – might disclose whether reduction in tissue exposure results from consumption of charcoal filtered cigarettes...”

“...I understand full well that such a study would represent a radical departure of philosophy for most segments of the industry and I sympathize with the dilemma of the industry...”<sup>398</sup>

Liggett was therefore, informed that smoking causes cough and that tar is probably at least one of the factors involved and that this should be studied with respect to the effectiveness of charcoal filter. This follow-up testing was not done, apparently because it would have constituted an acknowledgement of the adverse health effects of smoking.

Internal studies at Liggett indicated that the Lark filter did not significantly reduce most components of the smokes that were toxic:

“The difference of the quantities involved, is so small that we cannot demonstrate it analytically and any statement that [Lark] smoke is ‘lighter’ than ordinary cigarette smoke would be based on very tenuous grounds.”<sup>399</sup>

He furthermore noted:

Suffice it to say that the particulate phase of cigarette smoke contains many compounds that have been demonstrated to have detrimental physiologic effects. At the top of the list would be compounds such as series of polycyclic aromatic hydrocarbons (PAH). Some of which have shown carcinogenicity in animal tests, and nicotine which has a variety of effects.

With respect to these compounds, the Lark filtration efficiency approximately equals that of conventional cellulose acetate filters.”<sup>400</sup>

None of Liggett’s advertising took this into account.<sup>401</sup> These charcoal filters were clearly meant to imply a health benefit and thus were directly misleading to the consuming public.

Ultra low tar cigarettes were actually in part to be designed to be “starter cigarettes”. These cigarettes were less likely to cause initial nausea or vomiting. In addition to being offered as viable alternatives to quitting, they are viable entry vehicles for young smokers.<sup>402</sup>

## 20. Additives

Humans, like animals, have a natural aversion to smoke. This is particularly true of first-time smokers especially children. Tobacco companies realize this and designed chemicals to remove the natural "onion" properties from the smoke. Tobacco companies add chemicals to cigarettes to improve the taste of tobacco smoke, and to mask the natural warning properties of tobacco. As a result, users are deprived of their normal defense mechanisms. Although seemingly innocuous the addition of flavorings creates a hazard. Added sweeteners and chocolate make cigarettes more palatable to children and first time users; eugenol and menthol numb the throat and mask the smoke's aggravating effects. Additives such as cocoa dilate the airways causing the smoke to pass deeper into the lungs exposing the body to more nicotine and higher levels of tar. Broncho-dilation increases the dose of smoke, inhibits the body's natural defense against smoke (broncho-constriction) and fools the user because it prevents the normal physiologic response to smoke a “sensation of shortness of breath”. The sensation of shortness of breath is one the most powerful human warning sensations. Loss of breath is fatal in minutes -no other warning sensation call for as fast a response.

Some tobacco additives are carcinogens when burned or otherwise enhance the toxic properties of the smoke. Additives mask the smell and visibility of side-stream smoke, making non-user exposures more likely.

Since the tobacco companies have chosen not to inform users of the ingredients added to cigarettes, users are deceived. Tobacco is the only product designed for human ingestion that does not inform users of its ingredients. They claim the information is kept secret to hide it from “competitors, but secret documents reveal that the Industry reverse engineers cigarettes and know how the additives used by their competitors.

Tobacco companies frequently utilize ideological arguments like "free choice" or "individual rights" to both oppose regulations and blame their customers for the health effects suffered from the use of the products they sell. There is no "free choice" if the tobacco companies conceal the toxic nature and components of their product and it is addictive.

### Masking warning properties and increasing toxicity

A BAT document explains of the role of tobacco additives. Four of the seven reasons for additives involve masking the taste of tobacco.

"The Role of Tobacco Flavor Additives. Tobacco flavor additives of all types are gaining importance in manufacturing practice for a number of reasons. Additives may be required:

1. To introduce a u.s.p [unique selling point] to a product.
2. To modify the smoke sensory characteristics of poorer quality grades particularly where government or economic compulsion dictates that the better quality material is not available for manufacturing.
3. To achieve a satisfactory smoking quality in situations where league tables influence the design of the product.
4. To counter the effect on smoke quality of including synthetic smoking materials in the blend.
5. To maintain brand character.
6. To improve the smoking quality of an existing brand.
7. To improve side-stream smoke character."<sup>403</sup>

Here is why additives are added:

"The wide scale use of sugars in casing formulas (adopted originally on the basis of smoker acceptance) and the general observation that most blends which have received wide scale consumer acceptance have significant sugar levels would certainly suggest that sugar level is important to quality." <sup>404</sup>

Liquorice boosts the sweetness of tobacco

According to BAT:

"Although each tobacco manufacturer carefully guards the secrets of his casing (and flavor) formulas, it is well known that casings for smoking products often contain sugar, liquorice, cocoa, or chocolate liquor and sometimes natural extracts. Of these, liquorice deserves special mention. Just as sugar is used in 'casing' the tobacco to mellow and smooth the smoke, liquorice is used as an adjunct to boost the sweetness of tobacco products. The taste of liquorice to the smoker is that of a mellow sweet woody note which, at proper use levels, greatly enhances the quality of the final product." <sup>405</sup>

"As far as liquorice is concerned, the smoothing effect of this is probably due to the Glycyrrhizin present which is renowned for its demulcent therapeutic property." <sup>406</sup>

Glycyrrhizin is an effective demulcent; it is also a bronchodilator and carcinogenic when burnt. <sup>407</sup>

Additives may be flavor enhancers or flavor suppressers:

"The greater use of reconstituted tobaccos presents two major problems to the flavor industry. Stems have higher nicotine content. You run into a second problem with them that you don't run into with the blend tobaccos. Reconstituted tobaccos will start off with a bad character. You've got a twofold problem. You've got to suppress a bad flavor and neutralise [sic] harshness, and you've got to put a good flavor back in. So, in some cases, we make suppressants ---- flavorings that, in effect, neutralise [sic] and diminish a bad flavor. On top of that, we have to add a flavor to bring it to a point where it's acceptable. One is an eraser and one is a writer." <sup>408</sup>

Chocolate gives better mouth feel

"The tobacco leaf of and by itself does not have sufficient impact. So, what you do is try to round off some of the harsher edges; try to add nuances of chocolate, for instance, which give you a better mouth feel when the smoke comes in and that's why these additives go in." <sup>409</sup>

Cocoa butter reduces harshness of smoke

"Although by no means conclusive, the results now presented lend some support to the claim that treatment of tobacco with cocoa butter reduces the harshness of the smoke." <sup>410</sup>

BAT adds around 1250 tons of cocoa to its cigarettes per year.

"I have circulated all Companies in the Division, and from their replies, estimate that the Company uses about one and a quarter million kilos of Cocoa in its tobacco products each year." <sup>411</sup>

j) Addicting the user

Nicotine

Adding nicotine to tobacco makes the smoke harsh and difficult to smoke, and increases the FTC nicotine rating. RJR patented a way to deceive both the public and the FTC by using a nicotine salt of an organic acid, (e.g., nicotine levulinate) to increase the bio-availability of nicotine while maintaining a low tar to nicotine ratio on the FTC reading:

"It would be desirable to provide a cigarette such as an 'ultra low tar' cigarette, which is capable of delivering a good tobacco taste, strength and smoking satisfaction characteristic of a 'full flavor low tar' cigarette while not being perceived as being overly harsh or irritating. In addition, it would be desirable to provide a cigarette such as a 'full flavor low tar' cigarette, which is capable of delivering a good tobacco taste, strength and smoking satisfaction characteristic of a 'full flavor' cigarette while not being perceived as being overly harsh or irritating. Cigarettes having incorporated therein a salt such as nicotine levulinate exhibit low FTC 'tar' to nicotine ratios while (i) having a smooth palatable, flavorful taste, and (ii) providing smoking satisfaction to the user. The cigarettes do not exhibit a harsh or irritating character; and do not exhibit a non-tobacco or off taste." <sup>412</sup>

And:

"Nicotine levulinate and levulinic acid significantly increased the amount of L (3H) nicotine bound to nicotinic receptors in rat brain tissue. The observed increase ranged from 20 - 50 %, with a mean value of around 30 %. The total amount of radio labeled nicotine bound to receptors was more than could be accounted for by binding to high affinity receptors alone. The maximal effect which was observed at concentrations of nicotine levulinate and levulinic acid in the low nano-molar range was reversed at higher concentrations. A computer model consistent with the results was developed and tested. According to the model, levulinic acid binds to an allosteric site on a class of low-affinity receptors and increases the affinity of these receptors for nicotine. At higher concentrations, this effect is reversed by the levulinic acid itself, assuming that it also has a reasonable affinity for the nicotine binding sites." <sup>413</sup>

"Levulinic acid (4-oxopentanoic acid) is primarily a breakdown product of starch, cane sugar and other cellulosic materials." <sup>414</sup>

Toxic additives

21. *Coumarin (Rat poison)*

In the late fifties, members of the food industry raised health concerns about the use of a highly toxic flavoring compound called coumarin (which causes severe liver damage and is used as a rat poison). Cigarette manufacturers voluntarily removed coumarin from the permitted list of additives in September 1997. BAT was aware of this in 1959.

"In the meantime we think you would be interested to know that in America the manufacturers of all food products intended for human consumption abandoned the use of coumarin during 1953/54 'until such time that adequate tests and investigations were completed wherein the use of coumarin may be considered to be deleterious and injurious to health."<sup>415</sup>

The tobacco companies have concealed the nature of coumarin and other toxic additives from users. It is likely that some users would want to know that they were inhaling combusted rat poison that had been added to their cigarettes. The publication of this information would be likely to adversely impact sales.

## 22. *Freon*

Puffing (a process of expanding reconstituted tobacco to increase its volume) of tobacco for cigarettes was once accomplished by adding Freon to the reconstituted tobacco."<sup>416</sup>

Burning Freon produces the toxic gas phosgene.

## 23. *Carcinogenic additives*

The tobacco companies added carcinogenic substances to tobacco.

"Mutagenic Activity of Flavor Compounds: Some 270 compounds have been assayed for mutagenic activity in Ames test...In these experiments a number of flavor compounds have been shown to be positive mutagens...

Acetaldehyde: Is a positive mutagen, it is embryotoxic, teratogenic and induces respiratory tract tumors in hamsters when inhaled.

Furfural: This is confirmed by complementary work as a clear mutagen and, in conjunction with other respiratory tract carcinogens, e.g. benzo(a)pyrene, it may act in a concerted way to increase the yield of tumours.

Furfural Acetate: The work of Mortelmans et al. is the only mutagenic study on this compound. However, the experiments on fufural and furfuryl alcohol would seem to indicate a general mutagenic reactivity of this family of compounds.

Maltol: The positive mutagenic activity is confirmed by other studies in vitro; however, the compound does not seem to have been tested in vivo.

O-Methoxycinnamaldehyde: Does have the potential to be a positive carcinogen.

Recommendations:

Acetaldehyde, furfural and furfural acetate... If these agents are to be added to tobacco, it would appear prudent to review the levels of addition in the light of the above evidence. For maltol and o-methoxycinnamaldehyde, the evidence indicates a possible carcinogenic potential of these agents. This would again suggest reviewing the use of such agents for human use."<sup>417</sup>

24. *Tobacco Companies conduct research to reduce side stream smoke not toxicity.*

After tobacco companies were criticized for irritating and injuring bystanders they fell back to the usual strategy of deceiving the public. They developed a research program that would make side stream smoke last visible but ignored toxicity.

"Strategic objectives (of side stream smoke research) remain as follows: 1. Develop cigarettes with reduced side stream yields and/or reduced odor and irritation. 2. Conduct research to anticipate and refute claims about the health effects of passive smoking."<sup>418</sup>

"To pre-empt potential volume decline from smokers under pressure in social and work environments by providing them with an offer which combines re-assurance in social smoking with taste and satisfaction."<sup>419</sup>

"Studies into alternative burn additives that reduce visible side stream: As a result of these studies sodium acetate has been used to replace tri-potassium citrate in low visibility side stream papers...Potassium salts give greater reductions in side stream visibility."<sup>420</sup>

"It has been found that a 'Ca (OH)2 filled cigarette paper gives a reduced visible side stream smoke...It was noticed that the cigarettes made with treated papers gave a more pleasant and less irritating side stream aroma than the cigarettes made with untreated papers. Also the taste of the mainstream smoke had changed and seemed to be milder than for the cigarettes made with the treated papers"<sup>421</sup>

"Smoke control: side stream reduction: Visibility. RD&E is interested in work dealing with side stream smoke reduction, but is not interested in the biological testing of products produced. David will explain this to Allen Herd and ask whether projects could be run without biological testing."<sup>422</sup>

#### Fire-safe cigarettes

Cigarettes have been known to be a major cause of death from fires for over fifty years.<sup>423</sup> Tobacco companies have failed to use available technology to make their cigarettes less likely to start fires.<sup>424</sup> Furniture makers have made their products more fire resistant.<sup>425</sup>

#### Removal of warnings

Many if not all of the additives that tobacco companies receive from chemical company suppliers are shipped with warnings called material safety data sheets (MSDS). For example, eugenol is a tobacco additive. When tobacco companies receive eugenol it is shipped with an MSDS that includes these statements:

"Burning liberates carbon monoxide, carbon dioxide and smoke ...  
May be irritating to skin or eyes...  
Prolonged ingestion at high levels may cause liver damage..."<sup>426</sup>

Tobacco companies secretly take the eugenol out of containers that are accompanied by warnings or have warnings on them, place the material in cigarettes and expect customers to burn and inhale these toxins. The user has no reasonable expectation that this has occurred and since the cigarettes do not list ingredients, users are unable to determine the hazard for themselves.

## D. Failure to Educate

### 1. *Tobacco Companies Education efforts were inadequate*

#### (a) Failure to Educate About Many Diseases

##### Oral Cancer

The tobacco industry failed to educate users about other tobacco caused diseases that were recognized and uncontroverted in the medical literature. The tobacco companies never disputed the smoking relatedness of these diseases before the mid 1960s when the government mandated caution labels. One example is oral cancer. By 1915, it was established that tobacco caused or contributed to tongue and oral cancer.<sup>427</sup> Had the tobacco industry educated users about the fact that tobacco use causes oral cancer when this was first accepted in the medical community, they would have adequately educated, by inference, on all types of cancer.

The adverse effects of smoking on reproduction:

### **Low Birth Weight, Premature Birth, and Fetal Injury**

In 1965, the CTR sponsored a study that established a connection between smoking and low birth weight. This information was not yet generally available to the medical community. Joseph Cullman, President of Phillip Morris, noted, “some women would prefer having smaller babies.”<sup>428</sup> Cullman did not dispute the fact that smoking caused or contributed to low birth weight babies. His statement also indicates that women were not aware of the medical significance of low birth weight babies. Women would not “prefer” smaller babies if they knew that premature births lead to malformations, developmental difficulty and neonatal and peri-natal mortality. In 1982, the industry submitted the results of a non-industry funded study to Congress that indicated that smokers had no greater risk of premature babies and that low birth weight was not related to smoking. They did not reveal the results of their 1965 study.<sup>429</sup>

#### **c) Reduced length of gestation - Low birth weight:**

Cigarette smoking during pregnancy induces fetal hypoxia through two independent pathways:

Nicotine activates adrenergic discharge, resulting in vasoconstriction<sup>430</sup> and decrease in placental intervillous blood flow<sup>431</sup> leading to uteroplacental under perfusion.<sup>432</sup> Smokers' placentas seem to have an increased frequency of lesions that are characteristic of under perfusion, such as obliterative endarteritis and cytotrophoblastic hyperplasia in villi as well as necrosis of the decidua basalis at the margin of the placenta, all of which are thought to contribute directly to reduced fetal nutrition and hence to fetal growth retardation.<sup>433</sup>

Smoking increases carboxyhemoglobin level, which causes sustained reduction of fetal oxygenation.<sup>434</sup> In fact it has been found that the level of carboxyhemoglobin in the fetus is usually 10-15% higher than that of the mother.<sup>435</sup>

The combined effect of continuous smoke-induced reduction of uteroplacental blood flow and prolonged increase in the carboxyhemoglobin on the fetus has been shown through numerous research studies to contribute to a reduced length of gestation,<sup>436</sup> prematurity,<sup>437</sup> as well as frequently to a lowered birth weight of the newborn.<sup>438</sup> The average reported weight reduction can fluctuate between 120g to 430g, or more, depending on the number of cigarettes consumed.<sup>439</sup>

Environmental Tobacco Smoke (ETS) is also detrimental for the fetus. Based on all sources of data ETS exposure appears to be associated with a slight decrement in birth weight. (See Tab 15, Figures 7 & 8).<sup>440</sup> The studies reviewed were even more consistent in showing a decrement in mean birth weight with ETS exposure. Qualitatively, the best studies showed decrements from 25 to 100 g. The pooled estimate of all studies revealed a birth weight decrement of 25 g, although higher quality and more homogeneous studies showed a magnitude of effect closer to 35–40 g, and a few studies suggested even greater differences. Since some studies did not adjust for gestational age, some of the weight decrement may be confounded by prematurity.<sup>441</sup> An increased risk of 20% in SGA could affect thousands of infants because of the high prevalence of ETS exposure.<sup>442</sup>

**TABLE I: Studies of mean birth weight and ETS exposure defined as paternal smoking status<sup>443</sup>**

Author <sup>Ref</sup> (by year)	Location	Study size/design	Exposure definition	Weight difference (g) [95% CI]
MacMahon <i>et al</i> <sup>10</sup> (1966)	MA, USA	5935 Retrospective, mail	Any	-22 [-57, 13] Female -20 [-55, 15] Male <sup>b</sup>
Comstock <sup>11</sup> (1967)	MD, USA	448 Record linkage	Any	-42 <sup>c</sup>
Underwood <i>et al</i> <sup>12</sup> (1967)	US Navy Inst Worldwide	24674 Medical records	1-10 cigs/day 11-30 >30	-7 -5 -3
Borlee <i>et al</i> <sup>13</sup> (1978)	Belgium	238 Case-control of defects	Any	-228 [-429.0, -26.7]
Magnus <i>et al</i> <sup>14</sup> (1984)	Norway	5188 Retrospective	Each 10 cig/day	-48 [-65, -31] crude -5 [-23, 13] adjusted <sup>d</sup>
Rubin <i>et al</i> <sup>15</sup> (1986)	Denmark	500 term births Interview at delivery	Each cig/day 10 cigs/day	-6.1 [-12, -0.2] adjusted <sup>d</sup> -61 (extrapolation) <sup>b</sup>
MacArthur & Knox <sup>16</sup> (1987)	England	180 quit smoking Unknown	Any	-14 g <sup>c</sup> +123 g, 'standardised'
Schwartz-Bickenbach <i>et al</i> <sup>17</sup> (1987)	Germany	108 Interview at delivery	Any	-205 [-440, 30]
Campbell <i>et al</i> <sup>18</sup> (1988)	England	518 whites Interview 1 month post delivery	Any	-113 [-216, -8] adjusted <sup>d</sup>
Brooke <i>et al</i> <sup>19</sup> (1989)	England	1018 whites Prospective interview	Any	-18 [P=0.56] adjusted <sup>c</sup>
Chen <i>et al</i> <sup>20</sup> (1989)	China	1058 Retrospective, mail	≥10 cigs/day ≥10/day other household smokers	-11 [-82, 64] <sup>b</sup> -15 [-95, 64]
Saito <sup>21</sup> (1991)	Japan	3000 Retrospective, interview	Any ≥40 cigs/day	-33.4 [-66.3, -0.5] <sup>b</sup> -111 [-191, -32]
Mathai <i>et al</i> <sup>22</sup> (1990)	England	285 whites Prospective interview	Any	-66 [-213, 81]
Mathai <i>et al</i> <sup>23</sup> (1992)	India	994 Interview (retrospective?)	Any	-63 [-114, -12] adjusted
Zhang and Ratcliffe <sup>24</sup> (1993)	China	1785 Retrospective interview	Any	-30 [-66, 7] adjusted
Martinez <i>et al</i> <sup>25</sup> (1994)	AR, USA	907 Interview at delivery	Every 10 cigs/day	-34 [-63, -5] adjusted

<sup>a</sup>Spouse of pregnant woman, or some studies include other household smokers.

<sup>b</sup>Indicates estimate used in data pooling (when more than one).

<sup>c</sup>No data provided to calculate CI or SE, so not included in meta-analysis.

<sup>d</sup>Includes maternal smokers but adjusts for it.

#### d) Perinatal mortality, stillbirths and spontaneous abortions:

The relationship between maternal smoking and perinatal loss is impressive, ranging from 5-70% depending on the population studied.<sup>444</sup> Smoking greatly increases the risk of maternal rejection of the fetus at apparently all stages of gestation. It also increases the risk of bleeding, which in most cases can be regarded as a threatened rejection.<sup>445</sup> Antepartum bleeding or abruptio placentae has been linked directly with an excessive cigarette consumption.<sup>446</sup>

A report using data from the Ontario Survey<sup>447</sup> concluded that as much as 30-40% of the excess perinatal mortality of smoker's babies was found to be directly attributable to abruptio placentae.<sup>448</sup> A further substantial part of antepartum bleeding, generally about 25%, is associated with placenta praevia,<sup>449</sup> which has been increasingly detected among expectant cigarette smoking mothers.<sup>450</sup> Placenta praevia in turn has been related to spontaneous abortions and, in some cases, to fetal malformations.<sup>451</sup>

#### **d) Fetal malformations:**

Experiments on non-human subjects have shown that smoking reduces the cell number without affecting the cell size.<sup>452</sup> Furthermore, smoking reduces the rate of cell replication in all organs, which is associated with a reduced rate of DNA synthesis.<sup>453</sup> Tobacco smoking has also been found to reduce the rates of protein synthesis.<sup>454</sup>

As maternal smoking reduces both the rate of cell replication and protein synthesis, it is therefore felt that maternal smoking causes most of its damage during the first weeks of gestation when the rates of embryonic and fetal cell replication are the most active, leading to various congenital malformations.<sup>455</sup>

A study among 10,523 health professionals showed a 29% increase in malformations, such as hare lip, cleft palate and various central nervous system abnormalities among infants born to mothers who smoked during pregnancy.<sup>456</sup> Another study found significant over representation of malformations of the central nervous system, digestive system and the heart, among babies born to smoking mothers compared to controls.<sup>457</sup>

Maternal smoke inhalation has also been found to increase significantly the fetal heart rate.<sup>458</sup> One study reported a large statistically significant increase in the rate of congenital heart defects among infants born to mothers who smoked during pregnancy compared with non-smoking mothers.<sup>459</sup> The mutagenic compounds of tobacco, not only can cause damage during embryonic development but also before conception, by modulating susceptibility to chromosomal aberrations of the sperm.<sup>460</sup>

##### ii. Thrombo-Angiitis Obliterans

In 1935 Silbert stressed "the importance of tobacco as the exciting cause of thrombo-angiitis obliterans."<sup>461</sup> The tobacco smoke "produced vasoconstriction of the vessels of the extremities . . . further decreasing the already impaired peripheral circulation" of patients.<sup>462</sup> Furthermore, he noted that smoking cessation stopped the progression of the disease.<sup>463</sup> This link was not and is not now common knowledge. Unlike diseases such as emphysema and heart disease, thrombo-angiitis obliterans often has a visible effect. The medical literature included photographs of swollen arms and legs that often needed to be amputated. (See TAB-11) The tobacco industry should provide this health information to their product users. The photographs, in particular, would have a strong impact on smokers.

##### iii. Tobacco Amblyopia

Few people are aware of the connection between tobacco and the disease of amblyopia. Symptoms of amblyopia include complaints of "misty" vision, difficulty in reading, and a "dazzling" effect in sunlight.<sup>464</sup> In addition, they have difficulty seeing the color red.<sup>465</sup> Most people would not associate tobacco use with impaired vision, yet this disease has been linked to tobacco use for over a hundred years. In 1896, DeSchweinitz published the first paper on toxic amblyopia.<sup>466</sup> Since then, the medical community has gathered much research on the link between tobacco use and amblyopia. The tobacco industry, however, has never acknowledged the problem of tobacco amblyopia. Vision impairment is a serious condition about which smokers are not educated. If a tobacco user abstains from tobacco, he will experience at least a partial improvement in his vision.<sup>467</sup> Tobacco amblyopia is still a problem today.<sup>468</sup> Unless the tobacco industry educates users about tobacco amblyopia with their products, users such as airline pilots, truck drivers, and police officers, may never associate their altered vision with their use of tobacco.

2. *Inadequate label.*

There is some evidence that tobacco companies performed experiments to determine the least effective location and content for the health information. Since this taxonomy only raises an inference for this activity my full opinion on this matter will be supplemented after I have an opportunity to review the documents coded under these categories.

a) Location

AAAE Eye Movement Data: Documents concerning a test which studies the path a viewer's eye follows as he scans an ad and the amount of time spent looking at each part of the ad. This test is used to evaluate elements of advertising and/or packaging. Both product and user imagery are also usually measured in this test. Responsive documents include ads with percentages written by various sections of the ad (e.g., the picture or the title). Perception Research, Inc. is one of several of Brown & Williamson's suppliers of this test."<sup>469</sup>

KA ADEQUACY: Documents discussing the adequacy of various warnings (e.g., static warning vs. rotating warnings, strength of the warning, etc.)

KB DESIGN OF WARNING (SIZE, COLOR PLACEMENT, ETC.): Includes studies to determine effectiveness of various formats for the warnings.

b) Effectiveness

KC EFFECT ON SMOKING BEHAVIOR/AWARENESS: Studies to determine the effects of warnings on smokers' behavior and smokers' awareness of smoking and health issues.<sup>470</sup>

c) Failed to comply with Government regulation by making health claims and providing inadequate labels (See time line of FTC violations)

KEA FTC v. Carter Investigation/Subpoena (1976-1979): The key word here is "subpoena". Subpoenas were issued by the FTC to obtain advertising and marketing documents from cigarette manufacturers since 1964. The case became a procedural question on the FTC's authority to issue the subpoenas and on the question of confidentiality of the documents. The subpoenas were enforced in January 1979.

KEB Consent Decree (1972): The FTC obtained consent decrees signed by six major cigarette manufacturers requiring appearance of the Surgeon General's health warning in all cigarette advertising. The announcement was made in April 1972. Key words were that the warnings were to be "clear and conspicuous."

KEC FTC v. Brown & Williamson. In 1974, the FTC began an investigation into the size of the health warnings required in cigarette advertising by the Consent Decree. On August 1, 1975, the FTC notified the six cigarette companies that it had determined that they were in violation and requested the Department of Justice to commence actions. Suits were then filed in the U.S. District Court against the manufacturers seeking civil penalties for the correction of asserted violations of the Consent Order.<sup>471</sup>

d) Over promoted their products (See marketing section, report by Dr. Cummings, videos and other pictures of advertisements, history of

health claims and denials of the health effects of smoke elsewhere in this report)

KD DILUTION OF WARNING/OVERPROMOTION: Documents Suggesting that Brown & Williamson or BAT used advertising and overpromotion to dilute the effect of the warning label on consumer awareness of risk.<sup>472</sup>

The tobacco company carried out a variety of campaigns to make the public think the cigarette cancer connection was “open”.

As recently as February 2, 1984, the president of RJR Reynolds appeared on Nightline and claimed that more research needed to be done on the problem. He furnished a variety of reassuring messages and said, “Despite all of the research to date, there is no causal link established [with respect to cigarette smoking and emphysema, cancer, and heart disease].” He did concede that tobacco stains your teeth. More notably he indicated that he had never smoked.<sup>473</sup>

E. Targeted marketing at children. (See Dr. Cummings report for a more detailed discussion of this issue).

The Tobacco companies violate their own alleged "standards" of good practice and target marketing at children. Such violations include:

- Marketing to children by placing their logos on children's clothing.
- Placing young appearing people in advertisements.
- Developing entire clothing and style lines with the name of their cigarette brand on it in order to get around bans on direct advertisement of cigarettes.
- Cigarette giveaways.

#### *Tobacco Industry Marketing Code*

US Violations (See TAB-15 Time line of FTC actions)

As this document reveals the companies are quite interested in children’s cigarette consumption in the US.

...Respondents twenty and younger produced by the new questionnaire.

Respondents age fourteen to twenty: Cards are to be punched for all respondents fourteen to twenty. Such respondents are to be used for the cigarette profile report on young smokers but are to be excluded from the R-Y-O analysis, and from cigarette and R-Y-O availability counts (males age seventeen and twenty will, as usual be included in analysis and availability counts of pipe smokers and tobacco chewers).

Respondents age thirteen and younger: Cards are to be punched for those who are cigarette smokers to provide a count by year of the very young smokers report.<sup>474</sup>

This document suggests that follow-up contacts be made by phone, to “respondents . . .to report cigarette brand name or smoking volume.” The tobacco companies discussed plans to call thirteen and fourteen year

olds to find out about their smoking habits. There is no indication that they made any effort to inform their parents of the survey.

In 1964, the Tobacco Industry voluntarily adopted the “Cigarette Advertising Code”. Their publicly stated reason for adopting the code was because of their concern for children and the marketing of tobacco to them. Their real reason was different they hoped the voluntary adoption of the code would “forestall” government regulation of the industry. Former New Jersey governor Robert, B. Meyner, oversaw the administration of the code, which became effective on January 1, 1965:

“The code was set up by the industry to forestall the Federal Trade commission which sought to require 1) that cigarettes be labeled as being hazardous, 2) that there be no advertising implying cigarettes are harmless, and 3) that there be no advertising involving numbers unless the numbers can be proved to be meaningful. The FTC dropped its second and third points, upon creation of the advertising code, but still seeks to enforce the first one, which is an outgrowth of the Report of the Surgeon General’s Committee.”<sup>475</sup>

In 1967, the FTC reported to congress and pinpointed ‘loop holes’ in the language of the advertising code. More importantly, the report criticized cigarette advertising for appearing during television shows with an audience of at least 45% of its viewers under 21 for portraying physical activity as long as the smoker was not a direct participant, and for inferring that smoking contributes to success. They then pointed out a variety of advertising examples that violated the code.<sup>476</sup>

“The use of smokers participating in or appearing to participate in athletic activity requiring physical exertion is forbidden by the Code. “However, so long as the smoker is not a prominent athlete and does not appear to participate in a rigorous sport or in rigorous activity, there are virtually no limitations on the use of sporting themes in cigarette commercials. It is arguable that even these boundaries can be crossed through sponsorship of sporting events.”<sup>477</sup>”

“...The Cigarette Code states ‘cigarette advertising shall not represent that cigarette smoking is essential (emphasis added) to social prominence, distinction, success or sexual attraction.’ The wording would appear to permit indicating that smoking may contribute to or even cause success, sexuality, etc., provided there is no representation that cigarette smoking must be present for these results to occur.”<sup>478</sup>”

“...Although minor changes have been made in some advertisements since promulgation of the Cigarette Code, their themes and basic impact have remained unchanged. Cigarette advertising continues to promote the idea that cigarette smoking is both pleasurable and harmless. On their face, the various advertising codes may appear to set proper guidelines for cigarette advertising, but in practice it is possible for cigarette manufacturers to comply with the codes without making known the health hazards of smoking or diminishing in any way the appeal of their advertisements.”<sup>479</sup>”

#### e) International Advertising

While the code was honored more in the breach than in the observance in the United States, it was never applied to the US tobacco companies’ overseas operations. Ironically, the developing countries had less information on the health hazards of tobacco.

Some examples include: (Citations are reprinted from Global Aggressions)

“In Finland where there is a ban on any form of direct or indirect tobacco advertising, brand stretching is seen through Marlboro Classic clothes, Camel

boots and socks, Camel Trophy matches, and Formula One racing, where Finnish drivers sport uniforms emblazoned with the Marlboro logo, minus the word 'Marlboro.'<sup>480</sup>

...In Vietnam, even though there is a ban on all forms of direct advertising except point of sale (which is restricted), young women dressed in Marlboro outfits can be found distributing cigarettes because product sampling is still permitted.<sup>481</sup> (See TAB 8H for violation)

...In Bulgaria... concerts are tobacco sponsored and the tobacco corporation give out free samples.<sup>482</sup>

...Philip Morris began offering Marlboro sportswear in exchange for empty Marlboro cigarette packs in department stores in Beijing, when China took steps to restrict tobacco advertising.<sup>483</sup>

...RJR Nabisco opened the first US cigarette manufacturing facility in Poland in 1994.<sup>484</sup> Poland, which is in a region with the highest death rates in the world from tobacco<sup>485</sup>, passed legislation in 1996 banning sales of cigarettes in vending machines and sports arena, prohibiting TV and radio ads, as well as ads in newspapers and magazines for youth and the cinema.<sup>486</sup> Yet, children and youth are targeted with posters for Camel Planet next to schools<sup>487</sup>, promotions in discos, restaurants, even a circus- tent with free cigarettes on the beach.<sup>488,</sup>

Foreign marketing practices indicate that the tobacco companies are not really interested in children's health. Apparently the industry statement that "smoking should be an adult choice", was not applied to US or even attempted in foreign countries. Unfortunately all children are equally susceptible to tobacco health effects of tobacco and addiction and are equally unable to make appropriate adult choices.

F. Failed to fulfill their promise to stop selling products when the evidence for adverse health effects is overwhelming and admitted.

"We accept an interest in peoples health as a basic responsibility, paramount to every other consideration in our business."

A Frank Statement to Cigarette Smokers- January 4, 1954.

"If the industry leaders really believed that cigarettes caused cancer, they would stop making them."

Parker McComas, chief executive of Phillip Morris, temporary chairman of TIRC<sup>489</sup>

"We believe there is no connection [between smoking and disease], or we wouldn't be in the business."<sup>490</sup>

Phillip Morris CEO Joseph Cullman, 1963

These were the promises of the tobacco industry. The asbestos industry never made any promises, but have, for the most part stopped production of asbestos containing products and where no substitutes are available (Space shuttle O-rings) have provided a variety of education programs for users in the US. (Like

the Tobacco companies, Canadian asbestos producers continue to exploit developing countries and fight government controls in Europe.)

Tobacco company executives have now admitted that smoking has killed thousands of Americans. On Thursday August 21, 1997, under oath, Geoffrey Bible CEO of Phillip Morris stated, there's "a fair chance" more than 100,000 Americans might have died as a result of tobacco use.<sup>5</sup>

Mr. Lebow, President of Liggett, admitted smoking caused a variety of diseases. In addition his company voluntarily improved the label.<sup>491</sup>

8	Q.	So, you admitted that smoking causes -- your company
9		admits that smoking causes lung cancer?
10	A.	That's right.
11	Q.	Emphysema?
12	A.	That's right.
13	Q.	Heart disease?
14	A.	Right.
15	Q.	You admitted that cigarettes were addictive?
16	A.	That's right.
17	Q.	And did you change something on the warning labels?
18	A.	Yes. We also agreed to put on every one of our
19		packets finally the warning that smoking is addictive.
20	Q.	And did you put it on from the Surgeon General?
21	A.	No, from us. Just our own warning, you know,
22		caution, smoking is addictive.

These were not industries' first public acknowledgements of the adverse health effects of smoking. Clearance Little's testimony in 1957 stated, "any chronic irritation is a bad risk in any form of cancer and that inhalation of smoke is an irritant. Robert Hawk testified in 1978 that it is a "plausible possibility" that smoking has a "effect on small airways" that smoking causes "a certain amount of irritation" that for a small group of persons who "for genetic reasons are highly susceptible" to chronic pulmonary disease "smoking can be a grave danger" and that smoking reduces muscle and tissue production in youth.<sup>492</sup>

Private admissions also occurred (from a 1970 memo):

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<sup>5</sup> Motley -- Would Philip Morris agree that a single American citizen who smoked their products for 30 or more years, a single one, has ever died of a disease caused in part by smoking cigarettes?

Bible -- I think there's a fair chance that one would have, yes. Might have.

Motley -- How about a thousand?

Bible -- Might have.

Motley -- 100,000?

Bible -- Might have.

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Motley -- If it were established to your satisfaction that cigarettes were a cause of lung cancer, would you order your company to stop manufacturing cigarettes until what it is in cigarettes that caused lung cancer could be removed?

Bible -- My first reaction would be to very quickly see what it was that was causing the difficulty, and to see quickly if we could remove it, address it satisfactorily. I think I'd need to speak with the government very quickly to see if they would continue to consider the product a legal product, because if it were an illegal product, then naturally we couldn't continue to manufacture it.

Motley -- So while you decided what to do, Philip Morris would continue to produce two billion cigarettes a day?

Bible -- No, I didn't say that.

Motley -- Would you, would you shut it down?

Bible -- It would depend on the circumstances. It's a bit hard for me to say in a vacuum here. I think, if you'll force me to say what would I do in those circumstances, I'd probably say sure I'd shut it down instantly to get a better hold on things, but I would hope to get a better hold and talk with the government very quickly.

Although the results of the research would appear to us to remove the controversy regarding the causation of the majority of human lung cancer...

"To sum up, we have the opinion that this work proves beyond all reasonable doubt the causation of lung cancer by smoke, even though an ideal situation it would have been preferable to avoid a surgical technique, and to allow the animals to live out their life span. Nevertheless, there are certain shortcomings of the experiment that is easier to see these in hindsight.

This is not a serious criticism of the experiment and it obviously impossible to design an experiment of this type, which would cover every aspect of the problem.<sup>493</sup>

Not only have the tobacco companies failed to fulfill their promises and public health obligations, they knowingly violate their own advertising codes and increase sales to all markets as fast as they can.

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August 15, 1999  
Braintree, Massachusetts

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