

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITED STATES OF AMERICA

Plaintiff,

v.

PHILIP MORRIS USA INC.

(f/k/a Philip Morris Incorporated), *et al.*

Defendants.

)
)
)
)
)
)
)
)
)
)

Civil Action No. 99-C V-2496 (GK)

**Next scheduled appearance:
Trial (ongoing)**

**WRITTEN DIRECT EXAMINATION OF GRAHAM READ
SUBMITTED BY THE JOINT DEFENDANTS PURSUANT TO ORDER #471**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	EDUCATION AND PERSONAL EXPERIENCE	2
	A. Education	2
	B. BATCo Experience.....	2
III.	OVERVIEW OF BATCO’S PRODUCT MODIFICATION EFFORTS.....	8
IV.	BATCO’S HISTORICAL RESEARCH EFFORTS.....	10
	A. Establishment of BATCo’s R&D	10
	B. MRC/TMSC.....	12
	C. TMSC/TRC Research.....	18
	D. BATCo’s Biological Research.....	22
	1. Mouse Skin Painting.....	24
	2. Inhalation Animal Studies.....	27
	3. <i>In vitro</i> Testing.....	32
V.	PRACTICAL COMMERCIAL CONSEQUENCES OF RESEARCH EFFORTS	39
	A. Novel Products.....	40
	B. Selective Reduction	41
	C. General Reduction	43
VI.	BATCO’S RECORD KEEPING PRACTICES	52
VII.	PARTICULAR ALLEGATIONS BY GOVERNMENT WITNESSES	62
VIII.	BATCO’S DE MINIMIS U.S. BUSINESS	70

1 **I. INTRODUCTION**

2 **Q. Please state your name for the record.**

3 A. Graham Read.

4 **Q. With whom are you currently employed?**

5 A. I am employed by British American Tobacco (Investments) Limited ("BATCo").

6 **Q. How long have you been employed by BATCo?**

7 A. I have been employed by BATCo on a nearly continuous basis since 1976.

8 **Q. Please generally describe the type of work you have performed during your**
9 **career at BATCo.**

10 A. My employment has involved performing, managing and organizing the research
11 function for BATCo, which as you might imagine, covers a broad spectrum of topics
12 relating to tobacco and tobacco smoke and product use.

13 **Q. Do you understand that you have been designated by Defendants to testify as**
14 **a fact witness regarding: BATCo's research and development function and support**
15 **of independent smoking and health research; BATCo's product modification efforts**
16 **and interaction with public health authorities; BATCo's business practices; and**
17 **plaintiff's allegations related thereto?**

18 A. Yes.

1 **II. EDUCATION AND PERSONAL EXPERIENCE**

2 A. Education

3 **Q. Please give the Court a brief overview of your educational background?**

4 A. Under the U.K. educational system, I went to school until I was 16, and then
5 studied for another two years to gain qualifications, known as "A Levels", which are our
6 pre-University entrance exams. Then, in 1968, I entered Hull University. In 1971, I
7 received a degree in Biochemistry from Hull University. I then went on to Leeds
8 University for a period of another four years. At Leeds, I took up what's known as a
9 University Demonstratorship role, which was comprised of both teaching and research.

10 **Q. What subjects did you teach at Leeds during your University**
11 **Demonstratorship?**

12 A. I taught both biochemistry and medical laboratory sciences.

13 **Q. What did you do after attending Leeds?**

14 A. I took up a post with BATCo at the Group Research & Development Centre in
15 Southampton, England.

16 B. BATCo Experience

17 **Q. Could you please provide a brief description of your job titles and activities**
18 **throughout your career at BATCo.**

19 A. When I first joined BATCo in 1976, I worked as bench scientist in the Inhalation
20 Toxicology Division of the Life Sciences Department to develop a number of test
21 methodologies for toxicological assays for product assessment purposes. Within the next
22 year or so, I became head of the Animal Inhalation Toxicology Division and

1 subsequently was assigned responsibility for the biochemistry and hematology function.
2 Then, from about 1980 to 1985, I was head of the Human Smoking Behaviour Group. In
3 approximately 1985, I left the R&D center to work in BATCo's Head Office, known at
4 that time as Westminster House, in London in the Corporate R&D Department to work
5 on diversification programs involving the development of technology based agricultural
6 businesses. From 1988 to 1991, I was initially the business development Manager and
7 then General Manager of a company known as Advanced Technologies, Cambridge,
8 which was a BATCo affiliate that focused on plant biotechnology research. In 1991, I
9 was asked to return to the Corporate R&D Department, and in early 1992 became the
10 Head of R&D for BATCo, a position which I held until November 1998.

11 **Q. Did your employment continue with BATCo after 1998?**

12 A. Yes. I briefly took a Board position with Rothman's International, a competing
13 tobacco company in the U.K., as Director of R&D. That position lasted only about a year
14 due to a merger between British American Tobacco and Rothman's. After remaining in
15 somewhat of a holding pattern at Rothman's, I resumed my employment at BATCo in
16 1999, this time in the role of Head of Strategic Research.

17 **Q. What did your duties as Head of Strategic Research entail?**

18 A. I was tasked with giving shape and direction to the medium to long-term research
19 and development in support of the business objectives of the company.

20 **Q. What is your current position at BATCo?**

21 A. My current title is Global Head of R&D Strategy and I'm also a Director of
22 BATCo.

1 **Q. What does your position as Global Head of R&D Strategy entail?**

2 A. I'm responsible for the development and coordination of BATCo's prospective
3 long-term research programs and providing scientific guidance to senior executives at our
4 organization in the area of reduced harm products and the assessment thereof.

5 **Q. Do you hold any other relevant positions?**

6 A. Yes. I have been a long-standing Board member of CORESTA, which is a global
7 tobacco-related association, which focuses on science and technology in particular areas
8 related to tobacco products, standards, and methodologies. Recently, I was elected
9 President of CORESTA.

10 **Q. In your nearly thirty-year tenure with BATCo, have you gained personal**
11 **knowledge relating to BATCo's historical research programs and practices?**

12 A. Yes, both directly and through my roles and working relationships with BATCo's
13 scientists and managers, some of whom were employed from the time of inception of
14 BATCo's R&D capability. I also reviewed historical documents, which were kept in the
15 ordinary course of business, to further understand our research history.

16 **Q. Please explain how this near thirty year work experience contributed to your**
17 **personal knowledge of BATCo's historical R&D efforts.**

18 A. Since day one at BATCo, I have been personally involved in BATCo research.
19 When I began at BATCo, I worked as a hands-on, bench level scientist in BATCo's
20 biological division, and worked in particular with inhalation research and the
21 development and assessment of toxicological assays. As I continued with BATCo, I
22 worked in, and had responsibility for, the biochemistry division, as well as other parts of

1 BATCo's R&D center, including the Human Smoking Behaviour Group. As I moved up
2 in the company, my role included setting and supervising nearly all aspects of BATCo's
3 biological research programs. In all of my career positions at BATCo, I have focused on
4 biological research and its potential application to BATCo's, or its affiliates', products.
5 Clearly, when I became Head of R&D, I was responsible for all facets of our R&D
6 program, which of necessity required an appreciation and understanding of what work the
7 Company has undertaken historically, as well as setting the future research direction.

8 **Q. In connection with your job responsibilities at BATCo, did you also**
9 **familiarize yourself with both BATCo's and others' biological research pre-dating**
10 **your employment?**

11 A. Yes. It is the normal practice for a scientist to have an understanding of what
12 others have done previously in an area. The area of biological research is an evolving
13 one. The science necessarily builds upon what has come before it. If, for example, an
14 area of research showed promising results, I would need to know that to make
15 determinations of how to proceed. If, on the other hand, a line of research yielded no
16 helpful information or avenues of further research, then I would also need to know that so
17 to best utilize our resources toward worth-while, potentially promising, projects. On
18 joining BATCo, I familiarized myself with our external and industry programs including
19 the activities of the Tobacco Research Council and Tobacco Advisory Council and our
20 ongoing external mouse skin painting programs. My key contact in this respect was Dr.
21 Sam Evelyn who had responsibility for BATCo's external research projects. I was
22 responsible for presenting my own work area and participated in the review of our other

1 R&D programs at least one or two times per year. At these project and program review
2 sessions, the direction and progress of the R&D work would be presented and then
3 discussion would ensue with all the senior scientific management of the R&D center.
4 This would include Dr. S.J. Green and Dr. Felton prior to their retirements and
5 subsequently Dr. L.C.F. Blackman and Mr. A.L. Heard. The reviews would take place in
6 the presence of all the Center's Scientific Group Leaders responsible for particular
7 scientific functions, such as filtration, ventilation, combustion, biological research,
8 manufacturing and engineering, as well as scientific and management representatives of
9 our overseas affiliates. From the earliest time of my joining BATCo, I had a number of
10 projects that were instigated following discussions with Dr. Felton and Dr. C.I. Ayres and
11 subsequently reviewed the projects' progress with Dr. Green. Our R&D center had a
12 vigorous scientific conference and review program in which I was an active member
13 working closely with key personnel at the time such as Dr. R.E. Thornton, Dr. R.A.
14 Baker, Dr. Geoff Hook, Dr. Richard Binns, and many others.

15 **Q. During your tenure at BATCo, did you also gain personal knowledge**
16 **regarding research at BATCo affiliated entities, including Brown & Williamson?**

17 A. Yes, I did.

18 **Q. Please explain how, as a BATCo employee, you would have personal**
19 **knowledge regarding research and development outside of BATCo.**

20 A. BATCo's Southampton R&D provided a centralized, state-of-the art research
21 institution for use by BATCo, B&W, and other affiliate companies. Affiliate companies
22 would share the costs of research, and all the affiliates would benefit from the pooled

resources invested in a centralized, high-level research center at Southampton. The R&D would focus, for example, on biological research with potential group-wide applications. Working at BATCo's R&D center necessarily entailed familiarity and contact with BATCo affiliates' scientific efforts, which included reciprocal visits to their facilities.

Q. If the research and development activities were centralized in Southampton, does this mean that BATCo affiliates, such as Brown & Williamson, did not do any of their own research?

A. No. Affiliate companies within the group did their own research and development specific to products within their own, individual markets. For instance, Brown & Williamson had extensive research and development facilities in Louisville, Kentucky, and subsequently Macon, Georgia. However, the research performed at such laboratories usually focused on the affiliate's market specific issues versus the group-wide, research and product development interests.

Q. During your tenure at BATCo, have you also gained personal knowledge of biological research conducted by entities outside the BAT Group, including industry-wide groups and governmental organizations?

A. Yes.

Q. Please explain.

A. BATCo's research is not conducted in isolation. Research, regardless of its source, contributes to the research knowledge base. Throughout my career at BATCo, I have kept abreast of the relevant research, with a particular emphasis on the biological,

1 both inside and outside the BAT Group, and attended many research forums and
2 symposia across the world.

3 **III. OVERVIEW OF BATCO'S PRODUCT MODIFICATION EFFORTS**

4 **Q. Can you give the Court a brief overview of BATCo's product modification**
5 **efforts?**

6 A. Continuously, since the 1950s, BATCo has vigorously engaged in efforts to find
7 ways to modify cigarettes to reduce health risks. BATCo's biological research work was
8 not looking at the question of whether smoking causes disease. That was left for experts
9 in the field, some of whom were funded in part by BATCo. Rather, because BATCo
10 from the outset employed a working hypothesis that smoking was an important factor in
11 contributing to lung cancer, BATCo's biological research was focused on modifying
12 cigarettes to reduce or eliminate the health risks. This is a complex mission across
13 several related endeavors. First, you have to find out what is it in cigarette smoke that is
14 causing the problem. Next, you have to find out whether the source of the problem can
15 be either eliminated or reduced. Then, you have to ensure that the modification does not
16 inadvertently increase risk. And finally, you need to determine whether the contemplated
17 product modification results in a viable cigarette with reduced risk. So this singular
18 mission, to find product modifications that would improve the product, relates to all
19 facets of the research work that BATCo has undertaken, such as chemical analysis to
20 identify what is in smoke, fractionization work to find out what parts of the tar contain
21 the suspect constituents, and all the various bioassays to evaluate the relative biological
22 activity of different condensate/smoke generated from different cigarettes with changed

1 design parameters. BATCo's efforts in this regard are ongoing. To date, because of the
2 complexity of cigarette smoke and the limitations of bioassays, the only product
3 modification that BATCo has been able to bring to market that was encouraged by
4 Government and public health authorities and acceptable to consumers has been lower tar
5 cigarettes.

6 **Q. You mentioned limitation of bioassays, what do you mean?**

7 A. For us, bioassays are a tool to enable us to evaluate whether particular cigarette
8 design modifications result in a product likely to be less hazardous. One of the great
9 challenges we have faced is identifying useful bioassays for our product modification
10 work. Early on we investigated biological tests including paramecium, ciliastasis, chick
11 embryo and sebaceous gland tests. We also worked with mouse skin painting, smoke
12 inhalation and mutagenicity tests. We examined these tests and others to see what we
13 could use to help evaluate product modifications. We have been frustrated to date
14 because, while we have a working hypothesis that smoking is a cause of disease, science
15 lacks the knowledge of disease mechanisms. This absence of knowledge of disease
16 mechanisms, combined with the complexity of cigarette smoke, makes it extraordinarily
17 difficult to devise bioassays that can provide sufficient information to conclude whether a
18 particular product modification makes a cigarette safer. Coupled with this are limitations
19 inherent in the bioassays themselves, such as inconsistent results both within and across
20 bioassays, non-reproducible results, and results that because of lack of sensitivity are
21 unable to discriminate among the effects from different cigarette designs. These
22 problems continue today. Although there have been improvements in the test systems,

1 until the basic cellular processes involved in disease causation demonstrate that the
2 processes in man and the test methodology are comparable, we are prevented from
3 adopting any test or tests as dispositive for supporting product modifications. The
4 frustrations we have experienced in this area were recognized in the recent report by the
5 Institute of Medicine ("IOM") in 2001 entitled Clearing the Smoke, Assessing the
6 Science Base for Tobacco Harm Reduction. [U.S. Ex. 20,919] Specifically, the report
7 says in one of its conclusions that "[t]here is no one panel or group of tests that the
8 committee could recommend at this time that would, as a whole, serve to assure that
9 morbidity and mortality would decrease with use of [cigarette design modifications]."
10 [Id. at p. 8-2].

11 **IV. BATCO'S HISTORICAL RESEARCH EFFORTS**

12 A. Establishment of BATCo's R&D

13 **Q. What do you know about BATCo's early R&D work?**

14 A. BATCo came into existence in 1902. And for its first 50 years it operated
15 essentially without a formal R&D department. And then, in the early 1950s, BATCo
16 came to realize the need for establishing an R&D department for principally two reasons:
17 (1) the Company had failed to modernize its manufacturing facilities due to the demands
18 and difficulties of World War II; and (2) in the early 1950s, there were a number of high
19 profile articles published implicating cigarettes as a factor in disease, most notably lung
20 cancer.

1 **Q. So what did BATCo do?**

2 A. In 1953, BATCo set up a committee to evaluate the research issues facing the
3 Company. By March of 1954, the Company decided to build an R&D facility and hire a
4 full R&D staff to carry out BATCo's R&D obligations. Interestingly, several of BATCo's
5 affiliates lobbied for the establishment of the research facility in their respective
6 countries. After considering possible locations, BATCo decided that the R&D facility
7 should be located in England, the home of the parent company. At that point, BATCo
8 searched for a scientific advisor to coordinate and oversee its R&D operations. BATCo
9 sought the most qualified and talented candidate it could identify and ultimately hired Sir
10 Charles Ellis to be BATCo's Scientific Advisor in 1955.

11 **Q. Who was Sir Charles Ellis?**

12 A. He was one of the most accomplished scientists in the U.K. His credentials were
13 impeccable. He was a Fellow of the Royal Society, which is a very prestigious group of
14 scientists in the U.K. You have to be invited to join based on academic standing and
15 reputation, and receiving such an invitation is a great honor. He had been the chief
16 scientist of the National Coal Board, which was formed by the U.K. government after the
17 War to oversee the national coal industry. Sir Charles Ellis had advised Winston
18 Churchill on scientific issues during World War II. Sir Charles Ellis was recognized as a
19 preeminent scientist, and he was hired to advise BATCo on R&D matters.

20 **Q. When did BATCo's R&D facility at Southampton open?**

21 A. The Company decided in 1954 to create a world class R&D function. In 1955 Sir
22 Charles Ellis was hired, and in 1956 a staff began to be assembled. In early 1957 the

1 R&D facility opened following the construction of a purpose built facility at
2 Southampton.

3 **Q. At that time how did BATCo approach its R&D work?**

4 A. The approach to R&D work was broad based and structured much like a
5 university in the sense that BATCo's scientists were told to find out everything they could
6 about tobacco and the cigarette product. The scientists had tremendous freedom to
7 pursue ideas and avenues of investigation that they felt were important. The basic
8 philosophy behind the R&D center at Southampton at this time was to conduct research
9 into smoke chemistry and cigarette design.

10 B. MRC/TMSC

11 **Q. At around the same time, was BATCo involved in other research in an**
12 **attempt to address the important issues of the day related to cigarettes?**

13 A. Yes. In 1954, a group of U.K. tobacco manufacturers, including BATCo, sought
14 the advice of the U.K. Minister of Health on how we could best support research on the
15 emerging issue of smoking and lung cancer. We were advised that pure biological and
16 medical research was best left to the U.K. Medical Research Council ("MRC") and the
17 U.K. industry should focus on research where it had special knowledge, which was the
18 chemistry and physics of tobacco leaf and tobacco smoke. [JD-010356]

19 **Q. Did the U.K. industry support the MRC research efforts?**

20 A. Yes. In 1954, the U.K. tobacco manufacturers, including BATCo, jointly donated
21 £250,000 with no strings attached to the MRC for medical and biological research
22 relating to smoking and health. [Id. at p.1].

1 **Q. Could you tell us what happened with the U.K. industry funding to the**
2 **MRC?**

3 A. The MRC sponsored numerous projects investigating epidemiological, chemical,
4 biological and other aspects of smoking and health. In 1962, the MRC exhausted the
5 £250,000 and advised the U.K. tobacco manufacturers that the MRC was in a position to
6 itself fund future relevant research from its own resources. [JD-011382 at p. 5]

7 **Q. Did the U.K. tobacco manufacturers heed the Minister of Health's advice to**
8 **focus their research efforts where they had expertise?**

9 A. Yes, around this time, the U.K. companies, in their respective research
10 laboratories, began research relevant to the chemical and physical properties of tobacco
11 and tobacco smoke and pooled their results. This then led to the creation of the Tobacco
12 Manufacturers' Standing Committee ("TMSC") comprising senior members of the
13 Industry, which continued this research on behalf of the U.K. industry. The TMSC also
14 formed a Technical Steering Committee comprising the leading industry scientists to
15 advise it and monitor research progress.

16 **Q. Did the U.K. industry continue its joint research efforts?**

17 A. Yes, the TMSC was established by BATCo and the other U.K. tobacco companies
18 in 1956 to liaise with the MRC, make further grants to other independent scientists and
19 institutions, and gather and distribute information on smoking and health. Initially, it did
20 not directly conduct biological research itself. By the early 1960s, the TMSC
21 reconsidered the question of directly conducting biological research and began doing
22 some work in this area. By 1963, the TMSC was renamed the Tobacco Research Council

1 ("TRC"). The TRC's main objective was to "conduct, promote and co-operate in and
2 keep in touch with research into all questions concerning the relationship between
3 tobacco smoking and health." [JD-030989 at p. 15] The TRC members also agreed to
4 pool information gleaned from any research that might have health implications.

5 **Q. You mentioned the U.K. industry's decision to pool research information**
6 **that might have health implications, why was that decision taken?**

7 A. The view was that, given the importance of the smoking and health issue, it would
8 be appropriate for the companies to pool their knowledge, thereby increasing the
9 likelihood for scientific advances. [U.S. Ex. 20,270 at p. 5] In addition, the U.K.
10 manufacturers informally agreed not to make health claims about their products. [U.S.
11 Ex. 20,152 at p. 10].

12 **Q. Why did the U.K. manufacturers agree not to make health claims about their**
13 **products?**

14 A. The 1962 Royal College of Physicians Report, Smoking and Health [U.S. Ex
15 21,023], clearly articulated the view that there should be a prohibition on health claims.
16 It noted: "It should be realized that since we cannot identify the substances in tobacco
17 smoke that may be injurious to health, no firm claims for the safety of modified cigarette
18 tobaccos or filters can be made." Id. at p. 49. This report noted that any effect upon
19 death rates resulting from product modification would take many years to become
20 evident. Id.

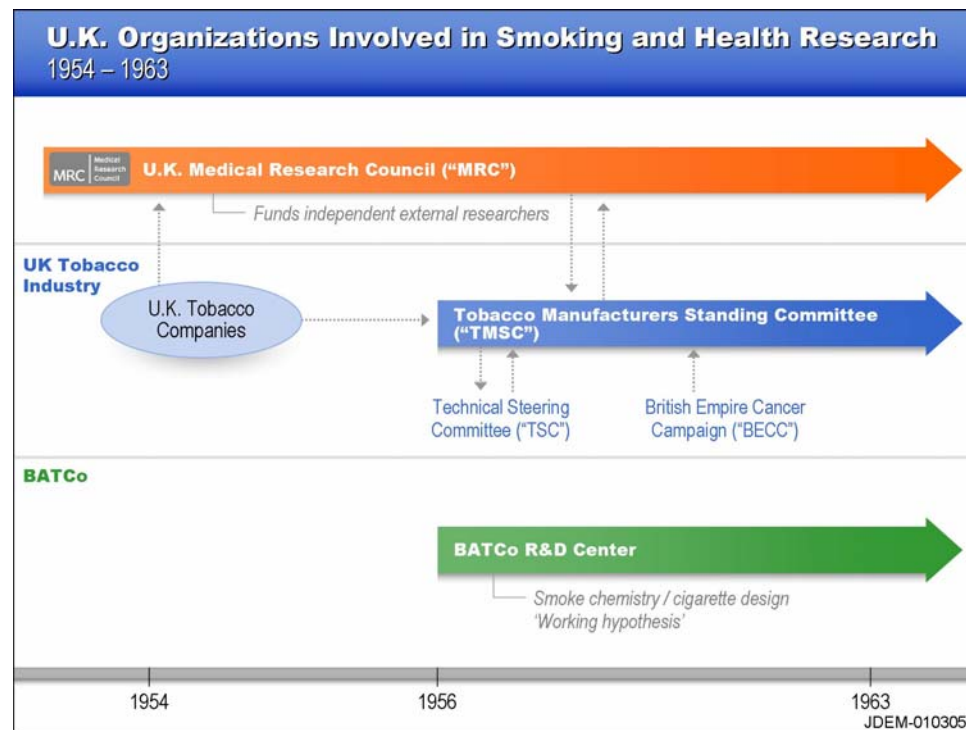
1 **Q. Before we get to BATCo's work on biological testing, can you tell us a little**
2 **more about the TMSC's research program?**

3 A. Originally, the TMSC's remit was to fund external research. And from 1958, the
4 TMSC took advice from the British Empire Cancer Campaign ("BECC") in deciding
5 what smoking and health research to fund. [JD-031848 at ¶12] Based upon the BECC's
6 advice including that of other eminent bodies, the TMSC funded a wide array of research,
7 including research on smoking behavior, the chemical and physical properties of tobacco
8 and tobacco smoke, the biological activity of tobacco smoke and factors affecting lung
9 cancer and other diseases. [JD-031462 at p. 4]

10 **Q. So, at this time the TMSC members were funding research through the**
11 **TMSC and the MRC?**

12 A. Yes they were.

- 1 Q. Let's stop here for a second because you have provided a lot of information
2 about numerous U.K. organizations involved in research identified by acronyms.
3 Does the chart [JDEM-010305] below accurately summarize this information?



- 4
5 A. Yes it does.
6 Q. Were the TMSC members content to simply fund external research
7 themselves and through the MRC?
8 A. No. The TMSC determined that the fundamental issues of disease causation were
9 being adequately addressed through the external research but concluded that additional
10 research was needed to find practical solutions to product issues based on what was
11 known at the time.

1 **Q. How did this evolution in the TMSC's thinking occur?**

2 A. Its evolution of thought is set out nicely in the 1958 Trip Report, authored by
3 D.G. Felton and two other TMSC representatives. [U.S. Ex. 21,135]. These TMSC
4 representatives visited the U.S. seeking information regarding the utility of biological
5 testing. They met with a number of individuals, including Dr. Ernst Wynder, and the
6 National Cancer Institute, TIRC and U.S. tobacco company representatives. Their two
7 principle areas of interest were to obtain information about the practical methodology of
8 biological testing and to gain information about the extent to which extrapolation from
9 animal testing to man might be justified. Id. at p. 2. Based upon this trip, they identified
10 two potential approaches to biological research. These approaches were either to carry
11 out research with tobacco smoke related directly to smoking and lung cancer or to fund
12 long range research on carcinogenesis in an industry endowed institution with no strings
13 attached. They recommended that the TMSC pursue the former. Id. at p. 9.

14 **Q. What did BATCo do in response to the TMSC recommendation?**

15 A. From BATCo's perspective, the options were to have the TMSC either embark on
16 a broad based fundamental research program that would be founded in science and have
17 good public relations value or to fund first-class research scientists with prior expertise in
18 the area of carcinogenesis. BATCo felt that, while either course could be sincerely and
19 strongly supported, the latter course had the best chance for advancing scientific
20 knowledge, and, as a result, they were "profoundly convinced that the second objective is
21 the one that should be followed." [JD-039402 at p. 1]. BATCo also felt that part of the

1 research in this chosen area would include what was termed "carcinogen hunting." Id.
2 at 2.

3 **Q. What ultimately happened?**

4 A. By 1962, BATCo recognized that it needed to support smoking and health
5 research from two sides: "the first being medical research on the origin of lung cancer
6 and bio-assay on the biological effects of smoke, and the second being the composition of
7 smoke and the possibilities of modifying it." [U.S. Ex. 20,270 at p. 5]. Sir Charles Ellis
8 further explained: "The Board has therefore decided that they will wholeheartedly
9 support T.M.S.C. to carry out and co-ordinate all research on smoking and health.
10 T.M.S.C. will do this by itself carrying out biological work at its establishment at
11 Harrogate and by sponsoring biological and medical work at Institutions. T.M.S.C. will
12 depend on member companies for physical and chemical work." [Id. at p. 5]

13 C. TMSC/TRC Research

14 **Q. When did the TMSC begin doing its own research?**

15 A. TMSC laboratories at Harrogate came into operation September 1962 and on
16 January 1, 1963 the organization's name changed to Tobacco Research Council ("TRC")
17 to reflect this new role. The three main lines of research undertaken by the TRC were the
18 biological program, and additionally research on smokers, involving statistics, genetics
19 and psychology, and nicotine pharmacology. [JD-011382 at p. 7].

20 **Q. What was the TRC's approach to its biological research?**

21 A. The TRC recognized that there were broadly speaking two hypotheses to explain
22 the statistical association between smoking and lung cancer — one non-causal and the

1 other causal. To provide a framework to pursue biological research, TRC adopted a
2 working hypothesis that smoking is a major cause of lung cancer in some people [JD-
3 031871 at p. 10] and sought to devise animal experiments to ascertain the modifications
4 that should be made to cigarette smoke. Initially, the two criteria for these animal
5 experiments were that the test system produced cancer from cigarette smoke, or smoke
6 condensate, thereby providing a comparative basis for modifications, and that the animal
7 tests should reproduce realistic smoking conditions as much as possible. [Id. at p. 10]
8 Against these two criteria, TRC Director Todd recognized the limitations of the mouse
9 skin painting methodology and the benefits of developing inhalation test systems that
10 improved upon those available at the time.

11 **Q. Did BATCo continue to support this research?**

12 A. Yes, in 1964 BATCo Research Manager H.D. Anderson reviewed company
13 policy toward TRC and noted that: BATCo would continue membership in TRC;
14 BATCo would support increased facilities at Harrogate to "work on testing various kinds
15 of 'safer' cigarettes and that such research should be pursued with increased drive";
16 significant findings by TRC should be published; and, BATCo would obtain its own
17 biological testing capabilities if TRC delayed in testing any product of particular interest
18 to BATCo [JD-039403 at p.1].

19 **Q. What research did TRC actually do?**

20 A. The following excerpt from the 1971 Royal College of Physicians Report
21 provided a good overview of the TMSC/TRC research effort [JD-000757]:

22 "The British tobacco manufacturers have supported research into smoking
23 and health since 1954, when they gave £250,000 to the Medical Research

1 Council. In 1956 they set up their own Tobacco Research Council (TRC)
2 [sic, TMSC]. This has supported research on smoking and health by many
3 independent organisations and individuals, and this includes
4 epidemiological, clinical, and laboratory studies of chest and heart
5 diseases associated with smoking, and surveys on smoking habits. In
6 1962, work began in the TRC's own laboratories at Harrogate. There the
7 research includes animal studies related to the role of cigarette smoking in
8 lung cancer, on the working hypothesis that cigarette smoke affects the
9 respiratory epithelium by direct contact, and pharmacological studies of
10 nicotine. The Tobacco Research Council's annual contribution to such
11 research is about £1,000,000 per annum. In addition, the manufacturers
12 spend a similar amount on research in their own laboratories and
13 elsewhere. [at pp. 19-20]

14 **Q. Are there particular TMSC/TRC projects you would like to highlight?**

15 A. Yes. Dr. Day's mouse skin painting study published in 1967 is noteworthy [The
16 British Journal of Cancer, Vol XXI, No. 1, "Carcinogenic Action of Cigarette Smoke
17 Condensate on Mouse Skin," Day, T.D., JD-011162)].

18 **Q. What was the significance of the Day publication?**

19 A. At the time, it was the largest experiment of its kind and it replicated the results of
20 others, including Wynder, that showed the tumorigenicity of smoke condensate on the
21 backs of mice. It was especially significant because it used fresh smoke condensate
22 which was only a day old and compared it to condensate that was months old to assure
23 that the tumorigenicity of smoke condensate seen in past experiments was not an artifact
24 of the aging of the smoke. It also formed the basis for TRC's later smoke fractionization
25 work and established the protocol for mouse skin painting studies.

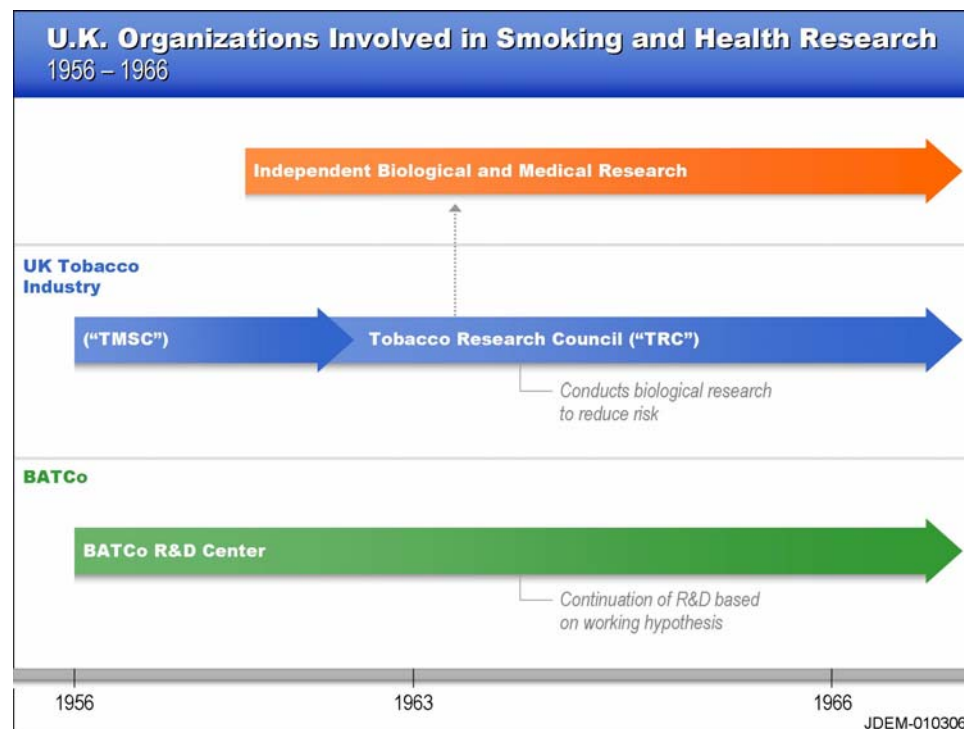
1 **Q. What is fractionization?**

2 A. In simple terms, it is an attempt to separate and isolate the chemical constituents
3 of smoke condensate and to identify the "fractions" that contain any carcinogenic or co-
4 carcinogenic activity as identified from the tumorigenic potential.

5 **Q. Did the TRC research on fractionization of smoke condensate lead to the**
6 **hoped for advances?**

7 A. No there were some key problems. By 1970, the TRC was becoming cautious
8 regarding the outcome of the fractionization work, noting that, although the fractions
9 being examined represented as little as 0.2% of the weight of the original condensate,
10 they nevertheless "still contain many constituents and the separation techniques are
11 working near their limits. Consequently it is possible that the knowledge of smoke
12 condensate, though greatly increased, will not be sufficiently precise to be used
13 effectively as a chemical index. In this event, it may be concluded that this work has
14 been taken as far as it profitably can." [JD-030988 at p. 14] The work however had
15 made a valuable contribution to the understanding of chemical carcinogenesis,
16 particularly the concept of initiation and promotion and laid the foundation for further
17 academic research.

1 Q. Again, to keep things organized, I think this is another good point to stop and
2 ask you if the chart below [JDEM-010306] accurately summarizes the information
3 you have provided about the various U.K. organizations involved in research
4 through 1966?



5
6 A. Yes it does.

7 D. BATCo's Biological Research

8 Q. Did there ever come a point in time when BATCo decided it needed its own
9 biological research capabilities?

10 A. Yes. BATCo decided that it needed to undertake parallel testing on further
11 experimental processes and materials. Not only would there be delays in feeding
12 BATCo's own experimental requirements into the shared Harrogate program, but some of
13 these materials and processes were of potential commercial value to BATCo, quite apart

1 from any benefit they might have offered to the smoker in terms of risk reduction. The
2 joint industry laboratories at Harrogate were clearly not an appropriate forum for the
3 examination of competitive product innovations. For example, there was a 1965 file note
4 which stated: "The successful operation of Harrogate has been established and can be
5 used as a model for further activities. However, it is quite clear that work carried out on
6 an industry basis must be acceptable to the whole of the industry and therefore concerned
7 with problems which are not necessarily those which any particular company may wish
8 to tackle at any particular time. It is necessary to disclose not only the details of any
9 proposed experiments, but the whole of the research thinking behind these experiments
10 and, although it is our clear intention to make available to the industry any important
11 discoveries in connection with health, it is commercially undesirable to reveal
12 approaches, particularly in the fringe areas. Obviously, for an international Group,
13 necessarily operating in widely different conditions, there are often good reasons for
14 avoiding premature disclosures. In addition, by their very nature, industry based
15 operations are relatively slow and difficult to organize, and for these reasons it has been
16 found necessary to have available additional biological testing facilities under direct
17 Company control." [JD-030147 at p. 1].

1 1. Mouse Skin Painting

2 **Q. What work resulted from this decision by BATCo to undertake its own**
3 **biological research?**

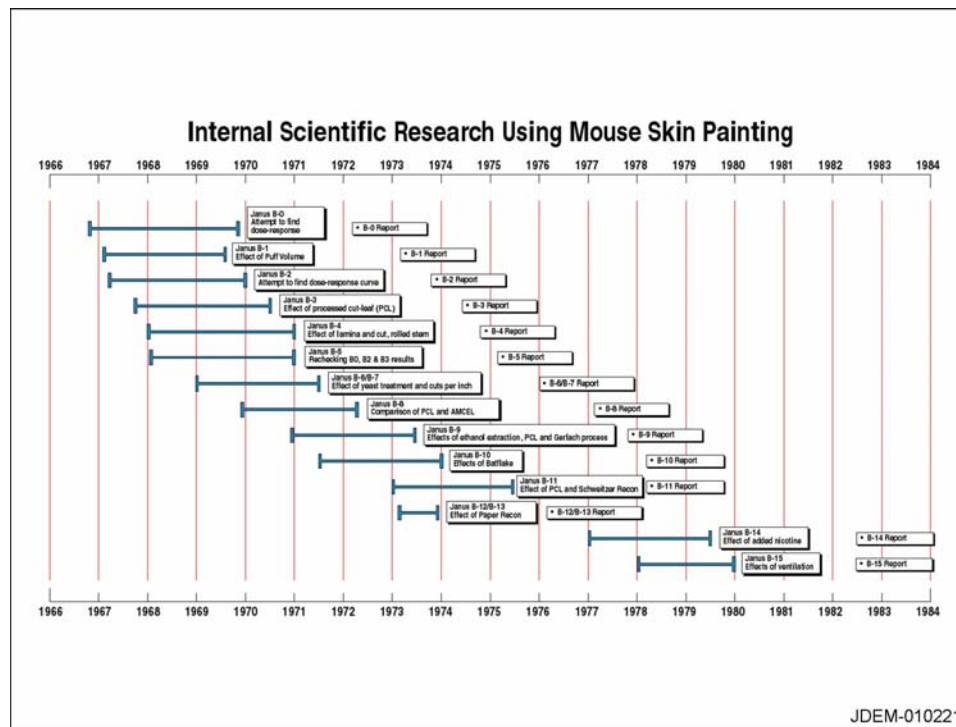
4 A. One key initiative instigated by BATCo was the mouse skin painting experiments
5 conducted under contract at Battelle Laboratories in Frankfurt under the name Project
6 Janus. The initial planning work for this project relied upon Day's TRC research.

7 **Q. Please explain what Project Janus entailed.**

8 A. Project Janus was a very full and thorough program with respect to mouse skin
9 painting. It was product modification research. It included the assessment of a whole
10 array of cigarette design variables and properties within the mouse skin painting studies.
11 It essentially was a continuation and refinement of the earlier published TRC mouse skin
12 painting work.

13 **Q. Have you prepared a summary chart to illustrate the significant events**
14 **related to the Janus Project, identified as JDEM-010221.**

15 A. Yes, this chart lays out the time line, the projects by name and number, and
16 identifies what was actually examined in this series of studies.



1

2 **Q. Roughly how many parts were there to Project Janus?**

3 A. Project Janus included 16 key projects summarized in 14 reports.

4 **Q. Are these projects fairly and accurately reflected on JDEM-010221?**

5 A. Yes, they are.

6 **Q. Was there also mouse skin painting research conducted in the United States?**

7 A. Yes, indeed, there was. There were parallel activities all around the world. In the
 8 U.S., the National Cancer Institute had a subdivision known as the Tobacco Working
 9 Group ("TWG"). The TWG commissioned and developed its own mouse skin painting
 10 test methodology as a means of trying to assess the properties of the product and tobacco
 11 smoke to get some direction for potential product improvements with respect to
 12 biological properties.

1 **Q. Do you have a demonstrative that assists you in explaining the sequence and**
2 **timing of both external and tobacco industry related mouse skin research?**

3 A. Yes. JDEM-010299 shows that product modification work using mouse skin
4 painting reached its peak in the 1960s and 1970s.

5 **Q. Were there any limitations to mouse skin painting tests?**

6 A. Yes, and that was recognized from the onset of the research. Condensate is not
7 the same as whole smoke, as the former has been through the collection, extraction, and
8 solvent processes before it is painted on the backs of mice. In addition, the smoke
9 condensate applied to the backs of mice is much more concentrated, in relative terms,
10 than whole smoke and will have different physiological and biochemical interaction with
11 skin compared to the lungs.

12 **Q. Is there any significance to the fact that the condensate is applied to the**
13 **backs of mice rather than their lungs?**

14 A. Yes. There are a number of factors. For instance, the surface area of the lung is
15 approximately the size of a tennis court and the lung has a number of defense
16 mechanisms unique to the lung and its interaction with the outside world. Humans are
17 constantly exposed to a whole array of environmental chemicals, particles and dusts. The
18 lung produces mucous and is equipped with little hair-like structures called cilia which
19 together clear out particles that obstruct the lung airways.

1 2. Inhalation Animal Studies

2 **Q. Did BATCo either directly or through the TRC pursue other types of**
3 **bioassays?**

4 A. Yes. In addition to the mouse skin painting program, many other lines of research
5 were pursued at the Harrogate laboratories. TRC scientists developed a system for
6 exposing laboratory animals to whole fresh smoke in an inhalation bioassay. Like other
7 workers in this field they were unable to develop this procedure into a useful assay for
8 tobacco smoke carcinogenicity, because of the very few, if any, lung tumours found in
9 exposed animals. [JD-030988 at pp. 29-30] In addition, BATCo established its own
10 inhalation facility at Southampton in 1974 under the direction of Dr. Binns who had
11 specific expertise in this area. It undertook extensive methodological work on
12 developing reliable inhalation assays. Previous animal inhalation work had been
13 conducted by confining animals to an area flooded with smoke. BATCo developed a
14 new exposure methodology, which was a more direct method to present the smoke to the
15 animals, and hence their respiratory tracts. There were many publications by BATCo
16 scientists in this area. [JD-010639, JD-039406, JD-045711, JD-039405, JD-030641, JD-
17 039410, JD-030643, JD-045710 and JD-011492].

18 **Q. What was the motivation for this movement toward inhalation testing?**

19 A. Science does not generally move in giant steps, but rather tends to be a
20 continuously evolving, unfolding series of knowledge. Through this time period,
21 scientists were gaining a better understanding about diseases and disease processes at a
22 fundamental scientific level. This occurred in parallel with the recognition that inhalation

1 systems may be a more relevant way of conducting these sorts of biological assessments.
2 In a book written by Drs. Ernst Wynder and Dietrich Hoffmann, they raised some of their
3 concerns regarding the limitations of mouse skin painting and the potential of using other
4 methods more representative of what actually goes on during normal human smoking.

5 **Q. Take a look at JD-000742, which is a 1967 book entitled *Tobacco And***
6 ***Tobacco Smoke: Studies in Experimental Carcinogenesis*. Is this the Wynder and**
7 **Hoffmann book to which you just referred?**

8 A. Yes it is.

9 **Q. And, if we turn to page 145 of the book, it reads:**

10 **The bioassay for tobacco on mouse epidermis have not answered the**
11 **questions on the problem of respiratory carcinogenesis. A bioassay of**
12 **the respiratory system of a laboratory animal should be useful**
13 **provided that sufficient smoke aerosols can be delivered to the**
14 **bronchial epithelium.**

15 **Is this the passage you discussed?**

16 A. Yes it is. Drs. Wynder and Hoffmann were authorities in the field and they
17 recognized that the mouse skin painting test was an approximation to try to get some
18 measure of the biological properties of condensates. They also recognized that lung
19 tissue would be a better site on which to apply the smoke and smoke aerosol if a test
20 model could be validated. The question remained, however, whether testing on lung
21 tissue would have practical utility in measuring the biological properties of whole
22 cigarette smoke.

1 **Q. Did there come a time when animal inhalation tests were utilized in**
2 **connection with cigarette design research?**

3 A. Yes there did. The inhalation studies related to cigarette design really got going
4 in the late 1960s and throughout the 1970s.

5 **Q. I want to show you a chart summarizing the timing of inhalation and other**
6 **related research, identified as JDEM-010309. Does this chart accurately set forth**
7 **the time periods for inhalation research?**

8 A. Yes, I believe the timing is accurate.

9 **Q. What U.K. companies or entities used inhalation test methods to look at**
10 **potential cigarette design modifications?**

11 A. The TRC's Harrogate Labs developed inhalation models and inhalation exposure
12 systems. In addition, BATCo utilized external contract labs to study animal inhalation.
13 Later, BATCo set up its own internal animal inhalation facility, which is where I worked
14 when I first joined the company in 1976.

15 **Q. Can you describe in more detail the BATCo inhalation work?**

16 A. Yes. Most BATCo inhalation experiments were short-term assays. Those
17 experiments attempted to assess the comparative toxicity of the smoke from different
18 cigarettes, at a number of defined sites in the rat respiratory tract. These studies resulted
19 in a number of significant pathological changes in the lung including keratinisation,
20 metaplasia and hyperplasia, following smoke exposure. These were not necessarily pre-
21 cancerous changes and indeed some regressed following termination of exposure. The
22 short-term assays were not used as tests of carcinogenicity but rather as comparative

1 irritancy assays. Scientists at Southampton conducted one pilot long-term inhalation
2 study, which was unsuccessful at elucidating the carcinogenic potential of whole fresh
3 smoke. A finding that came as a significant blow to the scientific program at the time.

4 **Q. Were there also institutions in the United States that utilized animal**
5 **inhalation studies?**

6 A. Yes. There were many independent researchers, and the NCI was also looking at
7 developing an animal inhalation exposure system. This external research is accurately
8 summarized on JDEM-010309.

9 **Q. We have previously discussed some of the limitations involved in mouse skin**
10 **painting. Were there also limitations related to the use of animal inhalation studies?**

11 A. Yes, indeed there were.

12 **Q. Could you please explain some of these limitations?**

13 A. Yes, as you can imagine animals don't normally inhale cigarette smoke, so we
14 have to place them in some form of holding tube attached to a smoke exposure chamber.
15 To be inhaled, the smoke has to be diluted and all in all is something of an artificial
16 process when compared to human smoking. There is a whole array of difficulties if you
17 want to conduct meaningful, controlled and validated inhalation studies. There are many
18 challenges to actually putting the exposure systems together in a way that minimizes the
19 stress to the animal, while at the same time maximizing the potential to get a reproducible
20 result in the respiratory system.

1 **Q. Did the Surgeon General of the United States recognize the limitations of**
2 **inhalation studies?**

3 A. Yes, he did.

4 **Q. I am showing you an excerpt from the 1982 Surgeon General's Report,**
5 **marked as U.S. Exhibit 60,598. At page 218, the Report says:**

6 **Attempts to induce significant numbers of bronchiogenic carcinoma**
7 **in laboratory animals were negative in spite of major efforts with**
8 **several species and strains. Neither rats nor hamsters nor baboons**
9 **inhale cigarette as deeply and as intensely as the cigarette smokers**
10 **who have provided the data with the consequences of their**
11 **"experiment" in the form of clinical evidence gathered by**
12 **epidemiologists. In view of this compelling evidence, it appears that**
13 **experimental induction of bronchogenic carcinoma should receive**
14 **limited priority as a research goal.**

15 **Is this excerpt from the Surgeon General's report consistent with your**
16 **understanding and personal knowledge of the limitations of inhalation studies?**

17 A. Yes, it is. And, in fact, the Surgeon General here was looking not only at the
18 practicality of exposing animals to cigarette smoke, but he was also noting the lack of
19 actual responsiveness in those animals' lung tissues to the exposure to smoke.

20 **Q. What was the significance of the lack of responsiveness?**

21 A. Basically, with few exceptions, researchers were unable to actually generate
22 bronchiogenic carcinomas in the respiratory tracts of these animals using inhalation
23 models. This is quite significant because if you cannot induce the desired experimental
24 endpoint being studied, then you have little basis for comparing the effects of product
25 modifications.

1 3. In vitro Testing

2 **Q. Did there come a time when another type of biological research, known as *in***
3 ***vitro* testing, was employed in an effort to identify potentially relevant cigarette**
4 **design modifications?**

5 A. Yes. Again, there was no clear cut start and stop point where one type of testing
6 method ended and another began. As we have discussed, science develops along a
7 continuum. And in the world of toxicology, scientists tend to build a body of knowledge;
8 they accept the limitations of one test, while trying to improve or introduce new tests to
9 minimize those limitations. Around the early 1970s, scientists were on the threshold of
10 beginning to understand molecular genetic principles and processes. So researchers
11 began to look to *in vitro* tests. These types of tests were thought to help understand how
12 components in smoke were specifically interacting with the genetic material.

13 **Q. I am showing you a chart that deals specifically with *in vitro* testing,**
14 **identified as JDEM-010296. Does this demonstrative accurately reflect the timing**
15 **and types of *in vitro* tests of which you are personally familiar?**

16 A. Yes, it does and these and other *in vitro* tests continue to be developed and used
17 today, including by ourselves.

18 **Q. Let's discuss one of the *in vitro* test methods referenced on JDEM-010296, the**
19 **Ames Test. Are you familiar with the Ames Test?**

20 A. Yes, I am. This test is one of the first, if not the first, *in vitro* test that came on the
21 scene during this era of early molecular genetics.

1 **Q. When did the Ames Test come into being.**

2 A. In the early 1970s.

3 **Q. Is the Ames Test a cancer test?**

4 A. No, it is not. The Ames Test is a mutagenicity test, not a carcinogenicity test.

5 One of our key scientists in this area, E.D. Massey, clearly recognized this distinction and
6 as early as 1982 noted that the Ames test was viewed as a "generalized screening
7 procedure to determine whether chemicals have an adverse toxicity" [JD-010592 at p. 1]
8 and "is not an infallible guide to cancer potential." Id. at p. 2. The Ames Test was a
9 chemical screening assay for mutagenic potential generally and not a tobacco specific
10 test. Professor Bruce Ames, an independent outside scientist, had developed a mutant
11 strain of microorganism. Its genetic make-up had been modified such that, it could not
12 grow without a growth supplement. Scientists would then treat the organism with an
13 array of test chemicals, after which the organism would or would not have the ability to
14 grow. If the treatment resulted in the organism being able to grow, then the chemical
15 would have interacted with the organism's DNA such that it could grow without the
16 growth supplement. The chemicals that caused this event would be known as mutagens.

17 **Q. Is there a relationship between mutagenicity and cancer?**

18 A. At the time the Ames Test was developed, there was a belief that if something
19 was mutagenic it would also be carcinogenic. We now know that mutagens are not
20 necessarily carcinogens.

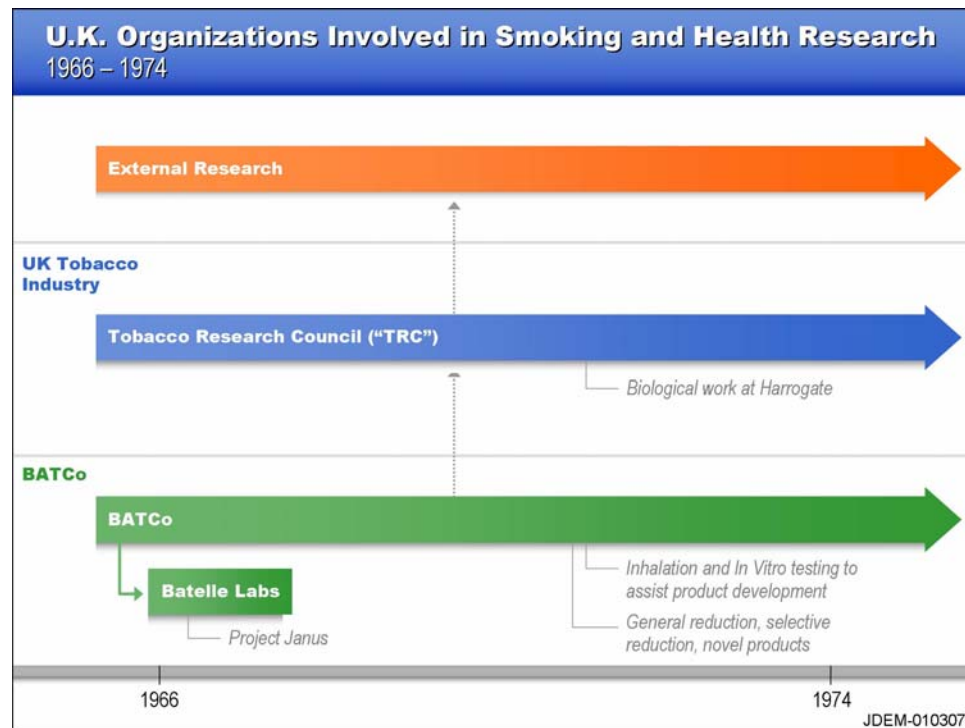
1 **Q** Did there come a time when biological research on product modification was
2 performed using the Ames Test?

3 A. Yes, there did and it continues to be used under defined circumstances.

4 **Q.** Did BATCo perform Ames or other in vitro research?

5 A. Yes, it did, and continues to do so to this day.

6 **Q.** Let me again stop and ask you whether the chart below [JDEM-010307]
7 accurately summarizes the research organization developments from 1966 to 1974?



8
9 A. Yes it does.

10 **Q.** Did BATCo ever apply Ames Test to its products?

11 A. Yes, one principle example is Project Rio, which applied the test in the 1980s to
12 evaluate a range of products in the marketplace.

13 **Q.** What, if any, conclusions were drawn from Project Rio?

1 A. We saw that a range of products had different responses in the Ames Test, but
2 couldn't explain at the time the reasons for the results. This led to a program of study
3 over time to pursue how these various design aspects might affect the Ames Test results.

4 **Q. Did the NCI's Tobacco Working Group use the Ames Test?**

5 A. Yes, it did.

6 **Q. Did the tobacco industry play any role with the NCI's Ames Test program?**

7 A. Yes. As I understand it, the NCI invited tobacco industry experts to give their
8 ideas and thoughts regarding this program, and even had industry experts administer
9 some of the programs.

10 **Q. I am going to show you a copy of file note from Kendrick Wells, dated June**
11 **12, 1984 [U.S. Ex. 52,687]. You can see in this note that Mr. Wells makes mention**
12 **that there should be "direct lawyer involvement" in all facets of project Rio. Do you**
13 **have a response to Mr. Wells's language?**

14 A. With all due respect, you have to understand how corporations work. They have
15 various functions and the people in those functions have particular roles and
16 responsibilities. Corporations take the advice of their various functions in formulating
17 business strategy, positions and responses. I am therefore not surprised by one function
18 expressing or formulating a particular view as a business consideration. In this instance, I
19 know that Project Rio ran to conclusion and reports were issued on the results of all
20 products tested with no lawyer control. Put simply, Project Rio was not under the control
21 of the law department and nor was any other scientific project or program.

1 **Q. Earlier in your testimony, you discussed the cilia of the lung. Were there also**
2 ***in vitro* tests related to the cilia?**

3 A. Yes. This work, known as ciliastasis research, began well before the development
4 of the Ames Test.

5 **Q. What is ciliastasis and the test methodology?**

6 A. Ciliastasis testing is a biological test which investigates the inhibition of ciliary
7 activity in response to exposure to a chemical agent.

8 **Q. Did there come a time when limits were also discovered with regard to *in***
9 ***vitro* tests, like the ciliastasis tests?**

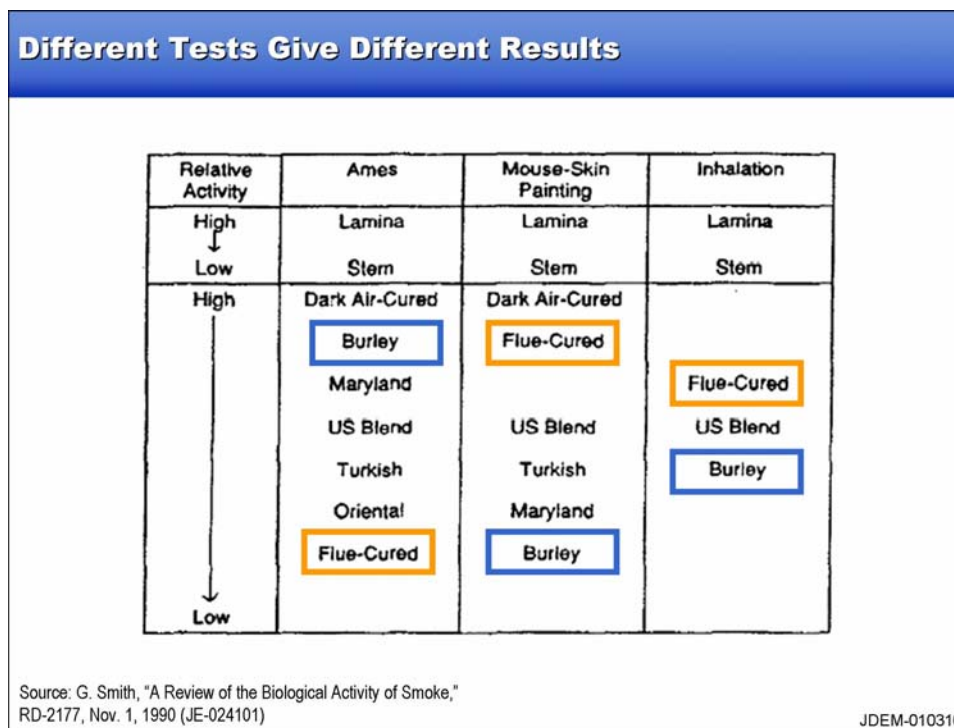
10 A. Yes, the issue became one of validation. Even though the *in vitro* tests showed an
11 acute ciliary response to cigarette smoke, the response occurred over a limited dose range
12 and its relevance to humans and any acute impairment in the ciliary activity following
13 smoke exposure was unclear. Because of these sorts of observations, the utility and value
14 of ciliastasis work tended to fall away toward the end of the 1960s. Both industry
15 researchers and external scientists stopped conducting the research which was recognized
16 to be of limited utility.

17 **Q. Does BATCo still use the ciliastasis test?**

18 A. No, because it has little or no practical utility and it is not indicative of real world
19 smoking.

1 **Q. Having discussed the various aspects of BATCo’s research, has this research**
2 **provided the answer for what is the “right” test or battery or tests for the**
3 **development of safer cigarette design modifications?**

4 A. No, unfortunately, it has not for some of the reasons already stated. Indeed it is
5 possible to further exemplify this point by looking at some of the test findings of BATCo
6 when it has assessed product design variables using MSP, inhalation and *in vitro* testing
7 which is shown in JDEM-010310.



8
9 **Q. Could you please explain what JDEM-010310 shows.**

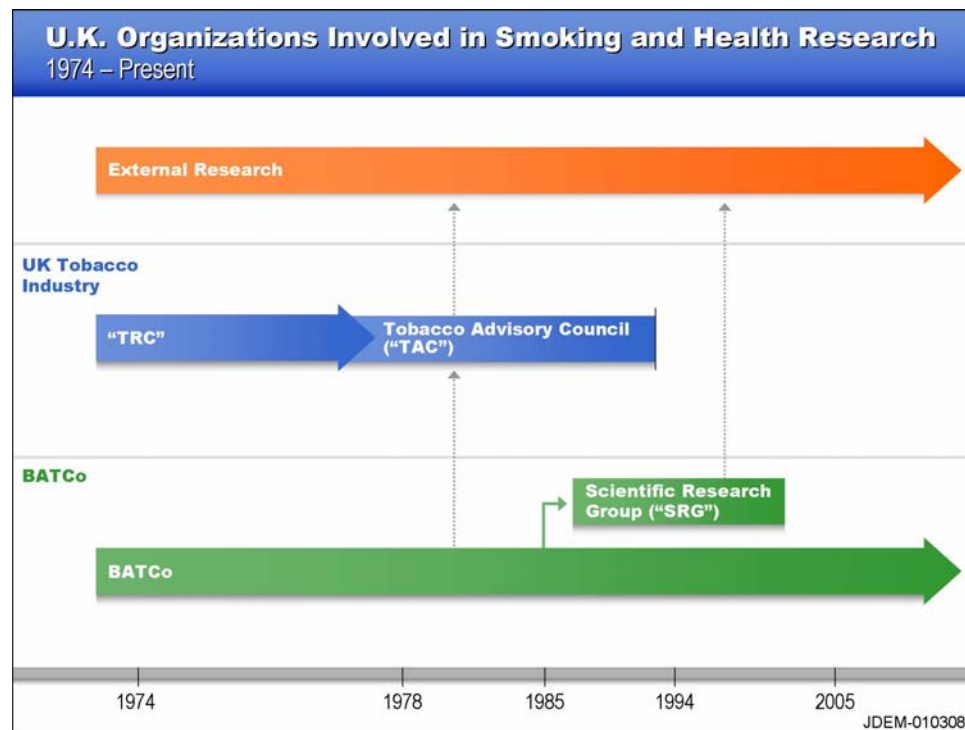
10 A. One potential design modification is to change the tobacco blend. As we
11 previously discussed, BATCo investigated three primary bioassays: (1) mouse skin
12 painting, (2) inhalation studies; and (3) *in vitro* tests. This chart provides an overview of
13 the types of results we received from these tests for some design parameters. For

1 example, if you compare the results for burley and flue-cured tobacco, you see different
2 results depending on the test method used. The burley mouse-skin painting tests yielded
3 relatively low values, while the converse was true on the Ames Test. So you have a
4 mixed picture. Moreover, there are multiple diseases associated with smoking. This
5 demonstrative relates to bioassays potentially relevant to cancer. It tells you nothing
6 about, for instance, heart disease, and, by way of example, there is some support for the
7 opinion that increasing the completeness of combustion might reduce some of the
8 constituents believed to be associated with cancer but that same process is also thought to
9 increase the production of carbon monoxide, which has been associated with heart
10 disease.

11 **Q. Does this mean that with all of this research, BATCo has learned nothing**
12 **helpful in terms of cigarette design modification?**

13 A. Absolutely not. Although there are many unanswered questions, we have
14 certainly learned many things. As scientists, we have utilized the best tools and most
15 currently available test methods for assessing biological responses. The conclusion we
16 have drawn — a conclusion that has been voiced by external scientists and governmental
17 and regulatory authorities — is that the best strategy is to target design modifications
18 toward lower deliveries. The challenge, however, is to make lower delivery products that
19 consumers find acceptable and deliver low tar in use by consumers.

1 Q. A final question in this area is, does the chart below [JDEM-010308]
2 accurately summarize the research organization developments you have provided
3 information about from 1974 onward?



4
5 A. Yes it does.

6 **V. PRACTICAL COMMERCIAL CONSEQUENCES OF RESEARCH**
7 **EFFORTS**

8 Q. From a practical commercial standpoint, what is the purpose for this
9 substantial and extensive biological research that you have described that BATCo
10 supported internally and externally?

11 A. For a cigarette manufacturer to achieve improvements in its products that lessen
12 or eliminate the adverse health consequences of smoking, several complex areas of
13 science must be understood. The purpose of the research program has been to provide

1 the tools to achieve these product improvements. And the sorts of tools you need in this
2 context relate to discovering what is it in smoke that is responsible for the adverse health
3 consequences, how can you affect the smoke in ways that might improve it, and how can
4 you evaluate whether these modifications have achieved the desired improvements with
5 respect to human health.

6 **Q. What, if any, product modifications have BATCo explored in this context?**

7 A. BATCo's efforts fall into three broad categories: novel products; selective
8 reduction; and, general reduction. Co-extensive with its biological research, BATCo
9 pursued these three areas of product modification.

10 A. Novel Products

11 **Q. What do you mean by novel products?**

12 A. I am referring to more radical approaches to cigarettes design, designs like our
13 1960s Project Ariel or, more recently, RJR's Eclipse product, which heat rather than burn
14 tobacco. The idea here is to produce an aerosol for inhalation with lower levels of the
15 harmful constituents than those found in combustion generated smoke.

16 **Q. Tell us about Project Ariel?**

17 A. Under the direction of Sir Charles Ellis, a series of Ariel prototypes were tested in
18 the 1960s. Ariel was a smoking device with a mouthpiece simulating a cigarette,
19 containing tobacco wrapped around an annular tube containing nicotine. Burning or
20 smoldering the tobacco in the conventional manner heated the nicotine, causing it to
21 evaporate, delivering the nicotine through the mouthpiece to the smoker without exposing
22 the smoker to the pyrolytic or combustion products normally associated with burning

1 tobacco. This device presented insolvable problems, including finding a suitable carrier
2 for the nicotine, controlling the heating function and delivering a palatable vapor to the
3 smoker without aversive levels of nicotine. A further problem was how to manufacture
4 such a device in quantities at a volume and cost acceptable to the market. Ultimately, the
5 development was not successful. [U.S. Ex. 21,547]. However, BATCo continues
6 actively to research new technical approaches to novel products.

7 B. Selective Reduction

8 **Q. Can you tell us about selective reduction?**

9 A. BATCo examined ways of modifying tobacco smoke to reduce or eliminate
10 constituents which might be responsible for biological activity.

11 **Q. In this context, what is the significance of biological activity?**

12 A. This is an example where the biological research and product modification efforts
13 interface. Since all diseases associated with smoking are chronic long-term diseases, it is
14 not possible to evaluate potential product modifications in smokers based on these
15 disease endpoints because they can take decades to occur and the experiments would be
16 unethical. But it is possible to study short-term outcomes in various models whether
17 animal or in-vitro; and if these consequences, which we refer to as biological activity, are
18 thought to be relevant to disease endpoints, then product modifications which result in
19 reduced or eliminated biological activity could be viewed as beneficial.

1 **Q. Can you give the Court a fuller understanding of BATCo's selective**
2 **reduction efforts?**

3 A. Selective reduction, as the name implies, is the attempt to reduce the yield of
4 specific suspect components relative to overall smoke yield. The TMSC/TRC had
5 already studied a variety of novel filters for their potential to reduce constituents
6 selectively. For example, as early as 1958, additives such as copper nitrate were used in
7 an attempt to reduce benzo(a)pyrene yield [JD-031045 at p. 4] BATCo examined a wide
8 variety of individual compounds and groups of compounds, including phenols,
9 aldehydes, nitrosamines, polycyclic-aromatic hydrocarbons, including 3,4
10 benzo(a)pyrene, oxides of nitrogen and carbon monoxide as potential targets for
11 reduction and continue to do so today. Moreover, U.K. regulators required tobacco
12 companies to investigate selective reduction of other noxa. [JD-000657 at p. 8]. In
13 response BATCo launched a program of other noxa research. [JD-039423, JD-039420,
14 JD-039422, and JD-039421].

15 **Q. Dr Wigand testified that BATCo's other noxa research was concealed from**
16 **B&W. Is that accurate?**

17 A. No. In fact, B&W generally and Dr. Wigand in particular, received documents on
18 the other noxa program. See, for example, JD-039423, which bears his receipt stamp.

19 **Q. How has BATCo's selective reduction research fared?**

20 A. To the very limited extent that it has been technically feasible to target individual
21 constituents for reduction, the extreme complexity of cigarette smoke means that such
22 changes can produce other unforeseen and possible undesirable changes in the smoke

1 chemistry: "There are many separate processes involved in the generation of different
2 smoke components, often interacting in a complex manner. Making a modification to
3 reduce the level of one group of substances in smoke usually also produces other
4 undesirable effects." [JD-031503 at p. 15] For example, reducing PAHs using nitric
5 oxide increases nitrosamines. [Id. at p. 15; see also U.S. Ex. 52,616]

6 C. General Reduction

7 **Q. Can you explain to the Court BATCo's efforts at general reduction of smoke**
8 **yields?**

9 A. Based on the sound toxicological principle that response is related to dose, there is
10 a reasonable possibility that reducing the smoker's overall exposure to cigarette smoke
11 might lead to a reduction in risk. Since at least the 1950s, through the introduction of
12 filters, tar yields had begun to decline with a corresponding reduction in observed
13 epidemiological risk, and this reduction continued to be seen during the 1960s through
14 the use of more effective filtration, changes in blending, and the use of ventilation. [JD-
15 000656 at p. 3] The principle of tar yield reduction became the key thrust of the U.K.
16 Government in what became known as the low tar program, which entailed a progressive
17 and gradual general reduction in smoke yields.

18 **Q. Can you provide the court with greater detail of what was known as the low**
19 **tar program in the U.K.?**

20 A. Although smoke yields in the U.K. had been slowly declining, in general, during
21 the 1960s, there wasn't an official low tar program until the early 1970's. This change
22 was initiated by the new Health Secretary, Sir Keith Joseph, the first person in that

1 position interested in working alongside the tobacco companies and having the
2 Department of Health offer some guidance on how the companies might develop less
3 dangerous cigarettes.

4 **Q. Had there been any dialogue between the companies and the U.K.**
5 **Government prior to Sir Keith Joseph coming to the Department of Health?**

6 A. Yes, there had been plenty of ad hoc contact and discussion, but it was Sir Keith
7 Joseph who set up a formal structure for the industry and Government, and independent
8 scientists appointed by the Government, to work together on the smoking and health
9 problem and the Standing Scientific Liaison Committee was formed as part of this
10 initiative.

11 **Q. What was its purpose?**

12 A. The terms of reference were described by Sir Keith Joseph in a statement to
13 Parliament. [JD-039426 at p. 1190]. The Committee was instructed to review less
14 dangerous kinds of smoking, and to determine satisfactory methods of measuring tar and
15 nicotine yields. It was the Government's intention that a "league table" should be
16 published, showing smokers the comparative yields of brands on the market.

17 **Q. What was the purpose of this league table?**

18 A. By 1971, there was a general consensus among the medical community that
19 smokers who chose to continue to smoke could reduce their risks of disease by reducing
20 their intake of tar, both by cutting down on the numbers of cigarettes smoked and by
21 smoking lower yield cigarettes. League tables provided a listing or ranking of cigarette
22 products on the basis of tar yield for consumer information and use.

1 **Q. Can you point to any reference for this consensus?**

2 A. Yes, the 1971 report of the Royal College of Physicians, entitled *Smoking and*
3 *Health Now*, [JD-000757], summarized the medical profession's views on a range of
4 issues related to smoking and health, including the significance of tar yields. In simple
5 terms, the report stated that the only cancer-causing substances found to date in tobacco
6 smoke were contained in the tar fraction, so reducing tar yields might reduce the risk of
7 cancer to smokers. [Id. at pp.131-32.]

8 **Q. Did they make any specific recommendations about tar yields?**

9 A. Yes, they said that the tar content of brands of cigarettes should be made known
10 to the consumer, and that an authoritative statement should be made about the
11 significance of that information. Specifically, they wanted to see people who continued
12 to smoke encouraged to change their behavior - and they list these options:

13 "smoking fewer cigarettes,
14 inhaling less,
15 smoking less of each cigarette,
16 leaving a longer stub...
17 taking fewer puffs from each cigarette,
18 taking the cigarette out of the mouth between puffs,
19 smoking brands with a low content of tar and nicotine." [Id. at p. 134]

20 The objective being to reduce the overall smoke dose to the consumer.

21 **Q. Have you reviewed the membership of the Standing Scientific Liaison**
22 **Committee?**

23 A. Yes, I have. It included some well known physicians, such as Professor Dollery
24 and Professor Lynne Reid, as well as representatives from the Medical Research Council
25 and similar institutions. A few tobacco company scientists also sat on the Committee.

1 **Q. Have you reviewed any reports of the Committee?**

2 A. In fact, they issued only one report, in 1972 entitled *Report of the Standing*
3 *Scientific Liaison Committee (on the scientific aspects of Smoking and Health) to the*
4 *Secretary of State for Social Services on the publication of Tar and Nicotine yields of*
5 *Packeted Cigarettes* [JD-031001]. I have reviewed it.

6 **Q. What were the main conclusions of that report?**

7 A. In particular, the Committee thought there was enough evidence of the advantages
8 of lower tar yield cigarettes that smokers of high tar brands should be encouraged to trade
9 down, and that smokers should be presented with the information which would enable
10 them to make that kind of decision. [*Id.* at ¶¶ 2.1, 2.2].

11 **Q. And did the Committee make specific proposals to that end?**

12 A. They proposed that tar and nicotine yields should be measured by the Laboratory
13 of the Government Chemist, according to a uniform methodology, [*Id.* at ¶¶ 3.1, 3.2 and
14 Appendix B] and they set out a number of options for ranking brands by tar delivery and
15 for labeling. [*Id.* at Appendix A.] They also suggested that smokers be provided with
16 advice on how to smoke, along almost identical lines to those suggested by the Royal
17 College of Physicians. [*Id.*]

18 **Q. Did the U.K. Government act on these recommendations?**

19 A. Yes. From 1973, the Government published tar league tables for brands on the
20 U.K. market, and the industry voluntarily agreed to publish tar group designations on
21 packs and in advertisements.

1 **Q. Was there any follow-up to the work of the Standing Scientific Liaison**
2 **Committee.**

3 A. Following its first report, that Committee was dissolved. The U.K. Government
4 was under pressure to pursue more anti-tobacco measures. In 1973, a different
5 committee consisting entirely of independent scientists, chaired by Dr. Hunter (who
6 subsequently became Lord Hunter), was set up to report directly to the U.K. Department
7 of Health. [JD-030100 at p. 7] This was the Independent Scientific Committee on
8 Smoking and Health. It's often known as the ISCSH or the Hunter Committee for short.

9 **Q. Did the ISCSH produce any reports or make recommendations?**

10 A. Yes, the ISCSH produced four reports. The first produced in 1975 entitled
11 "Tobacco Substitutes and Additives in Tobacco Products." One of the early initiatives of
12 the ISCSH was its tobacco substitutes program. Indeed, "tobacco substitutes" formed
13 part of the title of the ISCSH's first report. [JD-010621]

14 **Q. What was the tobacco substitutes program?**

15 A. It was a cooperative effort between the ISCSH and the U.K. tobacco
16 manufacturers to develop synthetic materials for incorporation into cigarettes to hopefully
17 reduce the adverse health effects of smoking. Although Lord Hunter expressed gratitude
18 to the U.K. tobacco companies for their cooperation in connection with this effort [JD-
19 010621 at p. 4], the tobacco substitute program ultimately failed due to what the ISCSH
20 termed "failure of market penetration" [JD-000657 at p. 2] and inconclusive scientific
21 data on whether tobacco substitutes provide a health benefit. [Id.; JD-003901 at p. 2].

1 **Q. Did the ISCSH make any recommendations about switching to lower tar**
2 **yield cigarettes?**

3 A. Yes, they were very much in favor of developing what they called "lower risk
4 cigarettes". They recommended that tar yields in general on the U.K. market be brought
5 down. They focused on what they called "sales-weighted average tar", or "SWAT",
6 which was essentially an average of tar yields on the market, taking into account the
7 popularity of the brands available. [JD-003901 at pp. 5-6].

8 **Q. Were any targets set for the reduction of SWAT?**

9 A. Yes, through a series of voluntary agreements which were developed and
10 implemented through the U.K. Tobacco Advisory Council negotiated on behalf of its
11 members. These agreements progressively reduced SWAT targets down to 15mg by the
12 end of 1983 and 13mg by the end of 1987. In their fourth report, in 1988, the ISCSH
13 recommended a 12mg SWAT average by the end of 1991, (Independent Scientific
14 Committee on Smoking and Health [JD-000656 at p. 4] but in fact that proposal was
15 overtaken when tar yields in the U.K. became regulated by the European Union which,
16 beginning with a 1990 Directive, set a series of tar ceilings for member countries. [JD-
17 039425]. The current ceiling is 10mg tar.

18 **Q. Is there any doubt in your mind that these targets for reduced tar were being**
19 **set by Government for health reasons?**

20 A. No, the ISCSH was quite explicit about the purpose. In the 1988 ISCSH report,
21 they said that for those smokers who did not take the advice to quit, it was "essential to
22 ensure that the toxicity of cigarettes was systematically reduced". [JD-000656 at p. 1]

1 **Q. Did this reflect the consensus of medical opinion in the U.K.?**

2 A. Yes. The reports issued by the Royal College of Physicians in 1977 [JD-000757]
3 and 1983 clearly indicate that a tar reduction program should remain part of Government
4 strategy, enforced by legislation if necessary. [JD-000322 at p. 90].

5 **Q. During the 1970s and 1980s, were any limitations to the low tar program**
6 **identified?**

7 A. Yes, in the 1960s it was realized that smokers who were accustomed to high tar
8 cigarettes might change the way they smoked when they traded down, and consequently
9 not benefit from the reduction in delivery if they smoke the cigarette in such a way that
10 they receive the same amount of tar delivery. This is the principle reason why the Royal
11 College of Physicians was suggesting smokers should be advised about their smoking
12 behavior back in 1971.

13 **Q. Did the ISCSH look at whether this was a real limitation?**

14 A. Yes. The ISCSH looked at this from both a smoking behavior and an
15 epidemiological perspective and confirmed its belief that lower tar products reduced lung
16 cancer risk.

17 **Q. And did the ISCSH look at whether the low tar program resulted in any**
18 **actual benefit to smokers?**

19 A. Yes, through the work of the Tobacco Products Research Trust (TPRT). The
20 TPRT was formed in 1982 to support projects for the ISCSH which would independently
21 monitor the results of the ISCSH's programs. The TPRT was funded with over £8
22 million from the tobacco industry. [JD-030100 at p. 1].

1 **Q. Can you describe some of that work?**

2 A. Sure. The smoking behavior work sponsored by the TPRT supported the
3 continuation of the low tar program. The TPRT stated: "It was important to thoroughly
4 investigate compensatory smoking since if it tended towards 'completeness' (i.e. 100%) it
5 could undermine the rationale of the product modification programme. The sponsored
6 projects, and many others in the scientific literature, showed that whilst compensation
7 almost universally occurred, it was never complete, figures of 60-70% being usual
8 depending on the methodology. This justified the continuation of the product
9 modification programme even though the results would be expected to be less marked
10 than those assumed on the basis of machine-derived yields." [Id. at p. 29].

11 **Q. Did some of these projects look at the effects of reducing tar yields on**
12 **disease?**

13 A. Certainly. The TPRT sponsored a significant amount of epidemiological
14 research, including work by important researchers like Professor R. Peto and Dr. R.
15 Pritchard. The TPRT epidemiological research concluded that: "The relative risk of
16 death was 0.77 in smokers of lower tar cigarettes (15mg/cigarette) compared to higher tar
17 cigarettes (30mg/cigarette), indicating that up to one-quarter of such deaths might have
18 been avoided by switching to lower tar yield cigarettes." [Id. at p. 24].

19 **Q. Do the timeline and chart marked as JDEM-010311 and JDEM-**
20 **010312 respectively, accurately summarize your understanding of the U.K. history**
21 **of the major scientific publications relating to compensation?**

22 A. Yes they do.

1 **Q. Can you summarize for the Court BATCo's general reduction efforts?**

2 A. Historically, the most promising approach to the developments of less hazardous
3 cigarettes has been to reduce all the smoke components rather than selective reduction of
4 specific components. The general reduction of smoke yields has proved technically
5 feasible and resulted in low and ultra low products acceptable to an increasing share of
6 the market through various combinations of filtration, ventilation, paper technologies and
7 blending. This approach has resulted in a gradual reduction of average tar yields in
8 cigarette to less than a third of their levels 30 years ago. Most other smoke constituents
9 have fallen to a similar level. [See JD-031503 at p. ii]

10 **Q. What impact does the idea of reduced delivery have on BATCo's research**
11 **today?**

12 A. BATCo has a three-pronged approach with respect to reduced delivery which is
13 embedded in its harm reduction strategy.

14 **Q. What is BATCo's "Harm Reduction Strategy".**

15 A. It is an approach that seeks to:

16 (i) develop products and technologies that reduce exposure to smoke and smoke
17 constituents when used by consumers.

18 (ii) generate technologies that can substantially reduce overall smoke exposure or
19 specific constituents exposure.

20 (iii) develop non-combustible products that have a lower risk profile compared to
21 conventional combustion product.

1 **Q. In the absence of bioassays that are indicative of long-term effects of**
2 **smoking, how will you know they are less hazardous?**

3 A. We have a broad based research program to address these issues. We believe that
4 it is critically important to be able to determine a consumer's exposure to smoke and
5 smoke constituents as a means of assessing potential long-term risk. In parallel with
6 determining how consumers use their products and the resulting exposure, we, like
7 others, are actively pursuing research programs aimed at developing biomarkers of harm,
8 which, if successful, would be indicative of a consumer's long-term risk of using
9 cigarette and other tobacco products.

10 **VI. BATCO'S RECORD KEEPING PRACTICES**

11 **Q. Switching gears now, can you provide an overview of the records keeping**
12 **procedure for research reports during the time that you were employed at BATCo?**

13 A. That spans a very long period of time, so I have to give some background. Let me
14 go right back to when I first joined the company in 1976. The general procedure was that
15 scientists kept what was known as benchbooks. These benchbooks were for the purpose
16 of collecting scientific information, data, and became the sort of work log of our
17 activities, and they were principally for patent purposes in the event that we wished to
18 seek patent application. So, at this time, people kept appropriate files for whatever they
19 thought was relevant to help them do their day's work.

20 **Q. Did scientists write reports?**

21 A. Oh, yes, that is an important point. Clearly not only did we keep benchbooks, but
22 we were actually judged by our superiors on the number and quality of the reports that we

1 actually wrote. Part of our performance review would be an expectation that we actually
2 had work output which would be captured in our scientific reports and documents.

3 **Q. Where were these reports and documents kept?**

4 A. They were all kept in the library, among other places, certainly since the day I
5 joined the company, and they are still there.

6 **Q. Did the procedure for scientists keeping records become more formal at**
7 **some point?**

8 A. Yes.

9 **Q. What were the circumstances surrounding that event?**

10 A. Somewhere into the middle of the 1980s, my understanding was that, because of
11 potential litigation in the U.S., our files were reviewed in terms of what files we actually
12 had within our organization.

13 **Q. Who decided to implement this process?**

14 A. It was an internal decision within BATCo.

15 **Q. I am going to show you a memo dated May 1986 which reflects statements**
16 **made by one of BATCo's internal lawyers, Nicholas Cannar. Can you read the**
17 **highlighted sentence on the page with bates 107443685? [U.S. Ex. 34,839]**

18 A. It reads: "BATCo wishes the discovery exercise to place them in such a position
19 as to be able to answer any Requests for Production or Interrogatories emanating from
20 U.S. courts."

1 **Q. What is the discovery exercise he is referring to?**

2 A. There was an independent legal firm that came in by the name of Lovell, White &
3 King, and they went to every single office and took all of the files, went through all of the
4 desks and did an extremely thorough process to make sure that they had captured all
5 documents, including those in the library. They photocopied our documents and
6 reviewed them right across the whole of the R&D organization. Then, following that
7 exercise, there was something that we called the red card that was actually put in our files
8 to indicate that it had been reviewed and copied. The documents were then all returned
9 to us and our files simply had a red card in them.

10 **Q. What was the significance of the red card?**

11 A. It indicated that the file had been copied and reviewed. There was also an
12 instruction that nothing should be added to and nothing should be subtracted from any
13 file that had a red card attached to it.

14 **Q. And what would happen if someone did add or subtract to a file that had a**
15 **red card in it?**

16 A. To give you a feel for the gravity of the situation, I remember communicating to
17 my junior staff, and in general, that it was a serious and potentially dismissible offense to
18 enter the file and add something to it, or take something from it, once it had a red card. I
19 know for a fact that staff took it extremely seriously.

1 **Q. And what was the direction to BATCo R&D scientists and personnel after**
2 **this review took place with respect to keeping their documents?**

3 A. There was a hold order put in place pursuant to which all previously reviewed
4 documents and all newly generated documents must be kept.

5 **Q. What was the instruction of the hold order?**

6 A. There was a categorical instruction that BATCo R&D documents should be
7 retained.

8 **Q. And after the hold order was put into place at this time, were memos, letters,**
9 **notes, or draft reports or any other documentation relating to an experiment, were**
10 **all such documents retained pursuant to the hold order?**

11 A. I think the simple and appropriate answer to that is yes, everything was kept with
12 perhaps one small caveat, that through electronic iterations of working drafts I think it
13 would be unreasonable to expect that one kept every single iteration, but certainly the
14 finished document would be categorically retained.

15 **Q. Is it just scientists that have been required to retain R&D documents since**
16 **the hold order?**

17 A. No. Anyone in the R&D center who generated any research related document
18 was subject to this blanket hold order.

19 **Q. And has that hold order remained in effect up until the present day?**

20 A. Yes it has.

1 **Q. Even before this hold order, as a general matter, has it been BATCo's**
2 **practice to retain its R&D documents?**

3 A. Without doubt. An R&D community is only as good as its knowledge base and
4 hence an absolute prerequisite of a preeminent center is to record and hold its data and
5 findings.

6 **Q. To your knowledge, did BATCo ever discard R&D documents pursuant to**
7 **its document retention policy?**

8 A. To the best of my knowledge, certainly in the time I have been in the R&D
9 department, all R&D documents have been retained as part of the document retention
10 policy.

11 **Q. Did anyone, through the course of your career, ever tell you to do anything**
12 **improper with respect to the creation or retention of BATCo R&D documents?**

13 A. Absolutely not.

14 **Q. Have you ever told anyone to do anything improper with respect to the**
15 **creation or retention of BATCo R&D documents?**

16 A. Certainly not.

17 **Q. If there was a grand plan at any time over the past 29 years to improperly**
18 **destroy or warehouse potentially damaging BATCo R&D documents would you**
19 **have known about it?**

20 A. Absolutely, and I know it did not happen because I was both a practicing scientist
21 and a manager of the R&D center and now am a senior executive within the company.

1 There has been no improper document destruction or warehousing by BATCo in
2 connection with its research.

3 **Q. Were BATCo R&D documents ever routed to Brown & Williamson in ways**
4 **that departed from normal practice?**

5 A. There are a couple of limited instances that I know occurred.

6 **Q. Can you tell me about that?**

7 A. In the mid-1980s, there was a temporary situation when Wally Hughes, the chief
8 executive of Brown & Williamson at the time, wanted to have the flow of documents
9 from BATCo's R&D department to Brown & Williamson routed to the law firm of
10 Wyatt, Tarrant & Combs, specifically through Robert Maddox, an attorney there.
11 Eventually, after less than a year, the normal routing practices resumed.

12 **Q. Was there any other time when Brown & Williamson requested that it not**
13 **receive communications from BATCo in the normal practice?**

14 A. Yes, in 1994 a request was made that written communications not be sent to
15 Brown & Williamson until further notice, and there was a short period of time between
16 1994 and 1995 for a matter of months when we simply complied with the request.

17 **Q. Did this affect other means of communication?**

18 A. Well, as a general rule, all scientists, wherever they reside, always want to discuss
19 their science, and one logical and practical means to do that is by visiting and/or talking
20 on the phone, and that was done quit a bit. So communication was carried on in this way,
21 and scientists at BATCo and Brown & Williamson remained informed in both directions,
22 and people felt that their scientific requirements were being fulfilled. And as I said, after

1 a few months, the written communications began again including material held in the
2 intervening period.

3 **Q. Generally speaking, has it been the practice at BATCo to have R&D reports**
4 **reviewed by others after drafted but before the reports were formally issued and**
5 **distributed?**

6 A. Yes. It has always been the case that our R&D reports are peer-reviewed
7 internally. Our internal peer-review process for R&D reports has always been rigorous.
8 After the draft report is in a form satisfactory to the author or authors it then goes to the
9 group leader for that section for critical review and perhaps other senior scientists in the
10 department depending on the scope of the paper and required expertise and then after all
11 comments are addressed the report is sent to the issuer, who may not be the original
12 author, for issuance. At one time, this process was modified for a period, to include an
13 additional or ancillary review by legal.

14 **Q. When?**

15 A. Around the mid-1980s. There is a period of 18 months to two years when that
16 additional legal process was included.

17 **Q. What was the purpose of this ancillary review by legal?**

18 A. From my understanding, the purpose of this ancillary review was to familiarize
19 legal with the science for potential competitive/proprietary reasons, and additionally to
20 have legal review the language of the reports to ensure clarity of expression and minimize
21 misunderstanding or misinterpretation. Obviously, if technical language were subject to
22 misinterpretation, this could negatively impact the Company in a variety of contexts,

1 including litigation. My experience has been that one of the strengths and purposes of a
2 lawyer is to ensure precision of expression. A problem developed, however, with this
3 process in the sense that it was delaying the issuance of reports to an intolerable degree.
4 So Ray Thornton and Alan Heard helped out with the review to accelerate the issuance of
5 the reports.

6 **Q. There is an April 22, 1985 memo from Richard Binns [U.S. Ex. 34,922] in**
7 **which he talks about what he sees as delays in obtaining review of reports by the**
8 **legal department. Can you explain what situation he was referring to?**

9 A. At this particular point in time I don't believe that Ray Thornton was yet a part of
10 the process. So documents, as usual, were being generated by the R&D community, and
11 a great mountain of them were building up on Anne Johnson's desk. She was the lawyer
12 conducting the legal review. The issue was, is she really able to read all these reports?
13 Can she make sense of them and can, with all of her other responsibilities, can she
14 efficiently manage the process? That is what I think Richard Binns was politely saying in
15 his memo. He is saying that this is administrative stupidity. That nothing is happening.
16 He was trying to sort it out as a good manager, and he was a good manager. Knowing
17 Richard Binns over many, many years, I believe he was expressing nothing more than
18 pure irritation and frustration at an administrative procedure that is not working. And he
19 would seek to rectify that. That is the man that he is.

20 **Q. Were any changes made as a result of this memo?**

21 A. Yes, as I mentioned, Ray Thornton, a BATCo senior scientist, was asked to help
22 Ms. Johnson to move things along.

1 **Q. How long was this legal review process in place?**

2 A. I think only a couple of years. Probably through 1985 and 1986 and possibly in
3 the early part of 1987. There is no document that says, "this policy ends", but I returned
4 to the R&D center at the end of 1991 and I know for a fact that it didn't occur then or
5 since.

6 **Q. Did lawyers at BATCo or outside counsel to BATCo ever have any control**
7 **over the content of R&D reports?**

8 A. To the best of my knowledge no lawyer or legal firm has ever intervened in terms
9 of either a study design, the execution of a study, the conducting of a study, the
10 interpretation of a study, or the drawing of conclusions from a study. It has never
11 happened in my experience.

12 **Q. What role, if any, does the Legal department play currently in the review**
13 **and control of R&D reports?**

14 A. None.

1 **Q. In the course of this trial, there have been allegations that research at**
2 **BATCo and its affiliates was controlled by lawyers. Are you aware of any limitation**
3 **ever being imposed on BATCo's safer cigarette research based on legal restrictions?**

4 A. Categorically not.

5 **Q. Based on your own experience, are you aware of any limitation ever being**
6 **imposed on BATCo's safer cigarette research based on agreements within the**
7 **tobacco industry?**

8 A. Categorically not.

9 **Q. Based on your own experience, are you aware of any research that a BATCo**
10 **scientist wanted to perform that was not performed because of lawyer involvement?**

11 A. Categorically not.

12 **Q. Are you aware of any R&D research that was in some fashion changed as a**
13 **result of legal reservations?**

14 A. I have had no experience of that whatsoever throughout the 29 years I have been
15 with the Company.

16 **Q. What is the arrangement of sharing of documents among members of the**
17 **BAT group?**

18 A. Pursuant to the cost-sharing agreements, all R&D reports generated by BATCo's
19 Southampton R&D department would be available to all BAT group companies,
20 including Brown & Williamson.

1 **VII. PARTICULAR ALLEGATIONS BY GOVERNMENT WITNESSES**

2 **Q. Let's focus on some specific allegations. Dr. Jeffrey Wigand has testified in**
3 **this case that it was clear to him "that Brown & Williamson had no desire to pursue**
4 **a safer cigarette and, in fact, feared that such an effort would suggest that its**
5 **current products were not safe." [Wigand Direct at p. 14] Is this consistent with**
6 **your personal knowledge and experience?**

7 A. Absolutely not. Since the day I arrived at BATCo, nearly every project I have
8 worked on has been aimed toward either developing or assessing potentially safer
9 cigarettes. Brown & Williamson — as one of BATCo's affiliates — not only shared the
10 costs of such research, but also performed its own research geared toward safer
11 cigarettes. To say that BATCo or Brown & Williamson had no desire to pursue safer
12 cigarette research is directly contrary to my experience at BATCo for the last nearly 30
13 years. And in fact, our eminent scientific advisor, Sir Charles Ellis, in the 1960s "urged
14 that [R&D] should attempt to produce the 'safest' cigarettes based on available knowledge
15 for examination" at that time. [JD-011430] Our records clearly demonstrate that this
16 challenge was pursued continuously to the present.

17 **Q. Mr. Read I'm going to show you a memo of comment by scientist Dr. Sanford**
18 **in 1968 and I want to draw your attention to the term "Health image (health**
19 **reassurance cigarette)" and the term "Health-oriented cigarette." [U.S. Ex. 54,206]**

20 A. Okay.

1 **Q. Can you provide the context for Dr. Sanford's memo?**

2 A. Yes. He is commenting on sections in a report of an internal Research
3 Conference held in September, 1968. [U.S. Ex. 54,206]

4 **Q. With your knowledge of the relevant science, government-industry**
5 **interaction, and BATCo's research, what do you understand the term here, "health**
6 **image (health reassurance)", to mean?**

7 A. A cigarette that is low in tar and nicotine and is acceptable to consumers.

8 **Q. And what do you understand the term here, "health-oriented cigarette", to**
9 **mean?**

10 A. A cigarette with virtually no biological activity in bioassays shown to be relevant
11 to human health.

12 **Q. What, if anything, is the difference between the two?**

13 A. While the Sanford memo makes the point that these are the two types of health
14 products possible, there are differences. In the context of the conference report, the
15 science at the time, the research progress at the time and the prevailing view of low tar by
16 governments at the time, the health-oriented cigarette would be the type of cigarette we
17 have been striving to make through the technologies and research we discussed earlier
18 today. It would be a cigarette that consistently produces virtually no biological activity
19 on a battery of bioassays shown to be relevant to human health. It was a goal in 1968 and
20 remains a goal today, but, despite our serious efforts, we so far have not been able to
21 develop that cigarette. The health image (health reassurance) cigarettes are the lower tar
22 and nicotine cigarettes which were publicly supported by governments and public health

1 authorities as lower in risk. Some consumers may assume those cigarettes are somewhat
2 less risky than higher tar and nicotine cigarettes based on government and public health
3 comments, and they may well be, but the risk reduction is not as dramatic nor as
4 demonstrable as what was contemplated by aspiring to devise the "health-oriented
5 cigarette."

6 **Q. There have also been allegations that tobacco companies had some sort of**
7 **"gentlemen's agreement" not to conduct safer cigarette research. Throughout the**
8 **nearly 30 years that you have been involved in BATCo scientific research programs,**
9 **are you aware of any biological or scientific work that BATCo wanted to do, but did**
10 **not do as a result of a request made by a competitor or competing tobacco**
11 **company?**

12 A. Absolutely not. In fact, our R&D records demonstrate quite clearly the falsity of
13 these allegations. BATCo conducted a tremendous amount of biological and product
14 research, and this work was sent to Brown & Williamson.

15 **Q. Looking at JDEM-010313 and JDEM-010314, could you please provide an**
16 **overview of some of the different groups that BATCo funded over the years?**

17 A. Yes. The Scientific Research Group or SRG, for example, was very much in
18 evidence in 1985 and is still in operation today. It funds external researchers. The SRG
19 has also given money in a cooperative relationship with the British Government to fund
20 research. As I discussed earlier, the Tobacco Product Research Trust or TPRT was
21 another entity we funded. And, as shown on this chart, through the whole of BATCo's

1 research history to the present, we have supported a whole plethora of programs and
2 researchers over the years.

3 **Q. Have publications resulted from the different research activities funded by**
4 **BATCo?**

5 A. Yes, there have been numerous publications resulting from all of these
6 organizations efforts to support research.

7 **Q. Could you describe in general terms the magnitude of published research**
8 **funded by BATCo?**

9 A. I need to break that into two basic categories. The first being research that
10 BATCo itself specifically funded. In terms of these studies, from 1956 through 1997,
11 there is a documented record of over 500 publications that have been put into the public
12 domain, principally through peer-reviewed journals. The second category consists of
13 jointly funded research, either by BATCo and other UK tobacco companies, or by
14 BATCo and other tobacco companies throughout the world. In terms of the second
15 category, from 1958 through 1996, there have been in excess of 500 publications put in
16 the public domain.

17 **Q. Are you familiar with a log of publications of BATCo-funded research, which**
18 **is contained in exhibit JD-010359?**

19 A. Yes, I am.

20 **Q. And does this log reflect the 500-plus BATCo publications you have just**
21 **described?**

22 A. Yes, it does.

1 **Q.** Similarly, are you familiar with a log or listing of publications resulting from
2 research funded on a joint basis, such as by the Tobacco Research Council,
3 contained in exhibit JD-010358?

4 A. Yes, I am.

5 **Q.** And does this log accurately reflect these publications?

6 A. Yes, it does.

7 **Q.** Dr. Wigand offered sworn testimony that, “[t]he research funded by the SRG
8 while [he] was at Brown & Williamson [from 1989-1993] was never focused on
9 addiction, causation, or making safer products.” [Wigand Direct at p. 41]. Do you
10 agree with this statement?

11 A. I do not. Over the years, such projects have been funded. And, in fact, during Dr.
12 Wigand's tenure we funded Dr. Gray's nicotine addiction related work. [JD-039427].

13 **Q.** Moving to a different point, are you familiar with the Vancouver conference
14 of 1989?

15 A. I am.

16 **Q.** Dr. Wigand has testified that “[n]ot long after the Vancouver meeting,
17 Tommy Sandefur called me into his office and told me that there would be no
18 further discussions or efforts on any issues related to safer cigarette.” [Wigand
19 Direct at p. 129]. Dr. Wigand further claimed that "after the New York City
20 meeting in January of 1990, there were more and more indications that scientists at
21 Brown & Williamson would not be allowed to pursue research related to a safer
22 cigarette in the United States.” [Wigand Direct at p. 128]. Based on your personal

1 **knowledge and experience with the research programs at BATCo and its affiliates,**
2 **are these statements correct?**

3 A. Absolutely not. Safer cigarette research continued in the U.S. and U.K. and has
4 been at the forefront of BATCo and its affiliates' research efforts since I joined BATCo
5 in 1976. There was no discontinuation of this research in 1989 or 1990, nor even a
6 hiatus. The research continued.

7 **Q. Dr. Wigand also alleges that after the 1990 NYC Meeting the procedure for**
8 **the generation and circulation of R&D Reports changed because BATCo was**
9 **worried about having "contentious" material in reports circulated to other BAT**
10 **Group companies, do you have a response to that allegation? [Wigand Direct at pp.**
11 **57-58]**

12 A. Yes, if you compare two Richard Baker memos on this topic, one from 1986 [JD-
13 039417] and the other from 1993 [JD-039415], you'll see that they set out virtually
14 identical policies for the generation and circulation of R&D Reports, rebutting Dr.
15 Wigand's allegation of a change in policy after 1990.

16 **Q. Dr. Wigand also alleges that after the 1990 NYC Meeting each company was**
17 **supposed to institute a "caution in writing seminar" where the lawyers would**
18 **instruct scientists on how to sanitize the documents they created, do you have a**
19 **response to that? [Wigand Direct at pp. 59:19-60:6]**

20 A. Well, I've had various roles in the R&D function, and I've never had such
21 instruction nor have I heard of it happening. Moreover, Dr. Baker's 1993 memo makes
22 clear the procedure to be followed in writing reports is to write "in a straightforward

1 manner the objectives of the work, any background information, what was done, what
2 was found, and what the results mean." [JD-039415 at p. 13] Richard Baker was tasked
3 with instructing on how to write research reports because he was a man of distinction in
4 the scientific arena, a Doctor of Science. In the United Kingdom, a Doctor of Science is
5 a higher doctorate which is issued by a committee on the basis of a long research and
6 publication record.

7 **Q. Are you familiar with a safer cigarette project known as Project Airbus?**

8 A. I am.

9 **Q. Please explain what Project Airbus was.**

10 A. Project Airbus was basically a resurrection of the previously unsuccessful project
11 Ariel which I discussed earlier. In response to a competitor's product — R.J. Reynolds's
12 "Premier" cigarette, B&W re-visited the Ariel work and tried to revive it under the title,
13 Project Airbus.

14 **Q. Was B&W able to successfully develop Project Airbus into a commercial**
15 **cigarette?**

16 A. No it was not. Project Airbus was fraught with insurmountable technical
17 programs, and the Airbus work was eventually stopped in the United States. However,
18 the work continued for sometime at Southampton R&D as Projects Nova and Warsaw.

19 **Q. Dr. Wigand claims that Project Airbus work was discontinued and "shipped**
20 **off to the U.K.," because of alleged concerns "that any safer cigarette work that was**
21 **done in the United States would be subject to discovery and would play well into the**
22 **hands of an adversary," and that "safer meant that everything else was unsafe and,**

1 **therefore, one of the fundamental tenets of the legal defense of the industry and**
2 **Brown & Williamson was that the products never showed causality to creating**
3 **disease.” [1/31/05 Tr. (p.m.) at pp. 11704-05]. Is Dr. Wigand correct?**

4 A. Categorically not. [JD-039416] Project Airbus simply was unsuccessful. The
5 competitive product Premier was also a failure. In an attempt to salvage some useful
6 design modification from the Airbus work, it was sent to Southampton where the group
7 resources and technologies could be applied to determine whether any commercial
8 modifications were feasible. It is worth noting that based on the Ariel and Airbus
9 technology, Brown & Williamson started working on another non-combustible product,
10 Project Trump. And this research was conducted by Brown & Williamson in the United
11 States.

12 **Q. Have you seen any documents that support your rendition of these facts**
13 **pertaining to Project Airbus?**

14 A. Yes. B&W R&D documents from March 1989 clearly make the points that
15 Project Airbus was being discontinued at Brown & Williamson R&D because, despite
16 extensive research, it was not technologically feasible and the fundamental research work
17 would be transferred to BATCo. [JE-053344].

18 **Q. Dr. Wigand testified that Brown & Williamson added sugar to its products to**
19 **increase smoke acetaldehyde. Has BATCo’s research addressed whether**
20 **acetaldehyde is produced in cigarette smoke as a result of sugar addition?**

1 A. Yes, we have, and it does not. Dr. Massey examined this for us in the 1970s and
2 concluded that acetaldehyde is produced from the combustion of cellulose not from sugar
3 additives. [JD-011164]

4 **Q. Has BATCo researched whether acetaldehyde in smoke reaches the brain of**
5 **smokers?**

6 A. Yes. Dr. Dixon of BATCo researched and published on this topic and concluded
7 that smoking does not increase acetaldehyde levels in the blood of smokers and that
8 acetaldehyde from smoke does not cross the blood/brain barrier. [JD-031677]

9 **VIII. BATCO'S DE MINIMIS U.S. BUSINESS**

10 **Q. Finally, Mr. Read are you familiar with any BATCo products that are**
11 **offered for sale in the United States?**

12 A. Yes. State Express 555 is the only BATCo brand sold in the United States.

13 **Q. What is the current volume for State Express 555?**

14 A. Volumes have been going consistently downward overtime from a very low
15 number to a current market share of less than .02 percent of the U.S. cigarette market.

16 **Q. Is State Express 555 unique compared to most other cigarettes available in**
17 **the U.S.?**

18 A. Yes. State Express 555 is an English style cigarette, which means it is made from
19 flue-cured tobacco with virtually no additives. This style of product is quite different in
20 taste from a U.S. blended cigarette, which includes different tobacco types and additives.
21 This probably explains why State Express 555 is simply not popular in the U.S. BATCo
22 manufactures State Express 555 for sale in the U.S. market primarily for brand visibility

1 for those foreign smokers who might expect to find the brand in the U.S., such as visitors
2 and immigrants from countries where State Express 555 is popular.

3 **Q. So, because it is an English style cigarette, does that mean that BATCo does**
4 **not use either sugar or ammonia additives in the manufacture of State Express 555?**

5 A. That is correct.

6 **Q. Going forward, what involvement, if any, will BATCo have in the U.S.**
7 **cigarette market?**

8 A. I don't see how BATCo will have any involvement in the U.S. cigarette market in
9 the foreseeable future. The BATCo brand cigarette is down to about less than .02%
10 market share here, and any support for that brand would be provided by its distributor,
11 Lane. Furthermore, while Brown & Williamson had been an important part of the BAT
12 Group, going forward Brown & Williamson will have no involvement in the U.S.
13 cigarette market. Brown & Williamson sold all of its U.S. related cigarette business
14 assets to Reynolds American last summer and now that is part of R.J. Reynolds Tobacco.
15 Going forward, British American Tobacco, plc is an ultimate minority shareholder in the
16 company that owns the former Brown & Williamson U.S. business, of which BATCo
17 owns no part.

18 **Q. Thank you, Mr. Read. No further questions.**