THE FIRST REACTION OF THE GUILTY: THE SCIENTIFIC BASIS FOR THE LIABILITY OF THE BRITISH TOBACCO INDUSTRY

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Introduction

The British tobacco industry, and particularly the British American Tobacco Company (BAT) is increasingly involved in litigation worldwide over the health effects of its products. To better understand and predict the outcome of this litigation, analysts should be conversant in the factual bases upon which the litigation is brought. This paper focuses on the scientific basis for disease and disease-cost claims against BAT.

A. Scientific knowledge available to the industry

The cigarette industry had ample warning of the medical disasters that occurred in the middle of the 20th century, but decided to confront the problem with deception and public relations instead of honest warnings and safer products.

In a comprehensive work summarising the world literature on the subject, Ochsner and DeBakey[1] correctly observed that the increase in smoking after World War I caused the increase in lung cancer in the 1930s, after a latency period of about 20 years. The authors wrote:

> "It is our definite conviction that the increase in the incidence of pulmonary carcinoma is due largely to the increase in smoking, particularly cigarette smoking, which is universally associated with inhalation. [T]here is an obvious parallelism between the increased production of tobacco and carcinoma of the lung."

Sir Richard Doll and Bradford Hill, perhaps England's most celebrated physician-statisticians, published a large scale survey[2] of 709 lung cancer patients. Only two non-smokers were found, leading the investigators to conclude that "smoking is a factor, and an important factor, in the production of carcinoma of the lungs". The study found, "Only one lung cancer patient in 200 was a non-smoker, as compared with one in 22 among the controls". Furthermore, the researchers found ample evidence of dose-response: "[T]he risk of developing carcinoma of the lungs *increases steadily as the amount smoked increases*." Doll and Hill stated:

> "We therefore conclude that smoking is a factor, and an important factor, in the production of carcinoma of the lungs."[3]

From England again came further confirmation in a major independent study. Reasoning that physicians were likely to be accurate in their reporting of their own

[1] Ochsner A, DeBakey M: "Carcinoma of the lung". Arch Surg 42: 209-258, 1941.
[2] Doll R, Hill AB: "Smoking and cancer of the lung". Br Med J 2: 739-748, 1950.
[3] *Ibid* at p 746.

smoke exposure and diseases, Doll and Hill conducted a major epidemiological study of over 40,000 British physicians[4]. Their report revealed that mild smokers were seven times as likely to die from lung cancer as non-smokers; moderate smokers were 12 times as likely to die from lung cancer as non-smokers, and "immoderate" smokers were 24 times as likely to die from lung cancer as non-smokers:

> "The [death] rates reveal a significant and steadily rising mortality from deaths due to cancer of the lung as the amount of tobacco smoked increases. There is also a rise in the mortality from deaths attributed to coronary thrombosis..."[5]

By 1957, the British Medical Research Council had studied all available literature on the subject and issued a report which was unequivocal, stating that cigarette smoke caused lung cancer by "direct cause and effect":[6]

> "1. A very real increase has occurred during the past twenty-five years in the death-rate from lung cancer in Great Britain and other countries.
>
> 2. A relatively small number of the total cases can be attributed to specific industrial hazards.
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> 3. A proportion of cases, the extent of which cannot yet be defined, may be due to atmospheric pollution.
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> 4. Evidence from many investigations in different countries indicates that a major part of the increase is associated with tobacco smoking, particularly in the form of cigarettes. *In the opinion of the Council, the most reasonable interpretation of this evidence is that the relationship is one of direct cause and effect.*
>
> 5. The identification of several carcinogenic substances in tobacco smoke provides a rational basis for such a causal relationship."[7]

The Royal College of Physicians of London set up a committee in 1959 to report on cigarette smoking and lung cancer. The report was published in 1962, a short but detailed work entitled "Smoking And Health"[8]. Analysing 23 retrospective studies in nine countries and at least four prospective studies in three countries, the report found the association between lung cancer and cigarette smoking "confirmed",

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[4] Doll R, Hill AB: "Lung cancer and other causes of death in relation to smoking. A second report on the mortality of British doctors". Br Med J 2: 1071-1081, 1956. Doll WR, Hill AB: "The mortality of doctors in relation to their smoking habits. A preliminary report". Br Med J. 1: 1451, 1954.

[5] *Ibid* at p 1455.

[6] Editorial: "Medical Research Council's statement on tobacco smoking and cancer of the lung", *Lancet* 29 June 1957, 1345-1346.

[7] *Ibid* at pp 1346-1347 (emphasis added).

[8] *Smoking and Health. Summary and Report of The Royal College of Physicians of London on Smoking in Relation to Cancer of the Lung and other Diseases* Pitman Publishing, New York 1962)

noting death rates "increase steeply" with increasing consumption to 30 times the rate of non-smokers. The report also found relationships between smoking and heart disease, cancers of the mouth and other organs, and chronic bronchitis, and suggested that nicotine was addictive.

B. The nicotine conspiracy

In the early 1960s the British American Tobacco Company (BAT), the parent of US manufacturer Brown and Williamson Tobacco Company, conducted extensive nicotine research in secret.

Certain documents disclose the companies' understanding of nicotine addiction, long before it was well understood in the medical community. In *Final Report On Project Hippo II*[9], the Battelle Laboratory, working for BAT, summarises experiments on nicotine and reserpine on various hormones in both intact animals and isolated organs:

> "A quantitative investigation of the relationships with time of nicotine and some possible brain mediators - on adreno-corticotrophin activity could give us the key to the explanation of both phenomena of tolerance and addiction, in showing the symptoms of withdrawal."[10]

In *The Fate Of Nicotine In The Body*[11], the researchers covered a variety of experiments on humans and animals to look at nicotine pharmacology in mechanisms of tolerance and addiction. The report shows that the absorbed nicotine is not related to the nominal levels in the smoke, and describes a whole variety of physiological experiments:

> "There is increasing evidence that nicotine is the key factor in controlling, through the central nervous system, a number of beneficial effects of tobacco smoke, including its action in the presence of stress situations . . . In addition, the alkaloid appears to be intimately connected with the phenomena of tobacco habituation (tolerance) and/or addiction. . . . Detailed knowledge of these effects of nicotine in the body of a smoker is therefore of vital importance to the tobacco industry, not only in connection with their present standard products, but also with regard to future potential uses of tobacco alkaloids."[12]

Of great importance, the researchers realised the connection of tolerance and addiction, a connection not made in the public medical journals until much later:

[9] 30 April 1963, Haselbach C, Libert O.
[10] *Ibid* at p 4.
[11] 1 May 1963, Geissbuhler H, Haselbach C.
[12] *Ibid* at p 1 (citations omitted).

"We believe that both tolerance and addiction are intimately connected, and that it would be most useful to investigate the two phenomena with regard to cellular adaptation, especially in target organs of the central nervous system."[13]

The critical memorandum[14] concluded that chronic intake of nicotine "weakened" the nervous system, and that addicted smokers sought a return to the "normal" equilibrium:

"In a chronic smoker the normal equilibrium in the corticotrophin releasing system can be maintained only by continuous nicotine intake. . . . If nicotine intake, however, is prohibited to chronic smokers, the corticotrophin-releasing ability of the hypothalamus is greatly reduced, so that these individuals are left with an unbalanced endocrine system. A body left in this unbalanced status craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine.

In conclusion, a tentative hypothesis for the explanation of nicotine addiction would be that of an *unconscious desire to restore the normal physiological equilibrium of the corticotrophin releasing system in a body in which the normal functioning of the system has been weakened by chronic intake of nicotine.*"

When these reports were received by BAT's medical director Sir Charles Ellis, he remarked that they represented important new research "far more extensive than exists in published scientific literature" and that they were to be kept at a "high level of secrecy . . . for good reasons": [15]

"As a result of these various researches *we now possess a knowledge of the effects of nicotine far more extensive than exists in published scientific literature.* It is indeed so extensive and represents so much new thought that it is not easy to condense the material of these several reports and working papers without the risk of over-simplification...."[16]

"We believe we have found possible reasons for addiction in two other phenomena that accompany steady absorption of nicotine".[17]

"*For good reasons, the results of Battelle's work have been kept at a high level of secrecy....*"[18]

[13] *Ibid* at p 27.
[14] A *Tentative Hypothesis on Nicotine Addiction* (30 May 1963) Haselbach C, Libert O.
[15] Ellis, Sir Charles: "The effects of smoking (13 February 1962).
[16] *Ibid* at p 9 (emphasis added).
[17] *Ibid* at p 10.
[18] *Ibid* at p 16 (emphasis added).

BAT's US subsidiary, Brown and Williamson, was let in on BAT's revelation that its return customers were responding to physical dependence, not just the "pleasure of smoking". Addison Yeaman, Executive Vice President of Brown and Williamson, was persuaded by the BAT research, and wrote in 1963 in a private memorandum, that they were "in the business of selling nicotine, an addictive drug:"[19]

> "Strictly Private and Confidential
>
> Moreover, nicotine is addictive.
>
> We are then in the business of selling nicotine, an addictive drug effective in the release of stress mechanisms. But cigarettes - we will assume the Surgeon General's Committee to say - despite the beneficent effect of nicotine, have certain unattractive side effects:
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> 1) They cause, or predispose to, lung cancer.
>
> 2) They contribute to certain cardiovascular disorders.
>
> 3) They may well be truly causative in emphysema, etc, etc."[20]

In 1963 the Surgeon General's committee was evaluating evidence to produce the first Surgeon General's report, and had requested all scientific evidence on smoking and disease, including addiction, possessed by the cigarette manufacturers. The BAT reports, demonstrating physical dependence before this was recognised by outside scientists, were never disclosed. A previously confidential memorandum from Addison Yeaman shows the reluctance to forward this research and states that submission of the Battelle research to the Surgeon General was "undesirable":[21]

> "Prior to receipt your telex July 3 Hoyt of TIRC agreed to withhold disclosure Battelle report to TIRC members or Sab until further notice from me. Finch agrees submission Battelle or Griffith developments to surgeon general undesirable and we agree continuance of Battelle work useful but disturbed at its implications re cardiovascular disorders."

Indeed, BAT's US subsidiary Brown and Williamson had been advised not to turn over any such information. Outside counsel had advised Brown and Williamson to lie and to "state simply that we have conducted no medical research":

> "*It is my suggestion that we state simply that we have conducted no medical research*, having left that to TIRC, and then proceed to enumerate the various scientific research programs sponsored or financed by Brown and Williamson without commenting upon them and inform the Surgeon General's Committee that in the event any particular program is of interest to the Committee it may be assured of B&W's full co-operation. In the event a program proves to be of

[19] Yeaman A: "Implications of Battelle Hippo I & II and the Griffith Filter". 17 July 1963.
[20] *Ibid* at p 4.
[21] Outgoing cable from Yeaman A to McCormick regarding disclosure of Surgeon General's committee, 3 July 1963.

interest to the Committee and a request for details is made, we will meet that problem when it arises. I repeat *it is unfortunate that Brown and Williamson must submit anything, but this approach seems to me to be the most innocuous of the alternatives*"[22]

The 1964 Surgeon General's report, *Smoking and Health. Report of the Advisory Committee to the Surgeon General of the Public Health Service*[23], found that cigarette smoking was a "habit" as distinguished from an "addiction". Critical to the 1964 Report's finding was a lack of information on the physiological effects of nicotine. The Report characterised this as a "gap in knowledge".

Unbeknownst to the Surgeon General, the cigarette industry had filled this "gap in knowledge" secretly. Nicotine was a real physiological addiction.

Because the 1964 Surgeon General's Report did not identify nicotine addiction (this was corrected when more public research was disclosed by 1988), the various cautionary labels on cigarette packages never disclosed that "Nicotine is Addictive". Nor was this voluntarily disclosed by the industry or any other cigarette manufacturer. The net result was millions of customers dying of diseases caused or mediated by addiction to nicotine.

C. Design for addiction

The Battelle concepts of physical dependence continued to be used in the design of BAT products, however. BAT scientists wrote in 1979 that the "high profits" of the industry were related to "the fact that the customer is dependent on the product":

"We also think that consideration should be given to the hypothesis that the high profits additionally associated with the tobacco industry are directly related to the fact that the customer is dependent upon the product".[24]

In 1991 a BAT researcher remarked that the cigarette's "perfect pleasure" was to leave one "unsatisfied" and that the company would profit by repeat business, because of addiction:

"A cigarette is the perfect type of a perfect pleasure. It is exquisite, and it leaves one unsatisfied. What more can one want?

Let us provide the exquisiteness, and hope that they, our consumers, continue to remain unsatisfied. *All we would want then is a larger bag to carry the money to the bank*". [25]

[22] Johnston J: Letter to Bryant of B&W editing Surgeon General's submission, 6 May 1963 (emphasis added).
[23] PHS Publication 1103 (1964).
[24] LCFB: "Product innovation over next 10 years for long term development", 28 August 1979 at p 4.
[25] Paper 7: Colin Greig. Structured Creativity Group, 1 January 1992 (emphasis added).

D. Hiding test results

From the 1950s the industry knew that consumers expected and demanded that it use its best efforts to make acceptably safe products. Tony McCormick, General Counsel to BAT, stated:

> "Consumers will continue to expect the industry to mitigate any harmful effects its products may have".[26]

The industry quickly developed testing methods to improve product safety. However, these tests were from the outset highly secret:

> "The general goals for this work are to determine the biological activity of our products and, on our part, what can be done to modify this activity. The ultimate goal then, is to produce a cigarette with minimum biological reactions. Due to the sensitivity and highly competitive nature of this effort it was emphasised that great care must be taken to protect the confidentiality of this work".[27]

The biological tests included the "mouse painting" studies, publicly criticised by the industry when announced in 1953 by the US researchers Wynder and Graham, and later toxicological studies using *in vitro* and *in vivo* methods. BAT scientists acknowledged the value of these tests in internal memoranda:

> "The application of tobacco smoke condensate to the skin of mice has been the dominant assay in tobacco smoke carcinogenicity studies for many years. . . . Although the assay has several shortcomings, it has provided a great deal of valuable information".[28]

The Ames test, which measured chromosome damage to bacteria, was widely used in the food and cosmetics industry to assess cancer hazard. BAT scientists secretly conducted Ames tests on their products, with disturbing results:

> "The Ames test, which assesses mutagenicity, is used within the BAT Group to evaluate the relative biological activity of tobacco smoke condensate, and thereby aids in developing products with lower biological activity".[29]

No such safer cigarettes were ever developed, however, and the results of the Ames tests, unfavourable to BAT, were never released:

> "The Ames test is the main screening assay and from the results to date it is clear that (i) Cigarette brands can be readily distinguished. . . . A further

[26] McCormick AD: "Agenda to Conference: Smoking and health assumptions, strategies, policies", 3 May 1974.
[27] Kennedy JE: *Biological Activity of Smoke* 4 October 1968 at p 2.
[28] Smith G, Ayres CI: *The Biological Activity of Cigarette Smoke - A Review of Mouse Skin Painting Studies. Report No RD 1974 - Restricted,* 30 May 1984 at p 1.
[29] Bilimaria MH, Ayres CI: *Tobacco Smoke Condensate Mutagenicity: A BAT International Collaborative Study. Report No RD 1919* - Restricted, 11 May 1983.

unfortunate examination is that, to date, it is not uncommon for BAT brands to have a higher result than those from the opposition".[30]

The top-secret Project RIO, a BAT project to test cigarettes for cancer using toxicological methods, gave results the BAT scientists wanted to bury:

"BAT products demonstrated to have the highest activity in 3 of the 4 countries assayed."[31]

BAT products failed all of the cancer tests as this 1974 memo attests:

"Permanent, non-reversible and hereditary changes in morphology and cell functions which may be invoked by cigarette smoke and its carcinogenic components are . . . described. *These changes may be equated with chemical carcinogenesis and result in the production of transformed, and usually malignant, cells*".[32]

E. The health image cigarette

The conclusion drawn from these development problems was to offer a "health-image" cigarette as distinguished from a minimal biological activity cigarette:

"Although there may on occasions be conflict between saleability and minimal biological activity, two types of product should be clearly distinguished, *vis*:

(a) A health-image (health reassurance) cigarette

(b) A health-oriented (minimal biological activity) cigarette, to be kept on the market for those consumers choosing it".[33]

Although the developmental tests were not going well, the *marketing* of a safer cigarette was even more problematic. To market a safer cigarette, one must, it would seem, admit that the former products were not completely safe, something BAT had never done. This problem was recognised early on. In 1961 at Southampton, BAT's global policy on research was discussed.

"Mr Anderson ... would like to ask 'Do we want to make a safe cigarette?' . . . Mr McCormick asked how, in the event of a cigarette modified in the way Dr Green suggested [engineering improvements] becoming a possibility, the industry was going to advertise it and sell it. We would be faced with a commercial problem which had arisen previously over filters, *namely how to justify continuing the sale of other brands*".[34]

[30] Anon: Biological Conference, Southampton, 9-11 April 1984.

[31] Massey ED: *Project RIO - Comparison of Commercial Cigarettes: Influence of Design Features in Mutagenicity as Measured by the Ames Test - A Summary Report: Report No RD 2040 - Restricted*, 26 January 1987.

[32] Newell DC, Evelyn SR: *The Qualitative and Quantitative Effects of Cigarette Smoke and Smoke Components on Cells and Tissues in Culture. Report No RD 1091 - R*, 8 April 1974 at p 1.

[33] Green S: "Research Conference held at Hilton Head Island, SC, 24-30 September 1968", 27 January 1969 at p 2.

[34] McCormick A: *Smoking and Health - Policy on Research*, 1 January 1962 at pp 26, 31 (emphasis added).

F. The first reaction of the guilty

The marketing problems of the safer cigarette were the natural result of BAT's bad-faith denial of the hazards its products posed. After many years of service as one of the highest-placed scientists in BAT, Dr SJ Green wrote in 1980 that BAT's demands for "scientific proof" were the "first reaction of the guilty":

> "In response to many published studies associating smoking with various diseases a great issue has been made of cause and effect relationships. Some might say that the cigarette industry has led the anti-smoking people 'up the garden path' by emphasising so much the issue of causality. Scientific proof, of course, is not, should not be, and never has been the proper basis for legal and political action on social issues. *A demand for scientific proof is always a formula for inaction and delay and usually the first reaction of the guilty.*
>
> *Thus the industry has publicly retreated behind impossible, perhaps ridiculous, demands for what in their public relations is called 'scientific proof'.*" [35]

Dr Green's confession was ignored. BAT continues, to this day, to demand "scientific proof" when all non-industry scientists agree that such proof was furnished in 1950. In the a 1990 internal document intended to furnish "party line" responses to hard questions, BAT's scientific director wrote:

> "Claim:
>
> You are working for a company that is selling a product that is claimed to kill people.
>
> Response.
>
> *There is no scientific proof that smoking kills people...*" [36].

Unfortunately for BAT, their customers, and the rest of the world, the response is a lie.

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[35] Green SJ: *Smoking, Associated Diseases and Casualty*, 1 January 1980.
[36] Anon: *Smoking Issues, Claims and Responses*, BAT, 1990 (emphasis added).