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-CV-2496 (GK)

UNITED STATES' WRITTEN DIRECT EXAMINATION OF

ALLAN M. BRANDT, Ph.D.

SUBMITTED PURSUANT TO ORDER #471

Q: Can you please state your name for the record?

A: Allan M. Brandt.

Q: Dr. Brandt, what is your current professional position?

A: I am the Amalie Moses Kass Professor of the History of Medicine at Harvard Medical School and Professor of the History of Science at Harvard University, where I am currently the chair of the Department of the History of Science.

Q: Have you been retained to testify as an expert witness in this case?

A: Yes, I have.

Q: Before we address the substance of your expert opinion, let us ask you a bit about your educational and professional background. First, where did you receive your professional education?

A: Following my graduation from Brandeis University in 1974, I began doctoral work in history at Columbia University.

Q: For what reason, if any, did you choose to pursue your Ph.D. at Columbia?

A: I selected Columbia because it had a particularly distinguished faculty, especially in the area of American social and political history during the twentieth century.

Q: Did you study with anyone in particular at Columbia?

A: I did. My principal advisor and mentor throughout my graduate education was William E. Leuchtenburg, a well-known and distinguished historian of the United States in the twentieth century.

Q: Did you concentrate on any specific areas within the field of American social and political history while you were at Columbia?

A: In my first year at Columbia, I wrote a master's thesis on the history of city

planning and soon became intensively interested in the history of American medicine.

Q: Was there a reason that you became interested in the history of American medicine?

A: Yes. During the mid-1970s historians were becoming engaged in the investigation of the history of everyday life: how people lived in families and communities and the character of social experience. These questions often had not been explored in traditional political, economic, and diplomatic historical accounts.

Q: While you were at Columbia, did you pursue these questions within the framework of the history of American medicine?

A: Yes. I began to explore how I might utilize the history of medicine to offer new insights into such common experience. I soon found myself taking the subway up to the Columbia College of Physicians and Surgeons where their excellent library provided me with a wide array of materials now principally of interest for their historical value. I found that the primary historical materials there – old medical journals, books, and pamphlets now relegated to the basement of the library – constituted a remarkable set of resources for recovering important elements about the past, especially as it related to the social experience of disease and social responses to disease. I became especially committed to exploring and understanding how the incidence of epidemic and chronic diseases could reveal central aspects of society, medical care, and professional relationships. This work was not unique. I was influenced by – and soon became part of – a group of medical historians who were actively re-orienting the field of medical history to make it a central aspect of American social and cultural history. By understanding experiences such as childbirth, aging, diseases, and health-seeking,

historians could make substantial contributions to a deeper understanding of American (and other nations') history.

I also became increasingly interested in the history of medical knowledge and the processes associated with its development, evaluation, and application. I began to conduct research on the historical processes of acquiring new medical knowledge, experimentation with human subjects, and the foundations of clinical knowledge and practices.

Q: Was this area of interest part of your degree program at Columbia?

A: Yes, it was. As a result of my strong interest in these areas, I developed a specialized field in the history of American medicine for comprehensive exams that were part of my graduate studies as well as preparing in the traditional areas of American political and social history (from the colonial period to the present). I read widely in both the traditional history of medicine (which centered on the progressive development of medical and scientific knowledge) as well as new works in the social history of medicine (which centered on the history of disease), and upon the successful completion of my comprehensive exams, I was awarded an M.Phil degree by Columbia in 1978.

Q: Did you publish any papers in the area of medical history while you were at Columbia?

A: Yes. While I was a graduate student, I published two scholarly, peer reviewed papers that attracted considerable interest. As a result of my growing interest in medical history and medical ethics, I spent the summer of 1977 as an Intern at the Hastings Center. The Center was established in 1969 as the first organization in the nation to focus academic and public attention on a series of critically important ethical debates in

medicine and society. I spent most of my time that summer conducting research on the history of the use of human subjects in medical research. In particular, I began an intensive investigation into the Tuskegee Syphilis Study. The Study had attracted considerable notoriety in 1972 when it was first exposed in the public press. As a result of these initial revelations, the Department of Health Education and Welfare had appointed a committee to investigate the charges of abuse of human research subjects that the press reports raised. Unfortunately, this committee never reviewed the historical records of the Study which had been preserved at the National Archives. I became aware of these materials when conducting initial research for my doctoral dissertation. They were so significant, and added so much to the very preliminary and incomplete account offered by the HEW investigation, that I briefly put aside my doctoral work to thoroughly investigate the history of the experiment.

My article on the Tuskegee Syphilis Study, which originally appeared in the *Hastings Center Report*, one of the nation's premier journals of medical ethics, has been widely reprinted since it was first published in late 1978. This article offered a historical assessment of why the study took place and how it continued for 40 years from 1932 to 1972. In this instance the men in the study, poor African American sharecroppers, had been told that they were receiving expert care from government physicians. In reality, the researchers worked to assure that the men did not receive treatment in order to study the effects of untreated syphilis. I evaluated how such fundamental breaches in prevailing medical ethics could occur.

Q: Outside of the article being reprinted, has your work in this area attracted any other attention?

A: Yes, it has. As a result of this work, Senator Kennedy wrote to the Secretary of HEW, Patricia Harris, requesting a further inquiry into the Study. Jay Katz, a physician and member of the Yale Law School faculty, who had been a member of the original HEW committee, invited me to visit him at Yale to review the documents I had discovered in the archives and cited in my work. He was shocked that his committee had not been provided with these materials and wrote in protest to Senator Kennedy and others. Ultimately, in 1997, President Clinton issued an official apology to the survivors of the study.

Q: Did the work on Tuskegee contribute to your expertise as a historian?

A: I believe that it did. In the course of working on this article and my subsequent research for my doctoral dissertation, I developed considerable experience in the use of government records and the National Archives specifically. Much of the material I used, both in my article on Tuskegee and in my doctoral dissertation, had never before been explored by historians, or for that matter, any researcher. I became highly expert in the use of published and unpublished sources in the medical and public health areas.

Q: You mentioned that as a graduate student you published two scholarly, peer reviewed papers that attracted considerable interest. Can you describe the second one?

A: I published an article on the history of the Salk polio vaccine. The Salk vaccine was widely recognized as one of the great triumphs of twentieth century medical research. As a result of my emerging interest in the history of human subject research, I became aware of the significant historical and ethical issues associated with the testing of this vaccine. The Salk trials were one of the largest medical experiments in modern

history, and I was eager to understand precisely how they had been conducted, and how the ethical issues of utilizing children in a research study had come to be considered.

Q: What was the significance, if any, of the article on the Salk vaccine for ongoing medical research?

A: The article on testing the Salk vaccine, like the article on the Tuskegee Study, raised important issues about the process by which medicine would utilize research subjects in order to attempt to develop new scientific findings. These two articles broke new ground in identifying the ethical debates in medicine as potentially important areas of historical research. They also centered attention on certain methodological considerations about the nature of presentism, historical context, and especially historical contingency.

Q: Dr. Brandt, did you write a doctoral dissertation at Columbia?

A: Yes, I did.

Q: Can you describe your dissertation topic?

A: Certainly. After considering a number of topics for my dissertation that would let me explore critically important questions about the nature of disease and society in the twentieth century United States, I eventually decided to concentrate my attention on the history of sexually transmitted diseases. My interest in this area preceded the HIV epidemic; I conducted a comprehensive investigation of the history of syphilis and gonorrhea in order to examine changing medical knowledge and the social meanings that had aided or inhibited the successful management of these diseases in clinical medicine, public health, and the military. Although my dissertation covered many areas, I focused on understanding why these diseases persisted so significantly in the face of the

development of remarkably effective treatments.

Q: Did you reach any conclusions as to the question of why the diseases persisted so significantly?

A: Yes. Ultimately, I wrote a dissertation that focused on aspects of the history of sexuality and sexual mores and how the social attitudes and values associated with these diseases had become a principal obstacle to the treatment of STDs in spite of the historical development of impressively effective treatments. It was for this reason that I entitled the book which came from a revised version of my dissertation: *No Magic Bullet*.

Q: When did you complete your dissertation?

A: 1983.

Q: Did you receive a doctoral degree from Columbia?

A: Yes. Upon completion of the dissertation, I received my Ph.D. from Columbia in 1983.

Q: What type of research did you undertake in order to write *No Magic Bullet*?

A: As noted, I had developed an especially strong commitment to the utilization of historical archives in my work as a graduate student. The book made extensive use of public health and military archives at the National Archives, as well as substantial unpublished materials in a number of other archival depositories. For example, I spent a considerable amount of time doing research in the Social Welfare History Archives Center at the University of Minnesota, which holds archival materials from the American Social Health Association, a national organization that addresses problems of sexually transmitted diseases that was founded in 1912.

Q: Was *No Magic Bullet* published?

A: Yes, it was published in 1985.

Q: What type of response did the book receive after its publication?

A: Upon its publication in 1985, *No Magic Bullet* was widely noted and read; a second edition appeared in paperback with a new chapter on AIDS in 1987. Many reviewers of *No Magic Bullet* observed the depth of the research, especially in archival materials. Its publisher, Oxford University Press, nominated it for a Pulitzer Prize and the Bancroft Prize, a well-known book prize in American history. The book was also selected as a finalist for the *Los Angeles Times* Book Award. The book has come to be widely used in college courses in medical history; American history courses, as well as courses in emerging fields like the history of sexuality. *No Magic Bullet* is now in its twelfth printing.

Q: Is that typical for published works in your field?

A: I think it is atypical. For a scholarly book in the history of medicine, *No Magic Bullet* attracted considerable interest and has been widely read. Coming as it did in the early phase of the HIV epidemic, public health officials and policy makers sought to utilize the narrative and analysis I had developed to seek insights into the important medical and policy debates surrounding HIV. For example, I was often asked to help assess the role that traditional contact screening programs for syphilis had played in the history of that disease and to evaluate their possible utility for addressing HIV.

Q: Would you describe that as a policy question?

A: Yes, I would.

Q: And from that point – the publication of *No Magic Bullet* in 1985 – forward, have you addressed policy questions in the course of your work as a medical

historian?

A: Yes. In many ways the next phase of my career led me to become more significantly involved in questions about how best to use history in the public sphere. I testified, for example, before both the Reagan and the Bush Presidential HIV Commissions. And I served on two important committees at the National Academy of Sciences Institute of Medicine (IOM) that examined critical aspects of the HIV epidemic. The first examined the social impact of HIV disease on American society. The second examined the complex issues associated with the contamination of the U.S. blood supply in order to make recommendations to avert future problems. In both instances, I participated in the collaborative process of writing portions of the published reports which came from these interdisciplinary study committees.

Q: Did you also continue to publish in the same subject area?

A: I did. During the 1980s and early 1990s I published a number of articles on both the history of STDs and the implications for HIV disease, as well as papers on specific HIV policies. For example, I published major articles in leading peer reviewed journals such as *Science* and the *American Journal of Public Health*. A central aspect of this work was the notion that historians of medicine could bring important findings and insights to a wider range of medical, public health, and policy issues. I also participated in several important collaboratively authored papers in the area of health policy that appeared in the *Journal of the American Medical Association* and the *New England Journal of Medicine*. These articles evaluated the problems with HIV premarital screening, as well as issues associated with screening of immigrants.

Q: During this period after completing your dissertation, were you doing

anything professionally other than research and publication?

A: Yes. In fact, I started teaching prior to completing my dissertation. In my final semester at Columbia, as I was completing my dissertation, I was offered an excellent one semester appointment in the Department of History at Smith College. At Smith I taught an undergraduate survey course in American history since the late nineteenth century, and a seminar course on the United States since 1945. Both courses provided me with an important opportunity to consolidate and define my graduate work in American history, as well as to design and implement sophisticated college level courses.

Q: Did you continue teaching after the semester appointment at Smith?

A: I did. After my semester at Smith College, I joined the Harvard faculty as an assistant professor in the summer of 1982. The position was as a historian of medicine and was split between Harvard Medical School and Harvard's Department of the History of Science. This was a somewhat unusual joint appointment in that it required teaching medical students, undergraduates, and doctoral students. It was also unusual in that it was not principally in either the medical or the arts and science faculty; it was a full-time joint appointment.

Q: Can you explain more about what the joint appointment involved?

A: In this position I had the opportunity to develop a range of original (and innovative) courses for students in a variety of programs. I developed a course for medical students that centered attention on changes and continuities in the practice of medicine. The course examined critical shifts in medical knowledge and inquiry; changing medical technologies; medical institutions for patient care and education; as well as important changes in public health and epidemiology. A major aspect of my work

with medical students has been and remains to demonstrate the relevance and utility of the history of medicine for understanding current medical practice and policy.

My position at Harvard Medical School also offered an unusual opportunity to join with other faculty in exploring the social and behavioral determinants of disease. Our Department of Social Medicine at Harvard Medical School, one of only 3 or 4 in the country, draws together social scientists whose work centers on social forces in the production of disease; the social meanings of diseases; and social responses to disease. The Department also centers attention on the patient-doctor relationship and core issues in medical ethics and health policy.

Q: Can you provide examples of other courses that you have taught at Harvard?

A: As a member of the Faculty of Arts and Sciences, during the mid-1980s I developed a course called Medicine and Society in America as part of Harvard's Core Curriculum. Core courses have a significant degree of peer review (something quite unusual for the most part in university teaching) in that syllabi and course materials are submitted to a committee of senior professors to evaluate both the content and the pedagogy associated with the course. At the time, it was quite unusual for a junior faculty member to be approved to offer a course in the Core Curriculum, which fulfills a key distribution requirement for Harvard undergraduates.

I have continued to offer this course regularly at Harvard since 1988, except for a brief period when I taught at the University of North Carolina in the early 1990s. The course offers a synthetic survey of central themes relating to patterns of disease in North America since the discovery of the New World. It examines historical epidemiology and demography; changing concepts of therapeutics; the history of attempts to address

epidemic disease; the rise of public health institutions; and the history of medical education and professionalism. Further it traces what has widely come to be known as the epidemiologic transition: the shift in the twentieth century from the predominance of infectious diseases to the predominance of systemic chronic diseases such as cancer and heart disease. I have now offered this course eight times and continue to revise it each time it is offered. It is probably the largest history of medicine course offered anywhere in the United States, with 200-300 enrollees in a typical year.

Q: You mentioned the University of North Carolina. How long were you there?

A: In 1990 I accepted a position at the University of North Carolina, where I spent two years in the Department of Social Medicine and the History Department. At the time, there was no opportunity for me to be promoted to a tenured position at Harvard, and I opted instead to take the position at UNC. UNC has among the best Departments of History and Social Medicine in the country. Shortly after leaving for UNC, however, a new position was endowed at Harvard in the history of medicine.

Q: When, specifically, was that?

A: 1992. In 1992, I was appointed as the Amalie Moses Kass Professor of the History of Medicine with a full joint appointment in the medical faculty and the faculty of arts and sciences. This named chair was the first in the history of medicine at Harvard.

Q: With the endowed position and joint appointment, have you continued teaching at both the medical school and the arts and sciences department?

A: Yes, I have. Since my appointment I have taught extensively in both faculties. Specifically, I direct a joint program in the history of medicine that brings together faculty and students from the arts and sciences and the medical school.

Q: Have you held any other appointed positions at Harvard?

A: Yes. First, in 1997, at the request of the Dean of the Medical School, I accepted the appointment as Director of the Division of Medical Ethics. This appointment reflected both my ongoing interest in medical ethics as well as my research work on the history of medical ethics. The Division of Medical Ethics has principal responsibility for teaching and research in this field at Harvard Medical School. The program is diverse and includes a post-doctoral fellowship, medical education, an instructional program to enhance scientific integrity, and a wide range of public programs. The Division also holds monthly meetings to discuss ethics case consultations in the Harvard teaching hospitals. After my seven years in this position, the medical school appointed its first full professor of medical ethics in 2004 who has recently assumed the responsibilities as director of the Division of Medical Ethics.

Second, in 1999, I became chair of the Department of the History of Science in the Faculty of Arts and Sciences, a position I continue to hold. As chair, I have principal responsibility for overseeing our undergraduate major, our doctoral program, curriculum and teaching in the Department. I also serve as a principal advisor to doctoral students working in the history of modern medicine and have taught a number of outstanding students over the last two decades who have gone on to have important scholarly careers.

In addition to this administrative role, I have served on a large number of departmental, school-wide, and university wide committees. I have been elected to the Faculty Council of the Faculty of Arts and Sciences and to the Faculty Council at Harvard Medical School. These administrative committees advise the Deans on policy and curriculum in their respective schools.

Q: Has your scholarly research continued during your teaching career?

A: It has, and it expanded beyond my early focus on sexually transmitted diseases. At Harvard, I became increasingly interested in conducting a major project on the history of cigarette smoking in the United States.

Q: Why did you become interested in such a project?

A: There were a number of factors that indicated to me that this would be a project of potentially great importance. First, by the time I began this work in the late 1980s, it was already clear how important cigarettes were as a major cause of disease and death. Given my strong interest in social and behavioral determinants of disease, I understood that cigarettes would provide an important avenue for understanding important social, cultural, scientific, medical, and public health developments of the twentieth century. In this sense the project was consistent with my commitment to utilizing aspects of the history of medicine to better understand American social and cultural history. Moreover, given the significance of tobacco-related disease, I was eager to understand the history of public health policy and politics associated with the control of tobacco. Finally, I believed the project would demonstrate the importance of the history of medicine and science to contemporary public health policy. In evaluating this topic, I also quickly came to the conclusion that it could be sustained by an impressive volume of primary sources, both published and unpublished.

Q: Have you published on the history of cigarette smoking?

A: Yes. Over the last decade, I have published more than fifteen peer-reviewed essays and articles on the history of cigarette smoking. And I have now nearly completed a book length manuscript on the history of cigarette smoking over the last century. The

book will be based upon intensive research in published and unpublished sources. This includes a wide array of primary and secondary materials including newspapers and magazines, advertisements, and medical and scientific literatures.

Q: Have you reviewed internal tobacco industry documents as part of your research?

A: Yes, I have, although when I began the project at the end of the 1980s, there were few archival materials available to evaluate the role of the tobacco industry in relation to the promotion of cigarettes, the science of tobacco and medical research, and American politics. As a result of the recent tobacco litigation and the discovery of millions of pages of company material now in the public domain, I have had the opportunity to extensively investigate the tobacco industry's reaction and response to scientific data implicating cigarettes as an important cause of serious disease as well as their ongoing efforts to deny and obfuscate the emerging science of the harms of smoking.

Q: Before we come back to the subject of the tobacco industry, let's talk a bit more about your professional background. Have you received any honors and awards?

A: Yes. Over the course of my career, I have received a number of honors and recognitions. In 1997, I was elected to the Institute of Medicine of the National Academy of Sciences (IOM). The IOM is made up of individuals whose work has made important contributions to medicine, science, and public health policy. There are only five other historians whose work has been recognized in this way. Membership in the IOM is not, however, exclusively honorific. Rather, members serve on committees and panels that evaluate important aspects of medicine and public health.

I have also been elected to the American Academy of Arts and Sciences (AAAS). The AAAS is the oldest academic society in the United States. It was founded in 1780 by Thomas Jefferson and Benjamin Franklin among others and recognizes distinguished figures in academic and public life.

In addition, I have received funding to support my research and writing from a number of private foundations: these include the Rockefeller Foundation for the Humanities, the Culpeper Foundation and the Burroughs-Wellcome Fund. These grants have supported work on the history of cigarette smoking and other historical projects I have been conducting.

In 2003, the Flight Attendants Medical Research Institute selected me as a Dr. William Cahan Distinguished Professor, their highest honor. This award provides me with research funding to pursue my work on the history of tobacco and public health policy.

I have also been elected to membership in the Massachusetts Historical Society, and I am a member of several historical professional associations including the American Historical Association, the Organization of American Historians, the History of Science Society, and the American Association for the History of Medicine. Each of these organizations holds annual meetings, and I have been a frequent participant, delivering papers and offering commentaries on other scholars' work.

Q: Dr. Brandt, I'd like you to take a look at the document that has been marked as U.S. Exhibit 78,546. Do you recognize this document?

A: I do. This is a copy of my curriculum vitae as of October 2002.

Q: Dr. Brandt, does exhibit 78,546 accurately reflect your professional

appointments, fellowships and awards, professional service, University committees, memberships, major research interests, current projects, books, articles and book reviews as of October 2002?

A: It does.

Q: In order to bring us up to the present date, what additions are there to your curriculum vitae as marked as exhibit 78,546?

A: The principal changes in my CV since October 2002 would be the addition of several new publications:

Brandt, AM. "Difference and Diffusion: Cross-Cultural Perspectives on the Rise of Anti-Tobacco Policies," in *Unfiltered: Conflicts over Tobacco Policy and Health*, Eric A: Feldman and Ronald Bayer, eds. (Cambridge: Harvard University Press, 2004);

Brandt, AM. "From Analysis to Advocacy: Crossing Boundaries as a Historian of Health Policy," in *Locating Medical History: the Stories and Their Meanings,* Frank Huisman and John Harley Warner, eds. (Baltimore: Johns Hopkins University Press, 2004); and

Brandt, AM. "From Nicotine to Nicotrol: Addiction, Cigarettes and American Culture," in *Altering American Consciousness: Essays on the History of Alcohol and Drug Use in the United States*, Sarah W. Tracy and Caroline J. Acker, eds. (Amherst: University of Massachusetts Press, 2004).

I also have two forthcoming publications:

Brandt, AM. "Engineering Consumer Confidence in the Twentieth

Century," in *Smoke: A Global History of Smoking*, Sander L. Gilman and Xhou Zun, eds. (London: Reaktion Books, forthcoming); and

Brandt, AM. "The First Surgeon General's Report," in *A Safer and Healthier America: Public Health Achievements in the 20th Century*, John W. Ward and Christian Warren, eds. (New York: Oxford University Press, forthcoming).

In addition, I have served (or am currently serving) on several additional committees at Harvard. These include the University Committee on Alcohol Use (Faculty of Arts and Sciences), the Faculty Advisory Committee on Resources (Harvard Medical School), the Harvard Medical School M.D./Ph.D. Committee in the Social Sciences, and the Harvard Program in Ethics and Health (Steering Committee).

Q: Dr. Brandt, in addition to publishing your written work, have you presented your research through speeches and lectures?

A: I have. I have spoken widely in the United States and abroad about my historical work. Most recently, I gave the Edward Kass Lecture at the Wellcome Institute for the History of Medicine in London. In addition, I have on occasion appeared in the media to discuss my research and other questions relevant to the history of medicine. My work on Tuskegee was featured in a segment of NOVA on PBS, and I have appeared in other documentary films and news programming. I have, for instance, appeared on 20/20 to discuss my work on STDs.

Q: Have you ever testified as an expert witness before?

A: I have not.

Q: In any subject area, tobacco or otherwise?

A: That is correct. I have never before testified in any litigation. Although in the past both plaintiffs and defendants approached me to testify, I had been concerned that the courtroom might not be the best context in which to present my historical findings. My preference was to produce work on the history of tobacco and tobacco policy that would be subject to traditional scholarly assessment and peer review. I did however follow carefully the development of tobacco litigation through the 1990s. The litigation was of considerable interest to me in part because the legal arguments depended on historical assessments of scientific knowledge regarding the harms of smoking. Moreover, it was of great importance to my research because it began to produce a remarkable archive of industry materials on questions of great significance in the history of cigarette smoking.

Q: Why did you agree to serve as an expert witness in this case?

A: In early 2002, lawyers for the US Department of Justice visited me at Harvard to discuss the case and my possible involvement as an expert witness. Although I had previously declined all such participation, in this instance I agreed to reconsider. The government lawyers shared with me expert statements that had been prepared in the case by historians of medicine (English, Ludmerer) and an American historian (Wilson) that I found to be grossly inadequate and poorly researched. As a result, I reassessed my position about testimony. By that time I had published a good deal about the history of tobacco, so I believed any opinions I offered in the case could be evaluated against my substantial record of publication.

Q: Are you being compensated for the time you work on the case?

A: I am. I am being compensated at a rate of $350 per hour for my work on the case.

Q: Before we discuss your specific opinions, can you describe, generally, the work of a professional historian?

A: Yes. I think it is appropriate as a general description to say that historians are committed to developing sophisticated explanations of the events of the past. We are eager to produce narratives of past occurrences and peoples that are comprehensive and nuanced. In seeking to understand historical change, we make sure to take into account the range of important variables. If historical methods are systematically and rigorously applied, it is possible to arrive at interpretations and conclusions that are both persuasive and authoritative, and that meet professional standards of evidence and objectivity.

Q: Do historians specialize in certain areas within the field of history?

A: Yes. Although historians do possess a series of common approaches to historical change, as in most academic fields, there is a good deal of specialization among historians today. A specific area of inquiry becomes an important basis for our research and writing, and we gain familiarity and depth of knowledge in our particular area of expertise.

Q: Can you give me an example of an area of specialization?

A: Yes, I can. The history of science and medicine is an example of this specialization. Historians of medicine and science like myself have come to focus our studies on the nature of scientific and medical change. We are especially interested in how scientific knowledge is developed and the impact it has on the practice of medicine and the public health policies. Further, we seek to understand the impact of medical knowledge on patterns of health and disease. Just as a diplomatic historian of the 20th century might not be familiar with materials associated with studying the Civil War, so in

the area of the history of medicine, a historian who specialized elsewhere would not have the critical depth of knowledge necessary to fully interpret historical sources in the field. It is crucial to have a strong background in the medical and public health literature, the sociology of scientific practices, and the social context of scientific and medical change. This training and experience is critical for establishing the specific contexts in which historical events in medicine and science occur, as well as evaluating important aspects of change and innovation.

Q: How does a historian approach a historical issue like the health consequences of smoking?

A: Across the historical disciplines, there is actually considerable consensus about the specific skills, methods, and orientations to historical research, argument, and interpretation. Among the goals of historical research is to root events in the specific times and cultures in which they occur, and therefore to evaluate source materials in the specific context in which they were produced. In this respect, we work to avoid applying the standards or values of our own times back into the past (what historians refer to as presentism).

Q: Does the evaluation of source materials involve anything more than the collection and assembly of facts?

A: Yes, much more. Historians do not simply collect facts (although we have great interest in facts and truth). Rather, we are eager to account for the character of historical change and to develop sophisticated and comprehensive explanations that elucidate the range of forces affecting change over time. This requires us to develop precisely-framed questions that are broadly analytic and to develop carefully reasoned and substantiated

conclusions based on relevant evidence. Our conclusions must be explicitly directed to the questions that we pose. For example, a historian might research the causes of the Civil War. Such a project, however, would require the framing of a series of explicit questions about those factors that are presumed (at the outset of the investigation) to be significant. How would the recognition that there are multiple causes be assessed? And on what basis will each possible cause be evaluated for its relative significance? The character of the questions framed will in part dictate the research agenda.

Q: Can you provide an explanation of what you mean when you indicate that "the character of the questions framed will in part dictate the research agenda"?

A: Certainly. Historical interpretations are based on an extensive process of collecting evidence and its critical and careful evaluation. In conducting historical research it is crucial to examine the widest range of materials from diverse sources. Otherwise, making important historical judgments about the representativeness and relevance of particular sources becomes extremely problematic. No historian can possibly review all the materials associated with a particular investigation. This is especially true in research on 20th-century topics where there is often a profusion of potentially relevant materials. Nonetheless, it is important in evaluation of the quality of a historian's conclusions to ask if they are adequately comprehensive in their research approach to well-framed questions.

Q: How do historians address new materials that are identified for an area of research?

A: Historians continually test their understanding and interpretations against new materials. With each new document they recover and review, they make an assessment

of how it sustains, modifies, or contradicts their current understanding of the question they are investigating. Evidence that appears to contradict any particular interpretation is crucial and needs to be explained fully. Since historians focus their work on change over time, it is important that they introduce themselves to a wide range of sources in both the published and unpublished literatures over an appropriate expanse of time. Historians typically begin a project by identifying those primary source documents—materials produced by historical actors at specific points of time—that will be critical to their investigation and dependent on their particular questions. This strategy permits them to assess a public record and public knowledge in light of what historical actors were doing and saying privately and informally among colleagues and confidantes.

Q: Does a professional historian bring expertise to these assessments?

A: Yes. Historians develop considerable expertise in the analysis of different types of historical sources. They work to locate and contextualize any particular document under investigation.

Q: How is this accomplished?

A: As one example, a scientific article published in a medical journal will be critically reviewed in specific ways. What are the characteristics of the particular journal and what is its significance? Who reads this particular journal? What are the processes of publishing (peer review, specialists, etc.)? On the other hand, archival memoranda and letters would be scrutinized in different ways. Who is the author and what is his or her standing in the institution in question? Who is the audience for the document? What does the document reveal about its author and his/her perspective? Without careful contextualization, these questions would be difficult to answer fully and correctly.

Q: Are secondary sources also a part of historical investigation?

A: Yes, they are. Historians utilize what are commonly called secondary sources when seeking to develop a comprehensive understanding of what other historians and scholars have previously written about the area they are investigating. Such secondary sources offer important guides into primary materials, as well as an indication of prevailing historical interpretations and arguments. These materials offer an opportunity as well to see how primary sources have been effectively used, and where additional research is required. Finally, in critically assessing secondary sources, historians frequently identify new and unexplored questions for additional research.

Q: In historical investigation, what follows the identification of questions and the conduct of research?

A: Following the development of explicit questions and comprehensive research, historians typically develop interpretations and conclusions that are directly responsive to the questions at hand. This process of developing and presenting arguments is a central aspect of historical reasoning and scholarship. We are generally interested not only in what happened, but why it happened in the way it did. Our ability to offer persuasive accounts of historical developments rests heavily on our effective use of evidence (based upon research) and our ability to marshal this evidence in support of interpretive claims and generalizations. Ultimately, peers critically evaluate historians' interpretations as presented in books, scholarly journals and public forums. It is one thing to hold a particular historical position, quite another to seek its publication where it will receive critical assessment. Peer review, therefore, is a crucial aspect of historical work because it subjects our arguments, findings, and interpretations to the scrutiny of accomplished

and proficient scholars and the public.

Q: How have you framed questions in your own work on the history of cigarette smoking in the United States?

A: I began this project as a result of my assessment of the impact that cigarettes have had on patterns of disease over the course of the last century. I felt it would be important to understand from a historical viewpoint the emergence of cigarette smoking as a popular behavior, the rise of medical and scientific understandings of the harms caused by smoking, and the responses to this knowledge on the part of the tobacco industry, and public health officials. When I began this work in the 1980s, it had already become very clear that tobacco had a dramatic impact on patterns of disease in the twentieth century. As a result, I was eager to understand several important historical questions. First, when and how had cigarette smoking become such a popular behavior in American society? Second, what was the nature of scientific knowledge about the harms of smoking during the course of the twentieth century? Third, how did this knowledge change over time and what were the processes of its development? Fourth, what was the relationship of scientific knowledge to public policy and regulatory initiatives?

I was also eager to understand the character of the controversy about the harms of smoking that came about in the 1950s. My question was not, was there a controversy, but rather what was the nature of the controversy. Who were the parties engaged in the controversy? What were their particular positions and interests? What were the obstacles to resolving this controversy? What interests would be served by its resolution?

Q: How have you addressed these questions?

A: To approach these questions I have relied on explicit and specific historical

methodologies. Understanding the rise of cigarette consumption and its health implications, as with any historical development, requires the collection and evaluation of evidence and the development of careful conclusions that are fundamentally based on the substantiating materials.

Q: Can you describe, generally, that evidence?

A: Yes, I can. In my research I have attempted to be as comprehensive as possible. I have reviewed a large volume of published and unpublished source materials, both primary and secondary. In the case of cigarette smoking these materials range from papers in medical journals, the popular press, public health reports, newspapers, advertisements, and other documents produced by the industry, by the government, and other institutions. Since I have been investigating the history of cigarette smoking and its health impacts for more than a decade, I have now had the opportunity to read and study closely an expansive literature, as well as review many archival materials.

Q: Can you describe the sources for these materials?

A: Yes. When I began this project, among the first places I did research was the National Archives. I had considerable experience working with materials in the National Archives from my earlier historical investigations of the history of sexually transmitted diseases. The National Archives housed the archival materials from the 1964 Surgeon General's Advisory Committee, and I spent a good deal of time utilizing these documents to account for the development of the Surgeon General's Report of 1964. In 1986, I also visited the Tobacco Institute, located in Washington, D.C., to investigate if they possessed historical materials that would assist in my research. At that time, an employee of the Tobacco Institute explained that their materials were not open to outside

researchers. But as a result of subsequent litigation and materials discovered in this case, there is now a remarkable volume of internal industry material that sheds important light on the history of research into the health risks associated with tobacco; the strategies of the industry for marketing cigarettes; as well as the industry's internal and sponsored research programs. As part of my research, I have spent considerable time reviewing and analyzing these documents. In the course of my historical investigations on the history of tobacco I have utilized a number of additional, important archival collections, including those of Harvard University (William Cochran); the Countway Library at Harvard Medical School (J. McKeen Cattell), the University of Maine (C.C. Little); Washington University, St. Louis (Evarts Graham); the Wisconsin Historical Society (Bruce Barton, John W. Hill, Robert Lasch, M.V. O'Shea); the Alan Mason Chesney Medical Archives at the Johns Hopkins Medical Institutions (Lewis Robbins); University of Washington, Seattle (Warren Magnuson); the Library of Congress (Edward Bernays, Harvey Wiley); Yale University (Chester Bliss, Lester Savage); Duke University (the John W. Hartman Center for Sales, Advertising and Marketing History); the Smithsonian (NC Ayer Collection, The Warshaw Collection of Business Americana); the National Library of Medicine (Stanhope Bayne-Jones); and the National Archives (The Surgeon General's Advisory Committee).

Q: Are there other archival materials that were relevant to your research?

A: Yes. In the preparation of this testimony, as well as in my ongoing research on the history of cigarette smoking, I have made extensive use of the on-line archives of tobacco industry materials. These archives, which are searchable through a number of web-sites, make accessible a wide-range of materials, both published and unpublished,

relating to tobacco in the twentieth century. Placed on the web following the litigations of the 1990s, these collections include a vast number of internal industry correspondence, reports, and memoranda on a range of industry activities and programs. Additionally, the industry collected a wide array of published materials including medical, scientific, and popular articles that are found in their records. According to most estimates, there are more than 40 million pages of tobacco documents now available online. Unlike the majority of non-digitized archival materials, these records are generally searchable through the web. Among the main websites are: Tobacco Documents Online (http://www.tobaccodocuments.org), which was set up by Michael Tacelovsky in 1999, and the Legacy Tobacco Documents Library (http://legacy.library.ucsf.edu), which was established at the University of California, San Francisco in 1994. Both of these websites are grant-supported, primarily from the National Cancer Institute and the American Legacy Foundation, respectively.

Q: How are archives important to the work of a historian?

A: Archival records are critical to historical work in a number of ways. Archival collections typically hold correspondence, memoranda, minutes of meetings, and other unpublished reports and documents which greatly amplify our research in published materials. Through research in such manuscript collections historians gain insights into the internal behind-the-scenes processes, planning, and activities of individuals and institutions. In this way, such materials are utilized in historical research to deepen and enhance our understanding of the logic of decision-making, planning and the deeper contexts of issues than might be available in the public record. Archival materials provide access to motivations, strategies, and actions not always available in printed

sources. Further, they provide another form of evidence in the rigorous development of historical analyses, interpretations and opinions.

Q: As a historian, how do you know when you have reached the point where you have done enough research to form conclusions about a historical question?

A: Quite often my doctoral students in the history of medicine and science come to me and ask, "how will I know when I have done enough research—there is always more I could do." And there are, of course, always additional documents, sources and data which could be researched, especially when one is investigating topics in the twentieth century. As a general guide, I suggest that when new research begins to resubstantiate themes for which an individual already possesses significant evidence, this is an important indicator that one may be entering a final stage before writing and publication. In other words, there may well be additional primary materials that a historian has not reviewed, but if such materials can be understood according to arguments and themes that the historian has developed, it is appropriate to move forward and report one's conclusions. Of course, new, unexplored materials may alter one's view of what happened and why. And in some instances important new materials may become available that fundamentally shape and reshape our previous understandings of the past. Historians need to be open to new materials which offer opportunities for re-interpreting conventional historical conclusions. In this instance, for example, the relatively recent accessibility of tobacco industry documents has offered important new opportunities to understand more deeply and completely the history of medical and scientific debates about smoking and health that would have been impossible prior to the availability of these materials. Putting it in the context of this case, a critical question is what was

known within the industry? And how did industry actions and activities shape medical and public knowledge about the harms of smoking? The defendants' historical experts have entirely avoided these two critical questions. For example, it seems strikingly naive from a professional historian's viewpoint to discuss what some have called "common knowledge" of the harms of smoking without carefully analyzing cigarette advertisements from the period under investigation. Additionally, a trained historian would be eager to understand what the tobacco industry was saying about the risks of its product as public knowledge came to be shaped. Based on traditional historical research methods, it seems a striking omission to avoid the investigation of internal corporate memoranda relating to the formation of the TIRC when one is investigating the controversy about the harms of smoking in the 1950s.

Q: If, as you suggest, context and social forces are important, do you also believe that historical events are inevitable?

A: No, I do not. Historians generally have a strong commitment to what they refer to as contingency. By contingency we mean that historical events are not pre-determined or inevitable, but rather they are the result of a combination of human action and social forces that can be carefully studied and enumerated. Historians, therefore, often center attention on important decisions and choices, on the rise of new knowledge and technologies, on the role of institutions and organizations that have shaped and reshaped the character of human knowledge, society, culture, and politics. One of the reasons that I am an advocate for historical inquiry is that it clarifies the significance of such decisions and their larger implications for subsequent historical developments and outcomes.

Q: Has your research on the subject of cigarette smoking contributed to your

understanding of the methodology necessary for historical research?

A: I think it is more accurate to say that my research has confirmed the importance of examining diverse sources. For example, it was not difficult to find data on the changing prevalence of tobacco use in the twentieth century. But explaining the rise of consumption over time required careful inquiry into a wide range of forces—advertising and promotion, changing social mores, and the biological and psychological aspects of this particular behavior.

Q: I'd like to turn to the substance of your opinions in this case. Let's start with what you just mentioned – the rise of cigarette consumption over time. First, are questions concerning cigarette consumption relevant to your historical analysis?

A: Yes, they are, because changes in consumption led to changes in patterns of disease, which in turn led to an increase in medical and scientific investigation of cigarettes as a cause of disease. There was speculation about the connection between smoking and disease even before the beginning of the last century, but scientists began to give serious attention to the connection during the first half of the twentieth century.

Q: Can you explain more specifically what prompted the serious attention to the connection between smoking and disease at that time?

A: I can. By the 1930s and 1940s, physicians and public health officials in the United States had widely noted an alarming increase in numbers of cases of lung cancer. Virtually unknown as a cause of death in 1900, by 1935 there were an estimated 4,000 deaths. A decade later, such estimates had nearly tripled. By 1950, lung cancer deaths among men had surpassed prostate, colon, and stomach cancers. As this trend became apparent in the first half of the twentieth century, it generated a number of theories

among scientists, physicians, public health officials, and actuaries.

Q: What types of theories were generated during this time period?

A: Some attributed the rise in cases to better reporting, more sophisticated diagnostic abilities, the widespread use of x-rays, and the ability to make precise pathological analyses. Others suggested that increasing life expectancy permitted the development of diseases that in an earlier era would not have had the chance to kill individuals who would die earlier from other causes. Still others speculated that the rise of the automobile, asphalt pavement, or other environmental changes had precipitated this increase in rates of lung cancer. All during this period, however, some physicians and scientists pointed to the dramatic rise in cigarette smoking as a possible cause.

Q: Was the rise in cigarette consumption documented?

A: Yes, it was. The rise in lung cancers had followed the dramatic increase in cigarette consumption beginning early in the twentieth century. Yearly per capita consumption of cigarettes in 1900 had stood at approximately 49; by 1930, per capita consumption was already over 1,300; by 1950 it would be over 3,000. Even though the increases in lung cancer cases and deaths substantially lagged this increase in cigarettes use, it led to considerable speculation about this relationship.

Q: Was this the first time that the relationship had been suspected?

A: No, it was not. Concern about the health consequences of smoking cigarettes – and their possible relationship to cancer – was longstanding. But the way in which it was comprehensively examined as a result of the dramatic rise in the number of lung cancer cases was very different from prior speculation, as I will explain. The medical literature in the nineteenth century is replete with clinical descriptions of smokers' heart, smokers'

cough, respiratory and other ailments, all attributed to cigarette smoking. Most such studies relied – as did much of the medical literature of the time – on anecdote and clinical observation. As a result, from this literature it was difficult to assess the precise character of the risks smoking posed. A reasonable clinical assessment of such literature typically resulted in the clinical maxim: some patients should not smoke.

Theories associating smoking with cancers were based, in part, on early and ongoing research into the biological processes of carcinogenesis. As early as the late eighteenth century, Percival Pott, a London surgeon, had noted the high incidence of scrotal cancer among chimney sweeps. By the late nineteenth century, a number of substances including shale oil, coal distillates and petroleum products had been linked to skin cancers. By the late 1920s and early 1930s, E. L. Kennaway, the Director of the Chester Beatty Research Institute at the Royal Cancer Hospital in London, had identified polycyclic hydrocarbons as among the active chemicals in carcinogenesis.

Q: You said that the examination of the connection between smoking and lung cancer was different from the early theories you've described. Can you explain that for the Court?

A: Yes. By the late 1920s the potential dangers of smoking began to attract more concerted attention. Researchers began to focus on the specific health consequences of smoking. As early as 1928, researchers conducting a large field study associated heavy smoking with cancer, and their results were reported in the *New England Journal of Medicine* as marked as U.S. Exhibit 39,010. In 1931, Frederick L. Hoffman, a well-known statistician for the Prudential Insurance Company, tied smoking to cancer, reporting his results in *Annals of Surgery*, as shown in U.S. Exhibit 63,597, which is a

copy of Hoffman's article. Hoffman assessed the basic methodological questions of such research: issues of representativeness, sample size, and the construction of control groups. All presented researchers with a series of complex problems, problems which they were aware of and began to find ways to resolve.

In 1938, Raymond Pearl, the Johns Hopkins population biologist and biometrician, published among the first significant statistical analyses of the health impact of smoking in the journal *Science*, published on March 4, 1938 as it appears in U.S. Exhibit 20,714. Pearl came to the conclusion that in individuals it was difficult to assess the risks of such behaviors, especially when their impact was not immediate and when many intervening variables also affected health. Therefore, he concluded, the only precise way to evaluate their effect on health was to employ statistical methods after collecting data on large groups. Comparing the mortality curves of smokers and non-smokers, Pearl found that individuals who smoked could expect shorter lives.

Q: Were there other investigations in the 1930s that, as a medical historian, you consider to be important in the development of our understanding of the connection between smoking and lung cancer?

A: Yes, there were. Although many research questions were left to be resolved, these early researchers began to consider the best ways to uncover proof of the association between lung cancer and smoking. The first case control study that showed the connection was published in Germany in 1939, and translated and reprinted in the *Journal of the American Medical Association (JAMA)* the same year. In addition, noted chest surgeons like Alton Ochsner in New Orleans and Richard Overholt in Boston drew attention in the 1930s to their observations that patients with advanced lung malignancies

typically had smoked.

Q: Dr. Brandt, I'd like you to take a look at U.S. Exhibits 63,595 and 63,596. Do you recognize these documents?

A: I do. The first one, 63,595, is the English translation of the German case control study that I referred to, as published in *JAMA* in September 1939. The second, 63,596, is Ochsner's 1939 article on his clinical observations.

Q: Did Ochsner reach specific conclusions about the connection between smoking and lung cancer in the document marked as U.S. Exhibit 63,596?

A: Yes, he did. Ochsner and surgeon Michael DeBakey, assessing the increase in cases of primary carcinoma of the lung concluded:

> In our opinion the increase in smoking with the universal custom of inhaling is probably a responsible factor, as the inhaled smoke, constantly repeated over a long period of time, undoubtedly is a source of chronic irritation to the bronchial mucosa.

Q: How do you view the early studies and conclusions of Hoffman, Pearl and Ochsner and their colleagues from a historical perspective?

A: These early clinical and population observations of the impact of smoking are, in retrospect, quite impressive. Almost all the risks that would come to be attributed to smoking in the second half of the twentieth century had been well-documented – from a clinical perspective – in the first decades of the century. Even the risks of passive exposure to cigarette smoke had been well articulated. And yet, physicians and researchers could not easily move from such observations to more powerful and generalizable assessments of the specific causal relationship of smoking to disease.

Physicians such as Ochsner might well be convinced that tobacco had caused their patients' malignancies, but the larger questions of cause and effect could not be definitively resolved on the basis of such observations.

Q: Did the observations nevertheless cause concern?

A: Yes, they did. By the late 1940s there was adequate evidence linking the rise of cigarette use to the rise in lung cancer incidence for the medical and public health community, the tobacco industry, and the public to be highly concerned.

Q: What do you rely on to identify that concern?

A: The concern, for example, was clearly reflected in tobacco ads at that time. Camel Cigarettes featured a series of ads through the last years of the 1940s and early 1950s such as that reproduced as U.S. Exhibit 63,556, proclaiming, "More Doctors Smoke Camels Than Any Other Cigarette." Thinly veiled in such campaigns was the notion that if a smoker had concerns about the impact of cigarettes on their health, Camels offered a "safer" smoke. In this time frame, before the groundbreaking epidemiological studies that began to appear in the late 1940s and 1950s, tobacco advertising made cigarettes seem healthy. Throughout the 1930s and 1940s as new evidence about the potential harms of smoking was developed, the cigarette advertising responded by reassuring smokers (and potential smokers) concerning the use of their particular brands. Lucky Strikes promised that their "toasting" process removed harmful irritants; Old Golds, in the advertisement marked as U.S. Exhibit 63,562, assured "not a cough in a carload." The Camel ads announcing "More Doctors Smoke Camels than any other cigarette" also touted the "T-Zone" for taste and throat: "only your taste and throat can decide which cigarette tastes best for you… how it affects your throat" such as in the

advertisement marked as U.S. Exhibit 63,554. Other examples included Chesterfields, which advertised "Pure…from start to finish! The cleanest 'bill of health' any cigarette could rate" (early 1930s, marked as U.S. Exhibit 63,560), Lucky Strike, which proclaimed "'It's toasted' No Throat Irritation-No Cough" (1929, marked as U.S. Exhibit 63,564) and "Luckies employ the exclusive 'Toasting' process to remove certain irritants found in all tobacco…. A Light Smoke Easy On Your Throat – 'It's Toasted'" (1937, marked as U.S. Exhibit 63,558), Philip Morris, touting "Perfect smoking pleasure without smoking penalties" (1940s, marked as U.S. Exhibit 63,566) and "…the ONLY leading cigarette scientifically proved far less irritating to the nose and throat" (1947) and Camel, which promoted to consumers a "30 day personal test… Noted throat specialists…report 'Not one single case of throat irritation!'" (1949, marked as U.S. Exhibit 63,552).

Q: You indicated that the larger questions of cause and effect could not be definitively resolved on the basis of observations by physicians such as Ochsner. Can you explain why you feel that such observations were not sufficient to do so?

A: Ochsner's clinical observation that among his patients with lung cancer virtually all had been smokers certainly raised important questions about the relationship between smoking and health. But such observations were not made in a systematic way, and they left a number of important questions open. For example, perhaps these individuals had some other exposure or common experience that might account for their disease. Perhaps they were especially heavy smokers. Perhaps they were unusual individuals who were for some genetic or other reason especially vulnerable to the inhalation of cigarette smoke.

Without conducting a systematic, rigorous study that permitted the comparison of

smokers to non-smokers, it simply would not be possible to address effectively the hypothesis that smoking was causally related to lung cancer and other diseases. This need for systemic study, of course, is not to deny the critically important clinical observations made by Ochsner and other physicians that led researchers to scientifically evaluate the hypothesis. As has so often been the case in the history of medicine, acute clinical observations were the critical starting point for raising hypotheses of great medical and public health significance.

Q: Did researchers address the larger questions of cause and effect in this same time period?

A: Yes, they did. Beginning in the late 1940s researchers began to devise studies that would directly address and resolve the persistent and increasingly important questions concerning the possible harms of cigarette smoking.

Q: Can you describe these studies?

A: Yes. One of the early notable investigations was undertaken by Evarts Graham and Ernst Wynder. Graham, a leading surgeon at Barnes Hospital in St. Louis, and Wynder, then a medical student at Washington University in St. Louis, designed and implemented such a study in 1948. Graham, a nationally-known surgeon who had performed the first pneumonectomy, was a heavy smoker himself and skeptical of the cigarette-lung cancer hypothesis. He initially had speculated that if smoking was a cause of lung cancer it would occur more bilaterally (rather than in a single lobe). Wynder and Graham collected extensive data on a group of 684 patients with lung cancer located in hospitals throughout the U.S. These patients were extensively interviewed about their smoking levels and histories. Histological exams confirmed the diagnosis in all cases.

This group was then compared to a "control group" of non-smokers, similar in age and other demographic characteristics.

Q: Did Wynder and Graham report the results of their study?

A: They did. The results were reported in the *Journal of the American Medical Association*, a prestigious peer reviewed journal, on May 27th, 1950.

Q: Please take a look at U.S. Exhibit 63,605. Do you recognize this document?

A: Yes. This is a copy of Wynder and Graham's May 27th, 1950 article in *JAMA*, as I have just described.

Q: In your opinion, did Wynder and Graham reach conclusions that were significant to the development of a scientific consensus that smoking is a cause of lung cancer?

A: They did. Wynder and Graham noted that lung cancer could occur among non-smokers and that heavy smokers did not necessarily develop cancer. Therefore they reasoned that "smoking cannot be the only etiological factor in the induction of the disease." Nonetheless, they explained, "the temptation is strong to incriminate excessive smoking, and in particular cigarette smoking over a long period as at least one important factor in the striking increase of bronchogenic carcinoma." They offered four reasons to support this conclusion. First, it was very unusual to find lung cancers among non-smokers. Second, among patients with lung cancer, cigarette use tended to be high. Third, the distribution of lung cancer among men and women matched the ratio of smoking patterns by gender. And finally, "the enormous increase in the sale of cigarettes in this country approximately parallels the increase in bronchogenic carcinoma."

Q: Was the work of Wynder and Graham recognized at the time to be

qualitatively different from the prior observations of Ochsner and other physicians?

A: It was. In fact, also included in the issue of the *Journal* with the results reported by Wynder and Graham was another investigation reaching similar conclusions by Morton Levin and colleagues. In his commentary on research into the connection between cigarettes and lung cancer, Levin compared the current epidemiological research on cigarette smoking to research on the smoking/lung cancer connection done in the preceding 20 years, arguing that the past work was "inconclusive because of lack of adequate samples, lack of random selection, lack of proper controls or failure to age-standardize the data." In the case of the data gathered for his study, careful attention to "excluding bias" had been central, and Levin wrote: "...in a hospital population, cancer of the lung occurs more than twice as frequently among those who have smoked cigarets for twenty-five years than among other smokers or nonsmokers of comparable age." At this point, Levin and colleagues were appropriately cautious in drawing causal conclusions, but nonetheless these methodologic approaches would be central to resolving the causal hypothesis.

Q: Dr. Brandt, are you familiar with the document marked as U.S. Exhibit 63,606?

A: I am. This is a copy of the Levin piece in *JAMA.*

Q: Were other researchers doing work that you consider significant to the resolution of the causal hypothesis in this time period?

A: Yes, they were. Most notably, under the auspices of the Medical Research Council, an independent research organization funded by the government in the United Kingdom, A. Bradford Hill and Richard Doll conducted a similar study beginning in

1948. Following World War I, Hill had become one of the most distinguished medical statisticians in Great Britain. Doll, a physician, also possessed sophisticated training in statistics and epidemiologic methods. Eager to investigate the rising incidence of lung cancer, they realized that questions concerning the causality of systemic chronic diseases would not readily succumb to experimental laboratory investigation.

With the rise in incidence of systemic chronic diseases such as cancer and heart disease widely noted by the 1940s, it became readily apparent that there would be important limitations to laboratory experimental investigation. First, unlike the study of infectious disease where the concept of specific causality had proven so important, in the study of systemic chronic disease a single specific cause of disease could not typically be isolated and studied under laboratory conditions. Unlike the search for microbes, which had dominated the medical sciences in the late 19th and early 20th centuries, researchers began to look for a range of factors which significantly contributed to the prominent diseases of mid-century. Finally, even in those unusual instances where a specific cause of disease could be identified and isolated, there was no simple and obvious manner in which to move laboratory observations to the study of pathogenesis in humans. Nonetheless, the timeliness and public health significance of these questions demanded immediate attention and the development of new knowledge.

Q: Is Doll and Hill's research significant to your evaluation of smoking-related disease as a medical historian?

A: Yes, it is extraordinarily significant due to their findings, as well as the strength of their conclusions about the connection between smoking and lung cancer, which stemmed from the manner in which their investigation proceeded.

Q: Can you explain the manner of their investigation in more detail?

A: I can. As their data from lung cancer patients and the control group came in in late 1948 and early 1949, it became clear to Doll and Hill that cigarettes were the crucial factor in the rise of lung cancer. With data on almost 650 lung cancer patients, they concluded that they had in fact found cause and effect. Even without the sophisticated statistical analyses they employed, the findings were impressive: among the 647 lung cancer patients entered into Doll and Hill's study, all 647 were smokers. They waited to publicize their results, however, until they had additional data, further strengthening their conclusions.

Notably, the conclusions reached by Doll and Hill were not based on mere percentages of lung cancer patients who were smokers. They understood that it would be easy to dismiss such findings – as the tobacco industry would try – as "merely" statistical. As a result, they meticulously described the specific criteria that they required before an "association" could be identified as a genuine causal relationship. First, they worked to eliminate the possibility of bias in the selection of patients and controls, as well as in reporting and recording their histories. Second, they emphasized the significance of a clear temporal relationship between exposure and subsequent development of disease. Finally, they sought to rule out any other factors that might distinguish controls from patients with disease. This explicit search for possible "confounders" and their elimination marked a critical aspect of their arrival at a causal conclusion. They insisted on carefully addressing all possible criticisms and all alternative explanations for their findings. In this respect, Doll and Hill and the other epidemiologic investigators expressed a strong commitment to investigatory science, hypothesis-testing, and

scientific method.

Q: Dr. Brandt, please review U.S. Exhibit 63,604. What is this document?

A: This is a copy of the *British Medical Journal* article where Doll and Hill presented their findings in 1950. In their own words, they explained: "Consideration has been given to the possibility that the results could have been produced by the selection of an unsuitable group of control patients, by patients with respiratory disease exaggerating their smoking habits, or by bias on the part of the interviewers. Reasons are given for excluding all these possibilities, and it is concluded that smoking is an important factor in the cause of carcinoma of the lung."

Q: In your opinion, did the 1950 conclusions of Doll and Hill withstand subsequent scientific evaluation?

A: Absolutely. In fact, the conclusions were confirmed by Doll and Hill themselves. Two years later, in a follow-up report, they offered additional evidence for sustaining their conclusion, again fully considering alternative explanations when they reported in the *British Medical Journal* in 1952, as reproduced as U.S. Exhibit 63,603: "We have now extended the investigation to other parts of the country and have made more detailed inquiries into smoking habits. . . . The present analysis of nearly 1,500 cases, or more than double the number dealt with in our preliminary report, supports the conclusion then reached and has revealed no alternative explanation – for example, in the use of petrol lighters. It has been suggested that subjects with a particular physical constitution may be prone to develop (*a*) the habit of smoking and (*b*) carcinoma of the lung, and that the association might therefore be indirect rather than causal (Parnell, 1951). We know of no evidence of such a physical constitution characteristic of patients with lung carcinoma. If

it does exist we should still have to find some environmental factor to account for the increased incidence of the disease in recent years."

Q: Are there other investigations that you consider to be significant to the smoking and health question in the same time period?

A: There are. For instance, like Doll and Hill, Wynder and Graham quickly followed their findings with additional investigations.

Q: As a medical historian, how do you view the importance of these follow-up studies for our understanding of the connection between smoking and lung cancer?

A: These additional investigations are important for the historical analysis of the formation of scientific consensus, because no single study would carry the day in conclusively demonstrating the causal relationship between smoking and cancer. Rather it was the aggregation of similar repeated studies with consistent findings that together would build a convincing case.

Q: What additional studies, if any, do you consider significant in building a convincing case that smoking was a cause of lung cancer during this time period?

A: Other retrospective studies in this period included that of Levin, mentioned previously, investigations by Schrek, Baker and colleagues, by Mills and Porter, and by Sadowsky, Gilliam and Cornfield. And perhaps most notably, Doll and Hill sought to confirm the findings of their retrospective study through prospective investigation.

Q: What, specifically, is a retrospective study?

A: A retrospective study is one that starts with a group of individuals who have been identified as having the condition under investigation. These individuals are then carefully interviewed and examined to confirm their diagnosis. Interviewers

systematically collect data, interested in every aspect of their histories. In order to determine if there were particular reasons why these individuals became sick with their particular disease, the researchers collect data on a group of individuals who are similar in every respect except for the noted disease. In other words, the group of healthy individuals are the same age, gender, socio-economic status, and other key variables to the group being investigated. These studies are called retrospective (or historical or case control) because they look back on individual's experience after they have already become ill.

It was precisely this approach that was taken in the original studies by Doll and Hill and Wynder and Graham. What they found was that the only difference between their study group of individuals with lung cancer and the group of individuals who did not have lung cancer was that the lung cancer patients had been smokers. Although all the researchers well understood that a small number of lung cancer patients never smoked, this was true only in exceptional instances. Retrospective studies are understood to have some limitations, of which the researchers were well aware. In particular, in such studies there is concern about the potential bias of the sick individuals in reporting their health histories and behaviors. For example, it was suggested that patients with lung cancer might exaggerate the duration and daily level of smoking. There were also concerns that researchers could be biased in their conduct of interviews and collection of data. It was for this reason that Doll and Hill did not reveal the diagnosis to their research assistants who collected the data. Doll and Hill, especially expert in their research and methodological skills, worked assiduously to assure that they had identified – and eliminated – potential sources of bias in their studies.

Q: You indicated that "Doll and Hill sought to confirm the findings of their retrospective study through prospective investigation." Can you explain how they did so?

A: They designed and initiated a prospective investigation. This study sought data concerning smoking from some 40,000 British physicians, who would then be followed to see if they developed lung cancer. Unlike case control studies that begin with individuals who are already sick, prospective studies (also known as cohort studies) begin with two groups selected for their similarities except for a single variable, in this case cigarette smoking. These two groups are then followed to see who develops any particular disease. While the retrospective studies began with lung cancer and identified cigarette smoking as the principal factor, the prospective studies began with cigarette smoking as the variable and found lung cancer to be a significant outcome. As their earlier studies had shown, they found an impressive "excess" of deaths among the doctors who smoked. Heavy smokers had death rates 24 times higher than non-smokers did, as Doll and Hill reported in the *British Medical Journal* in 1954 and 1956 in the articles contained in U.S. Exhibits 63,612 and 63,611. Doll and colleagues have continued to follow the morbidity and mortality of these physicians and in June 2004 published an original article in the *BMJ* on 50 years of observations showing that prolonged cigarette smoking tripled age-specific mortality rates. The long-term follow-up also demonstrated that quitting at any age confers health benefits.

Q: As a medical historian, do you have an opinion as to the level of scientific knowledge concerning smoking as a cause of lung cancer in the early 1950s?

A: Yes, I do. By late 1953 there had been at least five published epidemiologic

investigations, as well as others pursuing carcinogenic components in tobacco smoke and its impacts. The researchers had come to a categorical understanding of the link between smoking and lung cancer.

Q: Why do you conclude that the researchers reached a categorical understanding of the link between smoking and lung cancer?

A: The scientists using the epidemiological methods that showed smoking to be a cause of lung cancer were careful to approach them in a thorough manner; these methods were completely consistent with established scientific procedure and process. And epidemiology was not only based on statistics, but instead was an interdisciplinary, applied field. The studies had substantially transformed the scientific knowledge base concerning the harms of cigarette use. Unlike earlier anecdotal and clinical assessments these studies offered approaches to investigating and resolving causal relationships. Indeed, medical historians would come to view these studies as among the most important contributions to public health and medicine in the twentieth century. They offered a sophisticated scientific methodology for resolving central questions of causality and efficacy. Indeed, it was these methods that would be utilized to evaluate the effectiveness of new drugs or other medical therapies.

As noted historian Charles Webster would later observe of the first Doll and Hill paper, published in 1950: "This modest paper is now regarded as a classic. From these findings emerged the realization that smoking has been responsible for as many deaths per annum as were claimed by the great cholera epidemics of the nineteenth century. Smoking was thus established as a major cause of preventable disease." Webster was writing in the *British Journal of Addiction* in 1984, marked as U.S. Exhibit 63,589.

Q: Had these studies attracted any attention outside of the scientific community by 1953?

A: They had. By 1953, the importance of such findings attracted considerable interest among physicians, scientists, public health officials, and, of course, the public. Newspapers and magazines widely reviewed these investigations, heightening both public concern about the cigarette and industry concern about its future.

Q: U.S. Exhibit 63,549 is a copy of a *Reader's Digest* article titled "Cancer by the Carton" and U.S. Exhibit 63,548 is an article from *Time* titled "Beyond Any Doubt." Have you seen these articles before?

A: I have. These are examples of the type of publicity the groundbreaking epidemiological investigations received outside of the scientific community.

Q: Based on your work as a historian studying tobacco and disease, do you believe that the public review of these investigations impacted cigarette manufacturers?

A: Yes. The public reporting of these new findings in national magazines like *Time* and *Reader's Digest*, as well as declines in sales and stock prices, forced tobacco executives to assess strategies for responding to growing medical and public concerns about their product.

Q: Have you formed opinions concerning the impact that these studies had on the tobacco industry in the United States?

A: I have. The scientific findings identifying cigarette smoking as a cause of serious disease – and their reporting in the public media – shook the tobacco industry. For decades the industry had developed advertising and public relations strategies for dealing

with ongoing concerns about the health impact of smoking. By 1953, however, it had become abundantly clear that the character and quality of the evidence implicating cigarette smoking as a factor in carcinogenesis was of a different order. The major tobacco companies found themselves in a state of crisis. In this respect, the actions of company executives reflected an understanding that these new reports were substantially different from the ongoing health concerns raised about their product in the past. These new findings constituted a critical threat to their industry.

Q: What actions, in your opinion, demonstrate an understanding on the part of company executives "that the new reports were substantially different from the ongoing health concerns raised about" cigarettes previously?

A: Initially, as scientific evidence of the harms of smoking accrued, aggressive and reassuring marketing persisted. Arthur Godfrey, for example, who promoted Chesterfields on television, touted studies in 1953 which he claimed exonerated Chesterfields from the rising public concerns about the health implications of smoking. But the scientific studies demonstrating the causal connection between smoking and lung cancer generated a heightened level of concern among major manufacturers. To say that executives and other employees of the tobacco industry were aware of the studies and their findings linking cigarettes and cancer is an understatement. These findings created an unprecedented crisis for the industry. By 1953-1954, executives in the industry were aware both of these findings and the public attention they were receiving, and their statements and actions reflected an understanding that this new scientific evidence constituted a full-scale crisis for their respective corporations.

Q: Are there particular statements that you believe illustrate the industry's view

of the new scientific evidence as a full scale crisis?

A: One example comes from George Weissman, a Vice President with Philip Morris, who reiterated this view of the crisis publicly in March 1954 in a speech to the National Association of Tobacco Distributors: "For never in the history of American industry – a history that not so incidentally had its origins in tobacco – has one industry been under attack as we are today, never has an industry's very existence been so dependent on its relations with the public. . . . If we had any thought or knowledge that in any way we were selling a product harmful to consumers, we would stop business tomorrow."

Q: Dr. Brandt do you recognize U.S. Exhibit 21,766?

A: Yes, I do. This is a copy of the text of Weissman's March 1954 speech.

Q: And please examine U.S. Exhibit 59,809. Do you recognize this document?

A: Yes.

Q: Can you explain what U.S. Exhibit 59,809 is?

A: This is a copy of a public statement from Paul Hahn, the President of American Tobacco, in 1953 that also illustrates the industry's response to the new scientific evidence. In the statement, Hahn noted the need to reassure the American public, stating: "Believing as we do that cigarette smoking is not injurious to health, I feel that a statement of reassurance to the public should be made. What the public wants to know about is whether it is true that smoking has been proved to contribute to the incidence of lung cancer. The fact, of course, is that it has not been so proved."

Q: You mentioned that the actions of the cigarette companies at this time – 1953-1954 – reflected an understanding that the scientific evidence represented a crisis for the industry. What actions do you rely on for this view?

A: In December 1953, Paul Hahn called a meeting of all the major tobacco chief executives. The meeting was attended by Paul M. Hahn, President of American Tobacco, E. A: Darr, President of RJR, William J. Halley, President of Lorillard, Timothy V. Hartnett, President of B&W, O. Parker McComas, President of PM, Joseph F. Cullman, Jr., President of Benson and Hedges, J. B. Hutson, President of Tobacco Associates, Inc., J. Whitney Peterson, President of US Tobacco, and executives from the public relations firm Hill and Knowlton. Only Liggett declined. The purpose of the meeting was to develop a collaborative public relations plan in response to the new scientific evidence concerning the harms of cigarette use. When they met together on December 14, 1953 at the Plaza Hotel in New York City, it marked the first time since 1939 that the group had come together. Executives of the tobacco companies had stopped meeting in 1939 following a conviction for price fixing. Now, however, their fear that working together would be perceived as an anti-trust violation was trumped by their major concern over public reactions to the emerging scientific findings.

The tobacco executives had agreed to meet with John Hill of the New York public relations firm Hill and Knowlton in order to consider how best to shape their new strategy in this moment of crisis. The following day, Hahn, McComas, Cullman and Peterson met again and agreed to the program developed by Hill and Knowlton. A series of additional meetings occurred in the following two weeks in order for Hill and Knowlton executives to hear from other industry staff. Finally, on December 28, 1953, the CEOs met again with Hill and his colleagues Bert Goss and Richard Darrow to approve the formation of the Tobacco Industry Research Committee (TIRC) and its public announcement.

Q: Is there historical documentation of Hill and Knowlton's role in the tobacco industry's response to the emerging scientific evidence?

A: Yes there is. The John Hill papers at the Wisconsin Historical Society include extensive records of the activities of Hill's public relations firm, Hill and Knowlton, and their activities on behalf of the tobacco industry. After the CEOs of the companies collectively hired Hill and Knowlton to conduct a public relations campaign on behalf of the industry**,** members of the firm produced extensive memoranda, correspondence and records documenting their efforts. At the time of the creation of the Tobacco Institute in 1958, Hill and Knowlton also secured this account to handle its public relations. The Hill manuscript collection contains thousands of pages of correspondence, internal memoranda, reports, and other materials relating to these important accounts. In the Hill collection there are 112 archive boxes which comprise nearly 45 cubic feet.

Q: How is this archive important to your research as a medical historian?

A: These manuscript materials are characteristic of archival collections that historians utilize to reach judgments and interpretations about historical actors and episodes. In relation to other published source materials, they offer an internal view to the logic of the actions and behaviors of particular individuals. In this instance, these materials (which include clippings, drafts, and printed matter) provide a remarkably clear picture of the industry and their public relations counsel during the tumultuous period from 1953 to around 1966.

The papers have been in the possession of the Wisconsin Historical Society since 1964 when they were donated by John Hill. Client files, which include those of the tobacco industry, were closed to research until 1989, and only became available for

research after they were organized in 1992.

Q: I'd like to show you U.S. Exhibits 21,152, 21,411, 87,211, 87,224 (and duplicate 21,408) 87,512 through 87,515, 87,517 through 87,528, 87,533 through 87,543, 87,720 through 87,732, 87,968, 88,043, 88,166, 88,168, 88,170 through 88,176, 88,179, 88,180, 88,182 through 88,192, 88,194, 88,197, 88,205 through 88,208, 88,210 through 88,227, 88,229 through 88,233, 88,251, 88,253, 88,254, 88,363 through 88,375, 88,378 through 88,384, 88,386, 88,388 through 88,397, 88,399, 88,400, 88,402 through 88,404, 88,407 through 88,411, 88,419 through 88,423, 88,439 through 88,441, 88,454, 88,491 through 88,493, 88,564, 88,780, 88,169, 88,181, 88,195, 88,196, 88,198, 88,199, 88,201 through 88,204, and 88,361. Do you recognize these documents?

A: Yes. All of these are papers from the Hill collection that document Hill and Knowlton's activities on behalf of the tobacco industry, which, as I indicated, provide valuable internal views to the logic of the actions and behaviors of individuals within the tobacco industry.

Q: Do the Hill papers provide additional historical evidence of the assessment of the threat that the scientific evidence posed to the industry?

A: They do. As an example contained in U.S. Exhibit 87,224 (and duplicate 21,408), Hill and Knowlton assessed their clients' problems in the following manner in an initial assessment:

> There is only one problem – confidence, and how to establish it; public assurance, and how to create it – in a perhaps long interim when scientific doubts must remain. And, most important, how to free millions of Americans from the guilty

fear that is going to arise deep in their biological depths – regardless of any pooh-poohing logic – every time they light a cigarette. No resort to mere logic ever cured panic yet, whether on Madison Avenue, Main Street, or in a psychologist's office. And no mere recitation of arguments pro, or ignoring of arguments con, or careful balancing of the two together, is going to deal with such fear now. That, gentlemen, is the nature of the unexampled challenge to this office.

In the same document, Hill and Knowlton warned their clients that competitive approaches of the past would not work in the current context, advising: "…on this problem none is going to seek a competitive advantage by inferring to its public that its product is less risky than others."

Q: Did Hill and Knowlton suggest an alternative to competitive approaches?

A: They did. The tobacco executives sought to create a "Tobacco Industry Committee for Public Information," to publicize health information and to preserve their public image. Hill, however, expressed skepticism that a public relations strategy that simply argued that the harms of cigarette smoking were "unproven" would succeed. Such a campaign, it was suggested, might appear self-interested in the face of the serious health concerns being raised. As a result, Hill suggested that the industry should sponsor new research. Thus he advocated instead a "Tobacco Industry Research Committee" (TIRC), which the executives adopted.

Q: How did the Tobacco Industry Research Committee address the "problem" identified by Hill and Knowlton in U.S. Exhibit 87,224, if at all?

A: Beginning in January 1954, the newly created Tobacco Industry Research Committee would take the lead in forging the industry's response to the scientific

evidence of tobacco's harms. That month the TIRC published "A Frank Statement to Cigarette Smokers" (written by Hill and Knowlton executives), which appeared in 448 newspapers in 258 cities. The Frank Statement, as an act of public relations, fit well with the essential strategy that Hill and Knowlton identified with the tobacco industry. It reassured smokers; it promised them that the industry was absolutely committed to their good health. Such reassurances became characteristic even as the scientific evidence indicting cigarettes grew in strength, sophistication, and professional acceptance.

Q: I'd like you to look at U.S. Exhibit 21,418. Do you recognize this document?

A: I do. That is a copy of the Frank Statement, as it appeared in newspapers in January 1954.

Q: What was communicated by the Frank Statement?

A: The statement announced:

> We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business.
>
> We believe the products we make are not injurious to health.
>
> We always have and always will cooperate closely with those whose task it is to safeguard the public health.

Announcing the creation of the TIRC, the "Frank Statement" explained:

> We are pledging aid and assistance to the research effort into all phases of tobacco use and health. This joint financial aid will of course be in addition to what is already being contributed by individual companies.

Q: As a historian, do you look for sources to confirm the strategies that you have identified as having been articulated in the Hill papers?

A: Confirmation is valuable, and we find it in the statements of industry executives. T.V. Hartnett, President of Brown and Williamson, summarized the crisis of the industry on December 15, 1953, in the following terms in a document marked as U.S. Exhibit 20,190:

> But cancer research, while certainly getting our support, can be only half an answer. . . .The other side of the coin is public relations . . . [which] is basically a selling tool and the most astute selling may well be needed to get the industry out of this hole. . . . It isn't exaggeration that no public relations expert has ever been handed so real and yet so delicate a multi-million dollar problem. . . . Finally, one of the roughest hurdles which must be anticipated is how to handle significantly negative research results, if, as, and when they develop.

Q: Do you consider Hartnett to be a significant historical actor for these issues?

A: Yes, I do. Upon retirement from Brown and Williamson, Hartnett would become the first Chairman of the TIRC in 1954. He continued to advance the industry's position in that role. In the document marked as U.S. Exhibit 63,544, which is the press release announcing his appointment to the TIRC, Hartnett explained:

> It is an obligation of the Tobacco Industry Research Committee at this time to remind the public of these essential points:
>
> 1. There is no conclusive scientific proof of a link between smoking and cancer.
> 2. Medical research points to many possible causes of cancer…
> 5. The millions of people who derive pleasure and satisfaction from smoking can be reassured that every scientific means will be used to get all the facts as soon as possible.

Q: Have you reviewed other sources to confirm the strategies identified in the Hill papers?

A: Yes I have. All of the relevant sources that I have examined, both published and unpublished, have confirmed the tobacco industry's consistent adherence to the public relations strategy devised and implemented by John Hill and his staff.

Q: In your opinion, did the TIRC use scientific research for public relations purposes?

A: Absolutely. The TIRC deftly exploited scientific research for the purposes of public relations. From the outset the dual functions of TIRC, public relations and scientific research, were intertwined. The scientific program of TIRC was always subservient to the goals of public relations. Rather than carefully and critically assessing the emerging scientific data concerning the harms of smoking, the TIRC took the lead in denying and distorting these harms. Instead of "getting all the facts" in a timely way, the TIRC focused its energies and resources in two areas.

First, it served as a public relations unit for the industry, especially in relation to growing public concerns about the risk of smoking. It repeatedly attacked scientific studies demonstrating the harms of cigarette smoke. It worked concertedly to reassure smokers about cigarettes.

Second, it ultimately developed a research program that focused principally on basic science mechanisms in cancers. This program was distant if not completely irrelevant to evaluating the risks and harms associated with smoking. The TIRC research program was organized and devised to *not* address the immediate and fundamental questions of the health effects of smoking.

In this way, both functions of TIRC (public relations and research) were integrally related; both were fully committed to the goals of denying and discrediting the substantial scientific evidence of smoking's harms and reassuring the public, especially smokers and potential smokers.

Q: In your opinion, were the public relations and research functions carried out through TIRC different from the tobacco industry's public relations and research activities prior to the founding of TIRC?

A: Yes, they were. Prior to the formation of the TIRC, the industry had conducted research on a somewhat *ad hoc* basis. Some of the research had been focused on the competitive health claims that were central to the advertising campaigns. For example, Philip Morris had hired researchers to investigate whether the smoke from their cigarettes was "less irritating" than the smoke from other brands. There is no evidence that the industry did anything to investigate the rising concerns through the 1930s and 40s about the health effects of smoking. In the period prior to the Plaza Hotel meetings and the formation of the TIRC many researchers advocated that the industry give funds to the National Research Council, the American Cancer Society, or National Cancer Institute to intensively study the relationship of smoking to disease. These individuals reasoned that only an independent assessment would be publicly credible. But ultimately, the industry would instead decide to set up its own research program under its own auspices and control.

In this way, the industry (and Hill and Knowlton) were able to assert control over the TIRC and its activities. The Scientific Director was selected by a group of Hill and Knowlton executives and industry scientists. The executive director of the TIRC, W.T.

Hoyt, had no scientific background whatsoever; he was initially a Hill and Knowlton employee. The first chairman of TIRC was Timothy Hartnett, the retired CEO of Brown & Williamson. A legal committee, made up of industry lawyers, oversaw the operation from its outset with particular attention to concerns about liability litigation. Hill and Knowlton, on behalf of the industry, worked to assure that TIRC accomplished its essential public relations mission; it was anything but an independent scientific research organization dedicated to investigating the relationship of tobacco and health.

Q: Have you looked to the cigarette manufacturers' internal scientific documents as part of your consideration of whether the tobacco industry utilized scientific research for public relations purposes through the TIRC?

A: Yes, I have. Internal industry assessments of the potentially carcinogenic characteristics of cigarette smoke stand in sharp contrast to public statements and reassurances, and the discrepancies between industry science and public statements support the conclusion that the industry's joint activities were undertaken for public relations purposes.

Q: What assessments, in particular, do you rely on to support your conclusion?

A: In February, 1953, for example, in a document that has been marked as U.S. Exhibit 21,407, Claude Teague, an RJ Reynolds research scientist, closely examined the available data – clinical, biological, chemical and epidemiological – linking cigarette use to human cancers and summarized clearly the state of existing knowledge:

> Several statistical studies, based on clinical data, on cancer of the respiratory system have been made, and these studies indicate an abnormal increase in the incidence of such cancers, particularly among men, during the last several

decades.... There appears to be a growing suspicion, or even acceptance, among medical men and cancer researchers that the parallel increase in cigarette consumption and incidence of cancer of the respiratory system is more than coincidence. The statistical studies continue, and their implications have become the subject of much speculation....

CONCLUSIONS: The increased incidence of cancer of the lung in men which has occurred during the last half century is probably due to new or increased contact with carcinogenic stimuli. The closely parallel increase in cigarette smoking has led to the suspicion that tobacco smoking is an important etiologic factor in the induction of primary cancer of the lung. Studies of clinical data tend to confirm the relationship between heavy and prolonged tobacco smoking and incidence of cancer of the lung.

Alan Rodgman, a scientist at RJ Reynolds, drew similar conclusions in 1956. He wrote an extensive paper on "The Analysis of Cigarette Smoke Condensate," that is marked as U.S. Exhibit 20,667. In it, Rodgman explained:

The research described in this report represents a concerted effort to determine whether or not the polycyclic aromatic hydrocarbons are present in cigarette smoke condensate. One of the major objections offered to previous investigations is that the identification of specific compounds solely on the basis of ultraviolet absorption studies is not definitive. Since the present research describes the actual isolation, identification, and characterization of several polycyclic aromatic hydrocarbons, including the highly carcinogenic 3, 4-benzpyrene, the major criticism of past research are now nullified…

Standard Camel cigarettes were utilized for these studies. Rodgman further wrote:

> In view of this data, it is logical to assume that the carcinogenic activity of cigarette smoke condensate is due to the presence of one or more carcinogenic polycyclic aromatic hydrocarbons. . . .
>
> Since it is now well-established that cigarette smoke does contain several polycyclic aromatic hydrocarbons, and considering the potential and actual carcinogenic activity of a number of these compounds, a method of either complete removal or almost complete removal of these compounds from smoke is required.

In 1959, in a document marked as U.S. Exhibit 21,249, Rodgman again summarized his current research on known carcinogens in cigarettes:

> Some thirty-odd polycyclic hydrocarbons have since been similarly characterized in these laboratories. Of these eight are carcinogenic to mouse epidermis. Cholanthrene, a potent carcinogen, is one of three not yet reported by other investigators. In April of 1959, the first positive isolation and identification of 3, 4 benzpyrene, citing data similar to ours, was reported by other investigators.

Q: Can you explain how internal assessments of the scientific evidence like those cited from Rodgman and Teague support your opinions regarding the discrepancies between industry science and public statements?

A: The documents illustrate that at the same time that the industry assured the public through its "Frank Statement" that "there is no proof that cigarette smoking is one of the causes [of cancer]" it documented a large number of known carcinogens in its product. At the same time that the industry announced "we accept an interest in people's health as

a basic responsibility, paramount to every other consideration in our business" it established a sophisticated public relations apparatus – based on the "cover" of conducting research – to deny the harms of smoking and reassure the public. Medical and scientific knowledge concerning the harms of smoking--including cancer and premature death--continued to grow impressively, in spite of a barrage of critiques and distortions by industry spokespeople and the TIRC. But once the essential strategy was organized and implemented in 1953-54, the industry's approach was unwavering.

Q: Did the medical and scientific knowledge concerning the harms of smoking grow during the period following the formation of TIRC?

A: Yes, it did. While the industry structured its public response and developed its own research plan, considerable new scientific evidence was developed during the course of the 1950s and early 1960s.

Q: What types of scientific evidence developed during this period?

A: Much of the scientific investigation concerned animal testing and pathological research. There was also a considerable expansion of the epidemiological evidence confirming the health effects of smoking during this period.

Q: I'd like to take each of the three areas in turn, starting with animal testing. Can you explain the animal testing research during this period?

A: Animal testing in the form of mouse skin painting was undertaken by Wynder and Graham, as they turned their attention to the question of the "biological plausibility" of their epidemiological findings. In conducting animal investigations, Wynder reasoned that if tumors could be produced in animal models, it would be an important step in confirming the early epidemiologic findings.

Q: Can you explain Wynder's research?

A: I can. Noting that smoke condensates, also known as tars, contained benzpyrenes, arsenic and other known carcinogens, he painted the backs of mice to evaluate their effects. 58% of the mice developed cancerous tumors. Wynder concluded that "the suspected human carcinogen has thus been proven to be a carcinogen for a laboratory animal." These findings were reported in *Cancer Research* in December 1953, as reproduced in U.S. Exhibit 58,868.

Q: What is pathological research?

A: Pathology is the area of medical science that centers attention on abnormalities in anatomy and/ or cells and the specific changes attributed to disease. Usually this research requires microscopic examination of specimens and the comparison of normal and abnormal tissues. Research on the pathology of lung cancer centered on the examination of tissue specimens from lung cancer patients.

Q: Can you explain the pathological research that examined the connection between smoking and disease during the period between 1954 and 1964?

A: Yes, I can. During this period, surgeons and pathologists published clinical reports associating cancer in their patients with their smoking habits. In 1957, Oscar Auerbach and colleagues first reported in the *New England Journal of Medicine* on "Changes in the Bronchial Epethelium in Relation to Smoking and Cancer of the Lung." Auerbach's study evaluated patients who died and were autopsied with confirmed smoking histories. Microscopists were kept ignorant of the smoking histories in the 30,000 examinations that they made to assure against potential bias. Auerbach and his colleagues concluded in the *New England Journal of Medicine* in an article marked as

U.S. Exhibit 54,185:

> These findings are fully consistent with the hypothesis that inhalants of one sort or another are important factors in the causation of bronchogenic carcinoma. The findings are also fully consistent with the theory that cigarette smoking is an important factor in the causation of bronchogenic carcinoma.

Auerbach presented additional confirmatory findings in 1961 and 1979, including the 1979 *New England Journal of Medicine* article marked as U.S. Exhibit 63,538.

Such studies underscored and strengthened the epidemiological findings. For this reason, to say that the evidence demonstrating a causal relationship between smoking and lung cancer was based exclusively on statistical data – as the tobacco industry would claim – was to fundamentally misrepresent the emerging scientific knowledge.

Q: Would the tobacco industry's claim that the evidence demonstrating a causal relationship between smoking and lung cancer was based exclusively on statistical data have been accurate in the absence of the animal testing and pathological experiments?

A: No. Epidemiology is the study of disease – its incidence and determinants – in populations. It is necessarily a multidisciplinary field that utilizes many complementary approaches to the understanding of disease and its causes. Although, of course, epidemiologists utilize statistical techniques in their researches, it would be incorrect to say that epidemiological research is "merely statistical." Epidemiologists are generally seeking explanations for patterns of disease. As a result, they collect a wide range of quantitative, biological, and pathological data. Their assessments are based on the consistency of a wide range of data across medical and scientific areas of knowledge and

specialization. This was certainly true of the epidemiological investigations of lung cancer and other diseases associated with tobacco use in the 1950s. The question pursued by researchers was not only, is smoking statistically associated with lung cancer and other diseases? Rather, they asked, was smoking consistent with what was known about the biochemistry of tobacco, biology of exposure, the pathology of cancer, and other available (or obtainable) data? They also scrupulously considered, what was the nature and merit of alternative explanations? Were there alternative explanations for the significant rise of lung cancer for which there was important supporting data?

Q: You also mentioned "a considerable expansion of the epidemiological evidence confirming the health effects of smoking" in the 1954-1964 time period. What were you referring to?

A: Following the early studies by Wynder and Graham, Doll and Hill and others, a number of important attempts to replicate and assess their findings were undertaken in the U.S. and abroad. Impressively, study after study confirmed and built upon these findings.

Q: Can you identify what you consider to be the most significant of these studies for the Court?

A: Yes, I can. Notably, E. Cuyler Hammond and Daniel Horn conducted a massive epidemiological study of smoking and lung cancer under the auspices of the American Cancer Society. In the Hammond and Horn study more than 200,000 men were followed prospectively for nearly four years; during this period 12,000 died. They found that not only was lung cancer far more prevalent among those who smoked as a cause of death (24 times more than non-smokers), so too was heart disease and circulatory disease.

Hammond and Horn estimated that among smokers, smoking might account for up to 40 percent of their mortality.

Q: When did Hammond and Horn publicize their results?

A: Findings from their studies began to appear in the medical literature and in the public media in 1954. The final results were reported in the *Journal of the American Medical Association (JAMA)* in 1958.

Q: Dr. Brandt, do you recognize U.S. Exhibit 63,609?

A: I do. This is a copy of the *JAMA* article by Hammond and Horn where they reported the final results of their epidemiological study.

Q: As a medical historian, do you have an opinion as to whether there was a mainstream scientific consensus that smoking was a cause of lung cancer during the 1950s?

A: Yes. During the course of the 1950s the evidence implicating cigarette smoking as a cause of lung cancer became overwhelming. As a result, there was substantial scientific and medical consensus concerning this finding. The research that appeared in the most elite, peer-reviewed journals all reached the same conclusion: that cigarette smoking was a serious health hazard that caused lung cancer and death. Especially impressive was the fact that many studies from a variety of methodological approaches all reached this same conclusion. Moreover, the findings were supported by investigations of cigarette tars and animals, as well as pathological observations of human tissues exposed to cigarette smoke.

Q: What is your opinion based on?

A: Beyond the quality of the investigation already discussed, there are a number of

indications that a powerful consensus had emerged among physicians and scientists. My opinion is based upon an extensive review of the peer-reviewed medical and scientific research on tobacco and lung cancer published during this period. More importantly, comprehensive reviews conducted by independent researchers at the time all reached the same conclusions. And during the 1950s, not a single substantial study came out which contradicted these findings.

Astute observers of clinical medicine frequently pointed to the persuasiveness and authority of these conclusions. Assessing the evidence in September 1953 – three months prior to the Plaza Hotel meetings – Joseph Garland, editor of the *New England Journal of Medicine*, noted that the most recent Doll and Hill publication "yielded evidence of an association between cigarette smoking and lung cancer so strong as to be considered proof within the everyday meaning of the word." Garland continued, "If similar data had incriminated a food contaminant that was not habit forming and was not supported by the advertising of a financial empire, there is little doubt that effective counter measures would have followed quickly."

"The situation," concluded Garland, "affords unusual opportunities for the vast tobacco interests to support impartial researches into the effects that their products may have on human health."

In 1956, Charles Cameron, Medical Director of the American Cancer Society, offered a similar perspective. Cameron, who had initially been skeptical about the link between smoking and disease, now joined the growing medical consensus, indicating: "There is in some quarters an unbecoming skepticism of statistics in general and of these remarkably consistent results in particular. By some – a diminishing band, as I see it –

the findings are rejected because there is not 'laboratory proof.' We must remember that far less efficient statistical methods have pointed to direct and effective means of preventing illness many times in the past."

Cameron pointed out the limitations in seeking "experimental proof": "What is the nature of the proof which is demanded to establish the cancer-causing effect of cigarette smoking? If it is that smoke or another tobacco product must be shown to cause cancer of the lung under conditions of experimental control using living human subjects, then I hope the experiment will never be undertaken. No standards of proof in the entire world of research demand as much as that."

Cameron explained: "If the degree of association which has been established between cancer of the lung and smoking were shown to exist between cancer of the lung, and say, eating spinach, no one would raise a hand against the proscription of spinach from the national diet."

These leading figures in medical science now argued that the evidence was clear, convincing and scientifically persuasive and that physicians and public health officials had a responsibility to warn their patients and the public. They reasoned that medical knowledge incorporates social responsibility. The findings about lung cancer and smoking, according to these observers, had reached a level of significance and certainty that now triggered these professional responsibilities.

One additional indicator of medical consensus was the very fact that many physicians who closely followed the emerging evidence began the process of quitting smoking. Throughout this period, as researchers came to know the data, they reported quitting smoking. John Hill, too, had quit smoking in the 1940s.

Q: When was consensus reached?

A: There is, of course, no single moment at which one can identify the emergence of a scientific and medical consensus. For this reason, historians weigh a range of diverse data and evidence to assess the emergence of consensus and the authority and legitimacy of new knowledge. In the case of cigarette smoking there was, by the mid-1950s a wealth of findings, rigorously replicated and validated across the domains of clinical, population, and laboratory investigation.

Physicians, scientists and public health officials critically evaluated and confirmed these findings. Additionally, researchers responded directly to criticism or skepticism of their initial studies by designing and implementing new research studies.

Another approach to evaluating scientific consensus would be to examine the series of consensus reports issued by voluntary health agencies and the Public Health Service in the 1950s.

Q: Can you explain what a consensus report is, as you refer to it here?

A: Yes. Because the tobacco industry continued to denigrate and vigorously attack this data, there remained considerable medical and public confusion concerning what was known, and with what degree of confidence. As a result, a number of public and private agencies took steps to make comprehensive and objective evaluations of the research findings. In every instance (except for assessments offered by the industry itself) such consensus committees reached the same conclusions: the evidence was clear and powerful.

Q: Do these consensus reports support your conclusions about the existence of a scientific consensus in the 1950s?

A: Yes, they do.

Q: What consensus reports do you specifically rely on to support your conclusion about the existence of a scientific consensus in the 1950s?

A: One is the report from a group organized at the urging of Surgeon General Leroy Burney. Specifically, in 1956, at the urging of Burney, a study group on smoking and health was organized by the American Cancer Society, the American Heart Association, the National Cancer Institute, and the National Heart Institute. This group of distinguished experts met regularly to assess the character of the scientific evidence relating to tobacco and health. At that time the group noted that sixteen studies had been conducted in five countries all showing a statistical association between smoking and lung cancer. Among the studies they summarized it was demonstrated that: lung cancer occurs 5-15 times more frequently among smokers than non-smokers; on a lifetime basis one of every ten men who smoke more than two packs a day will die of lung cancer; and cessation reduces the probability of developing lung cancer.

They also noted that the epidemiological findings were supported by animal studies in which malignant neoplasms had been produced by tobacco smoke condensates. Further, human pathological and histological studies added evidence to strengthen the "concept of causal relationship." The authors concluded:

> Thus, every morphologic stage of carcinogenesis, as it is understood at present, has been observed and related to the smoking habit.
>
> The sum total of scientific evidence establishes beyond reasonable doubt that cigarette smoking is a causative factor in the rapidly increasing incidence of human epidermoid carcinoma of the lung. The evidence of a cause-effect

relationship is adequate for considering the initiation of public health measures. The group also recognized the value of continued investigation, noting that "additional research is needed to clarify many details and to aid in the most effective development of a program of lung cancer control."

Q: Were the conclusions you have cited published?

A: Yes, they were published in the journal *Science* in 1957. U.S. Exhibit 63,610 is a copy of the journal as published in 1957.

Q: Was the recognition of a need for additional research inconsistent with the group's conclusion that "the sum total of scientific evidence establishes beyond a reasonable doubt that cigarette smoking is a causative factor in the rapidly increasing incidence of human epidermoid carcinoma of the lung"?

A: No, it was not inconsistent. The researchers who had demonstrated the causal relationship between cigarette use and lung cancer understood that there was, of course, more to know about the relationship of cigarette smoking to cancer and other diseases. All scientific knowledge, they reasoned, is limited and provisional. In fact, among those who had done the pathbreaking work demonstrating that cigarettes cause disease, there was no question that there was more to know. Nonetheless, they reasoned that what was *known* – known scientifically – should be utilized for the benefit of public health in a timely way. As A. Bradford Hill explained later, in 1965:

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

Q: You mentioned the review organized by the American Cancer Society, the

American Heart Association, the National Cancer Institute, and the National Heart Institute in 1956. Were other assessments of the body of scientific evidence showing smoking to be a cause of disease undertaken in the 1950s?

A: Yes. In January 1959, another distinguished group of cancer researchers offered a substantive review of the available evidence linking cigarettes to lung cancer. The group was comprised of Jerome Cornfield, who was Assistant Chief, Biometrics Section, National Cancer Institute and Chairman, Department of Biostatistics at Johns Hopkins; William Haenszel of the Biometry Branch at the National Cancer Institute; E. Cuyler Hammond, Director of the Statistical Research Center Division of the American Cancer Society; Abraham M. Lilienfeld, Head of the Department of Chronic Diseases at Johns Hopkins; Michael Shimkin, Head of the Biometry and Epidemiology Branch at the NCI; and Ernst L. Wynder of Sloan-Kettering. This group carefully considered the range of alternative hypotheses to account for the significant rise in cases of, and deaths from, lung cancer. They concluded:

> The magnitude of the excess lung-cancer risk among cigarette smokers is so great that the results can not be interpreted as arising from an indirect association of cigarette smoking with some other agent or characteristic, since this hypothetical agent would have to be at least as strongly associated with lung cancer as cigarette use; no such agent has been found or suggested. The consistency of all the epidemiologic and experimental evidence also supports the conclusion of a causal relationship with cigarette smoking, while there are serious inconsistencies in reconciling the evidence with other hypotheses which have been advanced. Unquestionably there are areas where more research is necessary, and, of course,

no single cause accounts for all lung cancer. The information already available, however, is sufficient for planning and activating public health measures.

This paper, a copy of which is marked as U.S. Exhibit 63,607, also explicitly refuted ongoing critiques by statisticians R. A. Fisher and J. Berkson, often trumpeted by the industry.

Cornfield and his colleagues noted that investigations of the health implications of smoking had significantly accelerated following the epidemiological studies earlier in the decade. Not only did the new prospective studies conducted in diverse populations confirm and strengthen the earlier findings, so too did pathological and toxicologic analyses.

Q: You mentioned critiques by statisticians Fisher and Berkson. Can you describe those critiques?

A: Berkson, a physician and head of the Mayo clinic statistics unit, continually raised questions about possible bias in the selection of individuals in the respective epidemiological investigations. According to Berkson, the fact that a number of these studies had been conducted among hospitalized patients and utilized volunteers could result in bias and confounding. This critique was repeatedly addressed and responded to by the epidemiologic researchers. In addition, Berkson was especially skeptical about the findings since cigarette smoking seemed not only to result in more cases of lung cancer but in higher mortality from multiple causes. When such investigation "turns out to indicate that smoking causes or provokes a whole gamut of diseases, inevitably it raises the suspicion that something is amiss." But, of course, smoking did come to be linked to a wide range of different diseases. In this instance, Berkson's *a priori* commitment to

specificity (one cause, one disease) led him to dismiss findings of impressive significance. Despite new findings specifically addressing his critiques, Berkson remained unrelenting in his skepticism.

Fisher's critiques were based upon related concerns. The inability (based on obvious ethical objections) to conduct a randomized experiment, led him to question the results of the epidemiological studies. Additionally, he was deeply committed to constitutional or genetic notions of cancer causality. Fisher speculated that perhaps it was some constitutional factor that led individuals both to be smokers and to get lung cancer, even though smoking and lung cancer might not be causally related. Researchers such as Doll and Hill repeatedly rebutted this theory, returning to the critical question of how to account for the rise in lung cancers during the course of the 20th century, if the disease was simply "constitutional."

Q: Were the critiques of Fisher and Berkson considered to be legitimate at the time they were made?

A: Both Fisher and Berkson raised important questions, but their persistent critiques fell flat in the face of overwhelming evidence and the accumulation of studies replicating the findings. In the Cornfield paper marked as U.S. Exhibit 63,607, Cornfield and his colleagues observed:

> We see nothing inherently contradictory or inconsistent in the suggestion that one agent can be responsible for more than one disease, nor are we lacking in precedents. The Great Fog of London in 1952 increased the death rate for a number of causes, particularly respiratory and coronary disease, but no one has given this as a reason for doubting the causal role of the Fog. Tobacco smoke,

too, is a complex substance and consists of many different combustion products. It would be more 'incredible' to find that these hundreds of chemical products all had the same effect than to find the contrary. A universe in which cause and effect always have a one-to-one correspondence with each other would be easier to understand, but it obviously is not the kind we inhabit.

Nonetheless, the industry broadcast and rebroadcast these critiques. And ultimately, both Fisher and Berkson went to work for the industry as paid consultants.

Q: Did Cornfield and his colleagues reach any additional conclusions in their review that you find significant to your opinions as an expert witness?

A: They did. Importantly, Cornfield and colleagues noted that the persistent "debate" about the scientific findings regarding cigarette smoking was driven by the industry, indicating:

It would be desirable to have a set of findings on the subject of smoking and lung cancer so clear-cut and unequivocal that they were self-interpreting. The findings now available on tobacco, as in most other fields of science, particularly biologic science, do not meet this ideal. Nevertheless, if the findings had been made on a new agent, to which hundreds of millions of adults were not already addicted, and on one which did not support a large industry, skilled in the arts of mass persuasion, the evidence for the hazardous nature of the agent would generally be regarded as beyond dispute.

Cornfield suggested that the very idea of a "controversy" had been manufactured by the TIRC and other industry public relations efforts.

Q: We have now discussed the consensus reports contained in U.S. Exhibits

63,610 and 63,607. What other consensus reports, published in the same time period, that are important to your opinions?

A: Yes. By this time the Medical Research Council of Great Britain, as well as public health officials in the Netherlands, Norway, and the U.S. had all accepted the conclusion that cigarette smoking caused lung cancer. In 1957, the Medical Research Council issued a statement, printed in the *British Medical Journal* and the *Lancet* and marked as U.S. Exhibit 63,537, concluding: "Evidence from many investigations in different countries indicates that a major part of the increase [in lung cancer] is associated with tobacco smoking, particularly in the form of cigarettes. In the opinion of the Council, the most reasonable interpretation of this evidence is that the relationship is one of direct cause and effect. The identification of several carcinogenic substances in tobacco smoke provides a rational basis for such a causal relationship."

In November 1959, US Surgeon General Leroy E. Burney offered his own evaluation of the scientific evidence linking cigarettes to lung cancer. Burney revisited the epidemiologic data, as well as other confirmatory animal and pathological investigations. After a thorough assessment of current data, Burney came to the following conclusions in *JAMA*, as marked as U.S. Exhibit 21,022:

> There can be no doubt that a significant portion of the increase in lung cancer is real. This rise has not been caused solely by improvements in diagnostic techniques, better reporting on death certificates, or an increase of older persons in the population. If we accept as valid the sequence of pathological changes given above the prevention of lung cancer, to a large extent, becomes possible. This will be accomplished if carcinogenic substances from any source can be kept

out of the air inhaled into the lungs.

For Burney, this fact meant that there were important and timely opportunities to prevent disease:

> The Public Health Service believes that the following statements are justified by studies to date:
>
> 1. The weight of evidence at present implicates smoking as the principal etiological factor in the increased incidence of lung cancer.
> 2. Cigarette smoking particularly is associated with an increased chance of developing lung cancer.
> 3. Stopping cigarette smoking even after long exposure is beneficial.
> 4. No method of treating tobacco or filtering the smoke has been demonstrated to be effective in materially reducing or eliminating the hazard of lung cancer.
> 5. The nonsmoker has a lower incidence of lung cancer than the smoker in all controlled studies, whether analyzed in terms of rural areas, urban regions, industrial occupations, or sex.
> 6. Persons who have never smoked at all (cigarettes, cigars, or pipe) have the best chance of escaping lung cancer.
> 7. Unless the use of tobacco can be made safe, the individual person's risk of lung cancer can best be reduced by elimination of smoking.

As Burney's analysis had indicated, by 1959 the evidence of the harms of cigarette smoking was nothing short of overwhelming.

In 1960, the World Health Organization also issued a statement signaling its own confirmations of the US Surgeon General's and the Medical Research Council's

conclusions, after conducting their own review of the scientific findings.

In 1962, yet another thorough and far-reaching assessment of the scientific evidence reached these same conclusions. The British Royal College of Physicians, after two years of investigation, stated in a report marked as U.S. Exhibit 21,023 that: "Diseases associated with smoking now cause so many deaths that they present one of the most challenging opportunities for preventive medicine today." The report concluded:

> The strong statistical association between smoking, especially of cigarettes, and lung cancer is most simply explained on a causal basis. . . . The conclusion that smoking is an important cause of lung cancer implies that if the habit ceased, the death rate from lung cancer would eventually fall to a fraction, perhaps to one fifth or even, among men, to one tenth of the present level. Since the present annual number of deaths attributed to lung cancer before the age of retirement is some 12,000 . . . a large amount of premature shortening of life is at issue.

As this statement makes clear, lives were at stake in the assessment of this scientific evidence linking cigarettes to disease. Over and over again, independent critical evaluation of the scientific findings that cigarettes caused lung cancer reached the same conclusion.

Q: For your work as a medical historian, what is the value of assessments of the scientific consensus like those you have described?

A: The value arises in large part because of the fact that the TIRC, under the direction of the industry with the assistance of Hill and Knowlton, was actually quite effective in assuring that the industry position of "no proof" and the need for "more research" reached the national media. Typically news accounts of new medical findings

would be accompanied by a statement from TIRC insisting that "nothing new" had been found and that the studies were "merely" statistical. As a result, and perhaps to a degree unprecedented in the history of medicine, thorough and objective statements reviewing the findings came to be of greater significance. Indeed, the series of consensus statements on the part of major medical and public health groups had never before occurred in the face of a scientific "controversy." The TIRC had been very effective in mobilizing a relatively small group of skeptics and amplifying their views as if they were equal in number and significance to the scientific consensus about the harms of smoking. But these skeptics and the industry that broadcast their views produced no new research challenging the overwhelming evidence that smoking constituted a serious risk to health.

Because of the unprecedented resources brought to bear by the industry in shaping this controversy, it became critical that groups of independent scientists be brought together to offer their systematic assessment of the evidence.

Q: Dr. Brandt, you indicated that Cornfield and his colleagues suggested that the very idea of a "controversy" had been manufactured by the TIRC and other industry public relations efforts. Do you agree with Cornfield's suggestion?

A: I do agree with Cornfield's conclusion that the controversy was spurred on by the industry in their own interest. This conclusion, by the way, is not just my *post hoc* assessment; Cornfield's views were shared by other important contemporary observers, such as Alton Ochsner and Evarts Graham.

While there is no question that there was genuine skepticism among some scientists about the findings, this skepticism was sustained and amplified by the tobacco industry through the work of Hill and Knowlton and TIRC. The persistence of a small

group of skeptics is not an indication of a lack of consensus.

Q: How do you, as a historian of science, analyze skepticism in the face of new scientific findings?

A: Generally, historians of science and medicine would not simply identify those who come to accept a particular finding, on the one hand, and those who are skeptical on the other. We are typically interested in identifying the particular context, or, one might say "location," of the various positions that historical actors (in this case physicians and scientists) might take on a particular question. In the instance of assessing the relationship of smoking and lung cancer, it is important to consider that skepticism may be attributed to outside influences, or what today we call conflicts of interest. In the case of the smoking lung cancer controversy, such conflicts of interest played a particularly important role in the following way. The industry, through the TIRC and its public relations strategy, was especially effective in identifying and supporting skeptics. Skeptics were invited to join the Scientific Advisory Board of the TIRC; they and their home institutions were provided with research grants from the TIRC. Their views were effectively solicited and broadcast widely by the TIRC and the TI. In this way, the tobacco industry acted to create, sustain, and perpetuate the debates about the relationship of smoking and health.

As a result, there remained a widespread perception of an active and highly contested scientific controversy despite overwhelming evidence and impressive scientific consensus that smoking caused serious disease.

Q: In your opinion, was there a "real" controversy about smoking and health in the 1950s?

A: In my work on the history of tobacco, I have not approached the question in this way. To simply ask if the controversy was "real" suggests a bimodal response: yes, it was; no, it was not. The goal in my historical research has been to place the scientific and medical research about smoking and disease into a full context and to "locate" the various positions that physicians and scientists took as they individually and collectively evaluated the evidence.

Q: How have you approached the question in your work on the history of tobacco?

A: Rather than asserting that the controversy was real or not, I have evaluated the range of interests that were engaged in the controversy. And I have asked what were the causes of the controversy? What forces contributed to its resolution? And what forces and interests contributed to its continuation? Historians who claim that the controversy was "real" have often failed to fully examine the trajectory of research, evidence, and skepticism over the course of the 1950s. Initially there were a number of important skeptics, but even as early as 1953 many who had voiced skepticism had come to modify their positions in the face of new and convincing scientific research. To suggest that through the 1950s and 1960s that eminent scientists equally and independently lined up on both sides of a “controversy” about the harms of smoking is to grossly misrepresent the historical record.

During the decade the industry had developed explicit strategies to attempt to maintain and foment controversy in the face of new research, increasingly overwhelming evidence, and emerging scientific consensus. In my own work, I have centered attention on the role of the tobacco industry in shaping the particular character and nature of this

controversy. And I have concluded that the industry had a major role in perpetuating the notion of a controversy to serve their interests.

Q: What do you base your own conclusion on?

A: Focusing on the period from 1954-1964, I look to the public relations function of the TIRC, the TIRC's response to consensus statements, and the discrepancy between the industry's public message and internal company research. The TIRC was front and center in the industry's response to the mounting scientific evidence. TIRC representatives frequently issued statements during this period explaining: TIRC's "purpose is solely to obtain new information and to advance human knowledge in every possible phase of the tobacco and health relationship." Nonetheless, the TIRC program conducted very little research that focused on the constituents of cigarette smoke and/or the health of smokers. According to repeated claims of the TIRC, many independent and responsible scientists continued to voice skepticism – and opposition – to the findings that cigarette smoking causes serious disease. In reality, such views were increasingly marginal and typically voiced by those with financial ties to the TIRC.

Q: I want to take the public relations function of the TIRC, the TIRC's response to consensus statements, and the discrepancy between the industry's public message and internal company research one by one. Can you explain why you identify the public relations function of the TIRC as a basis for your conclusion that the tobacco industry had a major role in perpetuating the notion of a controversy?

A: Anything but an independent research organization committed to exploring the health effects of cigarette use, it instead proved to be a sophisticated public relations and legal tool of the tobacco industry: It worked assiduously and consistently to attack and

deride the emerging scientific consensus regarding the harms of smoking; its research program was generally irrelevant to the immediate questions of the harms of smoking; and it acted as a clearinghouse for misinformation and misdirection in the scientific debate.

Rather than conducting research to clarify the relationship of tobacco and health – as it promised it would – the TIRC stood firmly committed from the outset to insisting on a "controversy." Its principal commitment was to maintaining the notion of an "open question" regarding smoking and health.

Q: What do you rely on to reach the conclusion that the TIRC had a public relations focus during the 1954-1964 time period?

A: The history of the TIRC's activities, as shown by internal documents, public statements and its various programs and activities, including the formation of the Tobacco Institute as a separate public relations entity, support this conclusion. For example, while the industry publicly voiced over and over the research focus of TIRC, in fact internal documents show a recognition that TIRC was primarily a public relations vehicle. In April 1955, for instance, W.T. Hoyt, Executive Secretary of the TIRC explained the relationship of public relations and research in the TIRC's program in a document that has been marked as U.S. Exhibit 33,006:

> Essentially, the major purposes of the TIRC are Research and Public Relations. Our job is to maintain a balance between the two, and to continue to build soundly so that at all times Research and Public Relations complement each other. In that way we intend to assume the mantle of leadership and, ultimately, to create a condition where the public will look to the TIRC for answers rather than to others.

Just as significantly, representatives of Hill and Knowlton attended Scientific Advisory Board meetings of the TIRC from 1954 to 1964.

Industry accounts of the "controversy" consistently set up straw-men and misrepresented the evidence that smoking causes disease. Industry literature, for example, frequently pointed to the fact that nonsmokers also get lung cancer. Therefore, they argued, how could one attribute lung cancer to cigarette smoking? But none of the researchers exploring the relationship of smoking to lung cancer purported to find such a one-to-one relationship. And medical science had long accepted notions of cause which assumed that not every exposure to a causal agent resulted in disease.

Although the TIRC persistently castigated the major studies incriminating smoking as a cause of disease, they were far more sympathetic when an epidemiologic study apparently showed no harm. In *Tobacco and Health*, a publication sent to doctors and dentists, one copy of which is marked as U.S. Exhibit 72,185, the TIRC announced that "Cigarette smoking is compatible with normal health, and even heavier-than-average cigarette smoking is compatible with better-than-average mortality rates, according to a scientific report presented before the Southern Medical Association." The publication, which appeared 3 times a year, also declared in 1958: "Continuing scientific research lends support to the position that too many unknowns exist today concerning lung cancer to warrant conclusions placing a major causative role on cigarette smoking, according to the 1957 Report of the Scientific Director of the Tobacco Industry Research Committee." *Tobacco and Health*, with a circulation that ultimately exceeded 500,000, was utilized by TIRC as a public relations vehicle to influence health professionals. Targeting health professionals was particularly conducive to one of the major thrusts of the TIRC, which

was to emphasize that human cancers were complex processes, difficult to study, and difficult to understand.

Q: I'd like you to take a look at U.S. Exhibits 21,345, 21,264, 21,282, 22,459, 22,983, 21,299, 26,174, 62,851, 62,844, 62,845, 62,847, 62,849 through 62,851, 77,032, 77,059, 77,060, 77,068 through 77,071, 77,111, 77,112, 86,010, 86,011, 86,018 through 86,021, 86,044, 86,045, 86,048, 86,050, and 86,052. Can you describe these documents?

A: Yes, I can. These are additional issues of *Tobacco and Health* that were used by the TIRC to target health professionals.

Q: Dr. Brandt, have you studied the TIRC's scientific program?

A: I have.

Q: And in your opinion, notwithstanding what you've described as the TIRC's emphasis "that human cancers were complex processes, difficult to study, and difficult to understand," did the TIRC develop a scientific program with an approach to the study of human cancers in order to address questions concerning the harms caused by cigarette smoking?

A: It did not. The TIRC never developed an approach to carcinogenesis and tobacco that could resolve the question of the harms induced by cigarette smoking. Although some researchers explored alternative hypotheses, the TIRC did not typically pursue direct research on cigarettes and disease. Rather than addressing the constituents in tobacco smoke and their demonstrated effect on the human body, the TIRC directed the predominance of its resources to alternative theories of the origins of cancer centering on genetic factors and environmental risks. Most research projects funded through its

Scientific Advisory Board were irrelevant to the immediate questions of the harms of tobacco. At the same time, the TIRC used truisms such as the "need for more research," and "how much more there is to learn" to deflect attention away from what was known.

Q: I'd like to come back to questions about research funded by the TIRC, but first, are there other aspects of the TIRC that you rely on to support your conclusions about TIRC's devotion to public relations?

A: There are. One thing to look at in particular is the industry's selection of the first Scientific Director. The first Scientific Director of TIRC, appointed in 1954, was biologist C.C. Little, the former president of University of Maine, University of Michigan, and the founder of the Roscoe B. Jackson Memorial Laboratory. Little's personal commitments and assumptions about cancer causality made him an ideal proponent of the industry's goal of maintaining a "controversy" rather than scientifically resolving the questions regarding smoking and health. Little explained at the press conference announcing his appointment that: "I am an ultraconservative about cause and effect relationships." Little had no compunction, however, about offering unsubstantiated claims about the health benefits of cigarette use such as that found in U.S. Exhibit 20,278: "It is very well-known, for example, that tobacco has relaxed a great many people. It is a very good therapy for a great many nervous people."

C.C. Little also argued that there were no known carcinogens in tobacco tars (this despite clear industry documentation to the contrary). He repeatedly centered attention on the so-called "constitutional hypothesis"; other environmental risks; and the need for more research, stating in a document marked as U.S. Exhibit 20,686:

Too little is known about many factors, including why people smoke or what kind

of people become particularly heavy smokers. . . .

The problem of causation of any type of cancer is complex and difficult to analyze. All research on this so-called constitutional disease is, and must be, painstaking and time consuming. There is not known today any simple or quick way to answer the question of whether any one factor has a role in causing human lung cancer. . . .

Despite all the attention given to smoking as an accused factor in human lung cancer, no one has established that cigarette smoke, or any one of its known constituents, is cancer-causing to man.

Little tended to castigate as moralists those whose findings showed harms with tobacco use, arguing in the same document:

The right of an individual to determine his own level or threshold of convincibility is unquestioned. There are and will always be individuals who are convinced without the need of experimental evidence that *all* tobacco in *any* form is evil, noxious and toxic. There are individuals with a similar attitude toward alcohol, coffee, and the use of drugs, sera or medicines. . . .

Such assumptions stimulated some investigators to begin an enthusiastic hunt for *the* 'component' or 'components' in tobacco smoke that can be blamed for the unproved cause-and-effect relationship as well as for the reported production of skin cancer in some experiments with certain strains of laboratory mice.

The focus of the TIRC and Little on the need for more research would continue throughout the 1950s and beyond.

The selection of Little as the TIRC Scientific Director also contributed to the

TIRC's focus due to Little's direction of the TIRC towards what he called "pioneer research." He claimed that studies focused on cigarettes could "stifle or delay needed research to find the basic origins of lung cancer or cardiovascular diseases, which are most powerful, diversified and deadly enemies to our well-being." But this strategy precluded any significant investigation into the toxic effects of cigarette use.

Q: Dr. Brandt, I'd like to show you U.S. Exhibit 20,636. Have you seen this document before?

A: I have. This is a statement made by the TIRC in 1958 through its Chairman, Timothy V. Hartnett, reasserting the public commitments it had made in the Frank Statement: "At its formation in 1954, the Tobacco Research Committee stated its fundamental position: 'We believe the products we make are not injurious to health. We are pledging aid and assistance to the research effort into all phases of tobacco use and health.' That statement and pledge are reaffirmed today by the members of the Tobacco Industry Research Committee."

Q: In your opinion, at the time this statement was made by Hartnett, had the TIRC provided "aid and assistance to the research effort into all phases of tobacco use and health"?

A: For the reasons I have explained, no, it had not provided aid and assistance to the research effort into tobacco use and health.

Q: In your opinion, from the time this statement was made in 1958 going forward, did the TIRC provide "aid and assistance to the research effort into all phases of tobacco use and health"?

A: No, it did not. In fact, at about this time, the tobacco industry sought to amplify

its public relations presence on smoking and health issues through the formation of the Tobacco Institute, not only failing to aid research into questions of smoking and disease, but also increasing the effort to simultaneously deny or distort legitimate science.

Q: Can you explain why you believe the formation of the Tobacco Institute constituted an effort to amplify the industry's public relations presence on smoking and health issues?

A: By mid-1956 the industry found itself in yet another public relations dilemma. The utility of the TIRC was constituted in its stated commitment to "objective" science and its search for the "truth." At the same time, industry executives voiced a repeated desire for a more aggressive public relations campaign. The Scientific Advisory Board had expressed its "strong opposition" to entering the fray, and Little found himself caught between Hill and Knowlton and his scientific colleagues recruited to serve on the SAB.

The legitimacy and influence of the TIRC rested upon the perception of restraint. As a result, Carl Thompson of Hill and Knowlton argued in one of the Hill papers, marked as U.S. Exhibit 88,409, that "A flamboyant campaign against the anti-smoking propagandists would unquestionably alienate much of the support of the moderates in both scientific and lay publics." Therefore, he urged that TIRC stay the course.

The only way to protect the public relations "capital" invested in the TIRC was to create a separate entity for more aggressive public relations and political lobbying. In 1958, the industry announced the creation of the Tobacco Institute. With regulatory initiatives on the horizon, especially proposals to label cigarettes as hazardous, John Hill had advised the creation of a trade association that would not have the limitations associated with TIRC. Although the division of labor between TIRC and the TI was

never precise, it had become abundantly clear that the public relations value of TIRC would be compromised by the aggressive lobbying and press management that would characterize TI.

Q: What is the importance, if any, of the relationship between the TIRC and TI for your expert opinions?

A: Both groups were organized and administered by Hill and Knowlton. Concern had grown about TIRC making partisan arguments on behalf of the industry while at the same time sponsoring research that the industry wanted to be perceived as "objective." So, in the words of TI counsel as reflected in U.S. Exhibit 21,773:

> the creation of a separate organization for public information was hit upon as a way of keeping Little inviolate and untainted in his ivory tower while giving a new group a little more freedom of action in the public relations field. I understand that the legal people were especially interested in this argument because they thought of Dr. Little as a potential witness and were not anxious to have him making public statements which could compromise his usefulness to them in court.

The relationship between the two organizations, therefore, and the objectives disclosed by industry documents, makes their relationship important to the formation of my opinions.

Q: Let me ask you to turn back to the TIRC and, in particular, the TIRC's response to consensus statements. Can you explain why you identify TIRC's response to consensus statements as a basis for your agreement with Cornfield's suggestion that the very idea of a "controversy" had been manufactured by the

TIRC and other industry public relations efforts?

A: Yes, I can. The TIRC's direct responses to the public statements emerging from groups of scientists and policy-makers were consistent with TIRC's general message, as well as that of TI. Little issued the following statement upon the publication of Burney's 1959 evaluation:

> Despite the recent research trends, the conclusions set forth in the Public Health Service review rely almost entirely on past reports that are no more conclusive today than when these reports were first published. Most of the points are not new but are familiar to the American public because they were first advanced some years ago in statistical studies that admittedly are not supported by experimental evidence.

Q: Dr. Brandt, please review U.S. Exhibit 22,981. Have you seen this document before?

A: I have.

Q: What is this document?

A: This document is a copy of the statement issued by Dr. Little following publication of the 1959 evaluation from Leroy Burney, as I have just described.

Q: In your opinion, was there any basis for Little's assertion?

A: There was not. It misstates the substance of Burney's evaluation, particularly ignoring the fact that Burney had carefully evaluated the science of recent investigators, and did not limit his assessment to epidemiological studies. At the time Little issued this statement, there was critical evidence to confirm the hypothesis that smoking causes disease drawn from clinical, population, and laboratory investigations. Burney had

carefully and critically addressed the arguments that Little and the TIRC had used to denigrate the evidence. Moreover – contrary to Little's assertion – Burney's report made explicit that the evidence implicating cigarettes as a cause of disease had come not only from sophisticated and repeated epidemiological studies, but from intensive clinical and laboratory investigations as well.

Q: Do you rely on any other responses by the TIRC to consensus statements?

A: I do. Little continued to insist that the TIRC program offered substantial new insights into the problem of carcinogenesis, arguing in a document marked as U.S. Exhibit 86,018, "Literally hundreds of studies have demonstrated the possible relation of multiple factors in the complex chain that may result in lung cancer." In a letter marked as U.S. Exhibit 63,530 to Stanhope Bayne-Jones, a member of the Surgeon General's Advisory Committee, Little criticized the 1962 Royal College Report, referring to the "weaknesses inherent" in this type of report. He contended that it

> advances no new evidence, presents no new or more penetrating form of analysis, and therefore ends up being purely a statement of the individual opinions of the small group of its composers.

This was, of course, offered in response to an extensive and careful review of previous scientific findings by eminent scientists in Great Britain. Nonetheless, the TIRC offered no evidence whatsoever to question the findings that cigarettes caused lung cancer and other diseases. And although the industry had explicitly promised to work with public health officials in the "Frank Statement," to the contrary, it sought to undermine the findings of Burney, the Public Health Service, and voluntary health agencies.

Q: Dr. Brandt, please review U.S. Exhibit 21,177. What is this document?

A: This is one of the documents I have relied on when evaluating the tobacco industry's response to consensus statements. It was prepared by Hill and Knowlton in 1959 and states:

> Comment from TIRC for the press remains an effective way to meet anti-tobacco publicity efforts and emphasizes the multiple factors that should be considered. This, of course, is complemented with a continuing program of supplying information to give editors and writers a balanced perspective on questions of tobacco and health.
>
> Published in the November 28 issue of the *Journal of the American Medical Association*, the article signed by the Surgeon General presented a selection of published data about smoking as related to lung cancer. Anticipating the appearance of the Burney article and learning of its contents in advance of publication, it was possible to provide the press promptly with statements from Dr. C.C. Little, Mr. James P. Richards, president of The Tobacco Institute, and others. Press stories used the tobacco industry comment in covering the Surgeon General's article.

The industry's response to such carefully prepared consensus statements was to be prepared to attack them from a public relations perspective. The Tobacco Institute released a statement from James Richards, its president, on the day of the publication of the Burney Statement in 1959. In the statement, marked as U.S. Exhibit 22,720, Richards accused Burney of "largely ignoring the balanced evidence reviewed in his own scientific paper and summarizing his opinions with so little regard for that evidence . . . . During the months we have been hearing about this new study of old findings by the Surgeon

General's office, we had hoped that repeated assurances of fair play would be borne out. It is obvious they have not."

Hill and Knowlton's expert staff would then assure that Richards' statement received full coverage in the press, creating the notion that scientific controversy persisted. They vigorously pursued this public relations strategy, even as a great majority of physicians and scientists had come to accept the scientific findings produced during the decade.

Q: Let's now turn to the discrepancy between public message and internal company research. Can you explain why you identified the discrepancy as a basis for your opinion that the very idea of a "controversy" had been promoted and sustained by the TIRC and other industry public relations efforts?

A: As I've explained, historical evidence demonstrates that the TIRC never wavered from its essential mission of attempting to maintain "controversy" and an "open question" while avoiding research centered on the potential impact of smoking on health. Nonetheless, industry researchers did not accept this approach.

Q: Are there specific documents that you've identified in support of your opinion?

A: There are. In the document marked as U.S. Exhibit 21,369, drafted in 1958, for instance, visiting scientists (from British American Tobacco, Imperial Tobacco and Carreras) representing the Tobacco Manufacturers Standing Committee offered their impressions of their American colleagues. During their visit to the United States, Bentley, Felton and Reid met with research directors of major tobacco companies, the Scientific Advisory Board of the TIRC, its Industry Technical Committee, as well as

other experts in tobacco and disease in the academy and government. They noted that there was virtual consensus among researchers within the industry that cigarettes played a role in the production of human cancers.

> With one exception (H.S.N. Greene) the individuals whom we met believed that smoking causes lung cancer if by 'causation' we mean any chain of events which leads finally to lung cancer and which involves smoking as an indispensable link. In the U.S.A. only Berkson, apparently, is now prepared to doubt the statistical evidence and his reasoning is nowhere thought to be sound. . . .
>
> In their opinion T.I.R.C. has done little if anything constructive, the constantly re-iterated 'not proven' statements in the face of mounting contrary evidence has thoroughly discredited T.I.R.C., and the S.A.B. of T.I.R.C. is supporting almost without exception projects which are not related directly to smoking and lung cancer. Liggetts [sic] felt that the problem was sufficiently serious to justify large-scale investment by the Company directly in experimental research on smoke and cancer, accepting privately that a strong case against tobacco had been made out and avoiding any public comment until their own research had provided something concrete to offer. . . .
>
> The majority of individuals whom we met accepted that beyond all reasonable doubt cigarette smoke most probably acts as a direct though very weak carcinogen on the human lung. The opinion was given that in view of its chemical composition it would indeed be surprising if cigarette smoke were <u>not</u> carcinogenic. This undoubtedly represents the majority but by no means the unanimous opinion of scientists in U.S.A. These individuals advised us that

although it is not possible to predict unambiguously the effect of any substance on man from its effect on experimental animals the generally successful use of animals in other fields as a model for man fully justifies their use in our problem.

Q: Why do you find this document significant for the historical question of the source of the idea of a controversy over the health effects of cigarette smoking?

A: This document is important because it reflects the candid assessment of industry officials and scientists. In this instance, we have industry scientists confirming the idea that there was in fact broad consensus about tobacco as a carcinogen even among industry researchers, a fact the industry repeatedly denied publicly through its public relations operations. Further, the document indicates how marginal individual skeptics like Berkson and Greene had become by 1958. Finally, the document makes explicit that industry scientists had come to accept that smoking constituted a health risk, in spite of their public denials.

Q: What other documents have you identified in support of your opinion that the discrepancy between the industry's public message and internal company research demonstrates that the controversy over the health effects of cigarette smoking was perpetuated by the TIRC and other industry public relations efforts?

A: U.S. Exhibit 63,583 details the work of industry researchers to document potential carcinogenic agents found in cigarette smoke. In 1962, R. J. Reynolds chemist Alan Rodgman offered his own assessment of "the smoking and health problem." According to Rodgman:

> Although the major part of the sales of this company consists of cigarettes, what the Company sells is cigarette smoke. This company, therefore, should be

concerned with the physiological properties and composition of cigarette smoke. The benefits from such knowledge are obvious, particularly if it anticipates possible governmental regulation. During the past two decades, cigarette smoke has been the target of a host of studies relating it to ill-health and particularly to lung cancer. The majority of these studies incriminate cigarette smoke from a health viewpoint. . . .

Epidemiological data: The results of 34 different statistical studies show that cigarette smoking increases the risk of developing lung cancer. Many authorities believe the relationship to be one of cause-and-effect. . . . The statistical data from the smoking-health studies are almost universally accepted. After more than ten years, criticisms of the studies have been reduced to the dictum A statistical study cannot prove a cause-and-effect relationship between two factors.

Rodgman made explicit that reports within the industry considered the evidence of smoking's harm convincing.

The Evidence to Date: Obviously, the amount of evidence accumulated to indict cigarette smoke as a health hazard is overwhelming. The evidence challenging this indictment is scant. Attempts to shift the blame to other factors, e.g., air pollutants, necessitates acceptance of data similar to those denied in the cigarette smoke case. . . .

It has been repeatedly stated that some scientists discount the cigarette smoke-lung cancer theory. This is true. But it should be noted that many of those quoted in this regard are on record with contrasting views, e. g., Berkson, the statistician, has stated "…the definitive important finding of these statistical studies is not that

there is an association between smoking and lung cancer, but that there is an association between smoking and deaths from all causes generally."

Rodgman expressed concern and frustration that most aspects of the smoking and health questions had been left to the TIRC. He complained:

> If a company plead "Not guilty" or "Not proven" to the charge that cigarette smoke (or one of its constituents) is a factor in the causation of lung cancer or some other disease, can the company justifiably take the position that publication of data pertaining to cigarette smoke composition or properties should be withheld because such data might affect adversely the company's economic status when the company has already implied in its plea that no such etiologic effect exists?
>
> It is not my intent to suggest that this Company accept the cigarette-smoke-health data at face value, but I do suggest that we <u>actively</u> participate in cigarette smoke-health studies.

Q: Why do you find this document significant for the historical question of the source of the idea of a controversy over the health effects of cigarette smoking?

A: Again, this is an important document because it offers a candid, internal assessment from an industry scientist. According to Rodgman, the epidemiologic studies were "almost universally accepted" and the evidence that smoking was a health hazard was "overwhelming." This is not a *post hoc* assessment, but rather a contemporary evaluation by a senior company scientist written two years before the Surgeon General's Report. Further, it suggests how distant the public relations approach was from credible scientific assessments of the health effects of smoking. Despite such internal frustration

– and despite the unanimity of independent evaluations and the repeated confirmations of the scientific findings – the industry remained committed to the strategy it had devised in 1953 and 1954. It had soon become clear that no particular evidence or scientific approach would convince C. C. Little and the TIRC of the harms incurred by smoking.

Q: Dr. Brandt, as a medical historian, have you developed opinions about the 1964 Surgeon General's Report?

A: Yes, I have.

Q: What are those opinions?

A: The Surgeon General's Report of 1964 was an unimpeachable statement of scientific consensus. It is a document of genuine historical significance. It marked the critical recognition that the federal government would assume the responsibility of providing the public with a scrupulous non-partisan scientific assessment of the harms of a consumer product. No other public entity had the capacity or resources to offer such a comprehensive and objective assessment. Given the resources which the industry had brought to bear to foment and sustain the notion of a scientific controversy it became crucial for the government to develop a process to evaluate carefully and critically the available evidence. This process was important for at least two reasons. Only with this type of unassailable evaluation could the government adequately inform the public. And secondly, such evidence would be central to efforts to legislate programs for health promotion and disease prevention. Given the claims of "controversy" and widespread public confusion about the harms of smoking, the word of the Surgeon General's Advisory Committee provided a critical process in the production of useful public knowledge of science. The Report became a model for nonpartisan, independent

governmental assertions of scientific evidence of public moment.

Q: Will you explain the basis for your opinions?

A: My opinions are based on the circumstances surrounding the formation of the Surgeon General's Advisory Committee, the work of the Advisory Committee, and the substance of the Report itself, all of which contribute to the Surgeon General's Report of 1964 being widely considered by historians to be one of the most significant documents in the history of twentieth century public health.

Q: I'd like to examine those three issues – the formation of the Committee, the work of the Committee, and the substance of the Report – one at a time. As a medical historian, what do you find most significant in the circumstances surrounding the formation of the Surgeon General's Advisory Committee?

A: Since the early 1950s, with the publication of the pathbreaking epidemiological studies in the U.S. and the U.K., the findings demonstrating that smoking causes disease had been widely challenged and distorted by the tobacco industry and its representatives.

During the 1950s a powerful consensus had emerged in the medical and scientific communities concerning the harms associated with cigarette use. Nonetheless, the industry had been successful in creating the impression of a "continuing controversy" through its intensive public relations efforts (including the activities of TIRC, and, after 1958, the Tobacco Institute). At every opportunity industry representatives insisted there was "no proof," that the impact of smoking on health was an "open question," and that intensive additional research would be required to find the "truth." As a result of this campaign, there remained substantial public misconceptions about the state of scientific knowledge of the harms of smoking.

The Surgeon General's Advisory Committee on Smoking and Health was organized to evaluate the evidence about cigarettes and disease and offer a definitive assessment. As a result, the process of the committee's work, its selection, and its findings had to represent a model of objective, public scientific and medical inquiry. If the Committee was to offer a rigorous and systematic assessment of the health implications of smoking, it was crucial that it be committed to open inquiry.

Q: How were those concerns accounted for in the formation of the Committee, if at all?

A: To establish the Advisory Committee, Surgeon General Luther Terry created a list of some 150 individuals. None were known to have taken a public position regarding the relationship of smoking and health. These individuals represented a number of fields and medical specialties from pulmonary medicine to statistics, cardiology to epidemiology. This list was then circulated to the American Cancer Society, the American Heart Association, National Tuberculosis Association, American Medical Association, as well as the Tobacco Institute. Each group was permitted to eliminate any name, without any reason cited. Individuals who had already published on the issue or had taken a public position were also eliminated. The selection process indicated Terry's commitment to a process that would eventuate in a genuine and definitive conclusion. He had insured that the Report could not be attacked on the basis of its membership. All ten of the members were eminent physicians and scientists; eight were medical doctors, one was a chemist and the other a statistician. Three of the panelists smoked cigarettes, two others occasionally smoked pipes or cigars. Also, as the Report explained at page 14 as it has been marked as U.S. Exhibit 64,057:

All of the major companies manufacturing cigarettes and other tobacco products were invited to submit statements and any information pertinent to the inquiry. The replies which were received were taken into consideration by the Committee.

Terry's first ten selections all agreed to serve on the Committee, indicating to him, "that these scientists were convinced of the importance of the subject and of the complete support and confidence of the Public Health Service," as he wrote retrospectively in 1983 in the *New York State Journal of Medicine*, marked as U.S. Exhibit 21,376.

Q: Who were the ten members of the Committee?

A: Walter J. Burdette was a prominent surgeon and chair of the Surgery Department at the University of Utah; John B. Hickam the Chair of Internal Medicine at the University of Indiana. Charles LeMaistre was a pulmonary specialist and head of a very large cancer treatment center. The pathologists joining the Committee were Emmanuel Farber, Chair of Pathology at the University of Pittsburgh and Jacob Furth from Columbia, an expert on the biology of cancer. Maurice Seevers was Chair of the University of Michigan Pharmacology Department. Louis Fieser of Harvard University was an eminent organic chemist. Completing the Committee were Stanhope Bayne-Jones, a bacteriologist, head of New York Hospital and dean of Yale Medical School, Leonard H. Schuman, epidemiologist at the University of Minnesota, and William G. Cochran, a Harvard University mathematician with expertise in statistical methods. By appointing this distinguished group, Terry assured that the Advisory Committee would be protected from political attacks and charges of bias and subjectivity. The Report drew on the respective disciplinary strengths of the committee members.

Q: As a medical historian, what do you find most significant in the circumstances surrounding the work of the Surgeon General's Advisory Committee?

A: Terry set the charge for the Committee, and the charge itself is significant. He divided the work into two distinct phases. The first phase, the work of the Advisory Committee, was to determine the "nature and magnitude of the health effects of smoking."

Q: Where is that quotation taken from?

A: This quotation comes from one of the initial planning documents for the committee, reproduced here as U.S. Exhibit 63,531, now preserved in the Records of Public Health Service held in the National Archives in what is known as Record Group 90. I first conducted research in this collection in the late 1980s. It contains a great deal of unpublished correspondence, memos, and minutes relating to the process of the Surgeon General's Advisory Committee. Again, research in such collections is characteristic of professional historical investigation.

As these documents show, the committee understood that there had been considerable debate throughout the 1950s – and also going back in medical history – about how best to categorize the term cause. Was a cause both necessary and sufficient to result in disease? Might there be something that only sometimes causes disease? Might there be other factors? The industry had exploited these questions over the previous decade to obfuscate much that was scientifically known about tobacco and disease.

Q: Is there anything else included within what you find most significant in the

circumstances surrounding the work of the Surgeon General's Advisory Committee?

A: Yes. The Committee sought to arrive at a clinical judgment on smoking. As one public health official explained, also in U.S. Exhibit 63,531, "What do we (that is, The Surgeon General of the United States Public Health Service) advise our Patient, the American public, about smoking." At its first meeting in November 1962, the Committee decided that it would base its assessment on a comprehensive review of the now considerable existing data; new research would be outside the capability of the Committee and delay too greatly the report of any conclusions.

The Committee met together nine times in just over a year. In between these meetings both committee members and staff worked to review, critique, and synthesize what had become a formidable volume of scientific work on tobacco. Terry promised that the report on these findings would be followed by phase II, proposals for remedial action. This was significant, for it kept the Committee away from the politics which swirled around the tobacco question. What Terry sought – and ultimately got – was a document that would be unimpeachable from a scientific point of view. Terry astutely recognized that the Advisory Committee could only speak with authority about the scientific nature of the health risks of smoking; he would leave the policy questions to the political process.

The question at stake was what approaches could be utilized to assess scientifically the relationship between smoking and health? How could a variety of strategies and techniques be deployed in a timely way to devise answers to this important question? And, finally, what was the character and depth of the evidence presented on

which to make public policy and clinical and individual judgments? It is important to note that the conclusions of the report did not rely exclusively on statistics. Certainly the epidemiologic findings relied significantly on statistical methods, but the criteria that the Report promulgated to evaluate causality went significantly beyond any simple statistical association.

Q: Can you explain how the criteria utilized in the Report to evaluate causality went beyond simple statistical association?

A: Yes. In the Committee, William Cochran, the noted Harvard statistician, took the lead in organizing and drafting the Report's single most critical chapter, "Criteria for Judgment." Most centrally, the Committee labored over the issue of causality. What did it mean to say, for example, that cigarettes *caused* lung cancer? How should cause be distinguished from "associated with," "a factor," or "determinant"? The Report sought to clarify this issue at the outset, noting at page 21, "The word 'cause' is the one in general usage in connection with matters considered in this study, and it is capable of conveying the notion of a significant, effectual, relationship between an agent and an associated disorder or disease in the host." But members of the committee realized the complexity of saying simply that smoking causes cancer. Many individuals could smoke heavily throughout their lives, and yet not develop lung cancer; "cause" could imply a single process in which A, by necessity, would lead to B. Therefore they acknowledged the complexity:

> It should be said at once, however, that no member of this Committee used the word 'cause' in an absolute sense in the area of this study. Although various disciplines and fields of scientific knowledge were represented among the

membership, all members shared a common conception of the multiple etiology of biological processes. No member was so naive as to insist upon mono-etiology in pathological processes or in vital phenomena.

Despite the complexities in defining causality, the Committee nonetheless concluded that it was appropriate, given the evidence, to use this terminology. Therefore they concluded:

> Granted that these complexities were recognized, it is to be noted clearly that the Committee's considered decision to use the words "a cause" or "a major cause" or "a significant cause," or "a causal association" in certain conclusions about smoking and health affirms their conviction.

Q: How was the issue of cause ultimately addressed in the Report?

A: The Surgeon General's Committee understood that the public's health was at stake, and in the medical sciences, cause always demanded inference. The Committee identified a set of criteria to evaluate the significance of a causal relationship. Recognizing that the nature of inference, as a process, requires judgment, the Committee sought to explicitly define this process, outlining five specific conditions for judging causal relations.

First, the consistency of the association. Nearly all the retrospective and prospective studies produced comparable results, despite the fact that different methods were employed for collecting data.

Second, the strength of the association. The ratio of lung cancer rates for smokers versus non-smokers; age-adjusted for the two groups, that is, what is the size of the effect, and what is the size of the problem in relation to other diseases? The Committee

assessed the significance of the dose effect phenomenon, finding that risk increased with amount smoked. According to the Report:

> [A]verage smokers of cigarettes have a 9- to 10-fold risk of developing lung cancer, and heavy smokers, at least a 20-fold risk. Thus it would appear that the strength of the association between cigarette smoking and lung cancer must be judged to be high.

Third, the Committee looked to the specificity of association. This criteria, according to the Report:

> implies the precision with which one component of an associated pair can be utilized to predict the occurrence of the other, i.e., how frequently the presence of one variable (e.g., lung cancer) will predict, in the same individual, the presence of another (e.g., cigarette smoking).
>
> In a discussion of the specificity of the relationship between any factor possibly causal in character and a disease it may produce, it must be recognized that rarely, if ever, in our biologic universe, does the presence of an agent invariably predict the occurrence of a disease. Second, but not less important, is our growing recognition that a given disease may have multiple causes.

In the current case, the specificity of the association was especially strong. The Report explained, "of the total load of lung cancer in males about 90 per cent is associated with smoking."

Fourth, the temporal relationship of associated variables. As the Committee explained:

> [E]xposure to an agent presumed to be causal must precede, temporally, the onset

of a disease which it is purported to produce. . . . [N]o evidence has thus far been brought forth to indicate that the initiation of the carcinomatous process in a smoker who developed lung cancer antedated the onset of smoking.

Fifth, the Committee identified the coherence of the association, explaining in the Report that "[a] final criterion for the appraisal of causal significance of an association is its coherence with known facts in the natural history and biology of the disease."

Thus, the assessment of causality was part of a coherent and logical explanation.

Q: Were these criteria new to the evaluation of causal hypotheses at the time of the Report?

A: Physicians, scientists, and public health officials had utilized these criteria, in different ways, throughout medical history. Indeed, to an important degree, such approaches to assessing causality date back to the Hippocratic traditions in which agent, host, and environment were seen as interacting to determine health or disease. When James Lind concluded in 1747 that fresh fruit could prevent scurvy among sailors, he was utilizing related criteria; when John Snow came to the conclusion that cholera was carried in the London water supply in 1849 he was utilizing aspects of these criteria; when Joseph Goldberger discovered that pellagra was a vitamin-deficiency disease in 1917, he was applying aspects of these criteria. There are, of course, many other examples.

The clearly formulated criteria of the first Surgeon General's report did, however, bring together generations of observations across multiple scientific disciplines about disease and its causes in populations.

Q: As a medical historian, what do you find most significant in the substance of the 1964 Report?

A: The scope of material reviewed and the conclusions reached by the Committee are extraordinarily significant. In all, the 387-page report cited 7,000 articles; the critical review of this evidence substantiated the cigarette as a cause of disease. The *Report* came to the following conclusions:

> Cigarette smoking is associated with a 70 percent increase in the age specific death rates of males. The total number of excess deaths causally related to cigarette smoking in the U.S. population cannot be accurately estimated. In view of the continuing and mounting evidence from many sources, it is the judgment of the Committee that cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall death rate.
>
> Cigarette smoking is causally related to lung cancer in men; the magnitude of the effect of cigarette smoking far outweighs all other factors. The data for women, though less extensive, point in the same direction.
>
> Their risk of developing lung cancer increases with duration of smoking and the number of cigarettes smoked per day, and is diminished by discontinuing smoking.

The Report carefully evaluated the animal studies that had been conducted up to that time:

> Bronchogenic carcinoma has been produced in laboratory animals by the administration of polycyclic aromatic hydrocarbons, certain metals, radioactive substances, and viruses. The histopathologic characteristics of the tumors produced are similar to those observed in man and are predominantly of the squamous variety. . . .

> Condensates of tobacco smoke are carcinogenic when tested by application to the skin of mice and of rabbits, by subcutaneous injection in rats, and by painting the bronchial epithelium of dogs. . . .
>
> Bronchogenic carcinoma has not been produced by the application of tobacco extracts, smoke, or condensates to the lung or the tracheobronchial tree of experimental animals with the possible exception of dogs.

The Committee also found impressively high death rates among smokers, which increased with consumption:

> The death rate for smokers of cigarettes only, who were smoking at the time of entry into the particular prospective study, is about 70 percent higher than that for nonsmokers. The death rates increased with the amount smoked. For groups of men smoking less than 10, 10-19, 20-39, and 40 cigarettes and over per day, respectively, the death rates are about 40 percent, 70 percent, 90 percent, and 120 percent higher than for non-smokers. The ratio of the death rates of smokers to nonsmokers is highest at the earlier ages (40-50) represented in the studies, and declines with increasing age. The same effect appears to hold for the ratio of the death rate of heavy smokers to that of light smokers. In the studies that provided this information, the mortality ratio of cigarette smokers to nonsmokers was substantially higher for men who started to smoke under age 20 than for men who started after age 25. The mortality ratio was increased as the number of years of smoking increased. In two studies which recorded the degree of inhalation, the mortality ratio for a given amount of smoking was greater for inhalers than for non-inhalers.

From a clinical and public health perspective, the Report concluded that stopping smoking lowered an individual's risk of disease and health:

> Cigarette smokers who had stopped smoking prior to enrollment in the study had mortality ratios about 1.4 as against 1.7 for current cigarette smokers. The mortality ratio of ex-cigarette smokers increased with the number of years of smoking and was higher for those who stopped after age 55 than for those who stopped at an earlier age.

Q: You indicated that the Report is "widely considered by historians to be one of the most significant documents in the history of twentieth century public health." Do you agree with that assessment?

A: Yes, I do.

Q: Can you explain why you believe that the 1964 Report is one of the most significant documents in the history of twentieth century public health?

A: In the face of systematic efforts by the tobacco industry to obscure the science linking cigarettes to disease, the Surgeon General's Report provided a systematic, authoritative assessment of the evidence. Given the impact of the TIRC and the Tobacco Institute, such a review was essential. The Report confirmed and sustained the scientific findings relating smoking to disease that had been conducted over more than the preceding decade. Scientific questions about tobacco would persist, but the essential question of the hazards of smoking – critical to the public's health – had been systematically and thoroughly investigated, and definitively resolved. At the press conference announcing the Committee's findings, Terry was asked whether he would now recommend to a patient to stop smoking. His answer, reported in the *New York*

Times article reproduced as U.S. Exhibit 63,529, was an unequivocal "yes."

Q: Dr. Brandt, did the release of the Surgeon General's Report end the public idea of a "controversy" over the health effects of smoking?

A: It did not.

Q: Do you have an opinion as to why the Report did not end the public idea of a controversy?

A: Yes, I do. Although the Report was widely regarded within the scientific and medical communities as definitive, the industry continued to mount a major public relations campaign to encourage the public view that the "controversy" regarding cigarettes and their impact on health continued.

The Report offered the industry an important opportunity to change course by initiating a process of warning its patrons about the risks of using its product, but the industry nevertheless decided to maintain the essential strategy that it had established in 1953: first, insist that there is no proof that tobacco causes disease; second, disparage and attack all studies indicating a relationship between tobacco and disease; third, support basic science research on cancer, largely unrelated to the hypothesis that smoking and cancer are linked; and fourth, support research on alternative theories of carcinogenesis.

Even before the release of the first Surgeon General's Report, the scientific consensus regarding the harms of smoking was tacitly acknowledged among industry researchers and executives. And yet the public position of the companies remained one of distortion and denial of the scientific facts. Following the release of the Surgeon General's Report, the principal approach within the industry to the burgeoning knowledge of tobacco's harms was to "stay the course." The industry continued to rely

on the basic strategic formulations set forth in the mid-1950s. It continued to assert alternative causation theories (through arguments that had been effectively refuted scientifically). Despite overwhelming evidence from a wide range of disciplines including statistics and epidemiology, pathology and chemistry, clinical observation, and animal experimentation, the tobacco industry would continue to claim "no proof." Without offering explicit assurances of safety, the industry continued to attempt to create doubt about the scientific findings.

Q: What do you base your conclusions on?

A: My conclusions are based on industry public relations activity preceding the Report, internal industry assessments made prior to the publication of the Report, internal assessments of the industry's public relations strategy in the aftermath of the publication of the Report, and intense efforts by the tobacco industry to publicly contradict the Report's findings or otherwise minimize its impact on public consumption of cigarettes, all weighed against the backdrop of scientific knowledge and the actions of the public health community during this time period.

Q: As a medical historian, how are these things – industry public relations activity preceding the Report, internal industry assessments made prior to the publication of the Report, internal industry assessments of the Report upon its publication, and intense efforts by the tobacco industry to publicly contradict the Report's findings or otherwise minimize its impact on public consumption of cigarettes – important to your conclusions?

A: The Surgeon General's Advisory Committee and its Report generated considerable interest and concern within the tobacco industry. Much like the period in

1953 when scientific findings led to the plans for the TIRC and the industry's public relations campaign, the SGAC and its definitive report placed the industry into a new moment of assessment regarding its ongoing claims of "no proof" and its sustained denials of the impacts of smoking on health. These materials inform my assessment of the tobacco industry's activities in relation to the first Surgeon General's Report and the impact of those activities on the public idea of controversy.

Q: Can you provide examples of the first item you identified – industry public relations activity preceding the Report?

A: Yes, I can. Before the Surgeon General's Report was released in January of 1964, the tobacco industry took steps to minimize its impact. For example, George Allen, president of the Tobacco Institute, laid out the industry's ongoing position in a radio interview, the transcript of which is contained at U.S. Exhibit 63,600 and indicates in part:

> ALLEN: . . . All the medical authorities as far as I know, or practically all of them, agree that nobody knows what causes cancer, and specifically lung cancer, and this is a matter that remains to be found by thorough and energetic scientific investigation. . . .
>
> ALLEN: . . . That study [from the Royal College of Physicians, 1962], while considered very strong in its accusations, charges regarding smoking, nevertheless that study itself said that the majority of people smoke without any harm to their system. So if you say, am I going to get lung cancer if I smoke, a lot of people get lung cancer who have never smoked in their lives. We had a recent case, in which 27 nuns had died of lung cancer, not all together, not in the same place, but

among the statistics, who had never been near tobacco. So, certainly one would have to say that if you just ask the question flatly, if I smoke, will I get lung cancer, there are many, many cases and evidences - cited statements to the fact that there is no proved cause and effect relationship between the two.

This is just one example of the industry's public relations activity during this time period, but it represents a public statement that is flatly at odds with the scientific evidence at the time.

Q: And can you provide examples of the second item – internal industry assessments made prior to the publication of the Report?

A: Yes. Even though the public position of the tobacco industry remained unchanged, industry executives internally expressed great concern about the government's report. The Surgeon General's Report constituted the most significant crisis for the industry since 1953, when they created the TIRC. As a result, some executives argued for a new course of action in anticipation of its release. In their view, the traditional denials and calls for additional research would not suffice in the wake of such a definitive assessment as the Report would offer. In July 1963, in a document marked as U.S. Exhibit 63,599, Brown and Williamson's Chief Counsel, Addison Yeaman, offered his assessment:

> Assume the Surgeon General's Committee concludes (whatever the jargon of scientific analysis and to whatever degree specific) that there is real and compelling evidence of a causal - or even a strongly "predisposing" relation between smoking and cancer. Cardiovascular disorders will, in all probability, also be found related to smoking. Upon that event, it would seem clear to me the

industry must do two things.

> Whatever qualifications we may assert to minimize the impact of the Report, we must face the fact that a responsible and qualified group of previously non-committed scientists and medical authorities have spoken. One would suppose we would not repeat Dr. Little's oft reiterated "not proven". One would hope the industry would act affirmatively and not merely react defensively. We must, I think, recognize that in defense of the industry and in preservation of its present earnings position, we must either a) disprove the theory of causal relationship or b) discover the carcinogen or carcinogens, co-carcinogens, or whatever, and demonstrate our ability to remove or neutralize them. This means that we must embark - in whatever form of organization - on massive and impressively financed research into the etiology of cancer as it relates to the use of tobacco; what constituents or combination of constituents in cigarette smoke cause or are conducive to cancer of the lung. Certainly one would hope to prove there is no etiological factor in smoke but the odds are greatly against success in that effort.

Despite this candid assessment, no change in the industry's public posture of "ongoing controversy" resulted. In addition, Yeaman acknowledged that TIRC had principally acted as a public relations unit:

> The TIRC cannot, in my opinion, provide the vehicle for such research. It was conceived as a public relations gesture and (however undefiled the Scientific Advisory Board and its grants may be) it has functioned as a public relations operation. Moreover its organization, certainly in its present form, does not allow the breadth of research - cancer, emphysema, cardiovascular disorders, etc. -

essential to the protection of the tobacco industry. I suggest that for the new research effort we enlist the cooperation of the Surgeon General, the Public Health Service, the American Cancer Society, the American Heart Association, American Medical Association and any and all other responsible health agencies or medical or scientific associations concerned with the question of tobacco and health. The new effort should be conducted by a new organization lavishly financed, autonomous, self perpetuating, and uncontrolled save that its efforts be confined to the single problem of the relation of tobacco and human health.

But rather than collaborating with these health agencies – as they had promised to in the "Frank Statement" – the industry continued to oppose them. As Yeaman explained, the dominant concerns about litigation continued to dictate the industry's persistent denials.

...true we might worsen our situation in litigation, but that I would risk in contemplation of the greater benefits to be derived from going on the offensive.

...so long as the industry does not assume its research responsibility my long-held position would remain unchanged and I would oppose either outright attacks on the Surgeon General's Report or the giving of assurance to the smoking public not supported by research evidence.

All one can say is that the Report will in all probability greatly complicate the litigation problems.

Since denial of the relationship between smoking and disease had been deemed crucial to the industry's legal defense against liability litigation, as Yeaman indicated, any shift in position on the scientific evidence was viewed as potentially enhancing the litigation risk.

Q: And can you provide examples of the third item – internal assessments of the

industry's public relations strategy in the aftermath of the publication of the Report?

A: I can. For some in the industry, the Surgeon General's *Report* suggested the need to fundamentally rethink the earlier strategy of denial and obfuscation regarding the serious health implications of the cigarette. Future industry strategy, they suggested, would necessarily focus on technical competition to remove harmful substances from tobacco through effective filters and other innovations that they hoped to develop. Further denial, they believed, would only alienate the public. But there was no change in the industry's public insistence on a scientific controversy.

After the Report was released, executives continued to question internally the position of insisting on a "continuing controversy." By 1967 an RJ Reynolds executive, J.S. Dowdell, noted in a document marked as U.S. Exhibit 63,577 that "the industry has little, if any, positive evidence" to refute the findings that cigarettes cause disease. Indeed, after more than a decade of TIRC research, no single piece of evidence to contradict the knowledge of smoking's harm had been produced. In 1968, in a letter that has been identified as U.S. Exhibit 63,576, William Kloepfer, Jr., Vice-President of Public Relations for the Tobacco Institute, wrote to Earle Clements, President of the Tobacco Institute, expressing concern that the industry's strategy of consistent denial of harm and risk might now be untenable:

> Our basic position in the cigarette controversy is subject to the charge, and may be subject to a finding, that we are making false or misleading statements to promote the sale of cigarettes.

Indeed, from a historical viewpoint, there is much to be said for Mr. Kloepfer's

assessment.

Despite these suggestions, the cigarette manufacturers opted to continue to collude in a public relations approach that claimed that the evidence against their product was wholly inadequate; that the causes of lung cancer and other diseases were elusive; that attempts to regulate their product were unnecessary and inappropriate given the so-called "continuing controversy."

Q: You mentioned the "intense efforts by the tobacco industry to publicly contradict the Report's findings or otherwise minimize its impact on public consumption of cigarettes" as the fourth basis for your opinion that publication of the Report did not end the public idea of a "controversy" over the health effects of smoking. What specifically are the efforts by the industry that you rely on?

A: As I mentioned, despite internal industry debate about new strategies in the wake of the Surgeon General's Report, the industry continued to insist publicly that there remained an "open question" and "ongoing controversy" about the harms attributed to their product. In a memo to Kloepfer written a few months after Kloepfer's memo, Carl Thompson, who had worked on the tobacco account at Hill and Knowlton since 1953, described the research the tobacco industry should make public in their memos sent to doctors and dentists. The memo, marked as U.S. Exhibit 63,575, indicates:

> The most important type of story is that which casts doubt on the cause and effect theory of disease and smoking. . . . Thus, the headline should strongly call out the point - Controversy! Other factors! Unknowns!

Clarence Cook Little continued to insist that the evidence linking cigarettes to disease was nothing more than statistical noise. A 1969 CTR Press Release, marked as

U.S. Exhibit 63,574, explained:

> The scientist who has been associated with more research in tobacco and health than any other person declared today that "there is no demonstrated causal relationship between smoking and any disease. The gaps in knowledge are so great that those who dogmatically assert otherwise - whether they state that there is or is not such a causal relationship - are premature in judgment. If anything, the pure biological evidence is pointing away from, not toward, the causal hypothesis."

Little continued to imply that the evidence of a causal relationship was exclusively statistical:

> Statistical associations between smoking and lung cancer, based on study of those two factors alone, are not proof of causal relationship in the opinion of most epidemiologists. . . . According to Dr. Little, [the CTR] "has sponsored an increasingly effective program in tobacco and health research."

But Little offered absolutely no data to support such statements.

Q: Dr. Brandt, in your expert opinion, at that time – 1969 – had CTR and its predecessor, the TIRC, "sponsored an increasingly effective program in tobacco and health research"?

A: No, they had not.

Q: Dr. Brandt, in your expert opinion, was there ever a time – from the founding of the TIRC in 1954 through the dissolution of CTR – that the TIRC or CTR sponsored an effective program in tobacco and health research?

A: No, I do not believe that TIRC or CTR funded research was oriented to resolving

the question of the relationship of smoking to health.

Q: What do you base your opinion on?

A: My opinion is based on a number of sources and considerations, including the overall focus of the TIRC and CTR research program and certain of the structural and funding components of the organizations, as well as internal industry assessments of the program. CTR research centered attention on the basic science of cancer, rather than on immediate questions relating to epidemiology or carcinogenesis of smoke. Although a number of CTR grantees published papers based on their research, most grantees conceded that the work was not directed to questions associated with smoking and health. CTR's efforts often focused on aspects of research concerning cancer as a general issue, rather than the relationship of smoking to cancer.

Q: You mentioned internal industry assessments of the program. How do the internal industry assessments form a basis for your opinion?

A: Internal industry assessments of the research program show that the tobacco companies themselves viewed the research in this way. Again, it is important to note that my assessment of the industry research program is not merely based on my *post hoc* interpretation, but rather on the explicit views of industry executives. Brown and Williamson's Addison Yeaman, for example, conceded in a 1968 document marked as U.S. Exhibit 63,527:

> [T]he argument seems to be that by operating primarily in the field of research of the disease we do at least two useful things:
>
> First, we maintain the position that existing evidence of a relationship between the use of tobacco and health is inadequate to justify research more closely related to

tobacco.

Within the industry, the delays associated with this approach were well appreciated. Yeaman observed:

> Secondly, that the study of the disease keeps constantly alive the argument that until basic knowledge of the disease itself is further advanced, it is scientifically inappropriate to devote the major effort to tobacco.

Other industry executives admitted that CTR had not freely pursued the health impact of tobacco. Helmut Wakeham at Philip Morris candidly wrote in 1970 in a document marked as U.S. Exhibit 63,525:

> It has been stated that CTR is a program to find out the "truth about smoking and health." What is truth to one is false to another. CTR and the Industry have publicly and frequently denied what others find as "truth." Let's face it. We are interested in evidence which we believe denies the allegation that cigaret smoking causes disease.

By the 1970s the recognition of CTR as a public relations enterprise had become increasingly explicit. In 1972, Earl Newsom and Company evaluated the content of the CTR Annual Reports for the industry. In an assessment marked as U.S. Exhibit 63,570:

> From a public relations point-of-view, if from no other, it would seem that the Council should continue to receive support from its members, particularly in these times of mounting consumerism. . . .
>
> More specifically, we get the impression that when the use of laboratory animals indicates that the findings are favorable, or at least not unfavorable, to the use of tobacco, then the covering report either makes a positive statement about the use

of animals or no statement whatever. On the other hand, when the findings from any particular project indicate that tobacco use may be contributing to a discernible and unhealthy change in laboratory animals, then we get, in the covering report, mention of the limitations imposed by the use of animals. Whenever possible the reports pointedly refer to 'some who would' say smoking is dangerous, based on any given test, as scientific crackpots. When possible, Dr. Little qualifies the results of animal tests that tend to be critical, but emphasizes them when they do not find evidence of carcinoma, implying that smoking is harmless. The aim of his summations, much too apparently, seems to be to protect smoking. . . .

More recent annual reports show decreasing editorial comment. This may be the result of accumulating evidence, in the Council studies as elsewhere, which shows some of the deleterious effects of heavy smoking.

In 1974, Alexander Spears, at the time the Director of Research and Development at Lorillard, and who in 1995 was elected CEO and Chairman, confirmed this assessment of CTR's public relations, political and legal motivation in a memorandum marked as U.S. Exhibit 55,955:

Historically, the joint industry funded smoking and health research programs have not been selected against specific scientific goals, but rather for various purposes such as public relations, political relations, position for litigation, etc. Thus, it seems obvious that reviews of such programs for scientific relevance and merit in the smoking and health field are not likely to produce high ratings. In general, these programs have provided some buffer to public and political attack of the

industry, as well as background for litigious strategy.

And by the late 1970s it had become more than apparent that CTR had no intention of any serious investigation of the health impact of smoking. A memo written by Thomas Osdene at Philip Morris reviewing "Potential Long-Term Scientific Studies" in August of 1979, marked as U.S. Exhibit 35,899, noted:

SUBJECTS TO BE AVOIDED

1. Developing new tests for carcinogenicity.
2. Attempt to relate human disease to smoking.
3. Conduct experiments which require large doses of carcinogen to show additive effect of smoking."

Q: In your opinion, was the TIRC and CTR research program consistent with representations in the Frank Statement?

A: No, it was not. The TIRC/CTR research program explicitly contradicted the industry commitments offered to the American public in the Frank Statement of January 1954. At the time of the statement, the industry already possessed important evidence indicating the relationship of cigarette smoking to disease. The industry worked through TIRC/CTR to discredit and distort medical and scientific findings. Its commitment to research was dominated by public relations considerations and concerns about legal liabilities.

Rather than assisting public health efforts, the industry steadfastly worked to undermine them. In 1954, the Frank Statement had declared: "We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business." But rather than maintaining a public trust, TIRC/CTR worked to manipulate

and mislead the public concerning the harms of tobacco use.

Q: In your opinion, was the TIRC and CTR research program consistent with the industry objectives outlined in the Hill papers?

A: Yes. TIRC/CTR clearly followed the strategy articulated by Hill and Knowlton in 1953-54. Hill and Knowlton had centered attention on public relations strategies to assist the industry given the research findings linking smoking to serious disease and mortality. As a result they understood that smokers (and future smokers) would require assurance in denying those scientific findings. In 1964, Philip Morris Executive Vice President George Weissman wrote to Philip Morris President Joseph F. Cullman III, marked as U.S. Exhibit 20,189, "However, at some point, reflecting the same seriousness with which we met the Report, we must in the near future provide some answers which will give smokers a psychological crutch and a self-rationale to continue smoking."

Internal industry documents confirm my opinion. In 1972, for instance, Fred Panzer, Vice President of the Tobacco Institute, offered a comprehensive analysis of the industry's strategy since the early 1950s. The memo, marked as U.S. Exhibit 63,585, makes explicit the industry's ongoing concerns about regulatory legislation, liability litigation, and public relations concerning the health issues:

> For nearly twenty years, this industry has employed a single strategy to defend itself on three major fronts --litigation, politics, and public opinion.
>
> While the strategy was brilliantly conceived and executed over the years helping us win important battles, it is only fair to say that it is not – nor was it intended to be – a vehicle for victory. On the contrary, it has always been a holding strategy, consisting of

-- creating doubt about the health charge without actually denying it

-- advocating the public's right to smoke, without actually urging them to take up the practice

--encouraging objective scientific research as the only way to resolve the question of health hazard.

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

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

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

As Panzer noted, the industry's insistence on an "ongoing controversy" concerning the harms of cigarette use was, in his opinion, wearing thin. Nonetheless, he advocated reliance on the two central aspects of the traditional defense:

As things stand we supply them [the public] with too little in the way of ready-made credible alternatives. . . . Two such credible alternatives exist:

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

2) The Multi-factorial Hypothesis i. e. as science advances, more and more factors come under suspicion as contributing to the illnesses for which smoking is blamed -- air pollution, viruses, food additives, occupational hazards and stresses. Our 1970 public opinion survey showed that a majority (52%) believed that cigarettes are only one of the many causes of smokers having more illnesses. It also showed that half of the people who believed that smokers have more illnesses than non-smokers accepted the constitutional hypothesis as the explanation.

Industry data illustrated the inadequacies of public knowledge regarding the harms of smoking. The campaign of misinformation and distortion had an impact on the public's understanding of the health effects of smoking.

Q: Did the TIRC/CTR sponsor legitimate and credible scientific work?

A: In order to fulfill its larger public relations goals, it was critical that the TIRC/CTR sponsor credible scientific investigations, conducted by scientists with appropriate credentials and positions. Some TIRC/CTR sponsored research was published in reputable peer-reviewed journals. This process was essential to the goal of legitimating the TIRC/CTR as a scientific agency, and providing Little and other members of the Scientific Advisory Board with a forum for their statements. But, as industry officials frequently observed in internal documents, the research conducted under TIRC/CTR auspices did not focus on the central questions relating to the health impact of cigarette smoking. The TIRC/CTR through its Special Projects also allocated funding on a non-peer reviewed basis for research projects associated with litigation and witness preparation.

Q: You mentioned Panzer's opinion, as of 1972, that the industry's insistence on

an 'ongoing controversy' concerning the harms of cigarette use was wearing thin. Has your historical analysis revealed any change in the industry's public relations with respect to science at that time?

A: It has not. Once the die of denial was cast, it proved next to impossible to shift the industry's position of "no proof," "open question," and "controversy." Even as new data confirming the powerful harms of tobacco came to be understood and articulated, the industry held fast to its position that the dangers of smoking had not been demonstrated. The commitment to the "open question" led to fundamental misstatements and deceptions about the harms of smoking. Company executives and counsel had come to recognize that clear assurances that smoking was *not* injurious to health now exposed them to substantial claims of liability. Therefore, they utilized the "continuing controversy" strategy, which they recognized distorted the truth and encouraged public misunderstanding and denial.

Q: Can you provide examples of the types of public relations statements that you rely on for your conclusions about the industry's continued adherence public position of no proof, open question and controversy?

A: I can. The public relations campaign was extensive, and comprised of things like a 1970 Tobacco Institute statement, published as an advertisement in major American newspapers and marked as U.S. Exhibit 21,305, titled "The Question about Smoking and Health Is Still a Question":

> But - a major portion of this scientific inquiry has been financed by the people who know the most about cigarettes and have a great desire to learn the truth... the tobacco industry. And the industry has committed itself to the task in the most

objective and scientific way possible.

1115 reports in all. Through this work much valuable data have been produced about lung cancer, heart disease, chronic respiratory ailments and other diseases. However, there's still a lot more to be learned.

There are eminent scientists who believe that the question of smoking and health is an open one and that research in this area must go forward. From the beginning, the tobacco industry has believed that the American people deserve objective, scientific answers. With this same credo in mind, the tobacco industry stands ready today to make new commitments for additional valid scientific research that offers to shed light on new facets of smoking and health.

But the eminent scientists in such pronouncements were never named.

Tobacco Institute literature consistently argued as if the evidence implicating the cigarette remained hypothetical, limited and static, when just the opposite was true. A 1968 pamphlet marked as U.S. Exhibit 20,703 is representative:

Q: Has any important new evidence against cigarettes been reported in recent years?

A: No. Cigarettes today are branded guilty on virtually the same kind of evidence that was considered insufficient only a few years ago.

Entitled "The Cigarette Controversy," the pamphlet continued:

Q: Is smoking a health hazard?

A: That question is still an open one. . . .

At that time, most scientists considered the findings of these studies insufficient to prove a case against smoking. Since then, many other studies have been done.

But there is still no proof that cigarette smoking is a cause of lung cancer – or any other disease.

As another significant example, industry executives also continued to insist in the 1970s – as they had in the 1950s – that "if and when" any harmful elements were identified in cigarettes, they would take necessary steps to remove them. In 1971, Joseph F. Cullman III, President of Philip Morris, explained, as set out in the document marked as U.S. Exhibit 35,622:

> This industry can face the future with confidence because when, as, and if any ingredient in cigarette smoke is identified as being injurious to human health, we are confident that we can eliminate that ingredient.

Cullman insisted:

> We do not believe that cigarettes are hazardous; we don't accept that. But we are working with the government, working very hard with the government, on various methods of ascertaining whether or not cigarettes can be found hazardous…. I believe they have not been proved to be unsafe.

In support of my conclusions, I have also looked to continuance of the basic strategies of insisting on a continuing "controversy" persisted into the 1980s and 1990s. More than forty years after Hill and Knowlton crafted the Frank Statement and invented the TIRC, the industry's essential position on the relationship of smoking and health had remained largely unchanged. In 1994 – the fortieth anniversary of the Frank Statement – in Congressional hearings before the Subcommittee on Health and the Environment, industry executives asserted yet again that the causal relationship of smoking and cancer had not been proven, as reported in newspapers such as the *Los Angeles Times*,

reproduced as U.S. Exhibit 20,468. And in 1998, it was reported in the *New York Times* that Philip Morris CEO Geoffrey Bible, when asked, "Has anyone died from smoking cigarettes?" replied, "I don't, I just don't know." The *New York Times* article has been marked as U.S. Exhibit 22,167.

Q: Dr. Brandt, we've discussed your opinion about the impact that the public relations efforts of the tobacco industry had on the nature of the smoking and health "controversy." Shifting focus somewhat, as a medical historian, do you have an opinion on the impact of publicity the 1964 Surgeon General's Report on the public's recognition of the health effects of smoking?

A: I do. Some have argued that as a result of the media coverage of the data demonstrating the harms of smoking that the public was well-informed about the risks of cigarettes, or that the risks were "common knowledge." But there is no simple way to define "common knowledge" and I have generally avoided this phrase in my own work. Certainly in the mass media throughout the twentieth century there have been reports about the health impacts of smoking and medical and scientific research into this relationship. What seems clear from a variety of research about public knowledge about health and health risks is that it is highly dependent on certain groups and their particular social and educational contexts. As we have seen, the industry through their public relations efforts vigorously contested the emerging scientific knowledge concerning the harms of smoking from 1953 forward. Hill and Knowlton worked aggressively to influence the media and assure that the arguments and interests of the industry were well represented to journalists, broadcast reporters, and magazine writers. Hill and Knowlton staff carefully documented their interventions on behalf of their clients and their many

successes.

Additionally, and of central importance to understanding what we might call the information environment concerning tobacco and health, the industry sponsored massive advertising campaigns for filtered cigarettes which implied to consumers that they were protected from possible harms. For smokers and potential smokers, the combination of a scientific "controversy" widely reported in the press, and the promises associated with filtered products, widely advertised in the media, fundamentally shaped public knowledge.

Q: Why do you believe that advertising concerning filtered cigarettes is of central importance to understanding the information environment concerning tobacco and health?

A: At the same time that the tobacco industry continued to insist that there was no credible scientific evidence of the harmfulness of smoking, they nonetheless undertook major campaigns to develop and market filter cigarettes. The industry understood that in the face of the mounting scientific knowledge of the harmfulness of smoking, smokers needed various forms of support. This support or affirmation might come in the notion that there was a controversy about whether of not smoking was dangerous; or it might come in the notion that filters effectively eliminated those dangers. The industry walked a fine line in its aggressive marketing and promotion of filter cigarettes through the 1950s and 1960s. On the one hand, it sought scrupulously to avoid any public acknowledgement that its product was now, or had ever been, unsafe, a claim it would maintain into the 1990s. On the other, it sought to reassure smokers whose legitimate concerns had been raised by the emerging scientific data. As a result, the industry sought

to indicate that any harmful elements in tobacco smoke could be easily removed through the technical innovation of filters. With the impressive popularity of filters, the industry found itself in a delicate position of seeking to promote these new products as safer without explicitly indicating health problems with their product. Therefore, at the very time that the industry worked concertedly to disparage meticulously conducted scientific investigations, their ads offered unverifiable reassurances from "medical specialists." At the same time that industry researchers such as R.J. Reynolds's Alan Rodgman and Philip Morris's Helmut Wakeham were detailing carcinogenic substances in cigarettes and potential strategies for their removal, the TIRC put out a press release explaining: "Chemical tests have not found any substance in tobacco smoke known to cause human cancer or in concentrations sufficient to account for reported skin cancer in animals." The industry exploited public desire for a safe product while simultaneously denying any adverse health effects of smoking, as also shown by internal assessments and reports of the Federal Trade Commission.

Q: Please review U.S. Exhibit 63,601. Do you recognize this document?

A: Yes, I do. This is a copy of the TIRC press release that I referred to, dated in 1960.

Q: You mentioned a Philip Morris scientist named Helmut Wakeham. Who was Helmut Wakeham?

A: Wakeham, who joined Philip Morris as a research chemist in 1958, became Director of Research and Development in 1960. Wakeham introduced the use of gas chromatography for assessing the constituents in tobacco smoke. He would become active at Philip Morris in promoting the development of a "medically acceptable"

cigarette.

Q: Why do you believe that Wakeham was a significant figure for your historical analysis of the smoking and health controversy?

A: Wakeham recognized in numerous internal memoranda the cancer-causing effect of cigarette smoke. In a September 22, 1959 memorandum that is marked as U.S. Exhibit 21,657, for instance, he wrote: "One of the main reasons people smoke is to experience the physiological effects of nicotine on the human system. Nicotine, to the best of present knowledge, does not produce cancer. Hence, in theory one could achieve the major advantage of smoking without the hazard of cancer. But nicotine in tobacco smoke is present in the tar phase."

As a result of the popularity of filters, and the competitive advantage a safe cigarette would confer, Wakeham offered a proposal in 1961 to investigate the possibilities of reducing carcinogens in smoke. The proposal is identified as U.S. Exhibit 20,381. The proposal listed fifteen carcinogens and twenty-four co-carcinogens, or tumor promoters, in cigarette smoke. Wakeham also cited the belief that "cardiovascular ailments that may arise from smoking are due to the physiological effects of nicotine," noting, in particular, nicotine's "[s]pecific effects on the adrenal medulla, causing it to discharge epinephrine, a hormone which accelerates the heartbeat, contracts the peripheral blood vessels, and raises the blood pressure." Wakeham identified 84% of the more than 400 gas and particulate compounds in cigarette smoke, including those that he specifically recognized as carcinogens, in sidestream, or secondhand, smoke. He concluded:

> Low irritation and low nicotine cigarettes for commercial exploitation will be

developed in the course of our present R & D program during the next two to five years with an expenditure of not more than 25% of the R & D budgets during this period.

A medically acceptable low-carcinogen cigarette may be possible. Its development would require:

TIME

MONEY

UNFALTERING DETERMINATION

Later, on April 20, 1962, Wakeham recommended diversification of Philip Morris USA's business at a greater rate due to the reporting of evidence that smoking leads to disease.

Q: Is the April 20, 1962 recommendation you are referring to contained in U.S. Exhibit 20,120?

A: Yes, it is.

Q: You mentioned internal assessments of filtered cigarettes. Have you identified any assessments in support of your opinions about the role of filtered cigarettes in the information environment?

A: I have. In one particularly notable example, Myron Johnston of Philip Morris pointed out in June 1966 that smokers eagerly sought what they perceived to be "safer" products in a report marked as U.S. Exhibit 37,511:

Available evidence from surveys shows conclusively that smokers are concerned about the relationship of cigarette smoking to health but that they do not want to quit smoking. They are, however, changing their smoking habits, generally

toward higher filtration, even at the expense of a loss of some tobacco flavor. That these changes are health motivated is clear from the timing of the shifts: The boom in filters came on the heels of the first health scare, and the Surgeon General's Report stimulated the shift to charcoal filters. The acceptance of menthol cigarettes and Lark indicates a willingness to accept nontobacco flavor as a substitute for tobacco flavor. There is some evidence that the anti-cigarette propaganda is more effective in reducing the rate of smoker recruitment than in changing the habits of smokers.

The public had been conditioned to accept the filtering effects of charcoal in other fields, and when charcoal was added to cigarette filters it proved to be an effective advertising gimmick.

Q: You also mentioned reports of the Federal Trade Commission. Have you identified specific reports in support of your opinions about the role of filtered cigarettes in the information environment?

A: I have. In particular, in a 1967 examination of tobacco advertising practices marked as U.S. Exhibit 57,179, the FTC noted that the public had largely been convinced that filter cigarettes were less hazardous. Their report concluded:

> For the most part, however, assuaging of smoker anxiety has been a very low key. As previously indicated, the belief that filter cigarettes are less hazardous appears to be widespread. It may be assumed therefore that to people holding this belief, the word 'filter' itself connotes 'less hazard'. And through addition of suitable adjectives to the word 'filter', this impression of relative safety can be enhanced. Thus, in current advertising there are 'recessed filters' (Benson & Hedges and

Parliaments), 'white filters' (Yorks), 'menthol filters' (Springs) and 'filters with coconut shell charcoal' (Philip Morris).

Q: Can you identify the types of advertisements that you rely on to identify that tension between the industry's public position on the scientific evidence and the popularity of filtered products?

A: I can. There were many of them during the 1953-1964 time period that we have been discussing. As an example, in 1953, Liggett hired Arthur D. Little to test tobacco condensates on mice in an attempt to develop strategies for removing carcinogens, at the same time that it advertised its L & M filters, in the document marked as U.S. Exhibit 63,543, as "Just What the Doctor Ordered."

Kent cigarettes, with the new 'micronite filter,' were claimed to provide "the greatest protection in cigarette history": "For the greatest protection of any filter cigarette Kent with exclusive MICRONITE filter."

Similarly, in an advertisement in *Resident Physician* in 1961, marked as U.S. Exhibit 36,122, Lorillard explained the advantages of the Kent (filter) cigarette:

> Lorillard research has established that phenol is the major constituent of the phenolic group of compounds in cigarette smoke which depress ciliary propelled mucus flow. A highly effective method of selective filtration of phenols by addition of a phenol-combining agent to an acetate filter is reported. KENT cigarettes contain the new Micronite filter with PFA-17 pursuant to Lorillard policy of continuous improvement of products through research.

Q: What other factors do you rely on to support your opinion concerning the implications of safety by cigarette manufacturers as a critical historical aspect

relating to the publicity concerning evidence of the health effects of smoking?

A: I think it is important to recognize that health concerns on the part of the public led to a radical reconfiguration of the cigarette market, as well as promotional and advertising strategies. By 1954, filters had quickly come to comprise approximately 10 percent of the cigarette market. By the mid-1970s, this number would approach 90 percent. The introduction of many new brands in the late 1950s and early 1960s has typically been referred to as the "tar derby."

Of course, the tension that I spoke of is also reflected in the fact that the industry continued to insist that the rise of filter cigarettes merely reflected the nature of consumer demand. James P. Richards, President of the Tobacco Institute, explained in 1958 in a document marked as U.S. Exhibit 21,326:

> The cigaret industry has not changed its mind. Our position was and is based on the fact that scientific evidence does not support the theory that there is anything in cigaret smoke known to cause human lung cancer.
>
> ...the production and marketing of filter cigarets are matters of individual company competitive business. Anyone familiar with the tobacco industry knows that tobacco manufacturers constantly compete to make products to please customers.

Q: In summary then, how do you place filters and advertising for filtered cigarettes in the context of your testimony about the tobacco industry's efforts to create a "controversy" over the health effects of smoking?

A: It is my opinion that filtered cigarettes, and their advertising and promotion, constituted a critical aspect of industry strategy in the wake of categorical scientific

evidence demonstrating the harms of smoking. As I have suggested, the central part of this strategy was to utilize science to argue that there was "no proof," that there was a controversy about the scientific findings. At the same time, a consistent counterpart to this strategy was to imply that the product had been successfully modified to remove any hazards. Since these two related approaches were in tension (and there were important legal liabilities associated with them), the industry was forced to walk a fine line between them. Both the effort to sustain a controversy and the reassurance of filtered cigarettes were important in an ongoing effort to shape public knowledge about smoking and its harms in the interest of the industry, and to maintain and expand the sales of cigarettes. These objectives and the process of reaching them were precisely articulated in December 1953 by Hill and Knowlton and subscribed to by the tobacco industry for the next forty years.

Q: And, again in summary, how did the development of filtered cigarettes relate to the Hill and Knowlton public relations strategy for the tobacco industry?

A: Hill and Knowlton had, in December 1953, identified a critical problem for the industry as it faced new scientific evidence implicating their product as a cause of lung cancer. As the memoranda from 1953 make clear, they well understood that the health risks associated with smoking by that time had created a new environment that had dramatically changed the market for selling cigarettes. Unless consumers came to doubt the evidence, or came to believe that the product had been modified, the traditional rationale for the product would be severely damaged. The industry utilized its considerable resources in the aggressive implementation of this strategy. They repeatedly denied and distorted the massive scientific evidence through a sophisticated public

relations program. At the same time, they implied that modifications in their product protected consumers from these very harms.