MR WILNER'S "SCIENTIFIC BASIS FOR LIABILITY OF THE BRITISH TOBACCO INDUSTRY": A RESPONSE

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Introduction

Mr Wilner's article "The Scientific Basis for Liability of the British Tobacco Industry" seeks to present as facts the same arguments that he has unsuccessfully pursued in US courts. With two exceptions, Mr Wilner has lost his US cases at the trial level. In those two exceptions, his initial victories were reversed and vacated on appeal.

The premise of Mr Wilner's arguments - that by 1950 "all non-industry scientists" accepted the "scientific proof" that smoking causes lung cancer and that British American Tobacco "continues to this day" to deny such conclusions - is wrong on both counts. Years after 1950 the role of smoking in lung cancer was still unclear among scientists and the position of British American Tobacco is that smoking presents "real risks of serious diseases such as lung cancer, respiratory disease and heart disease" and "in the most simple and commonly understood sense, smoking is a cause of certain serious diseases".

This response puts the British American Tobacco Company Ltd's (BATCo's) historical actions and the current efforts and views of the British American Tobacco group companies in their proper and accurate context. All documents referred to in this response have been available to Mr Wilner.

A. The real scientific debate regarding smoking and health

Prior to 1950, there was a long-standing awareness among the lay public, based largely on anecdotal understanding, that smoking cigarettes could cause disease. Some scientists also suspected a relationship between smoking and the perceived increasing incidence of lung cancer. There was, however, considerable controversy among independent scientists as to whether the increase in lung cancer was real and whether other factors, in addition to or instead of smoking, were the cause of lung cancer. The well-known surgeon cited by Mr Wilner, Dr Ochsner, did write in 1941 that he believed the increase in lung cancer was due largely to smoking. In that same article, however, Dr Ochsner recognised that "there is considerable controversy concerning the increase in carcinoma of the lung, many believing that the increase is apparent and not real . . ." and Dr Ochsner also devoted five pages in that article to the then current theories of lung cancer causation, not involving smoking, which ranged from infectious diseases to radiation to pollution to occupational exposure.[37] Mr Wilner also fails to mention that Dr Ochsner later retracted his own conclusion on smoking and lung cancer. For instance, in 1947 Dr Ochsner wrote:

[37] Ochsner A, DeBakey M: "Carcinoma of the lung". Arch Surg 42: 209-258, 210, 214-218.

"Both occupation and smoking, which have been particularly emphasized by some observers, as possible etiologic factors, and which we were inclined previously to consider more seriously, were found to have no special significance . . . ." [38]

And, in 1948:

"The cause of bronchogenic carcinoma is not known."[39]

Dr Ochsner's reversal of opinion on the cause of lung cancer, his recognition of the controversy concerning whether lung cancer was actually increasing and his discussion of the possible theories of causation other than smoking, is characteristic of the actual uncertainty that surrounded this topic among scientists leading into and throughout the 1950s.

At the outset of the 1950s, a series of retrospective epidemiological studies were published by Sir Richard Doll and Bradford Hill in the United Kingdom, and Ernst Wynder and Evarts Graham in the United States. These studies showed a statistical association between smoking and lung cancer and led to increased investigation into the relationship between smoking and health.

Many scientists, however, including some of the very scientists who conducted the retrospective studies, believed that these studies were insufficient proof of a causal relationship[40]. Scientists criticised the methodology used in these studies because it was subject to bias and other shortcomings. Instead of providing the "confirmation" of a causal relationship, these studies merely provided an hypothesis for scientists to investigate and debate[41] [42].

Aside from methodological concerns, the investigations and debate continued for a variety of other reasons. First, in the 1950s, the use of epidemiology to show the cause of non-infectious disease was new, and many scientists did not accept that epidemiology could prove the cause of a chronic disease such as lung cancer[43]. Second, many scientists believed that confirming laboratory proof was necessary to show a causal relationship between smoking and lung cancer. When these

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[38] Ochsner A *et al:* "Primary cancer of the lung, Chairman's Address". JAMA 135(6): 321-327, 322, 11 October 1947.
[39] Ochsner A *et al*: "Primary malignancy of the lung". Presented at the 66th Annual Meeting of the South Dakota Medical Association in June 1947, S. Dakota J. Med. 43-47, February 1948.
[40] Doll R, Hill AB: "Smoking and carcinoma of the lung: preliminary report". BMJ 2: 739-748, 746, 30 September 1950 ("This is not necessarily to say that smoking causes carcinoma of the lung.").
[41] Levin ML et al: "Cancer and tobacco smoking. a preliminary report". JAMA 143(4): 336-338, 336, 27 May 1950 ("The published literature on the use of tobacco and its possible association with human cancer fails to show clear cut consistent observations.").
[42] Hammond EC: "Smoking in relation to lung cancer. a follow-up study". *The Connecticut State Medical Journal* XVIII(1): 3-9, 6, January 1954 ("All of the studies of smoking in relation to human lung cancer . . . were based on the 'backward method' of approach . . . because of the known difficulties with this method, certain investigators, including myself, are not completely convinced as to the validity of the results . . . .").
[43] Doll R: "Uncovering the effects of smoking: historical perspective". *Statistical Methods in Medical Research* 7: 87-117, 111, 1998 ("The epidemiological results were consequently undervalued as a source of scientific evidence.").

biologically based studies were conducted, however, they were found by many to constitute insufficient proof of lung cancer causation by smoking[44]. Third, none of the laboratory experiments were able to induce human-type lung cancers in animals through the inhalation of cigarette smoke[45]. In addition, scientists had been unable to identify the constituent in smoke that could account for the incidence of lung cancer[46].

Lending further fuel to the debate, well-respected scientists were finding that their research did not support a causal relationship between smoking and lung cancer. For instance, in 1955, the British Empire Cancer Campaign reported on experiments "for carcinogenicity in cigarette tar" that "gave completely negative results"[47]. That same year, the Surgeon General of the United States, Dr Leonard Scheele, stated that his office had no proof that smoking caused lung cancer[48].

Still other scientists questioned the inferences to be drawn from the statistical research. For instance, Sir Ronald Fisher, a prominent statistician, questioned the results of the British Physicians Study because it reported the anomaly that cancer mortality rates of inhalers were lower than those of non-inhalers[49].

Not only does Mr Wilner ignore these facts when denying that a significant scientific debate existed throughout the 1950s and into the 1960s, he also misrepresents one of the few studies he discusses in detail. The number of non-smokers that were found to have lung cancer in the Doll and Hill study was 21, not 2 as Mr Wilner states[50].

The extensive scientific effort to address smoking and its possible health consequences culminated in the publication of the 1962 Royal College of Physicians Report in the United Kingdom and the 1964 Report of the Surgeon General's Advisory Committee ("1964 SGR") in the United States, both concluding that there

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[44] Burney LE: "Smoking and lung cancer: a statement of the Public Health Service". JAMA 171(13): 1829-1837, 1834, 28 November 1959 ("[e]xperimental proof . . . to date has not been supplied . . . The findings of such experiments, *in toto*, are inconclusive . . . .").

[45] US Department of Health and Human Services, Public Health Service, Office on Smoking and Health: *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service*, 165, 1964 ("Few attempts have been made to produce bronchogenic carcinoma in experimental animals with tobacco extracts, smoke or smoke condensates. With one possible exception, none have been successful.").

[46] Wynder E *et al*: "Experimental production of carcinoma with cigarette tar". *Cancer Research* 13: 855-864, 862, 1953 ("The actual carcinogenic agent or agents in tobacco remain to be identified.").

[47] Passey RD *et al*: "Studies in carcinogenesis: cigarette smoking and cancer of the lung". Brit Emp Cancer Camp Ann Rep 33(1): 59-61, 59, 1955.

[48] "No Evidence That Smoking Causes Cancer of the Lung, Surgeon General Tells Enquirer". *The Cincinnati Enquirer* at 50, 23 January 1955.

[49] Fisher RA: "Cigarettes, Cancer, and Statistics" in *Smoking, The Cancer Controversy, Some Attempts To Assess The Evidence*, at 11-25, Oliver and Boyd, Edinburgh, 1959. *The Journal of the American Medical Association*, in 1959, questioned inconsistencies in the evidence against smoking and noted "[n]either the proponents nor the opponents of the smoking theory have sufficient evidence to warrant the assumption of an all-or-none authoritative position". Talbott JH: "Smoking and lung cancer". JAMA 162: 2104, 12 December 1959.

[50] Doll R *supra*, at 742.

was a causal relationship between smoking and lung cancer. These reports received immediate world-wide media attention. According to the latter, "few medical questions have stirred such public interest or created more scientific debate than the tobacco-health controversy" [51].

Notwithstanding the differing views among scientists on the role of smoking in the development of lung cancer in the 1950s and early 1960s, the studies finding a connection received prominent public attention. The potentially harmful health effects of smoking were widely discussed by the Government, by the public health authorities and by the media and were, therefore, well known by the public. The campaign to alert people to the risks of smoking was so extensive that, by 1959, a survey in Edinburgh reported that 98 per cent of those questioned had heard of the relationship between smoking and lung cancer [52]. Clearly, both prongs of Mr Wilner's introductory premise are wrong. It was not proved by 1950 that smoking caused disease and the public had not been deceived about the risks of smoking at any time.

B. BATCo's nicotine pharmacology research

In the 1950s, BATCo recognised the need to understand the relationship between smoking and disease and whether it was possible to modify its products in response to these health concerns. As part of this effort, BATCo sponsored research on the pharmacological effects of nicotine at an independent research facility, Battelle Laboratory (the "Battelle research"). For a variety of reasons discussed below, the Battelle research was flawed and produced no meaningful new insights. Mr Wilner's characterisation of the Battelle research presents a distorted image of its purpose, nature and results.

The Battelle research itself concluded that it failed to indicate a lead to "addiction"

Far from providing evidence that nicotine was addictive, the Battelle researchers concluded that their work "offer[ed] no conclusive evidence for any particular mechanism involved in tolerance to nicotine, nor do they indicate a lead to the phenomenon of addiction" and that the researchers' "attempts to explain nicotine activities on brain functions on a biochemical basis was not successful". The assertion that BATCo's understanding of nicotine "addiction" and the pharmacological effects of nicotine was superior to that of the scientific community in the 1960s is incorrect.

In addition, in a contradiction of the obvious, Mr Wilner quotes a "Tentative Hypothesis" written by two Battelle researchers to support his allegations regarding BATCo's state of mind. "A Tentative Hypothesis on Nicotine Addiction" is by no

[51] 1964 SGR, *supra*, at v.

[52] Cartwright A *et al*: "Health Hazards of Cigarette Smoking, Current Popular Beliefs". Brit J Prev Soc Med 14: 160-166, 161, 1960.

means a "critical" document, as Mr Wilner states. It was not a BATCo written research report - rather it was a three page *tentative hypothesis* as the title suggests, authored by researchers at Battelle with no supporting data, offering their own speculation based merely on "well-known fact". Moreover, subsequent research demonstrated that their "tentative hypothesis", that "nicotine addiction" was an unconscious desire to restore the equilibrium of the body's corticotropia releasing system, was incorrect[53].

Mr Wilner's discussion of "The Fate of Nicotine in the Body", another Battelle document, ignores that this document was merely a literature review and that numerous contemporaneously published scientific articles comprehensively addressed nicotine absorption, other pharmacological effects, and that nicotine had long been considered important to smoking motivation. This published literature was addressed in detail in *Tobacco*[54], a 1961 tobacco industry funded monograph discussing over 6,000 articles on tobacco research, which the 1964 Surgeon General's Advisory Committee ("SGAC") considered a valuable resource.

Lastly, contrary to Mr Wilner's allegation, the occasional statement by company employees in the 1960s that nicotine is addictive does not mean that BATCo or affiliated companies withheld material information about addiction or smoking behaviour. During this period, as today, the terms "addiction" and "habituation" were used so indiscriminately in common jargon that they had lost any real distinction. In fact, in 1962, Dr Maurice Seevers, a prominent pharmacologist and contributor to the chapter "The Tobacco Habit" in the 1964 SGR, wrote that there was no longer a qualitative distinction between the terms[55]. Notwithstanding such indiscriminate use, however, there was a prevailing technical and objective scientific definition of addiction. According to the 1964 SGR, addiction required, among other factors, intoxication, a tendency to increase the dose to achieve the same effect (tolerance) and physical dependence (significant objective physical withdrawal symptoms). In contrast, habituation required no intoxication, no tendency to increase the dose and no physical but some psychological dependence. Using those definitions, the 1964 SGR concluded smoking was a habit not an addiction[56]. None of the Battelle research, nor any BATCo research, provided any evidence that smoking would fit the prevailing scientific definition of addiction.

[53] Mangan G, Golding JF: "The psychopharmacology and psychopathology of smoking", in *The Psychopharmacology of Smoking*, Cambridge University Press 1984, pp 97-174, 135-136. The cited research "reinforces the view that corticosteroid release is not an important reinforcing factor in smoking".

[54] Larson PS *et al*: *Tobacco: Experimental and Clinical Studies: A Comprehensive Account of the World Literature* at 1-26, Baltimore, Williams & Wilkins Co, 1961.

[55] Seevers M: "Medical Perspectives on Habituation and Addiction". JAMA 181(2): 92-98, 92, 14 July 1962 ("Unfortunately, no qualitative distinction between these terms (habituation and addiction) is implied in their common use. These terms are usually employed as if they were synonymous.").

[56] 1964 SGR, *supra*, at 351.

BATCo did not publish the Battelle research because the research was severely criticised by external scientists

BATCo decided not to publish the Battelle research only after the Tobacco Research Council ("TRC"), an organisation funded by the tobacco industry in the United Kingdom to support scientific research related to smoking and health, reviewed the research, at BATCo's request, and concluded that it was flawed and not of publishable quality. In fact, BATCo initially intended to share the Battelle research with the 1964 Surgeon General's Advisory Committee to provide evidence of smoking's beneficial effects to balance the overall discussion concerning smoking and health. Recognising the importance of a critical review prior to publication, Sir Charles Ellis, an eminent scientist and advisor to BATCo, wrote that the Battelle research should be

> "kept strictly confidential . . . for the reason that we have not as yet had this work critically reviewed by our own scientific experts, and it is possible that they or your experts may not consider the Battelle conclusions are well founded. Since we hope these may be of assistance in orienting our attitude to the Smoking and Health problem it would be most unfortunate if we were to make public use of findings that could not subsequently be sustained."

The reason for secrecy, then, was not to mislead the public health authorities as Mr Wilner argues but, rather, to prevent premature circulation of findings that could not withstand scrutiny. Indeed, after the research was appraised by TRC scientists and found not to be "sufficiently complete to justify any form of publication", Sir Charles Ellis acknowledged that "it [would be] difficult to maintain the scientific value of HIPPO work against skilled criticism". He believed that BATCo's US affiliate, Brown & Williamson:

> "ought not to take the initiative in submitting anything to the Surgeon General's Committee but rather wait and hope that the Committee will ask the individual manufacturers for further details of their research work and then, should this happen, it would give B&W the opportunity of submitting the Battelle work . . . ."

Accordingly, the Battelle research was not submitted to the SGAC despite BATCo's strongly held belief that submitting evidence of smoking's beneficial effects would be "desirable" in "orienting" a smoking and health discussion.

Submission of the Battelle research would not have altered the SGAC's finding that cigarette smoking was an habituation, not an addiction

The Battelle research itself concluded that it had failed to provide a lead to the phenomenon of addiction. There is simply no basis at all to argue that disclosure of the Battelle research would have affected the scientific understanding of smoking behaviour. Further, sharing the Battelle research with the SGAC could not have

altered its finding that tobacco was habituating rather than addicting. The 1964 SGR's definition of addiction required, among other effects: intoxication, tolerance and physical dependence. The Battelle research did not provide any evidence of these effects.

Although the Battelle research was not shared with the SGAC for the reasons already mentioned, B&W did contribute information to the SGAC through the Tobacco Industry Research Committee ("TIRC"). The TIRC, in response to a request from the SGAC, submitted more than 70 citations to published articles on the "beneficial effects of tobacco". These articles included, among other things, studies investigating the same issues as the Battelle research. The SGAC's decision to characterise smoking as habituating was not due to a lack of information on the pharmacological effects of nicotine - in fact, the 1964 SGR reported in detail on the pharmacological effects of nicotine[57]. Indeed, the very same effects discussed in the Battelle research were reported in the published literature on which the SGAC relied.

Mr Wilner further suggests that, had the 1964 SGAC found nicotine to be addicting, cautionary labels warning of nicotine addiction would have been placed on cigarette packages. However, in 1988, the then Surgeon General classified nicotine as addictive by adopting a new definition of addiction (one which no longer required intoxication, tolerance and physical dependence). If Mr Wilner's conjecture is to be believed, a warning of nicotine addiction would have been required on US cigarette packages after the 1988 Surgeon General's Report was published. This did not happen.

Finally, Mr Wilner quotes from a BATCo internal marketing document that describes a cigarette as "a perfect pleasure" that "is exquisite" yet "leaves one unsatisfied". He fails to mention, however, that this comment is merely paraphrasing a passage from Oscar Wilde's 1891 novel *The Picture of Dorian Gray,* thus elegantly affirming that this aspect of cigarette smoking has been commonly known for over a century.

C. Development of a "safer" cigarette

For more than 40 years, BATCo has carried out a significant amount of internal product research aimed at exploring modifications and innovations that might produce "safer" cigarettes. In 1956, BATCo established a research centre at Southampton to pursue these goals. The research has been guided by what government, scientific and medical authorities have suggested as strategies for potentially safer products, as well as by BATCo's own monitoring and appraisal of the scientific literature. Specifically, these scientists have focused on designing cigarettes with lower biological activity and lower smoke constituent yields.

[57] 1964 SGR, *supra*, at 351-353.

BATCo pursued biological research by supporting the formation of the United Kingdom joint industry research organisation, the Tobacco Manufacturers' Standing Committee ("TMSC"), in 1956, later known as the Tobacco Research Council. The most significant project undertaken by the TMSC was the construction, in 1963, of bio-assay laboratories at Harrogate in Yorkshire. The research conducted there was intended to contribute to the development of acceptable and quantitatively reliable tests for measuring the biological effects of tobacco smoke. From 1962 to 1974, biological research was conducted at Harrogate and published in a series of reviews.

BATCo also conducted a significant amount of internal biological research, aimed at exploring modifications and innovations that might produce "safer" cigarettes. BATCo examined a range of biological assays and, of these, mouse-skin painting, inhalation studies and Ames testing were the most significant. The results of these studies allowed the comparison of products with different design parameters. Although none of these bio-assay tests was, or is, scientifically correlated to human health, BATCo used these methods because they were the state-of-the-art test methods available.

Notwithstanding extensive research, however, both external and BATCo scientists encountered considerable difficulties in developing a "safer" cigarette. There was, as there still is, no identified causative constituent of cigarette smoke and no proven biological mechanism for causation. After years of research, no test method has proved that reduced biological activity leads to reduced risk of disease in the smoker.

To date, the only acceptable product modifications that have been technically feasible, acceptable to consumers, and recommended, at times, by the United States and United Kingdom governments and public health authorities have been aimed at reducing tar and nicotine yields[58]. To this end, BATCo has been consistently lowering cigarette smoke yields and providing a range of options for consumers since the 1950s.

Mr Wilner mischaracterises BATCo's biological research by stating that BATCo products "failed all of the cancer tests". In fact, there are no reliable human "cancer" tests. Indeed, no government or public health authority has ever endorsed any biological test or battery of biological tests for the safety assessment of cigarettes.

Although dose-response data from epidemiology suggest that lower tar products are a sensible approach given all the limitations, BATCo's policy has never been to make health claims, either implicit or explicit, in its marketing and advertising, and BATCo has adhered strictly to government regulations (and its own policy) prohibiting such advertising. Although BATCo was constrained from making health claims regarding its products, this did not prevent it from attempting to develop "safer" cigarettes.

[58] Froggatt, P., *Third Report of the Independent Scientific Committee on Smoking and Health*, at 3 (Department of Health and Social Security 1983).

Mr Wilner's incomplete quote from a 1962 BATCo document, would have the reader believe that BATCo did not want to develop a "safer" cigarette because of the difficulty in marketing such a product. However, in reply to the queries posed to Dr Green which Mr Wilner selectively quotes, Dr Green's answer, recorded in the full document, was "that this was an extremely difficult policy decision which someone had to make but he felt that this difficulty *did not justify inaction*" (emphasis added). History demonstrates that action was taken.

Indeed, BATCo's efforts over the years to design a "safer" cigarette were commended by Sir Peter Froggatt, the former Chairman of the UK Independent Scientific Committee on Smoking and Health, who stated:

> "[The tobacco manufacturers] had, however, and still have, no desire to sell a harmful product either in the shorter or longer-term when they can sell a 'safer' one, and they invested very heavily in research and development into tobacco toxicity as well as product acceptability . . . [T]oday they are by a very long way the largest sponsors of research into smoking and health in the UK . . . [T]hey have substantially increased our knowledge of nearly every aspect of tobacco toxicity." [59]

Mr Wilner states that BATCo "continues, to this day, to demand scientific proof when . . . such proof was furnished in 1950". This is untrue on two levels. First, a scientific consensus on the effects of smoking on health did not evolve until long after 1950. Second, BATCo's position on smoking and health has evolved since 1950. In its 1998 annual report, British American Tobacco plc states that "[a]long with the pleasures of cigarette smoking come real risks of serious diseases such as lung cancer, respiratory disease and heart disease". In testimony before the House of Commons Health Committee on 13 January 2000, Mr Martin Broughton, chairman of British American Tobacco plc, stated "We accept, therefore, that in the most simple and commonly understood sense, smoking is a cause of certain serious diseases. This has been the working hypothesis of much of our research, has been believed by smokers for decades, and is the most appropriate viewpoint for consumers and public health authorities."

These statements accurately reflect the responsible public position of British American Tobacco.

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[59] Froggatt, P., *"Determinants of Policy on Smoking and Health". International Journal of Epidemiology* 18(1): 1-9, 3 (March 1989)