

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

UNITED STATES OF AMERICA,)	Civil Action No. 99-CV-02496 (GK)
)	
Plaintiff,)	Next Scheduled Court Appearance:
)	
v.)	Trial (ongoing)
)	
PHILIP MORRIS USA INC.,)	
)	
f/k/a PHILIP MORRIS INC., <u>et al.</u> ,)	
)	
Defendants.)	
)	

**JOINT DEFENDANTS' DIRECT EXAMINATION OF
HARMON MCALLISTER, Ph.D.
SUBMITTED PURSUANT TO ORDER #471**

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1 **I. BACKGROUND**

2 **A. Personal**

3 **Q. Would you state your name, please?**

4 A. Dr. Harmon McAllister.

5 **Q. Where do you live?**

6 A. I live in Larchmont, New York, which is a suburb of New York City.

7 **Q. What do you do for a living?**

8 A. On November 30, 2004, I retired after more than 21 years with The
9 Council for Tobacco Research – U.S.A., Inc., or CTR. My last position at CTR was Vice
10 President. CTR, which was dissolved in 1998, has had no employees since
11 November 30, 2004. Since December 2004, I have been a part-time consultant to CTR. I
12 have been appointed as CTR’s agent, with the responsibility for making sure that CTR
13 meets its continuing legal obligations as a dissolved corporation. As a consultant to CTR,
14 I also am available to testify and provide other litigation-related services.

15 **B. Education**

16 **Q. Would you briefly describe your educational background?**

17 A. I graduated with a bachelor’s degree in chemistry from the University of
18 North Carolina at Chapel Hill in 1958. I received a Ph.D. in biochemistry from the
19 University of North Carolina Medical School in 1963. I did two years of post-doctoral
20 work at the University of Michigan Medical School in Ann Arbor, followed by two more
21 years of post-doctoral work at the University of Kentucky Medical School.

22 **Q. Was any of your graduate work related to cancer research?**

23 A. Yes. My dissertation was on the role of certain proteins in the nucleus of
24 the cell and how they might regulate genetic activity. Our group at the University of
25 North Carolina was investigating what controls division of a particular kind of cancer

1 cell, called a hepatoma. Recently, the proteins in cancer cells that we were studying back
2 in the 1960s have been identified as potentially important in the process of
3 carcinogenesis.

4 **Q. When you were doing your training, did you receive financial support**
5 **from any funding agency?**

6 A. Yes. As an undergraduate, I received funding from the U.S. Public Health
7 Service. While I was doing my post-doctoral work, I applied for and received research
8 fellowships from the Muscular Dystrophy Associations of America and from the National
9 Heart, Lung, and Blood Institute, which is part of the National Institutes of Health, or
10 NIH.

11 **C. Pre-CTR Employment**

12 **Q. What did you do after you completed your post-graduate training?**

13 A. In 1967, I joined the faculty of Wayne State University in Detroit as an
14 Assistant Professor of Chemistry in the Biochemistry Division. For the next six years, I
15 taught biochemistry, primarily to graduate students, but also to medical students,
16 advanced undergraduate students and nursing students.

17 **Q. While you were at Wayne State, did you continue doing your own**
18 **scientific research?**

19 A. Yes. I did cancer research in my laboratory at Wayne State. I employed
20 several students and technicians who worked under my supervision. We were studying
21 the mechanisms of how proteins are made.

22 **Q. What do proteins have to do with cancer?**

23 A. When cancer strikes, the body creates huge amounts of proteins. We
24 thought that by understanding how the body makes proteins, we could understand
25 something about the mechanism of cancer.

1 **Q. Was any of your scientific research supported by research grants-in-**
2 **aid?**

3 A. Yes. We received research grants-in-aid from the National Science
4 Foundation and from the Heart, Lung, and Blood Institute of the NIH, both of which are
5 part of the U.S. government.

6 **Q. Have you published any scientific articles based on your research?**

7 A. Yes. Based on research I did during my graduate work, my post-doctoral
8 training, and at Wayne State, I published articles in a number of peer-reviewed scientific
9 journals, including *The Journal of Molecular Biology* and *The Journal of Biological*
10 *Chemistry*.

11 **Q. Have you ever served as a peer reviewer for a scientific publication?**

12 A. Yes. I have been a peer reviewer for two scientific journals: *Analytical*
13 *Biochemistry* and *Archives of Biochemistry and Biophysics*.

14 **Q. Have you published any books?**

15 A. Yes. I co-authored a college textbook for students of chemistry and
16 biochemistry. The book dealt with general, organic and biological chemistry. This book
17 was used in a number of U.S. colleges, including those in the California state college
18 system, and in some universities outside the U.S. I wrote the biological chemistry
19 portion of the textbook.

20 **Q. Are you a member of any professional organizations?**

21 A. Yes. I am a member of the American Society for Biochemistry and
22 Molecular Biology, the American Association for the Advancement of Science, the
23 American Chemical Society, and the New York Academy of Sciences.

24 **Q. While you were at Wayne State, did you shift your career path?**

1 A. Yes. In 1973, I moved into academic administration. I joined the Office
2 for Institutional Research, which was part of Wayne State’s Office of Programs and
3 Planning. In 1976, I became Director of the Office for Institutional Research, and
4 remained in that position until 1983.

5 **Q. What did the Office for Institutional Research at Wayne State do?**

6 A. The Office for Institutional Research was involved primarily with
7 analyzing data about the university for curriculum, planning and budget purposes. Our
8 data was used in securing funding from the state and for internal budgeting purposes.

9 **Q. While you were at Wayne State, did you have any other professional**
10 **affiliations?**

11 A. I was a consultant for four years to the Michigan Cancer Foundation, also
12 located in Detroit, which is an organization that does both clinical and basic research
13 related to cancer. Some of the scientists who worked at the Michigan Cancer Foundation
14 had research interests similar to mine, and we collaborated on research projects related to
15 the assembly of proteins that I mentioned before.

16 **D. CTR Employment**

17 **Q. What did you do after you left Wayne State?**

18 A. I joined CTR as an Associate Research Director in 1983.

19 **Q. How did that come about?**

20 A. Through my relationship with the Michigan Cancer Foundation, I got to
21 know Dr. Michael Brennan, the President of the Foundation and an oncologist at Wayne
22 State University School of Medicine. Dr. Brennan was a member of CTR’s Scientific
23 Advisory Board (also known as the SAB). In late 1982, Dr. Brennan told me that CTR
24 would soon have a position available and was looking for someone who had both hands-

1 on scientific research experience and administrative experience. I applied for and was
2 offered the job.

3 **Q. Can you briefly summarize your employment at CTR over the years?**

4 A. In 1983, when I joined CTR, I was one of four Associate Research
5 Directors. In 1986 I became CTR's Research Director. In 1991 I became the Scientific
6 Director, which meant that I also became a member of the Scientific Advisory Board. In
7 1992, I received the additional title of Vice President for Research. I held those positions
8 until 1999. In that year, CTR stopped all funding of scientific research, and as a result
9 there was no need to have a Scientific Director or any other positions related to research.
10 I remained Vice President of CTR until the end of my employment in November 2004.

11 **Q. Have you ever been an employee of a tobacco company?**

12 A. No.

13 **E. Familiarity With CTR's Files**

14 **Q. When you joined CTR in 1983, what did you do to learn about your
15 new job?**

16 A. I spoke extensively with all the members of CTR's scientific staff, and in
17 particular with Dr. Sheldon Sommers and Dr. Robert Hockett. Dr. Sommers, who was
18 the Scientific Director of CTR at that time, had been affiliated with CTR as a member of
19 its Scientific Advisory Board since 1966. Dr. Sommers had been chairman of the SAB
20 from 1970 until 1981, and he had served as the Scientific Director of CTR since 1981.
21 Dr. Hockett had been a member of CTR's scientific staff since 1954. Over the course of
22 many conversations, Dr. Sommers and Dr. Hockett provided me with extensive
23 information about CTR. I also had numerous conversations with CTR's other Associate
24 Research Directors: Dr. Donald Ford, Dr. David Stone and Dr. Vincent Lisanti.
25 Dr. Lisanti had been with CTR for almost 20 years.

1 Beginning at that time and continuing over a period of a number of years, I
2 reviewed voluminous documents from CTR’s files. I read all of the TIRC and CTR
3 Annual Reports. I also read minutes of meetings of the Scientific Advisory Board. I read
4 many of the papers that the researchers funded by CTR had published. I read the
5 materials dealing with the procedures CTR employed, the research it was funding, and
6 the research it had funded in the past. I read the files maintained by CTR on each grant
7 and grant application (whether or not CTR funded it), which showed me how CTR
8 administered the funding of research grants. At CTR, we called those the grant files. I
9 also attended the meetings of the Scientific Advisory Board, where I observed how the
10 SAB ranked grant applications. I also reviewed documents related to CTR contract
11 research, CTR’s correspondence with SAB members, outside reviewers and grantees, and
12 a variety of memos and reports about CTR-funded research.

13 **Q. Why did you read these documents?**

14 A. There were several reasons. First and foremost, I was new to the
15 organization, and I needed to know how CTR’s research program worked. The
16 organization at that point had been in existence for almost thirty years and had an
17 extensive history. My main purpose was to familiarize myself with that historical record
18 in order to do my job better since there was no “training program” for incoming
19 Associate Research Directors. Second, on a day-to-day level, I wanted to improve my
20 understanding of the research that was then being funded. The Associate Research
21 Directors had a role in reporting on the ongoing research that was supported by CTR
22 grants once they had been funded. Third, I needed to understand the specific research
23 projects that CTR was funding when I went on site visits to grantees. Fourth, I needed to
24 be aware of current developments in the areas of biomedical research that I was less

1 familiar with, in order to better assist the Scientific Director and the Scientific Advisory
2 Board if questions arose with respect to new applications for grants-in-aid.

3 **Q. As you continued in your work at CTR in the 1980s and 1990s, did**
4 **you continue to review documents such as you have discussed, including**
5 **correspondence, minutes, grant files, Annual Reports and other documents in**
6 **CTR's files?**

7 A. Yes, I did. As new grant applications came in, I often went to the grant
8 files and reviewed documents that informed me about similar research that CTR had
9 funded. In 1991, when I became the Scientific Director, I became a member of the
10 Scientific Advisory Board. As a member of the SAB, I evaluated and rated applications
11 for biomedical research just as the other members did. As Scientific Director, I had the
12 authority to decide, based on the advice of and evaluations by CTR's Scientific Advisory
13 Board, which grants CTR would fund and in what amounts. I regarded these as very
14 important responsibilities, and I often looked into the grant files to gain an understanding
15 of what had been done in the area of research that was being proposed.

16 **Q. Have you also reviewed documents in CTR's files to help you prepare**
17 **to testify in litigation concerning CTR?**

18 A. Yes, I have.

19 **Q. Please tell the Court about that review.**

20 A. I have been a witness in litigation involving CTR since about 1993. In
21 most cases, I have been both a fact witness and an expert witness. I have given testimony
22 by deposition in over 20 cases, and have testified at seven trials. In preparing to give
23 testimony, I have reviewed documents in CTR's files in addition to those I reviewed
24 otherwise.

25 **Q. Were you deposed in this case?**

1 A. Yes. I gave three separate depositions over the course of two days. I was
2 deposed as a fact witness, as CTR's representative, and as an expert witness.

3 **Q. What material in CTR's files did you review to prepare for your**
4 **depositions in this case?**

5 A. I have reviewed numerous documents from CTR's files. These documents
6 included the CTR Annual Reports, SAB meeting minutes, SAB members' curriculum
7 vitae, SAB members' files, grant binders, grant summary sheets and grant files, CTR
8 contracts files, CTR Special Projects publications, CTR Special Projects files,
9 correspondence (including correspondence with the 1962 Surgeon General's Advisory
10 Committee and with other public health agencies), press releases and other public
11 statements, corporate documents, including CTR's certificate of incorporation and by-
12 laws, minutes of the meetings of members and of the meetings of the CTR Board of
13 Directors from 1971 on, financial records (including financial statements and tax
14 records), copies of the Current Digest (a compilation that CTR prepared of scientific
15 literature relating to smoking and health), documents from Dr. Hockett's desk files and
16 my own desk files, and documents related to CTR's dissolution. With the help of legal
17 assistants from Debevoise & Plimpton, CTR's outside counsel, I identified the documents
18 that I had reviewed by TIF, or Tag Image File, number in two sets of lists that were
19 provided to the Department of Justice lawyers before my deposition in May 2002. Many
20 of these were documents in CTR's files that I had reviewed long before 2002, either as
21 part of my day-to-day duties at CTR during the time it was funding research, or as part of
22 my preparation for testimony in earlier cases.

23 **Q. Where are CTR's documents today?**

24 A. The originals are located in a commercial storage facility in New Jersey.
25 CTR's lawyers at Debevoise & Plimpton have copies of most of these documents. There

1 are copies of well over a million pages of CTR documents located on its website at
2 <http://www.ctr-usa.org/ctr>. Copies of these documents are available to the public at the
3 document depository in Minnesota, which was established in the State of Minnesota
4 litigation. There is an additional copy of most of CTR’s documents at the New York
5 Archives in Albany. In 1998, as part of the Consent Judgment in the State of Minnesota
6 case, CTR provided the U.S. Food & Drug Administration with documents related to the
7 research funded by CTR.

8 **II. WHAT WAS CTR, AND HOW DID IT OPERATE?**

9 **A. Overview of CTR’s History**

10 **Q. When did CTR come into existence?**

11 A. In January 1954, seven cigarette companies (American Tobacco, Benson
12 & Hedges, Brown & Williamson, Lorillard, Philip Morris, R.J. Reynolds and United
13 States Tobacco), as well as seven other tobacco-related companies (Bright Belt
14 Warehouse Association, Burley Auction Warehouse Association, Burley Tobacco
15 Growers Cooperative Association, Larus & Brother Company, Inc., Maryland Tobacco
16 Growers Association, Stephano Brothers, Inc., and Tobacco Associates, Inc.) joined
17 together to form an unincorporated association called the Tobacco Industry Research
18 Committee, or TIRC. TIRC’s formation was announced in an advertisement entitled “A
19 Frank Statement to Cigarette Smokers,” which was published in hundreds of newspapers
20 in the United States on January 4, 1954. The first TIRC grants for scientific research
21 relating to smoking and health were awarded in the summer of 1954, and the first papers
22 were published in 1955.

23 In January 1964, the Tobacco Industry Research Committee changed its name to
24 The Council for Tobacco Research – U.S.A. In January 1971, The Council for Tobacco
25 Research – U.S.A., Inc. was incorporated as a not-for-profit corporation under New York

1 law. When I use the term “TIRC,” I am referring to the original organization, which was
2 in existence from January 1954 to January 1964. Generally, I use “CTR” to refer to the
3 organization throughout the period from 1954 to the present, and that includes TIRC, The
4 Council for Tobacco Research – U.S.A., and the not-for-profit Corporation, The Council
5 for Tobacco Research – U.S.A., Inc. When I use “CTR” to refer more narrowly to the
6 corporation that was formed in 1971, I will try to be clear that I am doing that.

7 **Q. Can you identify Exhibit JD-090053?**

8 A. Exhibit JD-090053 is CTR’s Certificate of Incorporation, dated January 8,
9 1971.

10 **Q. Please read the purpose section on page 1 of JD-090053, CTR’s**
11 **Certificate of Incorporation.**

12 A. “The purposes for which it is formed are: To aid and assist research into
13 tobacco use and health and to make available to the public factual information on this
14 subject.”

15 **Q. Can you identify U.S. Ex. 21,420 and Exhibit JD-090055?**

16 A. U.S. Ex. 21420 and Exhibit JD-090055 contain the by-laws of the
17 Tobacco Industry Research Committee, The Council for Tobacco Research – U.S.A., and
18 The Council for Tobacco Research – U.S.A., Inc., as they were amended over the years.

19 **B. Dissolution of CTR**

20 **Q. What is CTR’s status today as a not-for-profit corporation?**

21 A. CTR was dissolved under the New York Not-for-Profit Corporation Law
22 on November 6, 1998, when it filed a certificate of voluntary dissolution with the
23 Secretary of State of the State of New York.

24 **Q. Does CTR still exist?**

1 A. As I understand it, CTR exists for the limited purpose of winding up its
2 activities. CTR is permitted, while it's winding up its activities, to defend itself in
3 litigation.

4 **Q. When did you find out that CTR was going to be dissolved?**

5 A. In June 1997, CTR's cigarette manufacturer members entered into an
6 agreement with the Attorneys General of a handful of States that identified federal
7 legislative proposals that these companies agreed to support. Under this agreement,
8 which was called the Memorandum of Understanding, CTR's member companies were to
9 "dissolve and disband" CTR within 90 days of the effective date of the legislation that
10 was contemplated. At that point, CTR's future was uncertain, and CTR's Chairman
11 decided after the spring 1997 meeting of the Scientific Advisory Board to suspend the
12 funding of new grants until that uncertainty was resolved one way or another. Later in
13 1997, legislation was introduced in Congress that contained provisions for the dissolution
14 of CTR. That legislation did not go through, but the uncertainty that had been created
15 about CTR's future remained.

16 In 1998, the State of Minnesota lawsuit against various tobacco companies as well
17 as CTR was tried in a Minnesota state court. The case was settled on or about May 8,
18 1998. Within a day or two after that, I learned, either from CTR's lawyers or from a
19 news report, that CTR's members had entered into a settlement agreement that required
20 them to dissolve CTR. In addition, later in 1998 CTR's member companies and a
21 number of states entered into a Master Settlement Agreement that required the companies
22 to dissolve CTR and other organizations.

23 **Q. Can you identify Exhibits JD-093316, JD-090039, JD-012501 and JD-**
24 **093326?**

1 A. Exhibit JD-093316 is one of the letters that Dr. Glenn, who was then the
2 Chairman, President and Chief Executive Officer of CTR, sent to the members of the
3 Scientific Advisory Board of CTR in the summer of 1997, discussing the Memorandum
4 of Understanding. Exhibit JD-090039 is CTR's 1997 Annual Report, which refers to the
5 suspension in the spring of 1997 of the process for approving new grants. Exhibit JD-
6 012501 is the Settlement Agreement in the State of Minnesota case. Exhibit JD-093326
7 is the Consent Judgment in the State of Minnesota case.

8 **Q. What was the effect on CTR of the Consent Judgment in the State of**
9 **Minnesota case?**

10 A. The Consent Judgment required CTR to "cease all operations except as
11 necessary to comply with existing grants or contracts and to continue its defense of other
12 lawsuits." CTR started to make arrangements to do that almost immediately. CTR also
13 made arrangements to send to the FDA copies of all smoking and health research in
14 CTR's possession, as required by the Minnesota Consent Judgment. Ultimately, we sent
15 to the FDA approximately 341,000 pages of documents from CTR's files.

16 **Q. Can you identify Exhibits JD-093327 and JD-093328?**

17 A. Exhibits JD-093327 and JD-093328 are letters dated July 30 and August 4,
18 1998, from CTR's lawyers at Debevoise & Plimpton to the FDA Tobacco Program in
19 Rockville, Maryland, identifying and then sending to the FDA copies of the 341,000
20 pages of documents discussed above.

21 **Q. What else did CTR do following the State of Minnesota settlement?**

22 A. During the summer of 1998, CTR prepared its Plan of Dissolution, which
23 was negotiated by CTR's attorneys with the Office of the Attorney General of the State
24 of New York. At a special meeting on October 19, 1998, CTR's Board of Directors
25 approved the Plan of Dissolution.

1 **Q. Can you identify Exhibits JD-093330, JD-093333 and JE-021048?**

2 A. Exhibit JD-093330 is the Plan of Corporate Dissolution and Distribution
3 of Assets of The Council for Tobacco Research – U.S.A., Inc., which I will refer to as
4 CTR’s Plan of Dissolution. As stated in the certification by Lorraine Pollice, CTR’s
5 Secretary, on page 70101648 of Exhibit JD-093330, CTR’s Plan of Dissolution was
6 approved by the members of CTR at a special meeting held on October 19, 1998. Exhibit
7 JD-093333 is an order dated October 21, 1998 by Justice Crane of the Supreme Court of
8 the State of New York, New York County, approving CTR’s Plan of Dissolution and
9 Certificate of Dissolution. Exhibit JE-021048 is CTR’s certificate of voluntary
10 dissolution, showing that it was filed by the Secretary of State of the State of New York
11 on November 6, 1998. That is the date on which CTR was officially dissolved.

12 **Q. What did CTR do to implement its Plan of Dissolution?**

13 A. CTR stopped funding new scientific research. We approved no new
14 research grants. We stopped going on site visits. We made arrangements to accelerate
15 the funding of the grants that had been awarded as of April 1997, so that each grantee
16 received the amount of a full three years of grant-in-aid support. We paid out the last of
17 the grant-in-aid funds by the end of March 1999. We stopped gathering the information
18 for an Annual Report. The last CTR Annual Report was the 1997 report, which had been
19 published and distributed in the spring of 1998.

20 **Q. Can you identify Exhibit JD-093371?**

21 A. Exhibit JD-093371 is one of the letters that CTR sent to its grantees in
22 1998, informing them of CTR’s dissolution and advising them that further distributions
23 of grant funds would be accelerated. Exhibit JD-093371, which is dated September 22,
24 1998, is to Dr. Edith Wang of the University of Washington. CTR’s other grantees with
25 active grants at the time received letters that were similar to this letter.

1 **Q. What else did CTR do to implement CTR's Plan of Dissolution?**

2 A. We took steps to reduce to a minimum the size of CTR's operations. As
3 of the dissolution in November 1998, CTR had nine employees: the CEO, Chairman and
4 President, Dr. Glenn; me; our Secretary and Treasurer, Lorraine Pollice; our Associate
5 Research Directors, George Hashim and Arthur Eisenberg; two secretaries; an
6 accountant; and a mailroom employee. The number of employees was reduced steadily
7 as we proceeded with the task of archiving CTR's documents. By 1999, there were four
8 employees, and by 2000 there were three of us. I gave up my titles of Scientific Director,
9 Research Director and Vice-President for Research, and became Vice President.
10 Ms. Pollice remained the Secretary and Treasurer of CTR. After 2001, Dr. Glenn retired
11 as CTR's President and became a consultant, leaving just Ms. Pollice and me as
12 employees. We moved our office in 1999 and again in 2000, both times to smaller
13 quarters. On December 1, 2004, our employment was terminated, and at the end of 2004
14 we gave up our office. CTR now has no office and no employees.

15 **Q. Can you identify Exhibits JD-093377 through JD-093382?**

16 A. Under CTR's Plan of Dissolution, we were required to provide monthly
17 progress reports to the New York Attorney General for six months. Exhibits JD-093377
18 through JD-093382 are CTR's reports to the New York Attorney General, in each month
19 from November 1998 through April 1999, after CTR was dissolved.

20 **Q. What has CTR been doing since 1999?**

21 A. CTR is permitted under Sections 5 and 6 of its Plan of Dissolution, Exhibit
22 JD-093330, to defend itself and to assist its members in the defense of litigation, and to
23 hire and pay counsel and expert witnesses for that purpose. CTR is still a defendant in a
24 number of lawsuits. For example, I have been listed as a witness in a number of cases
25 since the dissolution was effective, including this case. CTR also has ongoing

1 obligations with respect to document storage, maintenance and availability under its Plan
2 of Dissolution. We have moved CTR's original files to a commercial warehouse. We
3 made copies of practically all of CTR's documents available to the New York Archives.
4 CTR has continued to maintain a website that makes available to the public the
5 documents CTR has produced in litigation, including this case. More than 1.6 million
6 pages of documents are available on the CTR website.

7 **Q. After November 6, 1998, did any scientists write to or call CTR asking**
8 **how to apply for research funding?**

9 A. Yes. We had some requests, probably several dozen initially, and then
10 they trailed off. We have not had an inquiry about funding for well over a year. We
11 informed all these scientists that CTR no longer was funding research. We developed a
12 standard letter that we sent those who had inquired about how to receive funding from
13 CTR or who asked other questions.

14 **Q. Can you identify Exhibit JD-093601?**

15 A. Exhibit JD-093601 is one of the letters that CTR sent to scientists who
16 sought research funding from CTR after CTR's dissolution became official. Exhibit JD-
17 093601 was sent to Dr. Ofer Mandelboim at Hebrew University, in Israel, on or about
18 March 20, 2003. Since the dissolution in November 1998, all the letters we sent in
19 response to inquiries about research funding have contained similar language.

20 **C. CTR Structure**

21 **Q. Does CTR have a Board of Directors?**

22 A. Since CTR was incorporated in 1971, it has had a Board of Directors.

23 **Q. Who has been on the Board of Directors of CTR?**

24 A. When TIRC was founded in 1954 by cigarette manufacturers and other
25 industry-related companies, these manufacturers and other companies became the

1 “members” of TIRC. When CTR was incorporated in 1971, its members were divided
2 into two classes. The cigarette manufacturers were the Class A members, and the other
3 industry-related companies were the Class B members. Under Article II, Section 2 of
4 CTR’s by-laws, Exhibit JD-090055, to be a Class A member, a member company had to
5 manufacture its own brand of cigarettes and be regularly engaged in the sale of cigarettes
6 in the United States. For many years, the CTR Board of Directors had two
7 representatives from each Class A member. For the last few years, the Board of
8 Directors has had one representative from each of the Class A members. There are now
9 three of these members: Lorillard, Philip Morris and R.J. Reynolds. Brown &
10 Williamson was the fourth Class A member until it merged with R.J. Reynolds during the
11 past year.

12 **Q. When you use the names of the member companies of CTR, are those**
13 **the precise names of the corporate entities?**

14 A. No. I just know them as Philip Morris, R. J. Reynolds, Brown &
15 Williamson, Lorillard, and American Tobacco. I am not really familiar with the precise
16 corporate names of CTR’s members and their affiliated companies. I have seen from our
17 minutes that the names of some of the members have changed over the years. I do know
18 that the companies that were the Class A members of CTR have been the companies that
19 actually manufactured cigarettes. That is what the CTR by-laws require.

20 **Q. What have the functions of the CTR Board of Directors been over the**
21 **years?**

22 A. The Board of Directors’ primary functions have been to set CTR’s budget
23 for the upcoming year and to make decisions on major administrative matters such as
24 office leases, employee benefits, and the salaries of key employees. Each year, the Board

1 of Directors approved a budget for CTR, which was then funded by the member
2 companies.

3 **Q. Did the CTR Board of Directors play any role in deciding which grant**
4 **applications should be funded by CTR?**

5 A. The Board of Directors certainly did not do that after I joined CTR in
6 1983. So far as I can tell, the Board of Directors did not play any role of that kind before
7 I arrived at CTR, with one exception of which I am aware. In 1978, the Board of
8 Directors passed a resolution that explicitly authorized CTR's legal counsel to take steps
9 to assure that the research projects funded by CTR were within the scope of CTR's
10 legally permissible activities. For several years after that CTR's counsel, who I
11 understand also represented one or more of the companies, reviewed some grant
12 applications and provided legal advice to CTR about the funding of those applications,
13 and I will describe that in more detail later.

14 **Q. Did the Board of Directors have any other involvement in the**
15 **scientific research itself that CTR funded?**

16 A. The CTR Board of Directors had no involvement in CTR's scientific
17 program from 1983 on, and to the best of my knowledge it had no other involvement
18 before then. The Board of Directors was kept generally apprised of the research program.
19 Sometimes, members of the SAB made presentations at Board of Directors meetings in
20 which they talked about their own research or about recent developments in relevant
21 areas of research generally. The purpose of these presentations was to keep the Board of
22 Directors generally aware of some of the things that were going on scientifically and
23 some of the achievements of CTR-funded investigators.

24 **Q. Did the Board of Directors hold meetings?**

1 A. Yes. From 1971 through 1999, the Board of Directors generally met twice
2 a year. In some years, the Board of Directors met three times and in a few instances, they
3 met only once. Since 1999, the Board of Directors has not held meetings, but has taken
4 actions through written consents signed by all the directors.

5 **Q. Can you identify Exhibit JD-093208?**

6 A. Exhibit JD-093208 is a set of the minutes of the CTR Board of Directors
7 meetings from 1971 through 1999, along with a Unanimous Consent in lieu of Meeting
8 of Board of Directors from 2001.

9 **Q. Who was in charge of CTR's administration?**

10 A. CTR's Chairman was its highest ranking officer. In my experience, the
11 Chairman's main responsibilities, other than presiding at the meetings of CTR's members
12 and Board of Directors, was to prepare a proposed annual budget for CTR, obtain the
13 member companies' approval of a budget, and make sure CTR complied with that
14 budget, and to make or be involved in decisions about the administration of CTR, such as
15 personnel matters. Until 1991, each Chairman of CTR was a retired tobacco company
16 executive who became a part-time employee of CTR. In 1991, Dr. James F. Glenn, who
17 had been the Scientific Director of CTR and had not been a tobacco company employee,
18 became the Chairman and Chief Executive Officer.

19 While I was with CTR, the person with direct responsibility for CTR's day-to-day
20 administration was the President of CTR. Before CTR was incorporated in 1971, the
21 person in charge of its day-to-day administration was called the Executive Director and,
22 before that, the Executive Secretary. In 1993, Dr. Glenn became the President of CTR as
23 well as the Chairman. The Presidents of CTR did not come from tobacco companies.

1 **D. Means by Which CTR Funded Scientific Research**

2 **Q. Did CTR ever have a laboratory or any other kind of research**
3 **facilities?**

4 A. No. CTR never had any research facilities, and CTR itself never
5 conducted scientific research.

6 **Q. Who conducted the research that CTR funded over the years?**

7 A. The research was done by independent scientists in medical schools,
8 research institutes, hospitals, and other research organizations. These scientists were
9 employees of the medical schools, hospitals and research institutes where they
10 maintained their research laboratories.

11 **Q. How did CTR provide funding support to scientists conducting**
12 **research at universities, hospitals and laboratories?**

13 A. Throughout its history, from 1954 to 1999, CTR awarded research grants
14 to scientists in what was known as CTR's grant-in-aid program, sometimes referred to as
15 the SAB grant-in-aid program. These grants-in-aid were the core of the CTR research
16 program. In the 1970s and early 1980s, CTR also funded certain types of projects
17 through research contracts, mostly to commercial laboratories. In addition, in each year
18 from 1955 to 1969, CTR provided fellowships to a group of promising researchers who
19 were students at medical and graduate schools. In 1992, CTR instituted a Scholars
20 Awards program through which CTR provided funds to junior faculty members at
21 various medical schools who were doing research that was relevant to CTR's research
22 program. From 1966 until 1990, CTR also administered the funding for CTR Special
23 Projects.

24 **Q. Did CTR provide funds to scientists for anything other than hands-on**
25 **research?**

1 A. On occasion, CTR supported conferences on scientific topics relevant to
2 the research funded by CTR, such as mechanisms of carcinogenesis, atherosclerosis, and
3 actions of nicotine.

4 **E. Annual Reports**

5 **Q. During the 40-plus years when CTR was funding scientific research,**
6 **was there a publicly available source of basic information about the research that it**
7 **funded?**

8 A. Yes. This information was publicly available in CTR's Annual Reports.
9 Each CTR Annual Report contained information about the research that was funded as
10 part of CTR's grant-in-aid program. Beginning in 1956, there were Annual Reports
11 covering each year through 1997. The 1956 report contained information about all the
12 grants that CTR had awarded in 1954, 1955 and 1956, and after that time there
13 sometimes was one report for two years.

14 **Q. Can you identify Exhibits JD-090000 through JD-090039, which is a**
15 **total of 40 exhibits?**

16 A. Exhibits JD-090000 through JD-090039 are all of CTR's Annual Reports,
17 from 1956 through 1997. There were 40 of them. Each Annual Report covered the
18 research that had been funded, and the scientific articles that were published, in the year
19 or years in the title of the report.

20 **Q. Who received copies of CTR's Annual Reports?**

21 A. Copies of the Annual Reports were sent to the libraries and to the deans of
22 all U.S. medical schools. Copies were sent to science writers for the popular press and to
23 CTR's grantees. Until 1991, copies were sent to members of professional medical
24 societies such as cardiologists and cancer researchers. During my tenure at CTR, a copy

1 of the most recent Annual Report was sent to each applicant for a CTR grant-in-aid, as
2 well as to all active and former CTR grant recipients.

3 **Q. Could anyone obtain a copy of CTR's Annual Reports?**

4 A. Yes. In addition to being in medical school libraries, they were available
5 to anyone who called or wrote CTR requesting a copy.

6 **Q. Can you identify Exhibit JD-090039?**

7 A. Exhibit JD-090039 is CTR's last Annual Report, which was for 1997.

8 **Q. Can you use Exhibit JD-090039 to explain the contents of CTR's**
9 **Annual Reports?**

10 A. The inside cover page has an explanation of CTR's organization and a
11 general statement of its policy regarding the awarding of grants and the publication of
12 research results. The title page is followed by a list of the Scientific Advisory Board
13 members at that time. This is followed on page 5 by an Introduction that provides
14 statistics on CTR's research program, including the amount of funding awarded, the
15 number of completed projects, the number of principal investigators and their affiliated
16 institutions, and the number of published reports of CTR-supported research in peer-
17 reviewed journals. Beginning on page 7, the bulk of the 1997 Annual Report consists of
18 abstracts of hundreds of articles acknowledging CTR support that appeared in the
19 scientific literature over the previous year. Beginning on page 250, the 1997 Annual
20 Report lists grant-in-aid research projects that were active as of 1997, including the
21 names of the principal investigators and the institutions where their research was being
22 conducted. Beginning on page 278, the Annual Report lists the names and affiliated
23 institutions of the principal investigators of every CTR grant-in-aid project that had been
24 completed prior to that time. This list also includes the names of the entities that had

1 completed work pursuant to contracts with CTR. Finally, a list of all the CTR's Scholars
2 Award recipients begins on page 272.

3 **Q. Who prepared CTR's Annual Reports?**

4 A. It was a group effort by a number of people at CTR. As shown in the
5 1997 Annual Report, the main portion consisted of the abstracts of articles that
6 acknowledged funding support from CTR. These abstracts were compiled by CTR's
7 library staff. In most instances, the abstracts in the Annual Reports appeared in the
8 scientific journals in which the articles were published. In CTR's early years, before it
9 was the general practice for journals to provide abstracts with the articles, the library staff
10 wrote some of the abstracts, which were sent to the grantees for their approval. The
11 introduction to the Annual Report was generally written by CTR's Scientific Director.
12 The administrative staff prepared the updated lists of SAB members, as well as the lists
13 of active and completed research projects.

14 **Q. Can you identify Exhibit JD-090006?**

15 A. Exhibit JD-090006 is CTR's 1962 Annual Report.

16 **Q. Does Exhibit JD-090006 follow the same format as the 1997 Annual
17 Report?**

18 A. Exhibit JD-090006 has many of the sections that are in the 1997 report,
19 but the placement or content of some of the sections differs. For example, the statistics
20 that are included in the Introduction of the 1997 Annual Report are listed on the inside
21 cover page of the 1962 report. The Introduction of the 1962 Annual Report, which
22 begins on page 5, is much lengthier and discusses the general state of science regarding
23 issues of smoking and health as of that time, and the nature of CTR's efforts in
24 supporting research. In the 1962 Annual Report, the abstracts of scientific articles are
25 preceded by a section, beginning on page 8, that discusses projects in various fields of

1 research that were recently awarded funding by CTR. The list of grantees and their CTR-
2 funded projects, which begins on page 44, does not differentiate between active and
3 completed projects. There is no information about research contracts or about Scholars
4 Awards in the 1962 Annual Report since neither program was in existence at that time.

5 **Q. Was the Annual Report the only place where the results of the**
6 **research funded by CTR were published?**

7 A. No. The research results were published in thousands of scientific articles,
8 most of which were in scientific journals. The Annual Report contained the summaries
9 of those articles. These summaries are commonly referred to as abstracts.

10 **F. Scientific Director and Scientific Staff**

11 **Q. Who made the decisions about what scientific research CTR would**
12 **fund?**

13 A. The Scientific Director of CTR, who was a scientist with a research
14 background, was in charge of CTR's scientific program. The Scientific Director had the
15 ultimate authority for decisions about the funding of research by CTR. He made those
16 decisions on the basis of a formal peer review process that involved evaluations and
17 recommendations by the Scientific Advisory Board. I served as the Scientific Director of
18 CTR from 1991 to 1999.

19 **Q. Was the Scientific Director an employee of CTR?**

20 A. Yes.

21 **Q. Did CTR employ any additional scientists?**

22 A. Yes. There were several Associate Research Directors, which was my job
23 title when I joined CTR in 1983. That title changed over the years. These scientists were
24 also referred to as staff scientists. In the early years, CTR had one or two staff scientists

1 in addition to the Scientific Director. When I joined CTR, there were four staff scientists
2 in addition to the Scientific Director.

3 **Q. What kind of training and experience did the staff scientists at CTR**
4 **have?**

5 A. They had been research scientists before they came to CTR, and most of
6 them had extensive experience in conducting scientific research. With one exception,
7 they all held Ph.D. or M.D. degrees.

8 **Q. Had any of the CTR staff scientists been affiliated with any of the**
9 **tobacco companies before coming to CTR?**

10 A. No.

11 **Q. What were the main functions of the CTR staff scientists?**

12 A. Their principal responsibility was to assist in administering CTR's grant-
13 in-aid research program. They coordinated the application process, interacted with the
14 SAB, and answered applicants' questions. Later, after applicants became grantees, the
15 staff scientists maintained contact as monitors with the grantees and answered their
16 questions whenever they arose. As part of that function, the staff scientists made site
17 visits to CTR grantees.

18 **G. Scientific Advisory Board**

19 **Q. What was the Scientific Advisory Board, or SAB, of CTR?**

20 A. The SAB was a board of distinguished scientists from outside of CTR that
21 met several times a year to evaluate the applications that CTR had received for grants.

22 **Q. Were the SAB members employees of CTR?**

23 A. No. They were faculty members and researchers at universities and
24 medical schools, or researchers at other institutions such as hospitals and laboratories —

1 except for the Scientific Director of CTR, who was a member of the SAB and an
2 employee of CTR.

3 **Q. Were any of the SAB members employees, or former employees, of**
4 **the tobacco companies?**

5 A. No.

6 **Q. How often did the SAB meet?**

7 A. In its first two years, 1954 and 1955, the SAB met almost once a month.
8 From 1956 through 1972, the SAB generally met four times a year. Beginning in 1973,
9 grant application review meetings of the full SAB were held twice a year. An Executive
10 Committee of the SAB also held periodic meetings from 1973 to 1991.

11 **Q. Can you identify Exhibit JD-090960?**

12 A. Exhibit JD-090960 is a compilation of minutes of the SAB meetings from
13 1954 to 1998.

14 **Q. Were the members of the SAB compensated by CTR?**

15 A. SAB members received per diem payments for the days they attended the
16 SAB meetings. In 1983, when I came to CTR, the per diem payment was in the range of
17 \$600 to \$700 per day. In 1997, the rate was \$2,000 per day. The SAB members also had
18 to do a considerable amount of work to prepare for meetings, for which they were not
19 compensated. Before each grant review meeting, each SAB member was provided with
20 all of the grant-in-aid applications that CTR had received in that review period.
21 Typically, there were about 100 grant applications in a review period. Each SAB
22 member was assigned to prepare detailed written evaluations of 15 to 20 applications in
23 each review period.

24 **H. Grant Selection Process**

25 **Q. How many SAB grant application review meetings did you attend?**

1 A. I attended every SAB meeting from October 1983 until the SAB was
2 disbanded in the fall of 1998. That was a total of 39 grant application review meetings.

3 **Q. Are you familiar with the process by which the SAB evaluated grant-**
4 **in-aid applications?**

5 A. Yes. I observed that process directly from 1983 on. In the 1990s when I
6 was Scientific Director of CTR, I participated in the process. I am familiar with the
7 aspects of that process that were different before I joined CTR because they are spelled
8 out in SAB minutes that I have read.

9 **Q. Please describe the process that the SAB used to evaluate grant**
10 **applications in the 1990s, when you were the Scientific Director of CTR.**

11 A. The procedure that was in use when CTR's research program was
12 discontinued was a two-stage process. The first stage consisted of a preliminary
13 application review. Then, for the applications that survived the preliminary stage, full
14 applications were considered.

15 **Q. How did preliminary applications for funding reach CTR?**

16 A. Usually, the process was initiated when CTR received a phone call or a
17 letter from a researcher who believed he or she had a research project on a topic that
18 would be of interest to CTR. Occasionally the request came from a researcher who had
19 spoken with a member of CTR's scientific staff or a member of the SAB who suggested
20 that the researcher might consider submitting an application to CTR. CTR sent a
21 preliminary application package to any researcher who requested one.

22 **Q. Were any requests for funding turned down before CTR received the**
23 **preliminary application?**

24 A. Only a few. Occasionally, someone would call or write in to CTR who
25 did not have the necessary professional qualifications to receive a CTR grant. Grantees

1 were required to be members of the faculty at a college, university or medical school, or
2 hold an equivalent position at a research institution. The institution at which the grantee
3 worked had to be not-for-profit. CTR did not award research grants to commercial
4 laboratories or for-profit research institutions.

5 Once in a while, a scientist expressed an interest in obtaining funding from CTR
6 for a project to study better methods to grow tobacco, or something along those lines.
7 We did not accept those kinds of applications because they did not involve smoking and
8 health. In addition, CTR could not fund any research that had to do with the commercial
9 aspects of cigarettes: how to design cigarettes, the comparative health effects of different
10 brands of cigarettes, that sort of thing. On the rare occasions when individuals inquired
11 about CTR's possible funding of projects that were commercial in nature, they were told
12 that CTR did not fund such projects and that it would not be fruitful for them to go
13 through the process of sending in an application.

14 **Q. Did you know the source of these restrictions on funding research that**
15 **had commercial implications?**

16 A. I understood that they stemmed from limitations under the antitrust laws
17 about what competitors, like CTR's member companies, were permitted to do when they
18 acted together.

19 **Q. Can you identify Exhibit JD-090191?**

20 A. Exhibit JD-090191 is a letter dated January 21, 1954 from Stanley M.
21 Barnes, Assistant Attorney General in the U.S. Department of Justice, to Mr. Paul Hahn,
22 Temporary Chairman of TIRC.

23 **Q. Please read the body of the letter.**

24 A. "I read with interest the statement of the Tobacco Industry Research
25 Committee, which appeared in the newspapers on January 4, 1954, regarding the

1 Committee's pledge of aid and assistance to the research effort into all phases of tobacco
2 use and health. I would appreciate receiving as many details on the Committee's plans as
3 you may care to disclose at this time."

4 **Q. Can you identify Exhibit JD-000294?**

5 A. Exhibit JD-000294 is a letter from Mr. Hahn to Mr. Barnes in response to
6 JD-090191. The letter is dated January 26, 1954.

7 **Q. Please read the second paragraph of Mr. Hahn's letter, Exhibit JD-**
8 **000294.**

9 A. "I appreciate the interest you are taking in this matter, and I wish to assure
10 you of our desire to keep you informed. Of course, the committee is in its initial and
11 formative stage at the present time and is charting its future course and formulating its
12 plans and functions. We have already made an initial statement of our origin, purpose
13 and proposed functions, two copies of which I am pleased to enclose herewith."

14 **Q. What is the document that was attached to Mr. Hahn's letter as part**
15 **of Exhibit JD-000294?**

16 A. The document attached to Mr. Hahn's letter was titled "A Statement
17 Concerning the Origin and Purpose of the Tobacco Industry Research Committee and its
18 Proposed Functions."

19 **Q. Please look at page 70103761, which is the last page of Exhibit JD-**
20 **000294. What is the heading on that page?**

21 A. "Limit of Powers."

22 **Q. Would you please read the Limit of Powers section?**

23 A. "The purposes and objectives of the Committee are to aid and assist
24 research into tobacco use and health, and particularly into the alleged relationship
25 between the use of tobacco and lung cancer, and to make available to the public factual

1 information on this subject. It is the considered judgment of the Committee that its
2 activities shall be confined to the purposes set forth above, and it is in nowise to be
3 considered or to operate as a trade association or to participate in any activity, or give
4 consideration to any matters, affecting the business conduct or activities of its members,
5 and that its activities in every respect shall conform to law and all decrees or judgments
6 of courts affecting or relating to the tobacco industry. To this end the Committee is
7 proceeding under the advice of legal counsel selected from among the counsel or
8 nominees of its members.”

9 **Q. Let’s return to CTR’s grant review process. After preliminary**
10 **application packets were sent to researchers, what happened next?**

11 A. When a preliminary application was completed and returned to CTR, the
12 members of CTR’s scientific staff reviewed the application to determine which members
13 of the SAB would be the most knowledgeable about the subject of the proposed research.
14 An application was sent to three SAB members, selected by the CTR scientific staff,
15 based on the members’ expertise and research interests. Once all the reviews of the
16 preliminary applications that had come in within a particular period were completed, the
17 applicants whose ratings were high enough to have a chance of ultimately being funded
18 were sent a full application to be completed, which triggered the second stage of review.

19 A full application required the applicant to provide much more information about
20 the proposed research. Applicants were asked to provide information about the facilities
21 available for support of the project both institutionally and in the applicant’s laboratory,
22 their scientific training, and the amount of money they were seeking. When CTR
23 received a completed application, copies were made available to every member of the
24 SAB. Two of the SAB members who had been determined to be knowledgeable about
25 the area of science that was the subject of the application were assigned to do detailed

1 reviews. In some cases, one or more of the SAB members assigned to review an
2 application told CTR that it would be helpful to have it reviewed by a scientist outside the
3 SAB who had expertise in a particular area. In these cases, the SAB member or members
4 often identified a particular outside expert to review the application. The reviewing SAB
5 members and any outside reviewers sent their reviews to CTR.

6 All this material was assembled by CTR's support staff under the supervision of
7 the scientific staff for the next SAB grant review meeting. These meetings were held
8 over a two- or three-day period at CTR's office in New York. At an SAB review
9 meeting, each submitted grant application was discussed at length. The two SAB
10 members who had prepared detailed written reviews of an application first read their
11 critiques. If the two reviewers felt that an application was so weak that it had no chance
12 of being funded and if the rest of the SAB agreed, there was no further review of the
13 application. In all other instances, each application was discussed in detail by the full
14 SAB. After the discussion was concluded, ballots were distributed and each SAB
15 member rated the application on a scale of 1-5. The ballots were secret. This process
16 was repeated until all the applications before the SAB had been rated numerically.

17 **Q. What happened to the ratings that were assigned to each application**
18 **by the SAB members?**

19 A. The CTR staff scientists averaged the scores on the ballots for each
20 application. The average scores were then compiled in a list, which displayed them from
21 the highest to the lowest score. The Scientific Director and the scientific staff then held a
22 meeting at CTR at which the funding decisions were made. Ultimately, the Scientific
23 Director was responsible for the funding decisions.

24 **Q. How were these funding decisions made by CTR?**

1 A. The funding decisions followed the rankings that resulted from the SAB's
2 ratings. That is, those with the best average scores given by the SAB were awarded
3 funding. Sometimes exceptions were made to this rule because the Scientific Director
4 thought it would be important to have more balance among the various areas of research
5 than there would have been if the numerical rankings were strictly adhered to. For
6 example, during a review period if there was a disproportionately high number of projects
7 in the cardiovascular area relative to those with a pulmonary focus, the Scientific Director
8 might decide to fund an application in the pulmonary area that was not ranked quite as
9 highly as a proposed cardiovascular project, and the cardiovascular project would not be
10 funded. Let me be clear that, in my hypothetical example, the pulmonary application had
11 been approved by, and had received a good score from, the SAB; it just was a bit lower
12 than the score for the cardiovascular application. The funding of some applications that
13 were rated slightly lower than others that did not receive funding was done with the full
14 knowledge and approval of the SAB. The Scientific Director and scientific staff also
15 evaluated the financial requirements of each funded grant-in-aid project to be funded and
16 made determinations about whether to award the full amount of funding requested or a
17 lesser amount.

18 **Q. You said earlier that some applications for CTR funding were sent to**
19 **outside scientists for review. Were any of these outside scientists employees of**
20 **tobacco companies?**

21 A. No. Like the members of the SAB, they were scientists affiliated with
22 universities, medical schools and research institutions.

23 **Q. Was the grant application process you just explained the same one**
24 **that was used throughout CTR's history?**

1 A. The essential nature of the review process did not change. Grant
2 applications were always reviewed by the members of the SAB and then discussed at
3 their meetings. However, aspects of the process changed at various times over the years.

4 **Q. How did you become familiar with these changes?**

5 A. Some of them occurred while I was at CTR. The earlier ones are
6 documented in the minutes of the SAB meetings.

7 **Q. Can you explain the main changes in the grant application review
8 process that took place?**

9 A. Yes. The minutes of SAB meetings, Exhibit JD-090960, show that in the
10 early years of TIRC, from 1954 until around 1957, the SAB members themselves decided
11 at each SAB meeting, after their discussion of the grant applications, which ones would
12 be funded, and in what amounts. In 1957, the authority to allocate available funds
13 according to the ratings assigned by the SAB was given to a subcommittee consisting of
14 Dr. Little, Dr. McKeen Cattell and Dr. Hockett. At that time, the SAB instituted a system
15 for scoring grant applications competitively. This scoring system is described on page
16 CTR MIN-SAB 000106-107 of Exhibit JD-090960, in the minutes of the SAB meeting
17 on November 9-10, 1957.

18 In 1960, a subcommittee of the SAB recommended a procedure for the review
19 and rating of grant applications, and that procedure was adopted. It included having each
20 member of the SAB review each grant application on a scale of 1 to 3 (with 1 the best
21 score), and having the full SAB review the total score for each grant application and
22 consider which scores were high enough to merit funding. This rating system is
23 explained on pages CTR MIN-SAB 000181-182 of Exhibit JD-090960, which is an
24 attachment to the minutes of the SAB meeting on December 10-11, 1960.

1 In 1972, the SAB adopted a 1 to 5 point scale for evaluating grant applications,
2 with 1 the best score. This scoring system is described on page CTR MIN-SAB 000393
3 of Exhibit JD-090960, in the minutes of the SAB meeting on September 15-17, 1972.

4 In the late 1960s and early 1970s, as the number and complexity of research
5 proposals received by CTR increased, two changes were made to improve the efficiency
6 of the application evaluation process. First, the Planning Committee of the SAB, which
7 had been created in 1968 to recommend to the full SAB research areas that should be the
8 focus of CTR's funding, began in or about 1971 to review preliminary research proposals
9 received by CTR, and to decide whether to encourage or discourage the scientists who
10 submitted those proposals to make formal grant applications to CTR. These changes are
11 shown, for example, on pages CTR MIN-SAB 000351-359 and CTR MIN-SAB 000367-
12 374 of Exhibit JD-090960, in the minutes of the SAB meetings on January 15-16, 1971
13 and September 24-16, 1971.

14 In 1973, the Planning Committee was replaced by an Executive Committee of the
15 SAB, which continued to review research proposals submitted to CTR, and to decide
16 whether to encourage or discourage formal applications. This change is shown, for
17 example, on pages CTR MIN-SAB 000396-398, CTR MIN-SAB 000399-407, CTR
18 MIN-SAB 000408-410, CTR MIN-SAB 000813 and CTR MIN-SAB 000814-816 of
19 Exhibit JD-090960, in the minutes of the Planning Committee meeting on December 8,
20 1972, the minutes of the SAB meeting on March 14-16, 1973, and the minutes of the
21 meetings of the SAB Executive Committee on June 13, 1973, September 27, 1989 and
22 February 13, 1990.

23 In the early 1990s, the Executive Committee of the SAB was disbanded, and the
24 procedure that I previously discussed in detail was adopted, in which a panel of three

1 SAB members, selected on the basis of their areas of scientific expertise, reviewed each
2 preliminary application.

3 **Q. Did CTR research grants-in-aid provide funding for a specified**
4 **period of time?**

5 A. Yes. While the SAB anticipated that most research projects would be
6 funded by CTR grants-in-aid for three years, all funding awards formally were for only
7 one year. Thus, the initial award covered the first year's expenses. After that, each
8 grantee was required to submit a brief renewal application, which included progress
9 reports, for the next two years. These renewal applications were called "non-competing"
10 applications: they were not part of the rankings competition with new applications that I
11 have been describing. A renewal application had to demonstrate only that the research
12 was making reasonable progress in order for it to be granted and an additional year of
13 funding to be provided.

14 **Q. Are you familiar with the procedures under which the funding**
15 **agencies of the NIH award grants to researchers?**

16 A. Yes.

17 **Q. Are you familiar with the procedures of private funding organizations**
18 **such as the American Cancer Society and the American Heart Association?**

19 A. Yes, I am.

20 **Q. How are you familiar with those procedures?**

21 A. The peer-review process they use is a matter of very basic, common
22 knowledge among those in the scientific research community. These organizations
23 publish booklets that describe their programs. In addition, I have personal experience as
24 an applicant for funding from the NIH and the National Science Foundation.

1 A. CTR provided funding to scientists who were affiliated with most of the
2 significant research organizations, major universities and medical centers in the United
3 States, as well as some outside the United States. Some examples of these universities
4 and medical schools include Harvard, Yale, Princeton, Stanford, Columbia, MIT,
5 University of Chicago, Cornell, New York University, the University of California at
6 Berkeley, San Francisco and San Diego, Duke, Vanderbilt and Johns Hopkins. Other
7 research institutions include the NCI, the Mayo Clinic, the Salk Institute, the Pasteur
8 Institute, the Karolinska Institute in Sweden, the Institute for Cancer Research, Scripps
9 Clinic and Research Foundation, and the American Red Cross.

10 **Q. What is shown in Demonstrative Exhibit JDEM-010279?**

11 A. This shows some of the research institutions in the United States that
12 received grant-in-aid funding from CTR. These are only a portion of the institutions that
13 were funded through CTR-funded grants-in-aid. This exhibit shows less than 100
14 research institutions, compared to more than 300 other research institutions world-wide
15 where CTR funded scientific research.

16 **Q. Did any CTR grantees work for the research centers at any of the U.S.**
17 **Veterans hospitals?**

18 A. Yes.

19 **Q. Can you identify Exhibit JD-090126?**

20 A. Exhibit JD-090126 is an alphabetical list of the universities, medical
21 schools and other research institutions where the scientists who received CTR grants-in-
22 aid were affiliated and conducted their research.

23 **Q. What is the source of the information shown in Exhibit JD-090126?**

1 A. It was prepared based on information the grantees provided on their
2 applications to CTR and in subsequent correspondence. This information was compiled
3 for the grantees in each of CTR's Annual Reports.

4 **Q. During the period from 1983 to 1999, were you familiar with the**
5 **reputations of CTR's grant-in-aid recipients within the scientific community?**

6 A. Yes. Many of them.

7 **Q. Can you describe the reputations of CTR's grantees?**

8 A. It is difficult to generalize about a group of nearly 1,200 grantees, but
9 many CTR grantees were scientists with established careers who were well-known and
10 highly regarded in their particular fields. Other grantees were at earlier stages of their
11 research careers when they received CTR support; they were not as well-known at the
12 time but received funding because their particular projects reflected fresh ideas and the
13 potential to advance scientific knowledge. One quantifiable measure of CTR grantees'
14 professional reputations is the fact that, by my count, at least 35 of them, or about 3%,
15 were or are members of the National Academy of Sciences. The fact that this many
16 grantees were invited to be members of the National Academy indicates that they were
17 very highly regarded by their scientific peers.

18 **Q. Did any of CTR's grantees win recognition for their research?**

19 A. Yes. CTR's grantees received numerous honors and awards for their
20 research from many different organizations. Probably the highest honor a scientist can
21 attain is to be awarded the Nobel Prize. A total of seven scientists who received CTR
22 funding went on to receive the Nobel Prize. Five CTR grantees received the Nobel Prize
23 in Physiology or Medicine. In fact, from 1980 through 1998, the Nobel Prize in
24 Physiology or Medicine was awarded to 28 scientists at institutions in the United States.
25 Five of those 28, or more than one-sixth of Nobel Prize winners in that category from

1 1980 through 1998, had received CTR grants-in-aid. In 2004, two more former CTR
2 grantees won the Nobel Prize in Chemistry.

3 **Q. Please tell the Court who each of those seven Nobel Prize winners are**
4 **and the relationship of their CTR-funded research to the work for which they won**
5 **the Nobel Prize.**

6 A. Dr. Baruj Benacerraf of Harvard Medical School won the Nobel Prize in
7 Physiology or Medicine in 1980. He had received a CTR grant-in-aid from 1972 through
8 1974. Dr. Benacerraf, an immunologist, studied how the surface molecules of cancer
9 cells are different from those of normal cells. He was hoping that defining those
10 molecules on cancer cells might lead eventually to therapies that would enlist the body's
11 own immune system to attack those cells with antibodies, thus preventing or curing
12 certain cancers. He received the Nobel Prize for his description of those types of
13 molecules on the surface of the cells, which is research for which CTR provided funding.
14 Today, one of the most active areas of cancer research involves immunologic attack on
15 cancer cells.

16 Dr. Stanley Cohen of Vanderbilt University School of Medicine won the Nobel
17 Prize in Physiology or Medicine in 1986. He was awarded a CTR grant-in-aid earlier that
18 year, through which he received funding from 1987 through 1993. Dr. Cohen's research
19 involved growth factors, which are small proteins in the body that under certain
20 conditions are involved in causing cells to become cancerous. Dr. Cohen studied, with
21 CTR grant-in-aid support, the interaction of one of these factors, which is known as EGF,
22 with a specific receptor or docking molecule on the cell. The number of EGF receptor
23 molecules increases significantly in squamous cancer carcinoma, which is associated
24 with lung cancer. Dr. Cohen's work laid the foundation for chemotherapy for lung
25 cancer and other types of cancer that are currently in use.

1 Dr. Harold Varmus of the University of California School of Medicine at San
2 Francisco won the Nobel Prize in Physiology or Medicine in 1989 for his pioneering
3 work with oncogenes. Dr. Varmus made many important contributions to science's
4 understanding of how healthy cells become cancerous. He received a CTR grant-in-aid
5 from 1984 through 1986 to study the mechanism of action of particular oncogenes.
6 Dr. Varmus later served as the Director of the NIH from 1993 to 1999.

7 Dr. Ferid Murad of the University of Texas Medical School won the Nobel Prize
8 in Physiology or Medicine in 1998. He received CTR grants-in-aid from 1978 to 1989.
9 Dr. Murad made important discoveries concerning nitric oxide as a signaling molecule in
10 the cardiovascular system. Among other things, his discovery of nitric oxide's role has
11 led to the development of therapies for treating a variety of medical conditions, and has
12 contributed to the understanding of the possible role of smoking in cardiovascular
13 disease. Dr. Murad published about 40 scientific papers acknowledging CTR's funding
14 of his work.

15 Dr. Louis Ignarro of the University of California School of Medicine at Los
16 Angeles shared the 1998 Nobel Prize in Physiology or Medicine with Dr. Murad and a
17 third scientist. He received a CTR grant-in-aid from 1997 to 1999. Dr. Ignarro's CTR-
18 funded research focused on nitric oxide as one of the signaling molecules that appear to
19 be responsible for controlling the growth of cells and thus is of importance in
20 carcinogenesis.

21 Dr. Avram Hershko of the Israel Institute of Technology won the Nobel Prize in
22 Chemistry in 2004. He received two CTR grants-in-aid, from 1992 through 1994 and
23 from 1997 to 1999. The work for which Dr. Hershko received the Nobel Prize, and
24 which was the subject of his CTR-funded research, involved discovery of the mechanism
25 by which damaged or unwanted cellular proteins are tagged for destruction, the so-called

1 “kiss of death” as the Nobel committee put it. The orderly operation of this process is
2 critical during the phases of the ordinary life cycle of cells. Certain cancers and other
3 diseases are characterized by malfunctions in this tagging system.

4 Dr. Aaron Ciechanover, who is also at the Israel Institute of Technology, shared
5 the 2004 Nobel Prize in Chemistry with Dr. Hershko. He received a CTR grant-in-aid
6 from 1992 to 1997. Like Dr. Hershko, Dr. Ciechanover’s CTR-supported work involved
7 elucidation of the mechanism used by cells to tag cellular proteins for destruction.

8 **Q. Have CTR grant-in-aid recipients received other honors for their**
9 **research?**

10 A. Yes. There are several other awards that are widely recognized as being
11 among the most prestigious honors for biomedical research. One is the Albert Lasker
12 Award for Basic Medical Research. Well over 40 percent of Lasker Award recipients
13 have gone on to win the Nobel Prize. Seven CTR grantees have won the Lasker Award,
14 and five of those seven won the Nobel Prize. The other two CTR grantees who received
15 the Lasker Award are Dr. Harry Rubin of the University of California at Berkeley and
16 Dr. Emil Unanue of the Washington University School of Medicine in St. Louis.

17 Another of the highest honors in biomedical research is the Gairdner Foundation
18 International Award. Over 20 percent of Gairdner Award winners have gone on to
19 receive the Nobel Prize. Eight CTR grantees won the Gairdner Award. Four of those
20 eight also received the Lasker Award. The other four CTR grantees who won the
21 Gairdner Award are Dr. Ernest Beutler of the University of Texas Southwestern Medical
22 Center in Dallas, Dr. Jean-Pierre Changeux of the Pasteur Institute in Paris, Dr. Alvan
23 Feinstein of Yale Medical School and Dr. Carol Greider of Cold Spring Harbor
24 Laboratory.

1 **Q. Did CTR grantees receive support for their research from other**
2 **funding agencies?**

3 A. Yes. The vast majority of them did.

4 **Q. Did the articles that were published by CTR grantees reflect that the**
5 **scientists received funding support from other funding agencies in addition to CTR?**

6 A. Yes. In articles in the scientific literature, the scientists who conducted the
7 research that is being published usually acknowledge the organizations that provided
8 funding for that research. More than half of the 6,400 or so articles I am aware of that
9 acknowledge CTR support also acknowledge the support of government agencies and
10 public health organizations.

11 **Q. What are some of the other agencies whose support, along with that of**
12 **CTR, was acknowledged in these published articles?**

13 A. By far, the largest number of references was to the NIH, including many
14 of the institutes within the NIH such as the NCI and the National Heart, Blood, and Lung
15 Institute. That is what one would expect since the NIH is the largest source of funding
16 for scientific research in the country.

17 **Q. What is shown on Demonstrative Exhibit JDEM-010281?**

18 A. This exhibit is a list of some of the funding organizations whose support
19 was acknowledged by CTR grantees in the scientific articles reporting on the results of
20 their CTR-funded research. The 33 institutions identified on this exhibit are some of the
21 best-known and most prestigious research-funding agencies in the United States and
22 abroad.

23 **Q. Can you identify Exhibit JD-090125?**

1 A. Exhibit JD-090125 is a complete alphabetical list of funding organizations
2 that have been cited, along with CTR, in funding acknowledgements in articles published
3 by CTR grantees.

4 **Q. What is the source of the information in Demonstrative Exhibit**
5 **JDEM-010281 and in Exhibit JD-090125?**

6 A. The articles published by CTR grant-in-aid recipients that acknowledge
7 support from CTR and from these other organizations. This information is contained in
8 CTR's Annual Reports, and Exhibit JD-090125 was prepared on the basis of the Annual
9 Reports.

10 **Q. Using Exhibit JD-090039, which is CTR's Annual Report for 1997,**
11 **can you explain where this information is contained in CTR's Annual Reports?**

12 A. The easiest way to explain that is to give a few examples. If you look on
13 page 96 of the 1997 Annual Report, there is a listing of "Other Support" following the
14 abstract for an article co-authored by CTR grantee, T.D. Gilmore, which says "National
15 Cancer Institute, National Institutes of Health, and Howard Hughes Medical Institute."
16 On page 125, the agencies listed as "Other Support" for an article co-authored by CTR
17 grantee Jennifer Pietenpol, include the "American Institute for Cancer Research,
18 Department of Veterans Affairs, National Institute of Diabetes and Digestive and Kidney
19 Diseases, and the National Institutes of Health."

20 **Q. Can you identify Exhibit JD-001853?**

21 A. Exhibit JD-001853 is a memorandum in CTR's files by Dr. T.C. Tso of
22 the United States Department of Agriculture and is from about 1979. The memorandum
23 is entitled "Smoking and Health Research: An Evaluation of Current Status in the
24 U.S.A.," and it summarizes the research programs relating to tobacco and health funded
25 by the United States and state governments and by private industry. On pages 12-16, this

1 memo describes the CTR research program and at page 13 states that “[m]any of the CTR
2 research projects are jointly supported by other organizations, such as the National
3 Cancer Institute, National Institutes of Health, Swedish Medical Research Council,
4 Leukemia Society of America, National Heart and Lung Association and many others.”

5 **J. Research Contracts**

6 **Q. You mentioned earlier that in the 1970s and early 1980s CTR**
7 **supplemented research grants-in-aid by funding contract research. How did that**
8 **come about?**

9 A. From its early years, CTR provided grants for animal inhalation
10 experiments, in which attempts were made to have the animals mimic human smoking
11 behavior in order to test the hypothesis that smoking caused particular kinds of lung
12 cancers. Beginning in the late 1960s, CTR decided to expand its support of inhalation
13 research and to think about large-scale inhalation studies. The SAB’s recognition of this
14 as an important research objective is shown, for example, on pages CTR MIN-SAB
15 000290 and CTR MIN-SAB 000317-318 of Exhibit JD-090960, which are from the
16 minutes of the SAB meetings on March 2-4, 1968 and May 16-18, 1969. As it turned
17 out, this research required extensive preparatory work in designing the required
18 equipment, among other things, and that work had to be coordinated. Large-scale, long-
19 term animal inhalation research was an important part of CTR’s research program in the
20 1970s, and most of CTR’s contract research was related to the preparation for and the
21 carrying out of these experiments.

22 **Q. How is contract research different from research funded under**
23 **grants-in-aid?**

24 A. In contract research, a funding agency commissions a researcher, often a
25 commercial laboratory, to conduct scientific research with a specific question to be

1 addressed, and that question is specified in a written contract. The laboratory promises to
2 do the research project as specified in the contract, and the funding agency promises to
3 pay for it. Often, the contract specifications are very detailed. One of the primary
4 distinctions between contracts and grants-in-aid is where the idea for the research comes
5 from. In the case of a grant-in-aid, the idea for the research usually comes from an
6 individual investigator. He or she develops an idea for a particular project and applies to
7 a funding agency for a grant to pay for it. In the case of a contract, the idea usually
8 originates with the agency putting up the money. It wants a certain piece of research
9 done, and it hires a researcher or a research laboratory to do it.

10 **Q. Are you familiar with the reasons why funding organizations have**
11 **some scientific research done pursuant to a contract instead of a grant-in-aid?**

12 A. Yes. There are several reasons. Sometimes, a funding agency thinks it is
13 important that research be done to resolve a particular issue or answer a specific question,
14 but cannot expect to receive a grant application addressing that problem, let alone an
15 application from a scientist who is highly qualified to perform the research. Faced with
16 those circumstances, funding agencies sometimes cannot wait for someone in the
17 scientific community to submit a proposal for that project, and instead decide to
18 commission the research themselves. In addition, grant recipients have significant
19 latitude to shift the direction of their work if initial results suggest approaches other than
20 what they originally proposed. If the funding agency regards it as important to keep the
21 researcher on a particular track, that can be specified in a contract.

22 Another factor that may come into play is the scope of the project. Sometimes a
23 funding agency wants to have research done that requires a large commitment of
24 equipment and personnel for a long period of time, with significant expenses to be paid
25 on an ongoing basis. A party that is required to commit resources on that scale may want

1 a contractual commitment that funding will be provided for a number of years. At the
2 other end of the spectrum, some issues might involve a very limited time frame and
3 budget because what is needed is an answer to a relatively simple question, or the
4 production of a specific item or compound. A research project of very limited scope may
5 be better accomplished by a contract.

6 **Q. Is contract research unusual in the scientific research community?**

7 A. Not at all. The NIH, for example, has a very large contract research
8 program. There are regular listings by the NIH in journals and other scientific
9 publications requesting proposals from outside companies or individuals for contracts to
10 perform various types of work that the NIH wants to have done.

11 **Q. Do private funding organizations have contract research programs?**

12 A. Yes. Many large funding organizations, both public and private, rely on
13 research contracts for some projects.

14 **Q. What types of research did CTR fund pursuant to contracts?**

15 A. The delivery of tobacco smoke to the lungs of experimental animals is a
16 complex engineering process. In order to conduct these animal inhalation experiments,
17 the researchers needed to have devices to properly deliver smoke to the these animals, so-
18 called “smoking machines.” The design of such machines is not the type of research that
19 ordinarily would be proposed as a grant-in-aid. To ensure that this essential equipment
20 would be available for inhalation studies, CTR commissioned the necessary research to
21 develop these machines pursuant to contracts.

22 On a related subject, in 1973, CTR entered into a contract with Oak Ridge
23 National Laboratories, which was the primary research laboratory for the federal
24 government’s Atomic Energy Commission, to study particle size distribution in smoke
25 and to study methods of delivering the smoke mechanically. This type of research is not

1 something that would normally have been proposed in a grant application. So CTR
2 contacted Oak Ridge Laboratories, which was well known for its ability to do work on
3 particle size distribution of agents such as cigarette smoke. As another example, CTR
4 used a research contract in order to obtain smoke condensate for use in a different
5 research project.

6 Most of the animal inhalation studies themselves that CTR sponsored were also
7 done as contract research. The goal of these projects was quite specific: to develop an
8 animal model for lung cancer. That is, CTR was trying to identify strains of laboratory
9 animals that, when exposed to smoke by inhalation, would develop lung cancer of the
10 kind associated with smoking by humans. Such an animal model, if successful, would
11 have led to further experimentation into how lung cancer in the animal develops and how
12 cigarette smoking might be involved, with implications for lung cancer in humans.

13 Although CTR had sponsored inhalation research prior to the 1970s through its
14 grant-in-aid program, as science and technology evolved the scope and complexity of
15 inhalation research increased. In order to obtain more meaningful results, it was
16 important that some of these studies be larger and longer in duration than what had been
17 done in the past. Studies of this scale, which last for many years and require a substantial
18 commitment of financial resources, are not well-suited to the grant-in-aid process and are
19 usually performed by commercial laboratories.

20 The primary laboratory that CTR contracted to do animal inhalation research was
21 Microbiological Associates, Inc., or MAI, a large biomedical research company located
22 in Bethesda, Maryland, that had extensive research contracts with U.S. government
23 agencies. Eight of CTR's 30 research contracts were with MAI. These contracts,
24 involving the exposure of laboratory mice to cigarette smoke, ran from about 1970 to
25 1981, and CTR spent a total of nearly \$12 million on these contracts. In addition, from

1 1970 to 1973, CTR funded animal inhalation research under contracts with Bio-Research
2 Consultants, a commercial laboratory in Cambridge, Massachusetts, headed by
3 Dr. Freddy Homburger. The CTR contracts with Bio-Research Consultants involved the
4 exposure of laboratory hamsters to cigarette smoke.

5 **Q. Can you identify Exhibits JD-042032 and pages CTR CONTRACTS**
6 **013887 and 013888 of Exhibit JD-043290?**

7 A. Exhibit JD-042032 is the contract for the work performed by Oak Ridge
8 National Laboratory that I just discussed. The contract itself is between CTR and the
9 Nuclear Division of Union Carbide Corporation. However, as explained on pages CTR
10 CONTRACTS 013887 and 013888 of Exhibit JD-043290, the work under the contract
11 was performed at Oak Ridge National Laboratory, which was a U.S. Government-owned
12 facility of the U.S. Atomic Energy Commission (AEC), staffed and operated for the AEC
13 by Union Carbide Corporation's Nuclear Division under a management contract.

14 **Q. Did the SAB express any position as to the appropriateness of CTR**
15 **contract research?**

16 A. Yes. The SAB discussed this issue, as shown in the minutes of SAB
17 meetings. As noted on page CTR MIN-SAB 000130 of Exhibit JD-090960, the subject
18 of CTR contract research was first discussed at the SAB meeting on December 8-9, 1959.
19 At that meeting, the SAB appointed a committee to recommend an appropriate policy. At
20 a subsequent SAB meeting on June 13, 1959, as noted on pages CTR MIN-SAB 000136-
21 137 of Exhibit JD-090960, the committee reported its conclusions and recommended that
22 such contracts be included as a component of CTR's research program. The minutes note
23 that the recommendation was approved by the SAB.

24 **Q. Were the research contracts that CTR entered into in the 1970s and**
25 **early 1980s approved by the SAB?**

1 A. Yes. Although the members of the SAB did not assign numerical ratings
2 to contract proposals, they did review them before the research went forward, and all
3 CTR research contracts required the SAB's approval. The SAB's approval also was
4 needed for any contract extensions or renewals. These decisions are reflected in the SAB
5 meeting minutes. For example, as shown in the minutes of the SAB's May 16-17, 1970
6 meeting, on page CTR MIN-SAB 000340 of Exhibit JD-090960, after reviewing the
7 animal inhalation experiments proposed by Bio-Research Consultants, the SAB
8 authorized CTR's scientific staff to finalize a contract with Bio-Research Consultants.
9 As shown in the minutes of the SAB's October 10-12, 1973 meeting, on page CTR MIN-
10 SAB 000416 of Exhibit JD-090960, the SAB made the decision not to extend the contract
11 with Bio-Research Consultants.

12 The SAB approved each of the research contracts with MAI, and it was the SAB
13 that made the decision many years later to disapprove funding of any further contract
14 extensions. For example, as shown in the minutes of the SAB meeting on September 12-
15 14, 1969, on page CTR MIN-SAB 000323 of Exhibit JD-090960, the SAB approved the
16 first of CTR's research contracts with MAI. The minutes of the June 20, 1980 meeting of
17 the Executive Committee of the SAB, on page CTR MIN-SAB 000573 of Exhibit JD-
18 090960, show that it was unanimously decided by that committee to allow the final
19 contract with MAI to expire at the end of its term.

20 **Q. Did anyone criticize CTR for deciding to fund some research**
21 **pursuant to contacts?**

22 A. There was one instance of such criticism that I am aware of. I have seen a
23 letter written in the 1970s by Robert Heimann, the President of American Tobacco,
24 which was one of CTR's members, to Addison Yeaman, the Chairman of CTR at that
25 time. In the letter, Mr. Heimann suggested that contract research was inconsistent with

1 the pledge that CTR would sponsor objective and independent research, which
2 Mr. Heimann said CTR had adhered to prior to that time.

3 **Q. Can you identify U.S. Ex. 20084?**

4 A. U.S. Ex. 20084 is the letter from Mr. Heimann to Mr. Yeaman that I just
5 referred to. In his letter, Mr. Heimann said that with the introduction of contract research
6 as part of CTR's research program, it could no longer be said that "all grants are made
7 upon recommendation of an advisory board of independent doctors, scientists and
8 educators" and that the SAB would have "free rein in directing the research program and
9 awarding the money for grants." Mr. Heimann said that "the current shift to contract
10 research bastardizes a fine concept of objectivity which so many good people in past
11 years worked long and hard to establish."

12 **Q. Can you identify Exhibit JD-090064?**

13 A. Exhibit JD-090064 is a letter Mr. Yeaman sent to Mr. Heimann
14 responding to Mr. Heimann's letter, U.S. Ex. 20084.

15 **Q. What did Mr. Yeaman say in the letter in response to the concerns**
16 **Mr. Heimann raised?**

17 A. Mr. Yeaman said that Mr. Heimann was "completely mistaken" that the
18 use of contract research was contrary to the original purposes and principles of CTR.
19 Mr. Yeaman explained that contracts were fully reviewed by the SAB and were "subject
20 to the same consultation, scrutiny, discussion, modification and ultimate vote on approval
21 or disapproval as is every grant," and that "[t]here was no 'contrast between the CTR's
22 emphasis on fundamental and objective scientific research during its first two decades
23 and its current swing toward contract research.'" Mr. Yeaman explained that "[c]ontracts
24 are used because in each instance it has been found impracticable or impossible to carry
25 out the work through the medium of a grant-in-aid to an individual researcher."

1 **Q. Did CTR continue to fund contract research after Mr. Heimann**
2 **criticized their use in 1977?**

3 A. Yes. CTR's contract research, including the large-scale smoke-inhalation
4 experiments by MAI, continued for several years after that.

5 **Q. Can you identify Exhibit JD-001828?**

6 A. Exhibit JD-001828 is a memorandum about a meeting on June 20, 1968 in
7 San Francisco, among representatives of the NIH, the cigarette manufacturers, the
8 Scientific Advisory Board of CTR (mis-identified on page 8 as the Tobacco Research
9 Council), and a group from the American Medical Association called the AMA-ERF
10 Committee for Research on Tobacco and Health.

11 **Q. Do you see a reference to the use of contract research on page 3 of**
12 **Exhibit JD-001828?**

13 A. Yes. At this 1968 meeting, Dr. Endicott of the NIH said that because the
14 NIH had "received a rather limited number of proposals that are right on target ... in
15 smoking and health research, he thought the NIH's "most effective device for obtaining
16 specific answers has been the negotiated contract with the person selected as best
17 qualified to solve the problem." So Dr. Endicott was talking about using contract
18 research where grant applications for the desired, "on-target" research would have been
19 unlikely.

20 **Q. In 1968, when Dr. Endicott made these remarks, what was CTR's**
21 **experience with contract research?**

22 A. CTR started to enter into research contracts in connection with animal
23 inhalation studies about two years later.

24 **Q. At the 1968 meeting where Dr. Endicott made these remarks about**
25 **contract research, was there any discussion of animal inhalation studies?**

1 A. Yes. If you look at the previous page, page 2 of Exhibit JD-001828, you
2 will see that Dr. Little described for the group, which included representatives of the U.S.
3 Government, the SAB's interest in "working towards development of an animal model."
4 That was a consistent item on the SAB's agenda of research objectives in the late 1960s.

5 **Q. Do you know whether any organizations other than CTR were using**
6 **research contracts as the funding vehicle for animal inhalation experiments in the**
7 **1970s?**

8 A. Yes. The National Cancer Institute's Smoking and Health Program had
9 research contracts for smoke inhalation experiments.

10 **Q. Can you identify Exhibit JD-011826?**

11 A. Exhibit JD-011826 is the March 1979 Status Report of the NCI's Smoking
12 and Health Program. On page A-25, there is a listing of the Program's completed
13 research contracts, a number of which involved smoke inhalation experiments.

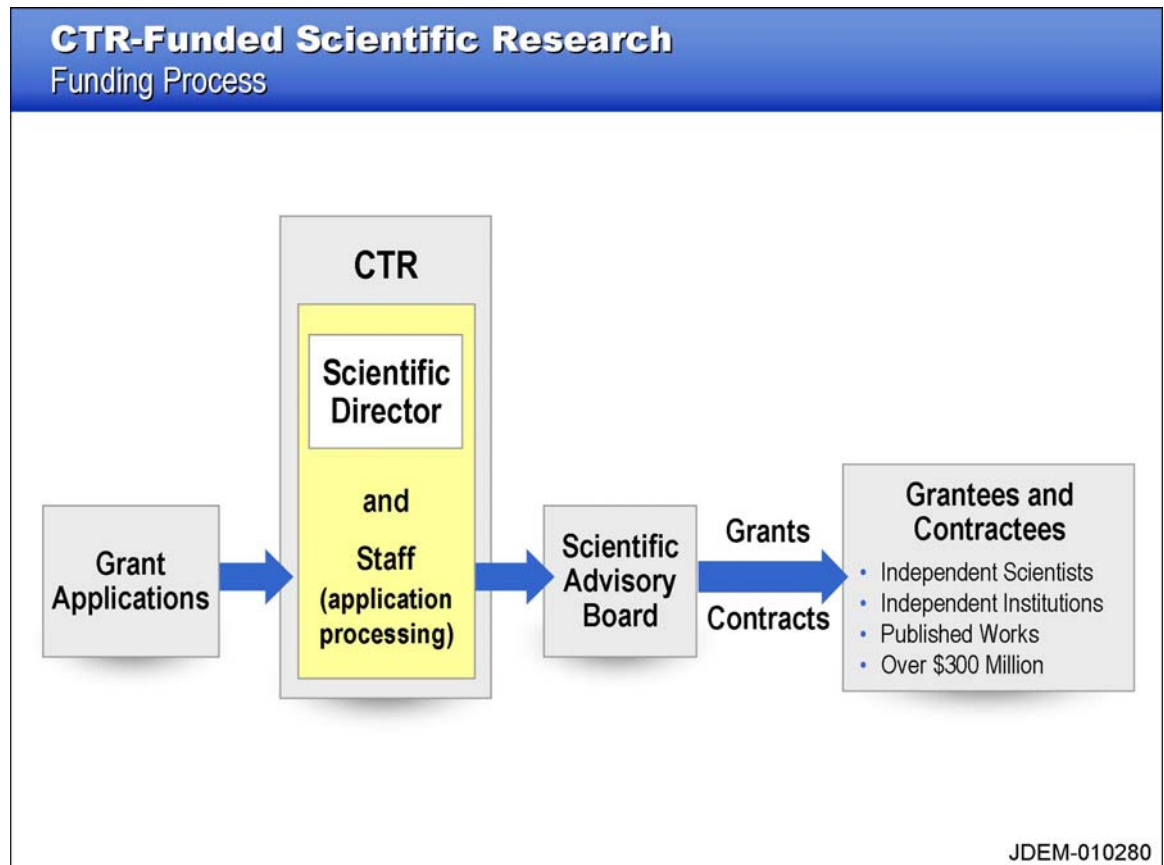
14 **Q. Did CTR fund contract research throughout the entire period when it**
15 **was funding research, from 1954 to 1999?**

16 A. No. CTR's contract research began around 1970 and ended in the early
17 1980s. CTR entered into about 30 research contracts, compared to over 1,300 grants-in-
18 aid. The total dollar amounts of these contracts was about \$15 million, about \$12 million
19 of which was spent on the contracts with MAI.

20 **Q. What is shown on Demonstrative Exhibit JDEM-010280, which is**
21 **reprinted below?**

22 A. This is a chart that I prepared to depict, in a very general way, the process
23 that led to funding CTR-supported grants-in-aid and contracts. In that process, as I have
24 explained, grant-in-aid applications were sent to CTR by independent investigators, were
25 processed by the CTR scientific staff, and were reviewed by the Scientific Advisory

1 Board. In the case of research contracts, the SAB also reviewed proposals and provided
2 its independent advice. The Scientific Director made the ultimate decisions as to research
3 funding, but these decisions followed very closely the advice of the SAB, and the SAB
4 was later informed of the decisions made by the Scientific Director.



5

6 K. Statistics About CTR Research

6

7 Q. From 1954 to 1999, how many scientists received funding for scientific
8 research through the CTR grant-in-aid program?

7

8

9 A. There were about 1,200 principal investigators who applied for and
10 received funding for scientific research through the CTR grant-in-aid program. These

9

10

1 scientists were affiliated with about 300 different universities, medical schools, and other
2 research organizations.

3 **Q. What is the source of the statistics you just provided?**

4 A. The totals as of each year were listed in the Annual Reports, and the
5 figures I just used are in the Introduction to CTR's 1997 Annual Report, Exhibit JD-
6 090039. The cumulative total of investigators and the number of institutions with which
7 they were affiliated were updated in each year's report. The 1997 Annual Report was
8 CTR's last one, and there were no new research projects funded through CTR grants-in-
9 aid after 1997. The names of the investigators and the institutions where they conducted
10 their research are in the back of the 1997 Annual Report, beginning on page 250.

11 **Q. How many research projects did CTR fund?**

12 A. CTR awarded 1,335 grants-in-aid as part of its research funding program
13 from 1954 to 1999, when that program ended. That number is larger than the number of
14 investigators because some of the investigators received more than one grant from CTR.
15 CTR also funded research through about 30 contracts. In addition, CTR sponsored a total
16 of 292 conferences on scientific topics that were relevant to its research program. In
17 total, CTR supported 1,657 research grants-in-aid, research contracts and scientific
18 conferences. This figure does not include CTR Special Projects.

19 **Q. What is the source of the figures that you just provided?**

20 A. The total as of each year was listed in the Annual Reports. The 1,657
21 figure is in the Introduction to CTR's 1997 Annual Report, Exhibit JD-090039. The
22 components that make up that number come from the SAB meeting minutes, as well as
23 the individual grant and contract files.

24 **Q. Over the history of CTR, how much money did CTR provide for**
25 **scientific research?**

1 A. About \$317 million. This includes over \$300 million for grants-in-aid,
2 \$15 million for research contracts, and the balance for scientific conferences, fellowships
3 and Scholars Awards. Again, this figure does not include CTR Special Projects.

4 **Q. What is the source of the statistics you just cited?**

5 A. Again, the yearly expenditures and cumulative total were listed in each
6 Annual Report. For example, the 1996 Annual Report, Exhibit JD-090038, shows a total
7 of \$282 million. For the 1997 Annual Report, Exhibit JD-090039, the total as of 1996
8 was increased by the amount that was subsequently paid to researchers in 1997. The total
9 listed in the 1997 Annual Report was \$302 million. After 1997, CTR provided an
10 additional \$15 million to grantees.

11 **Q. Is the \$317 million total adjusted for inflation over the past five**
12 **decades?**

13 A. No. That figure would be much higher if it were adjusted for inflation and
14 converted into 2005 dollars.

15 **Q. How many scientific publications have resulted from CTR-funded**
16 **research?**

17 A. At least 6,400. These are just the publications that CTR learned about.
18 The primary source of the articles reflected in this figure was the researchers themselves.
19 Grantees were supposed to send CTR reprints of articles that acknowledged CTR's
20 funding support, and they often did. In addition, in reviewing the scientific literature,
21 CTR staff scientists sometimes came across articles acknowledging CTR support. CTR's
22 library staff also found such articles while doing topical searches in the scientific
23 literature.

24 **Q. What is the source of the figure of 6,400 publications you just cited?**

1 A. The CTR Annual Reports and the articles themselves, copies of which are
2 in CTR's files.

3 **Q. Where did these 6,400 publications appear?**

4 A. The vast majority of them were published in peer-reviewed scientific
5 journals. A few are invitational book chapters or articles that were not peer-reviewed.

6 **Q. Can you identify Exhibit JD-090127?**

7 A. Exhibit JD-090127 is an alphabetical list of the journals in which articles
8 acknowledging research supported by CTR's grant-in-aid program have appeared.

9 **Q. What is the source of the information contained in Exhibit JD-**
10 **090127?**

11 A. Again, this information is presented in the CTR Annual Reports. It also is
12 in the articles themselves, copies of which are in CTR's files.

13 **Q. Do you know what journals published the most articles reporting on**
14 **CTR-funded research?**

15 A. I do know, for the articles abstracted in the 1995 CTR Annual Report,
16 Exhibit JD-090037. In 1996, in connection with a presentation that I made at a CTR
17 Board of Directors meeting, I prepared a list of all the publications in which articles
18 supported by CTR grants appeared, as cited in the 1995 CTR Annual Report. I counted
19 the number of times that such articles were published in those journals, based on the
20 information provided in CTR's Annual Report.

21 **Q. What journals published the most articles reporting on CTR-funded**
22 **research?**

23 A. The largest numbers of articles abstracted in the 1995 CTR Annual Report
24 were published in *The Journal of Biological Chemistry*, *Proceedings of the National*
25 *Academy of Sciences*, *Science*, *The Journal of the American Medical Association* and *The*

1 *New England Journal of Medicine*. Each of these six journals was, and still is, among the
2 most frequently cited journals.

3 **Q. How do you know that these journals are among the most frequently**
4 **cited journals in the field of science?**

5 A. Information about the number of citations of articles published in various
6 scientific journals is measured by a statistic called the Science Citation Index, which is
7 published annually by the Institute for Scientific Information. The Science Citation
8 Index lists the number of times that articles published in several thousand science
9 journals have been cited in subsequent articles, and ranks the journals based on the
10 number of times they have been cited.

11 **Q. How did you determine that articles resulting from CTR-supported**
12 **grants-in-aid appeared most often in the most highly ranked journals?**

13 A. In 1996, when I looked into this relationship, I compared my list of the
14 publications abstracted in the 1995 CTR Annual report to the 1994 Science Citation
15 Index, which was published on September 2, 1996 in an article in the journal *The*
16 *Scientist*. I used that year because most of the publications abstracted in the 1995 CTR
17 Annual Report were published in 1994. When I made the comparison, I found that the
18 two highest-ranked journals in the 1994 Science Citation Index were the journals in
19 which the largest numbers of CTR-supported articles, as abstracted in the 1995 CTR
20 Annual Report, Exhibit JD-090037, were published. I also found a high correlation
21 between other journals in which the results of research funded by CTR grants-in-aid were
22 published and those ranked high in the Science Citation Index.

23 **Q. Please review Demonstrative Exhibit JDEM-010282. What does this**
24 **exhibit show?**

1 A. This is a bar chart that I made some years ago, comparing the number of
2 times in which CTR-supported articles appeared in particular scientific journals, as
3 identified in the 1995 CTR Annual Report, with the published numerical rankings of
4 those journals in the 1994 Science Citation Index. The black bars represent the number
5 of the CTR-supported articles identified in the 1995 Annual Report that were published
6 in each of 13 prominent biomedical journals, and are in descending order from left to
7 right. The white bars represent the rankings of these journals according to the 1994
8 Science Citation Index.

9 **Q. What are the sources of the data in that chart?**

10 A. Again, the data come from the 1994 Science Citation Index, which I
11 obtained from an article in the September 2, 1996 edition of *The Scientist*, and CTR's
12 1995 Annual Report.

13 **III. WHAT WERE THE QUALIFICATIONS OF CTR'S SCIENTIFIC**
14 **DIRECTORS AND SCIENTIFIC ADVISORY BOARD MEMBERS?**

15 **A. Scientific Directors**

16 **Q. Other than you, how many Scientific Directors did CTR have over the**
17 **years?**

18 A. Four. They were Dr. Clarence Cook Little, Dr. William U. Gardner,
19 Dr. Sheldon C. Sommers, and Dr. James F. Glenn.

20 **Q. Can you identify Exhibits JD-092944, JD-091171, JD-091185 and JD-**
21 **091156?**

22 A. Exhibits JD-092944, JD-091171, JD-091185 and JD-091156 are the c.v.'s
23 of Dr. Little, Dr. Gardner, Dr. Sommers and Dr. Glenn that were in CTR's files. CTR
24 asked for and obtained c.v.'s of most of its employees, as well as members of the SAB,
25 and maintained these records in its files.

1 **Q. Who was the first Scientific Director of CTR?**

2 A. Dr. Clarence Cook Little. He started in June or July 1954 and served until
3 his death in December 1971.

4 **Q. What was Dr. Little's background before he became the Scientific**
5 **Director of CTR?**

6 A. Dr. Little was an internationally renowned cancer researcher. He was one
7 of the first scientists to identify genetics as a potential factor in cancer. Dr. Little was a
8 pioneer in developing genetically pure inbred strains of mice, which is regarded as the
9 birth of the modern lab mouse. In the 1920s, Dr. Little had been President of the
10 University of Michigan and, before that, he had been President of the University of
11 Maine. In 1929, Dr. Little founded the Jackson Memorial Laboratory in Bar Harbor,
12 Maine, where he served as Director until his retirement in 1956. The Jackson Laboratory
13 is now the world's largest supplier of experimental animals, particularly mice. Apart
14 from his full-time jobs, from 1929 until 1945, Dr. Little served as the Managing Director
15 of the American Society for the Control of Cancer, which is now the American Cancer
16 Society. In 1931 and again in 1940, he was the President of the American Association
17 for Cancer Research, the largest organization of cancer researchers in the United States.
18 Dr. Little played an instrumental role in the creation of the National Cancer Institute, or
19 NCI. He was a member of the National Academy of Sciences.

20 **Q. What is the National Academy of Sciences?**

21 A. The National Academy of Sciences is the most prestigious organization of
22 scientists in the country. Membership is by invitation only and is limited to a fraction of
23 one percent of practicing research scientists.

24 **Q. Before you joined CTR in 1983, were you familiar with Dr. Little?**

1 A. I never met him, but I certainly knew of his scientific reputation. Because
2 of his important contributions to genetics and cancer, he was a leading figure in the
3 scientific research community.

4 **Q. How was Dr. Little selected to be the first Scientific Director of CTR?**

5 A. The documents that I have seen show that the original plan of CTR's
6 organizers was to retain a Scientific Director and then select the Scientific Advisory
7 Board, but that the organizers were unable to recruit a Scientific Director as quickly as
8 they had hoped and decided instead to select the members of the SAB first, and the SAB
9 unanimously selected Dr. Little to be the Scientific Director. The TIRC Chairman, Mr.
10 McComas, then offered the job to Dr. Little, and he accepted.

11 **Q. Can you identify U.S. Ex. 88366 and Exhibits JD-090066, JD-092825,**
12 **JD-093893 and U.S. Ex. 85995?**

13 A. These documents refer to the formation of the SAB and the selection of
14 Dr. Little as the first Scientific Director. It says on page 1 of U.S. Ex. 88,363 that at the
15 SAB meeting on May 26, 1954, the SAB discussed the qualifications and candidates for
16 Scientific Director, and "it became more and more apparent that Dr. Little filled the bill
17 perfectly." When Dr. Little left for another meeting, the other SAB members
18 "unanimously agreed" that Dr. Little should be appointed Scientific Director.

19 **Q. Who succeeded Dr. Little as Scientific Director of CTR?**

20 A. Dr. William Gardner was the next Scientific Director. Dr. Little died in
21 December 1971, and Dr. Gardner started at CTR upon his retirement from Yale
22 University in mid-1973. During the period before Dr. Gardner started, Dr. Hockett, who
23 had been an Associate Scientific Director of CTR, served as Acting Scientific Director.
24 Dr. Hockett joined CTR in 1954. Before coming to CTR, Dr. Hockett had been a faculty

1 member at M.I.T., the Scientific Director of the Sugar Research Foundation Inc., and a
2 scientific consultant to industry.

3 **Q. What was Dr. Gardner's background before he became Scientific**
4 **Director?**

5 A. Dr. Gardner had been the Chairman of the Anatomy Department at Yale
6 Medical School. His specialty was endocrinology and endocrine involvement in cancer.
7 He had been President of the International Union Against Cancer, as well as President of
8 the American Association for Cancer Research, the same organization that Dr. Little had
9 been President of. Dr. Gardner had served as a member of the National Advisory Cancer
10 Counsel of the U.S. Public Health Service, and as a member of the Board of Scientific
11 Counselors of the NCI. Dr. Gardner's research was widely published in medical and
12 scientific journals.

13 **Q. For how long did Dr. Gardner serve as CTR's Scientific Director?**

14 A. For eight years, until 1981.

15 **Q. Who was the next Scientific Director of CTR?**

16 A. Dr. Sheldon C. Sommers, known as Charlie Sommers. I mentioned
17 Dr. Sommers earlier as someone from whom I learned a lot about CTR after I arrived in
18 1983. Dr. Sommers was a prominent research pathologist, meaning that his field of study
19 was the cause of diseases. Dr. Sommers was President of the New York Pathological
20 Society. He taught at Columbia College of Physicians and Surgeons and was Director of
21 Laboratories at Lenox Hill Hospital in New York City. Previously, he had been on the
22 faculty of the medical schools at Harvard, Boston University, and the University of
23 Southern California. Dr. Sommers' research was widely published in medical and
24 scientific journals.

1 Dr. Sommers served in a number of capacities at CTR before becoming Scientific
2 Director. He joined the SAB in 1966. From 1969 to 1972, he served as CTR's part-time
3 Research Director, helping out because Dr. Little's health problems limited his ability to
4 travel to CTR's offices in New York City. Dr. Sommers served as Chairman of the SAB
5 from 1970 until 1981, when he became the Scientific Director. He stepped down as the
6 Scientific Director in 1987, and remained an SAB member until 1989.

7 **Q. Who succeeded Dr. Sommers as Scientific Director?**

8 A. Dr. James Glenn. Before he joined CTR in 1989, Dr. Glenn had been
9 President of the Mount Sinai Medical Center in New York and Dean of its Medical
10 School. Before that, he had been Dean of Emory Medical School. His training was in
11 urology and surgery, and he was Chief of the Urology Department at Duke Medical
12 School before he went to Emory. In the 1990s, while he was Chairman of CTR,
13 Dr. Glenn served in a number of positions at the University of Kentucky, including
14 Executive Director of the Markey Cancer Center. Dr. Glenn served as President of the
15 International Society of Urologic Surgeons, authored a primary textbook used in urologic
16 surgery, and published hundreds of articles in scientific journals.

17 **Q. For how long did Dr. Glenn serve as Scientific Director?**

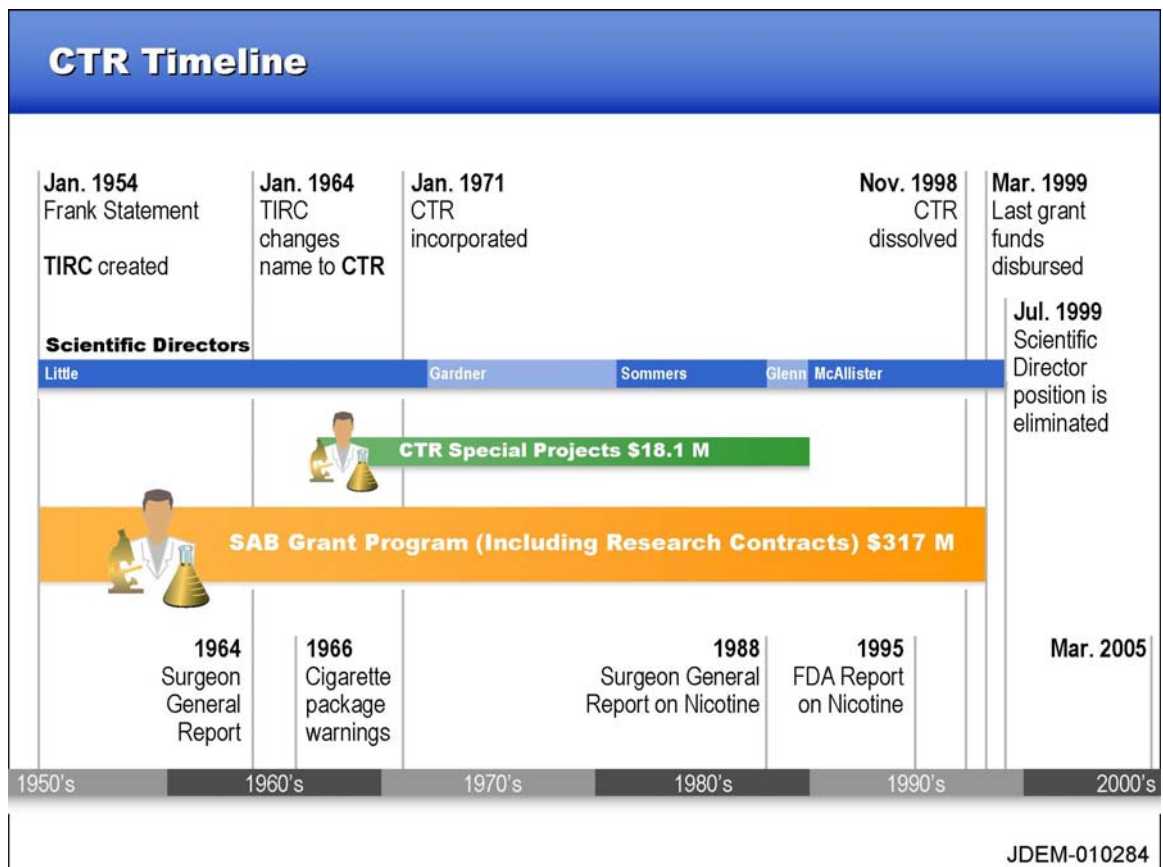
18 A. At the end of 1990, Dr. Glenn became the Chairman of CTR, and at that
19 time I succeeded Dr. Glenn as the Scientific Director. I held that position until CTR's
20 funding of research was discontinued in 1999.

21 **Q. What is shown on Demonstrative Exhibit JDEM-010283?**

22 A. This chart shows my predecessors as CTR Scientific Director – Dr. Little,
23 Dr. Gardner, Dr. Sommers, and Dr. Glenn – and summaries of their credentials.

24 **Q. What is shown on Demonstrative Exhibit JDEM-010284, which is**
25 **reprinted below?**

1 A. This is a timeline showing the tenures of CTR's five Scientific Directors,
 2 along with some of the key events in the history of the smoking and health in the past
 3 fifty years, and the periods when CTR grants-in-aid, CTR research contracts, and CTR
 4 Special Projects were funded with the amount of money distributed to research scientists
 5 through each of those programs.



6

7 **B. SAB Members**

8 **Q. Can you identify Exhibit JD-090123?**

9 A. Exhibit JD-090123 is a list of all the scientists who ever served on CTR's
 10 Scientific Advisory Board over the course of its existence.

11 **Q. When was the SAB formed?**

1 A. In 1954, shortly after CTR was created. The original SAB, which
2 included research scientists, doctors and statisticians, consisted of nine members. Over
3 the years, this number expanded to 15 members. All told, a total of 43 individuals served
4 on the SAB at some time from 1954 until 1998.

5 **Q. Can you identify Exhibits JD-091149 through JD-091178, JD-091180**
6 **through JD-091182, JD-091184 through JD-091188, JD-092943 through JD-092945,**
7 **JD-093862 and JD-095544, a total of 43 documents?**

8 A. These are the c.v.'s of the 43 scientists who served as members of the
9 SAB, the people listed on the exhibit we just looked at.

10 **Q. Can you describe in general terms the backgrounds and scientific**
11 **qualifications of the SAB members?**

12 A. Their backgrounds and expertise covered a broad range of biomedical
13 specialties: cancer, cardiovascular disease, pulmonary disease, immunology, toxicology,
14 pharmacology, neurology, epidemiology and statistics. Some were M.D.'s; some were
15 Ph.D.'s; some held both degrees. Many of them were members of the National Academy
16 of Sciences. In 1998, one-third of the fifteen members of the SAB had been elected to
17 the National Academy of Sciences. That is an extraordinarily high percentage of
18 National Academy membership on a scientific review board.

19 **Q. Were the SAB members themselves involved in scientific research?**

20 A. Yes. They were, or in some instances had been earlier in their careers,
21 active and prominent researchers.

22 **Q. Did the members of the SAB have experience with the peer-review**
23 **process and the publication of scientific research?**

24 A. Definitely. Practically all of the SAB members served on editorial boards
25 of prominent scientific journals. To have an article published in a peer-review journal is

1 to a certain extent an honor, but to be invited to serve on an editorial board of such a
2 journal is an even greater honor. Some SAB members, including Dr. Joseph Feldman
3 and Dr. Carlo Croce, were the editors-in-chief of leading scientific journals.

4 **Q. Please take a look at Exhibit JD-090039, which you identified earlier**
5 **as CTR's 1997 Annual Report. Please turn to pages 70000305-70000306. Can you**
6 **identify what is on those pages?**

7 A. Yes. These pages contain a list of SAB members as of 1997, when the
8 SAB last reviewed grant applications.

9 **Q. Could you go through this list and tell us a little bit about the**
10 **members of the SAB as of 1997?**

11 A. Dr. Barry Pierce, who was Chairman of the SAB, was the American
12 Cancer Society Professor of Pathology at the University of Colorado. The American
13 Cancer Society funds professorships for scientists whose research they feel has advanced
14 scientific knowledge. Dr. Pierce had been President of the American Society of
15 Pathology, as well as President of the Federation of American Societies of Experimental
16 Biology, which has 50,000 to 60,000 members and is the largest organization of health
17 research professionals in the United States. Dr. Pierce also was an editor of the journal
18 *Cancer Research*.

19 Dr. Leo Abood, who is deceased, was a professor of pharmacology at the
20 University of Rochester, New York Medical Center. He was an expert in the
21 pharmacology of nicotine, particularly its effect on the central nervous system.
22 Dr. Abood was on the editorial board of a number of journals, including *Neurochemistry*.

23 Dr. Barry Arnason was Chairman of the Department of Neurology at the
24 University of Chicago Medical School. His expertise is in the area of diseases and
25 functions of the brain. He was the Director of the Brain Research Institute at the

1 University of Chicago, an organization that does research on neurology, with emphasis
2 on the central nervous system. Dr. Arnason has been on the editorial board of about ten
3 journals and has worked extensively with organizations focused on diseases of the
4 nervous system, such as the Multiple Sclerosis Society and the ALS Society.

5 Dr. Drummond Bowden was an expert on pulmonology. He was Chairman of the
6 Department of Pathology at the University of Manitoba in Winnipeg, Canada.

7 Dr. Bowden discovered how one type of cell is involved in the progression of lung
8 cancer.

9 I mentioned Dr. Michael Brennan, the President of the Michigan Cancer
10 Foundation, because in 1983 he told me about the job opening at CTR. Dr. Brennan was
11 an oncologist, a cancer doctor. He was on the Board of Directors of the American
12 Association of Cancer Research, and at one time was Director of the Detroit
13 Comprehensive Cancer Center.

14 Dr. Carlo Croce was the Director of the Kimmel Cancer Center in Philadelphia
15 when he was on the SAB, and now is director of the Human Cancer Genetics Program at
16 Ohio State. He is a member of the National Academy of Sciences. He served for nine
17 years as editor-in-chief of the journal *Cancer Research*. Dr. Croce received the Gairdner
18 Foundation International Award. Dr. Croce has been a recipient of one of the three prizes
19 awarded annually by the General Motors Cancer Research Foundation.

20 Dr. Raymond Erikson, who is a member of the National Academy of Sciences, is
21 an American Cancer Society Professor of Cellular and Developmental Biology at
22 Harvard. Dr. Erikson also received a General Motors prize for cancer research, as well as
23 the Albert Lasker Award for Basic Medical Research, which is one of the most
24 prestigious awards in biomedical science.

1 Dr. Gordon Gill was Chair of Division of Endocrinology and, before that,
2 Chairman of the Faculty of Science at UC San Diego's medical school. He is an editor of
3 a number of scientific journals, and is on the editorial board of *The Journal of Biological*
4 *Chemistry*.

5 Dr. W. K. Joklik was Chairman of the Department of Microbiology and
6 Immunology at Duke University Medical Center. His expertise is in virology. He was
7 editor-in-chief of *The Journal of Virology*, and is on the editorial boards of numerous
8 scientific journals. Dr. Joklik received a career award from the NIH that allows him to do
9 research work at a high level of support without having to apply for grants from other
10 organizations.

11 Dr. Henry Lynch is Director of the Creighton Cancer Center and Chairman of the
12 Department of Preventive Medicine at Creighton. Dr. Lynch's work on the genetics of
13 cancer led to the identification of the genes that are involved in the susceptibility to or the
14 progression of some breast cancers. A syndrome for a particular cluster of cancer types,
15 Lynch Syndrome, is named for him. Dr. Lynch's research laid the groundwork for the
16 current ability of women to be tested for early onset breast cancer. He has won numerous
17 awards for his research, including the American Cancer Society Medal of Honor.

18 The next person on the list is me.

19 Dr. Hugh McDevitt is Professor of Microbiology and Immunology at Stanford
20 University School of Medicine. Dr. McDevitt was instrumental in the discovery of the
21 mechanism by which genes control the immune response. Many of the diseases
22 associated with smoking have an immunological component. Dr. McDevitt is a leader in
23 the search for vaccines for autoimmune diseases such as arthritis, Type I diabetes, and
24 lupus. Dr. McDevitt is a member of the National Academy of Sciences and has been
25 nominated for a Nobel Prize.

1 Dr. David Sabatini is Chairman of the Department of Cell Biology at New York
2 University Medical Center. Before he came to New York University, Dr. Sabatini was at
3 Rockefeller University, where he co-authored papers on the mechanisms of protein
4 synthesis with the 1999 Nobel Prize winner, Dr. Guntel Blobel. Dr. Sabatini is a member
5 of the National Academy of Sciences.

6 Dr. Judith Swain is the Chair of the Department of Medicine at Stanford. Before
7 that, she was Chief of the Cardiovascular Division at the University of Pennsylvania.
8 Dr. Swain is a member of the National Institute of Medicine. She has been President of
9 the Society for Laboratory Investigation.

10 Dr. Peter Vogt is Head of the Division of Oncovirology at the Scripps Research
11 Institute, which is a prominent research institution in La Jolla, California. He is another
12 National Academy of Sciences member. Dr. Vogt has received both a General Motors
13 Cancer Research Foundation prize and the Bristol Meyers Award for cancer research. He
14 has served on the editorial boards of ten scientific journals and is a former member of the
15 National Cancer Institute's Board of Scientific Advisors.

16 **Q. Did you know any of the SAB members, other than the members as of**
17 **1997 who are listed in Exhibit JD-090039?**

18 A. Yes. I know, or knew, all but sixteen of the 43 scientists who served at
19 one time or another on the SAB.

20 **Q. Can you tell the Court a little bit about some of the other scientists**
21 **who served on the SAB?**

22 A. Yes. Dr. Leon Jacobson was one of the original members of the SAB
23 when it was formed in 1954, and he remained a member until 1991. That 37 years
24 represents the longest tenure of any SAB member. Dr. Jacobson was Director of the
25 Argonne Cancer Research Hospital in Chicago and had been Dean of the University of

1 Chicago Medical School. He was an adviser to NASA and served on the National Cancer
2 Advisory Board. Dr. Jacobson was a member, and the head of the biological science
3 section, of the National Academy of Sciences.

4 Dr. Edwin B. Wilson was Professor of Vital Statistics at Harvard. He was
5 President of the American Society for the Control of Cancer which, as I said before, is
6 now the American Cancer Society. Dr. Wilson was president of the American Statistical
7 Society. In the 1950s he was widely considered to be the preeminent biostatistician in the
8 country.

9 Dr. Ros Boutwell was Professor of Oncology at the University of Wisconsin. He
10 was a member of the National Cancer Advisory Board of the NCI. He was also
11 Chairman of the American Cancer Society Advisory Committee. His specialty was
12 chemical carcinogenesis.

13 Dr. Alfred Knudson was one of the world's leading experts in cancer genetics.
14 He was at the Fox Chase Cancer Institute in Philadelphia. Dr. Knudson is famous for his
15 discovery of an important class of genes involved in cancer, called cancer-suppressor
16 genes. Defects in these cancer-suppressor genes are now known to be one of the causes
17 of cancer. Dr. Knudsen is a member of the National Academy of Sciences and has won a
18 number of the most prestigious awards in science, including the Lasker Award, the
19 Gairdner Award, a General Motors prize, and the American Cancer Society's Medal of
20 Honor.

21 Dr. Joseph Feldman was Professor of Immunology at the Scripps Research
22 Institute. He held a joint appointment at the University of California, San Diego. He is a
23 renowned pathologist, and he was very well known for his work in immunology. He was
24 editor-in-chief of *The Journal of Immunology*.

1 Dr. William Rienhoff, who was on the original SAB, was a famous lung surgeon.
2 He was the first to perform lung surgery using the process of intubation, which is the
3 procedure where a tube is inserted down a patient's throat to allow him or her to breathe
4 while surgery is taking place. This remains a common procedure today.

5 Dr. Gordon Sato was Professor of Biology at the University of California, San
6 Diego. He is another member of the National Academy of Sciences. Dr. Sato was the
7 first scientist to devise a way of growing tissue cells in a chemically defined medium.
8 Since his retirement, Dr. Sato has applied himself to an entirely new field, working with
9 impoverished coastal communities in the country of Eritrea. Through his Manzanar
10 Project, named after the internment camp in California where Dr. Sato lived as a teenager
11 during World War II, Dr. Sato and a team of Eritreans are working to develop a multi-
12 faceted agricultural program in one of the driest places on earth.

13 **Q. Did the members of the SAB have experience reviewing grant**
14 **applications for other sources of research funding?**

15 A. Yes. Virtually all if not all of them reviewed grant applications for other
16 funding agencies, including the American Cancer Society, the American Heart
17 Association, the NCI, and other institutes within the NIH such as the National Heart,
18 Lung and Blood Institute.

19 **Q. Did the members of the SAB have experience in applying for and**
20 **receiving grants from these various organizations?**

21 A. Yes. As prominent research scientists, they received support for their
22 research from major research funding institutions.

1 **IV. WAS CTR “INDEPENDENT?”**

2 **A. Meaning of “Independence” of CTR**

3 **Q. During your years as a member of CTR’s scientific staff, including**
4 **eight years as the Scientific Director of CTR, did you ever hear anyone refer to CTR**
5 **as “independent?”**

6 A. Yes.

7 **Q. Did you ever during those years use the term “independent” when you**
8 **referred to CTR?**

9 A. I’m sure I have done that.

10 **Q. What did you understand CTR’s “independence” to mean?**

11 A. Several things. Most important to me, the decisions awarding funds for
12 scientific research under CTR’s grant-in-aid program were made by CTR as it saw fit,
13 without being directed what to do by the cigarette manufacturers that had created and
14 funded CTR. CTR’s mandate, as I understood it, was to fund research relevant to
15 tobacco use and health. There were very few limitations on that broad scope, the main
16 one being the prohibition against research into cigarette design and other commercial
17 aspects. Within that scope and the annual budget set by the member companies, CTR
18 determined what grants-in-aid to award, based on the evaluations by the Scientific
19 Advisory Board. Those determinations defined, “independent” of the cigarette
20 manufacturers, a program of scientific research.

21 I also understood CTR’s “independence” to refer to the independence from the
22 tobacco companies of the Scientific Advisory Board. All the SAB members came from
23 outside the tobacco industry, as the Frank Statement said they would. In advising CTR,
24 the SAB members were free to form and express their scientific judgments as they saw
25 fit.

1 I also understood CTR's "independence" to refer to the scientific freedom that
2 was afforded to CTR's grantees. The grantees were scientists from outside the tobacco
3 industry, who were free to conduct their research and to publish their findings as they saw
4 fit. The tobacco companies did not tell them what to do or what to publish, and neither
5 did CTR. The grantees did their work independently of any such restrictions.

6 **Q. Can you identify Exhibit JD-090051?**

7 A. Exhibit JD-090051 is a statement by Robert Walker, an executive with
8 American Tobacco Company. According to the memo, he read this statement at a
9 meeting on November 30, 1970. It is not in CTR's files, but I have seen the document a
10 number of times in recent years.

11 **Q. Do you see Mr. Walker's references to "independent" research on**
12 **pages 1 and 2 of Exhibit JD-090051?**

13 A. I do, and that is very much consistent with the way in which I understood
14 the "independence" of CTR: the freedom of the SAB from industry influence and the
15 independence of CTR-funded researchers.

16 **Q. Did you understand that CTR was independent of its member**
17 **companies?**

18 A. No. When the cigarette manufacturers started TIRC in 1954, they referred
19 to TIRC in the Frank Statement as a "joint industry group." The manufacturers later
20 incorporated CTR, and they elected its directors. They in effect owned CTR. They had
21 the ability at all times to control CTR and tell CTR what to do. They could have put an
22 end to CTR at any time they decided to do so, and that is what they did in 1998.

23 Nonetheless, throughout my years at CTR, and so far as I can tell before that time,
24 the cigarette manufacturers never used their ability to control CTR's grant-in-aid
25 program, and they never told CTR how to run that program. This point is illustrated by

1 the documents written by company scientists and executives, mostly in the 1970s, that
2 propose that the scientific research funded by CTR should be re-directed by the
3 companies to provide more “helpful” science, or that recommend that the companies or
4 their representatives play a role in CTR’s scientific program. The manufacturers could
5 have directed that CTR make these or any other changes at CTR; the manufacturers could
6 have taken part in, or could have controlled, CTR’s funding decisions. But they didn’t do
7 those things. Instead, the companies left it to CTR and the SAB to determine what
8 funding mechanism should be used – grants-in-aid, supplemented by contracts when CTR
9 and the SAB saw fit to do so. And the companies left it to CTR to determine what
10 grants-in-aid it would award.

11 **Q. Did the CTR Board of Directors ever use its authority to set CTR’s**
12 **budget as a means to prevent the funding of CTR grants-in-aid or research**
13 **contracts that the directors did not want to have funded?**

14 A. No. The Board of Directors approved a research budget at the end of each
15 year, ordinarily at a meeting in December, for the following year. When it met, the SAB
16 knew how much CTR could spend on grants – roughly half of that year’s budget, since
17 there were two grant review meetings per year. After applications were rated by the SAB
18 and approved for funding based on those ratings, CTR notified the researchers and began
19 to fund them, with no input from the Board of Directors or the member companies. I
20 suppose that the Board of Directors could, theoretically, have asked CTR for information
21 about the research to be funded and then could have said to CTR, “We don’t like grants
22 A, B and C, and we’re not going to give you money to fund them.” I never heard of
23 anything like that happening, and I am sure it didn’t happen.

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B. Scientific Directors

Q. You have testified about Dr. Little, who served as CTR’s first Scientific Director from 1954 to 1971. Have you seen anything to indicate that the cigarette manufacturers controlled or influenced the way in which Dr. Little exercised his scientific judgment?

A. No. Absolutely not.

Q. Have you seen any contemporaneous comments by any scientists with the federal government about Dr. Little’s integrity?

A. Yes, I have seen a memo that was written in the early 1960s by Dr. Peter Hammill, the Medical Coordinator for the Surgeon General’s Advisory Committee about his meetings with Dr. Little, in which Dr. Hammill mentioned that.

Q. Can you identify Exhibit JE-076119?

A. Yes. Exhibit JE-076119 is a December 20, 1962 memorandum from Dr. Hammill to Dr. Hundley, describing his two days of meetings with Dr. Little, Dr. Hockett and Mr. Hoyt of TIRC. It’s the memo I just referred to.

Q. Can you read the second paragraph of Exhibit JE-076119?

A. “My impression of Dr. Little is that of one of the most estimable men I have ever met. For the past four years I’ve heard rumors that he was the soul of integrity, and also that he had been one of the true giants in the biological sciences, but that he was nearing his dotage and was a mere figurehead in the TIRC. After discussions of about twelve hours on Monday and another six hours on Tuesday, my impression was that the first two items were entirely accurate but the last two items were not quite accurate. Granted, he is 73 years old (and I have no firsthand comparative knowledge of his capacities twenty years ago) but he certainly seemed remarkably alert and incisive.

1 Furthermore, I'm absolutely satisfied that he is much more than a figurehead for the
2 TIRC efforts."

3 **Q. Did Dr. Hammill's memorandum, Exhibit JE-076119, say anything**
4 **about the independence of the SAB?**

5 A. Yes. In the paragraph after the one I read, Dr. Hammill stated that Dr.
6 Little told him that he, Dr. Little, acted as a buffer between the cigarette manufacturers
7 and the SAB, to ensure the SAB's "complete scientific freedom" in the grant review
8 process.

9 **Q. Can you identify Exhibit JD-090054?**

10 A. Exhibit JD-090054 is an obituary of Dr. Little, written by Dr. Walter E.
11 Heston of the NCI, that was published in 1972 in the journal *Cancer Research*.

12 **Q. Can you read what Dr. Heston of the National Cancer Institute said**
13 **about Dr. Little in 1972 in the final paragraph of the obituary?**

14 A. "Who can assess the contributions of this giant idealist? Who can measure
15 the breadth of a life that has influenced so many other lives? Clarence Cook Little was
16 the greatest man I ever knew."

17 **Q. How about Dr. Gardner, who succeeded Dr. Little as the Scientific**
18 **Director of CTR. Have you seen anything to indicate that the cigarette**
19 **manufacturers influenced his scientific judgments?**

20 A. No.

21 **Q. You were a member of the scientific staff of CTR under the next two**
22 **Scientific Directors, Dr. Sommers and Dr. Glenn. Did you ever observe, or have you**
23 **seen anything to indicate, that the cigarette manufacturers influenced their scientific**
24 **judgments?**

1 A. No. From my own personal experience, having known and worked with
2 both men, I am sure they would not have allowed that to happen.

3 **Q. While you were the Scientific Director of CTR, did the cigarette
4 manufacturers influence the way in which you exercised your scientific judgments?**

5 A. No. Nobody from the member companies ever tried to do that.

6 **C. Selection of SAB Members**

7 **Q. How were the original members of the SAB selected?**

8 A. I don't know the details, but I have seen from the documents that the
9 scientists with the tobacco companies were involved in that selection process in 1954.

10 **Q. As scientists left the SAB, how were their replacements selected?**

11 A. I do not know how that process worked before I arrived at CTR in 1983. I
12 did see firsthand how new members of the SAB were selected from 1983 on. There were
13 areas of expertise that clearly needed to be represented on the SAB: for example, cancer,
14 cardiology, pulmonology, neurological sciences, and immunology. If the SAB lost a
15 member who was an expert in one of those fields, CTR sought a replacement with similar
16 expertise. The members of the SAB were the primary source for identifying these
17 candidates for new members. If a vacancy was coming up, we would ask all the
18 members of the SAB to suggest candidates.

19 **Q. Once candidates for the SAB were identified, what happened next?**

20 A. There was no formal selection procedure. Typically, the SAB members
21 discussed the candidates. Sometimes SAB members talked with outside scientists about
22 the candidates who were being considered in order to narrow down our list. We talked
23 with the candidates themselves to determine their interest. We identified the most
24 promising candidates to come to an SAB meeting and give a presentation on their
25 research. Sometimes, we sent those candidates a limited number of grant applications to

1 review, and they participated in the grant application review meeting of the SAB at which
2 those applications were discussed. After the meeting, if the members of the SAB felt that
3 the person had the appropriate professional and personal qualities, an invitation was
4 extended to join the SAB.

5 **Q. What were the qualifications that the SAB looked for in its potential**
6 **members when you were there?**

7 A. The primary objective was to find a first-rate scientist who was willing to
8 spend the required time and was able to provide expertise in an area of scientific research
9 that was needed due to the retirement of an existing SAB member. It was also important
10 to add expertise in newly-developing fields of investigation. In addition, certain personal
11 qualities were considered. The SAB had a low turnover rate, and most SAB members
12 remained on the SAB for long periods. They spent a lot of time together, and it was
13 important to have members who would get along and work together well. Those were the
14 basic criteria.

15 **D. Grants to SAB Members**

16 **Q. Did CTR award grants-in-aid to any SAB members?**

17 A. Yes. I have looked into that, and I found that 16 of the 43 scientists on the
18 SAB received CTR grants for some period of time while they were SAB members.

19 **Q. Can you give examples of research by SAB members that CTR**
20 **funded?**

21 A. For many years, CTR supported the research of Dr. Henry Lynch while he
22 was an SAB member. Dr. Lynch was an epidemiologist who made extensive studies of
23 cancers within families. These studies led to the identification of the breast cancer genes
24 BRCA(1) and BRCA(2). In the 1970s and early 1980s, Dr. Lynch could not obtain

1 funding for his research from the NIH, and at that time only the American Cancer Society
2 and CTR supported his research.

3 Dr. Peter Vogt was on the SAB from 1987 to 1998. His research was supported
4 by CTR from 1970 to 1971, long before he was on the SAB, and again from 1986 to
5 1992, while he was on the SAB. In the 1970s, Dr. Vogt's CTR-funded research involved
6 the so-called RNA tumor viruses. Such studies eventually led to the discovery of
7 oncogenes, which are cancer-causing genes. Dr. Vogt's later CTR grant supported
8 important studies of factors that caused harmless genes already existing in human cells to
9 become oncogenes.

10 **Q. Why were members of the SAB permitted to obtain CTR grants?**

11 A. The members of the SAB were scientists of the highest standing in their
12 fields, and their research was of the highest caliber.

13 **Q. Did these SAB members evaluate, vote on, or score their own CTR**
14 **grant proposals?**

15 A. No. They were required to leave the room during the discussion and vote
16 on their applications. This procedure was followed even in the cases where an applicant
17 was from the same institution as one of the SAB members. Additionally, each
18 application from an SAB member typically was evaluated by one or more expert
19 reviewers from outside the SAB.

20 **Q. Were grant-in-aid applications from SAB members given any**
21 **preference over applications from other scientists?**

22 A. No. I am aware of nothing whatsoever suggesting that SAB members
23 received any special consideration in the grant-in-aid application process. Members of
24 the SAB were very accomplished scientists at prominent institutions, and in any instances
25 their research was worthy of funding. Certainly during my years at CTR, there was no

1 agreement or understanding whatsoever that any preference or advantage was to be
2 provided in exchange for a scientist's agreement to serve on the SAB.

3 **Q. Do other funding agencies such as the NIH or the American Cancer**
4 **Society permit members of their study sections to receive funding?**

5 A. Yes. It would be very hard to find an NIH study section without members
6 who have grants from the NIH.

7 **E. CNS Review**

8 **Q. During your time at CTR, did attorneys for CTR's member**
9 **companies have any role in reviewing applications for grants-in-aid from CTR, or in**
10 **making funding decisions?**

11 A. No.

12 **Q. During your time at CTR, did CTR's attorneys play any role in**
13 **reviewing applications for grants-in-aid, or in making funding decisions?**

14 A. No.

15 **Q. Before you came to CTR, did CTR's attorneys ever review**
16 **applications for grants-in-aid?**

17 A. Yes. That happened for a limited number of grant applications and for a
18 few years. From 1978 until sometime before my arrival at CTR in 1983, a small group of
19 grant applications was reviewed by CTR's counsel, Mr. Jacob, who I understand also was
20 a lawyer for one or more of the companies. For these research proposals during that time,
21 Mr. Jacob provided legal advice to CTR regarding the antitrust implications of joint
22 industry funding of research that appeared to have potential commercial implications for
23 the cigarette manufacturers and that appeared to lack a connection with the etiology of
24 disease.

1 **Q. Other than what you just referred to, did attorneys for CTR’s**
2 **member companies ever have any role in reviewing applications for grants-in-aid**
3 **from CTR, or in making funding decisions?**

4 A. Not to the best of my knowledge. I have never heard anything about that
5 and I have not seen any indication of that in any documents.

6 **Q. Can you identify Exhibit JD-090197?**

7 A. Exhibit JD-090197 is the minutes of a special meeting of the CTR Board
8 of Directors on April 21, 1978.

9 **Q. What do these minutes say in the first paragraph on the third page of**
10 **Exhibit JD-090197?**

11 A. The minutes show that a resolution was adopted by CTR’s Board of
12 Directors on April 21, 1978. The resolution stated: “RESOLVED, that funds may be
13 committed to any research project only when, in the opinion of [CTR’s] legal counsel,
14 that commitment is within the scope of [CTR’s] legally permissible activities.”

15 **Q. Can you identify pages CTR MIN-SAB 000510-519 of Exhibit JD-**
16 **090960?**

17 A. These pages are the minutes of the April 1978 meeting of the Scientific
18 Advisory Board. They show that CTR’s counsel, Edwin Jacob of Jacob & Medinger,
19 attended that SAB meeting. On pages 511-512 of Exhibit JD-090960, the legal advice
20 given by Mr. Jacob to the SAB has been redacted.

21 **Q. Did CTR’s counsel regularly attend meetings of the SAB?**

22 A. No. CTR’s counsel never attended any of the 39 SAB meetings that I
23 attended from 1983 to 1997. According to the minutes of all of the SAB meetings, this
24 meeting in April 1978 and one of the very first meetings in 1954 were the only times that
25 a lawyer for CTR (or for the companies) attended a meeting of the SAB.

1 **Q. Are you familiar with U.S. Ex. 87,142, which is in evidence?**

2 A. Yes. I have seen U.S. Ex. 87,142 a number of times in recent years,
3 although it is not from CTR's files. It is a memo by Preston Leake, a scientist with
4 American Tobacco, who for a time attended SAB meetings in his capacity as the
5 Chairman of the Industry Technical Committee. U.S. Ex. 87,142 is a report of the
6 April 26-28, 1978 SAB meeting, which is the SAB meeting that Mr. Jacob attended as
7 shown in Exhibit JD-090960. Dr. Leake stated on page 3 of U.S. Ex. 87,142 that
8 Mr. Jacob advised the SAB that central nervous system research could be subject to
9 misinterpretation as product development research, and also that CTR had to be mindful
10 of the representations its members made at the time of CTR's creation that it would not
11 get involved in the commercial aspects of the tobacco business.

12 **Q. Are you familiar with U.S. Ex. 20,281, which is in evidence?**

13 A. Yes. U.S. Ex. 20,281 is a letter from Dr. Sommers, who at that time was
14 Chairman of the SAB, to CTR's Scientific Director, Dr. Gardner. It is dated
15 November 3, 1978, about six months after the April 1978 SAB meeting that Mr. Jacob
16 attended. In U.S. Ex. 20,281, Dr. Sommers expressed his opinion that, with respect to a
17 grant application from Dr. Kjell Fuxe, he could see no "possible relevance to antitrust,"
18 and on that basis Dr. Sommers urged CTR to ignore the antitrust advice from its lawyer,
19 Mr. Jacob, and consider Dr. Fuxe's grant application as it would any other. Dr. Fuxe was
20 a researcher at the Karolinska Institute in Sweden. His 1978 grant application sought
21 funding for a study of the effect of nicotine on the central nervous system.

22 To support his argument about CTR ignoring legal advice, Dr. Sommers went on
23 to charge CTR with being, in effect, the prisoner of legal advice, and proposed an
24 alternative name for CTR that reflects that characterization. He even said he was
25 considering leaving the SAB, which says a lot about how important it was to him that the

1 SAB be free of industry control. At that point, Dr. Sommers had been an SAB member
2 for 12 years. The manner in which Dr. Sommers expressed his opinion in this letter is
3 typical of Dr. Sommers as I came to know him in the 1980s. He was very strong-willed
4 and was never hesitant to express his viewpoint and speak his mind. At the same time, he
5 had a sharp wit and a dry sense of humor, which he often used to express serious points.
6 Dr. Sommers did not resign from the SAB after he wrote this letter. He stayed on the
7 SAB until 1989, and he served as CTR's Scientific Director in the 1980s.

8 **Q. Can you identify Exhibit JD-093190?**

9 A. Exhibit JD-093190 is a letter from CTR to Dr. Fuxe advising him that his
10 research would be funded. This is the research that Dr. Sommers referred to in U.S. Ex.
11 20,281. Exhibit JD-093190 is dated January 12, 1979, a little over two months after
12 Dr. Sommers' letter.

13 **Q. Can you identify Exhibit JD-091894?**

14 A. Exhibit JD-091894 is a set of CTR's grant sheets for Dr. Fuxe's grants,
15 which show that CTR continued to fund Dr. Fuxe's research for eleven years, from 1979
16 through 1989.

17 **Q. After you arrived at CTR in 1983, did you learn anything about a
18 practice of CTR receiving legal advice about any grant applications in the past?**

19 A. Yes. I learned, I would estimate within a year after I arrived at CTR, that
20 for a few years CTR's counsel reviewed and gave legal advice about some grant
21 applications, and that the practice had ended at some point, maybe a couple of years,
22 before my arrival.

23 **Q. When you arrived at CTR in 1983, was CTR receiving legal advice
24 about any grant applications involving CNS research?**

25 A. No.

1 **Q. When you arrived at CTR in 1983, was CTR receiving legal advice**
2 **about any grant applications?**

3 A. Not to the best of my knowledge.

4 **Q. While you were with CTR, did CTR receive legal advice about any**
5 **grant applications?**

6 A. Not to the best of my knowledge.

7 **Q. While you were with CTR, was a grant application ever denied**
8 **because of a concern that the research might be disapproved of by the tobacco**
9 **industry?**

10 A. No.

11 **Q. While you were with CTR, was a grant application ever denied**
12 **because of a concern that it might establish or confirm a connection between**
13 **smoking and some disease?**

14 A. Not to the best of my knowledge.

15 **Q. Was the subject of whether the industry would like or dislike a**
16 **particular project discussed at any of the 39 grant application review meetings of**
17 **the SAB that you attended from 1983 to 1997?**

18 A. No. Never.

19 **F. Industry Technical Committee (“ITC”)**

20 **Q. Are you familiar with the Industry Technical Committee?**

21 A. Yes. CTR had some interaction with the Industry Technical Committee,
22 which also was known as the ITC, while I was at CTR. One member of the ITC regularly
23 attended SAB meetings until 1992. These ITC members were senior scientists employed
24 by a cigarette manufacturer. The ITC member’s role at the meetings was to be available
25 to answer technical questions that might come up concerning cigarettes such as their

1 design or the chemistry of their components, or the components of smoke, since the ITC
2 members had extensive knowledge of these subjects.

3 **Q. While you were with CTR, did any members of the ITC ever try to**
4 **express a view on which applications, or what kind of research, they thought should**
5 **or should not be funded by CTR?**

6 A. No.

7 **Q. Did you hear of any instances before you joined CTR when members**
8 **of the ITC got more involved in the grant evaluation process?**

9 A. I have read a document reflecting one such instance. In 1973, Dr. Helmut
10 Wakeham of Philip Morris was the Chairman of the ITC. After attending his first SAB
11 grant application review meeting, Dr Wakeham gave one of the scientific staff members
12 a piece of paper on which he listed his own personal ranking of some of the applications.
13 Dr. Wakeham assigned numerical rankings based on his idea of what he termed “industry
14 relevance.” It appears that Dr. Wakeham did not express his opinions about these
15 applications at the SAB meeting, and that he did not try to influence the SAB’s rankings.
16 That is consistent with my observation of ITC members: they never expressed views on
17 the merits of research proposals.

18 Years ago, I went back and compared Dr. Wakeham’s ratings to the decisions that
19 ultimately were made, and found there was no correlation between his ratings and which
20 applications CTR funded. Some applications that Dr. Wakeham ranked highly were not
21 funded by CTR, and some applications to which he gave low scores were funded.

22 G. CIAR

23 **Q. Are you familiar with the Center for Indoor Air Research, which is**
24 **also known as CIAR?**

1 A. Yes. These are two versions of the document I was just referring to.
2 Exhibit JD-092829 is a draft report by the Research Review Committee, which included
3 representatives of all the member companies of CTR, with an explanatory cover letter.
4 U.S. Ex. 29300 is the signed, final version of the report, dated October 3, 1974.

5 **Q. Can you identify U.S. Ex. 21600?**

6 A. U.S. Ex. 21600 is an April 29, 1974 letter from William Smith of
7 Reynolds to Henry Ramm, then the Chairman of CTR. Mr. Smith explained that the
8 tobacco companies were forming a committee to study their research programs, including
9 CTR, with the goal of producing a final report in the summer of 1974. As we saw in U.S.
10 Ex. 29300, this committee's final report was dated October 3, 1974.

11 **Q. What did the final report of the Research Review Committee, U.S. Ex.**
12 **29300, say about CTR?**

13 A. Paragraph 2 on page 3 of U.S. Ex. 29300 says: "The independence of the
14 Council for Tobacco Research should be respected at all times. It should continue under
15 its present structure and should be independent of any industry supervision or control."

16 **Q. Is that recommendation in 1974 consistent with, or inconsistent with,**
17 **what you experienced at CTR during your tenure there from 1983 until CTR was**
18 **dissolved in 1998?**

19 A. It is very much consistent.

20 **V. DID CTR HAVE RELATIONSHIPS WITH SCIENTISTS**
21 **WHO WORKED FOR THE FEDERAL GOVERNMENT?**

22 **A. SAB Members from the NCI**

23 **Q. Were any members of the SAB public health officials employed by the**
24 **federal government?**

1 A. Yes. The 43 members of the SAB included four employees of the NCI.
2 For 21 of the 23 years from 1963 to 1986, there was an NCI employee on the SAB.

3 The earliest of the four NCI employees on the SAB was Dr. Paul Kotin, an
4 original SAB member who served on the SAB from 1954 to 1965. Dr. Kotin was a
5 member of the SAB when he joined the NCI in 1963. He was an Associate Director, and
6 later Director, of Field Services with the NCI.

7 Dr. Howard Andervont served on the SAB from 1964 to 1966 and from 1968 to
8 1974. Dr. Andervont was an employee of the NCI from 1961 to 1967. He was Scientific
9 Editor of *The Journal of the National Cancer Institute*, which is the NCI's official
10 research publication.

11 Dr. Robert Huebner served on the SAB from 1968 to 1981. Dr. Huebner was an
12 employee of the NCI throughout that period. He was Chief of the Viral Carcinogenesis
13 Branch of the NCI.

14 Dr. Peter Howley served on the SAB from 1982 to 1986. Dr. Howley was an
15 employee of the NCI throughout that period. Dr. Howley was Chief of the Viral
16 Oncology and Molecular Pathology Section of the NCI's Laboratory of Pathology.

17 **Q. Why were there no NCI employees on the Scientific Advisory Board**
18 **of CTR after 1986?**

19 A. In 1986, the NCI's Director, Dr. Vincent DeVita, required Dr. Howley to
20 resign from the SAB. After that, CTR did not have any NCI employee on its Scientific
21 Advisory Board.

22 **Q. Can you identify Exhibit JD-093799?**

23 A. Exhibit JD-093799 is a memorandum, dated April 8, 1983, from
24 Dr. Howley to the Associate Director of the NCI. Exhibit JD-093799 was written when
25 Dr. Howley was asked to join the SAB. The subject line reads: "Request for Outside

1 Activity to Join the Scientific Advisory Board of the Council for Tobacco Research –
2 U.S.A., Inc.”

3 **Q. Please read the first paragraph of Exhibit JD-093799.**

4 A. “I have been asked to join the Scientific Advisory Board of the Council
5 for Tobacco Research – U.S.A., Inc. The CTR provides funding for scientific research
6 relating to tobacco-associated diseases, namely cancer, pulmonary disease, and
7 cardiovascular disease. Last year approximately seven million dollars of funding was
8 provided by the CTR for research in these areas. Research support is primarily through a
9 program of grants-in-aid with institutions and laboratories. Applications for grant
10 support are made by individual investigators and it is the function of the Scientific
11 Advisory Board to evaluate these applications judging them solely on the basis of
12 scientific merit and relevance.” The emphasis is Dr. Howley’s. “The CTR awards
13 research grants to independent scientists who are assured complete scientific freedom in
14 conducting their studies. It is the policy of the CTR that grantees alone are responsible
15 for reporting and publishing their findings through medical and scientific journals.”

16 **Q. Could you please read the last two paragraphs of Dr. Howley’s 1983**
17 **memorandum, Exhibit JD-093799?**

18 A. “The funding provided by the CTR often to young investigators has not
19 been insignificant. A listing of principal investigators who have been supported by CTR
20 grants in the past include Baruj Benacerraf, Carl Becker, Clifford Berger, Victor
21 McKusick, Richard Lerner, and Peter Vogt. The impact of the CTR can be measured by
22 the more than 2000 scientific and medical publications which have acknowledged CTR
23 support as well as by the investigators whose scientific careers have been established by
24 CTR support during critical periods.

1 “The CTR depends on the expertise of its Scientific Advisory Board in the
2 evaluation of the grant applications in determining which to fund. It is open-minded and
3 objective and concerned about the tobacco health-related problems of cancer,
4 cardiovascular diseases, and chronic pulmonary ailments. I believe the mission of the
5 CTR is good and as such, it should have access to top advisors for the purpose of
6 evaluating these grant applications. I do not see that it is a conflict of interest or
7 inappropriate for a scientist from the National Cancer Institute or any of the National
8 Institutes of Health to serve on this board. I therefore request permission to serve as a
9 member of the CTR Scientific Advisory Board.”

10 **Q. Can you identify Exhibit JD-094000?**

11 A. Exhibit JD-094000 is a letter, dated July 7, 1982, from Dr. Howley to
12 Mr. Hoyt of CTR, in which Dr. Howley accepted CTR’s invitation to become a member
13 of the SAB.

14 **Q. Would you please read the first two sentences of Dr. Howley’s letter to**
15 **CTR?**

16 A. “Thank you for the invitation to become a member of the Scientific
17 Advisory Board to the Council for Tobacco Research – U.S.A., Inc. I am pleased to
18 accept the invitation and will look forward to serving on the Board to advise the
19 Scientific Director on the allocation of funds towards research projects pertaining to all
20 phases of tobacco use and health.”

21 **Q. Can you identify Exhibits JD-093887 and JE-076360?**

22 A. Exhibit JD-093887 is a letter, dated June 13, 1986, from Dr. DeVita, the
23 Director of the NCI, to Dr. Sommers, the Scientific Director of CTR, in which
24 Dr. DeVita said that the NCI was opposed to tobacco products and would not permit the
25 expertise of its staff to be used in support of any program that could benefit the tobacco

1 industry, including the programs of CTR. Exhibit JE-076360 is a letter, dated April 2,
2 1986, from Dr. DeVita to Dr. Barry Pierce, who was a member of CTR's Scientific
3 Advisory Board, in which Dr. DeVita reiterated the NCI's position as to CTR and
4 Dr. Howley's service on the SAB.

5 **Q. Have you seen either of these letters before?**

6 A. I saw Dr. DeVita's letter to Dr. Sommers, Exhibit JD-093887, back in
7 1986 when it was received at CTR, and I have seen it in recent years. I have seen Dr.
8 DeVita's letter to Dr. Pierce, Exhibit JE-076360, only recently.

9 **Q. In 1986, to the best of your knowledge, did Dr. DeVita or others at the**
10 **NCI make any statements criticizing the quality or relevance of the scientific**
11 **research funded by CTR?**

12 A. No. Dr. DeVita did not say anything in these letters or anywhere else, so
13 far as I know, that was critical about what the SAB did, about CTR's decisions
14 concerning the funding of research, or about the research itself. In fact, in his letter to
15 Dr. Pierce, Exhibit JE-076360, Dr. DeVita acknowledged in the last sentence of the
16 middle paragraph that "[t]here is no doubt that the money given out is valuable and
17 supports good research."

18 **Q. Can you identify Exhibit JD-094008?**

19 A. Exhibit JD-094008 is a handwritten letter, dated June 12, 1986, from
20 Dr. Howley to Dr. Hockett of CTR.

21 **Q. Please read the last three full sentences of Dr. Howley's letter.**

22 A. "A letter of resignation from the SAB will be sent separately. I hope
23 things can be resolved some way in the near future. I have valued my association with
24 the SAB and would look forward to rejoining if circumstances permit."

1 **Q. Can you identify Exhibits JD-040267, JD-001838, JD-001837, JD-**
2 **001840, JD-093798, JD-001841 and JD-001843?**

3 A. Exhibits JD-040267, JD-001838, JD-001837, JD-001840, JD-093798, JD-
4 001841 and JD-001843 are documents in which the three other NCI employees who
5 served on the SAB – Dr. Kotin, Dr. Andervont and Dr. Huebner – expressed their views
6 about CTR’s research program and their experiences on the SAB.

7 Exhibit JD-040267 is a transcript of testimony that Dr. Kotin, who had been an
8 SAB member from 1954 until 1965, gave to Congress in 1968, in which he described the
9 research funded by CTR. Exhibit JD-001838 is Dr. Kotin’s 1965 letter of resignation
10 from the SAB, in which he described his participation on the SAB as one of the most
11 stimulating experiences he had had in the past decade.

12 Exhibit JD-001837 is a 1964 letter from Dr. Andervont to CTR, in which he
13 expressed his respect for Dr. Little and his esteem for members of the SAB. Exhibit JD-
14 001840 is Dr. Andervont’s 1966 letter of resignation from the SAB, in which he said that
15 he had never worked with a group of men who were so completely objective and fair in
16 their evaluation of applications for assistance.

17 Exhibit JD-093798 is an undated letter from Dr. Huebner to CTR, in which he
18 said that the scientific community at NIH greatly appreciated the critical role of CTR in
19 helping to support scientific grants. Exhibit JD-001841 is a 1968 letter from Dr. Huebner
20 to CTR, in which he accepted the invitation to join the SAB and said that CTR’s program
21 represented an excellent opportunity to provide needed support in critical areas on the
22 etiology of cancer.

23 Exhibit JD-001843 is Dr. Huebner’s 1981 letter of resignation from the SAB, in
24 which he said that the support provided by CTR helped advance some of the more
25 exciting developments in cancer research.

1 **Q. Have you seen documents from 1965 that state Dr. Kotin’s reasons for**
2 **resigning from the SAB in that year?**

3 A. Yes. In the letter of resignation that I just looked at, Exhibit JD-001838,
4 Dr. Kotin gave his reasons for resigning to Dr. Kenneth Lynch, who was Chairman of the
5 SAB.

6 **Q. In his letter of his resignation, what reasons did Dr. Kotin give for**
7 **resigning from the SAB?**

8 A. At the time, Dr. Kotin was about to assume new responsibilities as
9 Director of the newly created National Institute for Environmental Health Sciences. In
10 his letter, he said that the demands on his time were so great that he doubted that he
11 would be able to attend future meetings of the SAB. In fact, Dr. Kotin’s attendance at
12 recent SAB meetings had become irregular.

13 **Q. In paragraph 77 of Section I of its proposed findings of fact, the**
14 **United States says that in 1964, while he was a member of the SAB, Dr. Kotin was**
15 **highly critical of Dr. Little’s report that appeared in the CTR Annual Report. Have**
16 **you seen documents in CTR’s files that reflect comments by Dr. Kotin on that**
17 **subject in 1964?**

18 A. Yes.

19 **Q. Can you identify Exhibit JD-093183?**

20 A. Exhibit JD-093183 is a letter from Dr. Kotin to Dr. Little, dated May 27,
21 1964, in which Dr. Kotin commented on a draft of Dr. Little’s report, which must have
22 been his report for the 1963-64 Annual Report. Dr. Kotin said that he felt more strongly
23 than Dr. Little about the association between smoking and lung cancer, but he
24 acknowledged that the report was Dr. Little’s and said that he had only a few comments

1 on the report. Dr. Kotin added that he agreed enthusiastically with Dr. Little's call for
2 continued research.

3 **Q. In addition to these SAB members, did any employees of the federal**
4 **government act as outside reviewers for grant applications to CTR?**

5 A. Yes.

6 **Q. Can you identify Exhibits JD-001780, JD-001782, JD-001783, JD-**
7 **001785 through JD-001792, JD-001795, JD-001799, JD-001801, JD-001802, JD-**
8 **001803, JD-043185, JD-093760, JD-093767, JD-093770, JD-093771, JD-093773, JD-**
9 **093774, JD-093777, JD-093779 and JD-093782?**

10 A. These exhibits are letters from 26 scientists who are identified in those
11 letters as employees of the federal government, none of whom were members of the
12 SAB. They contain or attach reviews of grant-in-aid applications to CTR over a period of
13 25 years – from 1966 through 1991.

14 **Q. How many applications for CTR grants-in-aid were reviewed by these**
15 **26 government employees?**

16 A. Many of the government scientists reviewed multiple applications. I have
17 found in CTR's files 92 reviews of grants prepared for CTR by these 26 government
18 employees.

19 **B. Pre-1962 Contacts with the NCI**

20 **Q. Have you seen documents in CTR's files showing communications**
21 **between officials of the NCI and CTR before Dr. Kotin, an SAB member, went to**
22 **work for the NCI in 1962 while remaining an SAB member?**

23 A. Yes. According to the minutes of meetings of TIRC's members, there was
24 an effort during the first few months of TIRC's existence, in the spring of 1954, to reach
25 out to scientists from the NCI to see if they would be able to serve on the Scientific

1 Advisory Board. As these minutes show, two scientists employed by the NCI were asked
2 to join the SAB in 1954, but both declined the offer.

3 **Q. Can you identify Exhibit JD-093292?**

4 A. Exhibit JD-093292 contains the minutes of the meetings of the members
5 of CTR, from January 1954 through January 1969. Their discussion of efforts to solicit
6 scientists employed by the NCI appears in a Statement of the Executive Secretary of
7 TIRC that was made to the members on January 20, 1955, on page CTR-TIRC MIN
8 000021. The Statement of the Executive Secretary recounts TIRC's efforts to establish a
9 liaison with the NCI, as explained on page CTR-TIRC MIN 000023.

10 **Q. Do the meeting minutes or their attachments show other CTR**
11 **communications with the NCI?**

12 A. Yes. Dr. Little's Statement of the Scientific Director, dated April 28,
13 1955, which is on page CTR-TIRC MIN 000036 of Exhibit JD-093292, says that he was
14 corresponding with Dr. Wilton Earle of the NCI as well as others on the subject of tissue
15 culture research. These meeting minutes state that Dr. Little planned to consult further in
16 the future with Dr. Earle and other experts on this topic. In Dr. Little's Statement to the
17 November 3, 1955 meeting of the members of TIRC, which appears on pages CTR-TIRC
18 MIN 000055-56, he said that TIRC was planning a conference on tissue culture studies
19 and reported on the work done by the NCI on this topic.

20 **Q. Do the meeting minutes or their attachments state what happened**
21 **with respect to this planned conference on tissue culture?**

22 A. Dr. Little's Statement of the Scientific Director, which was presented at
23 the next meeting of the members of TIRC on February 14, 1956 and was attached to the
24 minutes of that meeting, discussed this TIRC-sponsored conference, which took place on
25 January 14, 1956. His statement, which appears on pages CTR-TIRC MIN 000081-82 of

1 Exhibit JD-093292, described this conference as “most interesting and productive.”
2 According to Dr. Little’s statement, the scientists at this conference included Dr. Harry
3 Eagle of the National Microbiological Institute of the NIH and Dr. Earle of the NCI.
4 Dr. Little stated, on page CTR-TIRC MIN 000082 of Exhibit JD-093292, that “[t]he
5 discussion was free and frank” and that the scientists agreed on the importance of tissue
6 culture research. Dr. Little stated that “[s]uch tissues, challenged by various tobacco
7 derivatives and known carcinogens, should give valuable information on the nature and
8 degree of susceptibility and/or of tolerance possessed by different tissues in relation to
9 their heredity, composition, sex, age and previous life history.” Dr. Little added, still on
10 page CTR-TIRC MIN 000082, that “[o]ut of this conference, in the near future will
11 come, without doubt, specific recommendations for support of certain of the leading
12 investigators who have indicated their interest in directing pioneer work in this field.”

13 **Q. Was this the only conference on tissue culture sponsored by CTR that**
14 **was attended by representatives of the United States?**

15 A. No. On September 12, 1958, the SAB held another conference on tissue
16 culture studies that was attended by Dr. Stuart M. Sessoms, Assistant Director of the NCI
17 and Dr. Katherine K. Sanford of the Laboratory of Biology of the NCI. The SAB held
18 another conference on tissue culture studies on May 24, 1960 that was attended by
19 Dr. Sarah E. Stewart, also of the Laboratory of Biology of the NCI.

20 **Q. Please look at page 20 of Exhibit JD-090002 and page 15-16 of Exhibit**
21 **JD-090004. What do these pages show?**

22 A. These are the references to the two additional meetings on tissue culture
23 studies that were sponsored by CTR and attended by staff of the NCI in 1958 and 1960.

24 **Q. Do CTR’s Annual Reports reveal any other conferences attended by**
25 **employees of the National Institutes of Health or other federal agencies?**

1 A. Yes. The 1957 TIRC Annual Report, Exhibit JD-090001, states on pages
2 26-27 that Dr. Harry Heimann of the Public Health Service and Dr. Stanley Sarnoff of the
3 National Heart Institute attended a CTR-sponsored conference on cardiovascular and
4 pulmonary disease on May 31 and June 1, 1957. The 1958 TIRC Annual Report, Exhibit
5 JD-090002, states on pages 18-19 that Dr. Howard Andervont, Chief of the Laboratory of
6 Biology of the NCI (who later became an SAB member), Dr. Stuart M. Sessoms,
7 Assistant Director of the NCI, and Dr. Murray J. Shear, Chief of the Laboratory of
8 Chemical Pharmacology of the NCI, attended a CTR-sponsored conference on problems
9 of bioassay on May 9, 1958. The 1959 TIRC Annual Report, Exhibit JD-090003, states
10 on pages 25-26 that Dr. Maurice Landy, Head of the Polysaccharide Section of the
11 Laboratory of Chemical Pharmacology of the NCI, as well as Dr. Shear of the NCI,
12 attended a CTR-sponsored conference on carcinogenesis and bioassay methods on
13 September 10, 1959, and states on pages 28-29 that Dr. Thomas Dawber, then of the
14 National Heart Institute, attended a CTR-sponsored conference on cardiovascular disease
15 on June 12, 1959. The 1960 TIRC Annual Report, Exhibit JD-090004, states on page 16
16 that Dr. Alan S. Rabson of the Pathologic-Anatomy Department of the National Institutes
17 of Health, and Dr. Sarah Stewart from the Laboratory of Biology of the NCI, attended a
18 CTR-sponsored conference on the subject of viruses and their possible relationship to
19 human cancer on May 25, 1960. The 1961 TIRC Annual Report, Exhibit JD-090005,
20 states on page 16 that Dr. Walter Heston, Dr. Murray J. Shear and Dr. Harold Stewart, all
21 from the NCI, attended a CTR-sponsored conference on the subject of bioassay and
22 carcinogenesis on May 25, 1961.

23 **Q. Can you identify Exhibit JD-001775?**

24 A. Exhibit JD-001775 consists of two letters in CTR's files from Dr. Harold
25 L. Stewart, Chief of the Laboratory of Pathology of the NCI, to Dr. Hockett of CTR.

1 Dr. Stewart was one of the NCI scientists who attended the May 25, 1961 CTR-
2 sponsored conference on the subject of bioassay and carcinogenesis. In the first letter,
3 dated May 18, 1961, Dr. Stewart thanked Dr. Hockett for the invitation to the May 25,
4 1961 conference. In the second letter, dated June 12, 1961, Dr. Stewart thanked
5 Dr. Hockett for sending him a set of references to help him prepare a paper.

6 **Q. Can you identify Exhibit JD-001776?**

7 A. Exhibit JD-001776 is a letter in CTR's files dated June 16, 1961 from Dr.
8 Stewart of the NCI to Dr. Hockett, in which Dr. Stewart thanked Dr. Hockett for sending
9 him a scientific reference on the exposure of mice to tar fumes.

10 **Q. Do documents in CTR's files reveal any other contacts between the**
11 **TIRC and the federal government during this period?**

12 A. CTR's files reflect a number of such contacts. For example, minutes of a
13 1956 meeting of members of TIRC reflect that Dr. Richard Bing, a member of the SAB,
14 was a member of the Joint Study Group on Tobacco and Health, consisting of the
15 American Cancer Society, the American Heart Association, the National Cancer Institute
16 and the National Heart Institute, formed in 1956.

17 **Q. Can you identify pages CTR-TIRC MIN 000090-92 of Exhibit JD-**
18 **093292?**

19 A. Pages CTR-TIRC MIN 000090-92 contain a statement of the Chairman of
20 the TIRC that was attached to the minutes of the TIRC meeting of members on
21 October 6, 1956. This statement reported Dr. Bing's membership in the Joint Study
22 Group on Tobacco and Health and says that the purpose of this group was "to investigate
23 work underway dealing with tobacco and health, and to make recommendations for work
24 to be done in that field" and that the group included Dr. Michael Shimkin of the NIH.

25 **Q. Can you identify page CTR MIN-SAB 000084 of Exhibit JD-090960?**

1 A. This is a page of the minutes of the August 20-21, 1956 meeting of the
2 Scientific Advisory Board of the TIRC, which mentions the formation of the Joint Study
3 Group on Tobacco and Health.

4 **Q. Could you please read the portion of these minutes of the August 20-**
5 **21, 1956 SAB meeting that relate to the Joint Study Group on Tobacco and Health?**

6 A. The portion of these minutes that mentions the Joint Study Group on
7 Tobacco and Health reports on statements by Dr. McKeen Cattell, a member of the SAB,
8 as follows: “Dr. Cattell commented on the Study Group which has been formed by the
9 American Cancer Society, American Heart Association, National Cancer Institute and
10 National Heart Institute to investigate work underway dealing with tobacco and health,
11 and to make recommendations of work which should be done in that field. He explained
12 that the Study Group expects to have a long-term program which will take as much as
13 several years. Dean Davies of the Cancer Society has, through Dr. Cattell, asked the
14 Board for suggestions of people to sit in with this Study Group and counsel with them. It
15 was the decision of the Board to consider this and make suggestions.”

16 **Q. Can you identify Exhibit JD-011816, at tab 1?**

17 A. Exhibit JD-011816, at tab 1, is a transcript of testimony given in July 1957
18 by Dr. John R. Heller, Director of the NCI, before a Subcommittee of the United States
19 House of Representatives Committee on Government Operations. There is a copy of this
20 testimony in CTR’s files.

21 **Q. Did Dr. Heller say anything in his July 1957 testimony about the**
22 **TIRC research program?**

23 A. Dr. Heller was asked whether he was familiar with the TIRC grants made
24 under Dr. Little’s supervision, and what progress had been made as a result. He testified,
25 on page 148 of Exhibit JD-011816 (July 18, 1957, tab 1), that he had “seen a list of the

1 grantees and the titles of the grants.” He described the TIRC-funded studies as “basic,
2 fundamental studies in what we call carcinogenesis” and noted that “there are no studies
3 in progress which are related directly to such things as filters or other applied-research
4 components.” Dr. Heller went on to state that he knew that “the recipients of these
5 [TIRC] grants are reputable scientists who are also recipients of grants from the Public
6 Health Service, and from other grant-giving bodies” and that “[t]he work they do we can
7 expect to be good work, and certainly, the research which is being conducted under the
8 auspices of the tobacco industry research committee can be classed as good research.”

9 **Q. Do CTR’s files show other communications between CTR and the**
10 **National Cancer Institute in this time period?**

11 A. In the early 1960s, the NCI designated a senior NCI scientist, Dr. Malcolm
12 Ray, to be its liaison representative to the SAB. Dr. Ray attended a number of SAB
13 meetings, reflected in correspondence from that time, as well as the SAB minutes.

14 **Q. Can you identify Exhibit JD-093200?**

15 A. Exhibit JD-093200 is a part of CTR’s correspondence with Dr. Ray. It is a
16 letter, dated February 17, 1961, from Dr. Kenneth Lynch, who was the Chairman of the
17 SAB, to Dr. Malcolm Ray of the NCI.

18 **Q. Could you please read the first two sentences of Dr. Lynch’s**
19 **February 17, 1961 letter to Dr. Ray of the NCI?**

20 A. “In behalf of the Scientific Advisory Board to the Tobacco Industry
21 Research Committee, as well as for myself, I am happy to learn that you will serve as a
22 liaison representative of the National Cancer Institute in connection with the
23 responsibilities of the Scientific Advisory Board. I am sure that your advice and
24 assistance will be valuable.”

1 **Q. Do the minutes of the SAB meetings, Exhibit JD-090960, say anything**
2 **that relates to how this February 1961 correspondence between Dr. Lynch and**
3 **Dr. Ray came about?**

4 A. The minutes of the February 14-15, 1958 SAB meeting, which appear in
5 Exhibit JD-090960 on pages CTR MIN-SAB 000113-117, report the following remarks
6 by Dr. Little: “Dr. Little told of visiting Marion Folsom, Secretary of Health, Education
7 and Welfare, with Mr. Hartnett and of subsequent discussions with Dr. Porterfield, the
8 Deputy Surgeon General. Dr. Little explained that he had suggested the desirability of
9 having the representatives of the National Institutes of Health in attendance at SAB
10 meetings on occasion in the future, and this was well received by Mr. Folsom. The
11 Board approved such invitations in principle.”

12 **Q. Can you identify pages CTR MIN-SAB 000183-186, 196-198, 202-205,**
13 **and 209-211 of Exhibit JD-090960?**

14 A. These are minutes of SAB meetings in March 1961, May 1962,
15 September 1962 and March 1963. These minutes show that Dr. Ray of the NCI attended
16 these four SAB meetings.

17 **Q. Please look at the minutes of an SAB meeting on March 11-12, 1961,**
18 **which appear at pages CTR MIN-SAB 000184 of Exhibit JD-090960, and read the**
19 **second-to-last paragraph.**

20 A. “Dr. Malcolm Ray, representing the National Cancer Institute, attended
21 the meeting during the period when applications related to carcinogenesis were discussed,
22 and expressed himself as very agreeably surprised at the breadth and scope of the SAB
23 program.”

1 **C. Surgeon General's Advisory Committee**

2 **Q. In connection with your work at CTR evaluating research proposals**
3 **related to smoking and health, did you review the 1964 report of the Surgeon**
4 **General's Advisory Committee on Smoking and Health?**

5 A. I did, beginning in the 1980s, not long after I came to CTR.

6 **Q. Do CTR's files contain documents that show communications between**
7 **TIRC and the Surgeon General's Advisory Committee in the period before the 1964**
8 **Surgeon General's Advisory Committee's Report on Smoking and Health was**
9 **published?**

10 A. They do. From 1962 when the Surgeon General's Advisory Committee
11 was formed to the time the 1964 report on Smoking and Health was published, there were
12 many communications back and forth between TIRC and the Surgeon General's
13 Advisory Committee. In many of these communications the staff of the Surgeon
14 General's Advisory Committee asked for information from TIRC, and, in response, TIRC
15 furnished information as requested. This is reflected in correspondence in the files at
16 CTR. In addition, according to memoranda in the files at CTR, there were meetings
17 between Dr. Hammill, the Medical Coordinator for the Surgeon General's Advisory
18 Committee, on the one hand, and Dr. Little and Dr. Hockett of TIRC on the other. I
19 mentioned earlier Dr. Hammill's comments about Dr. Little when they met in 1962.

20 **Q. Can you identify Exhibits JD-000817, JD-001806, JD-093057 through**
21 **JD-093071, JD-093074 through JD-093076, JD-093686 through JD-093717, JD-**
22 **093802, JD-093804, JD-093805, and JD-093531?**

23 A. Yes. These are copies of correspondence from CTR's files. These are a
24 few of the many letters in CTR's files to and from TIRC, principally from Dr. Little or
25 from Dr. Hockett, to the Surgeon General's Advisory Committee in 1962 and 1963.

1 **Q. Can you identify Exhibits JD-093535, JD-093532, JD-093055 and JD-**
2 **093056?**

3 A. Yes. These are internal memoranda from CTR's files, documenting
4 meetings and conversations in February, April and June 1963 between representatives of
5 TIRC and Dr. Hammill on behalf of the Surgeon General's Advisory Committee.

6 **Q. I am showing you U.S. Ex. 64057, a copy of the 1964 report of the**
7 **Surgeon General's Advisory Committee on Smoking and Health, which is in**
8 **evidence. Could you please turn to page 14 and read the first four sentences of the**
9 **second full paragraph?**

10 A. "As the primary duty of the Committee was to assess information about
11 smoking and health, a major general requirement was that of making the information
12 available. That requirement was met in three ways. The first and most important was the
13 bibliographic service provided by the National Library of Medicine. As the annotated
14 monograph by Larson, Haag, and Silvette – compiled from more than 6,000 articles
15 published in some 1,200 journals up to and largely into 1959 – was available as a basic
16 reference source, the National Library of Medicine was requested to compile a
17 bibliography (by author and by subject) covering the world literature from 1958 to the
18 present."

19 **Q. Did TIRC have any role with respect to "the annotated monograph by**
20 **Larson, Haag and Silvette" that the 1964 Surgeon General's Advisory Committee**
21 **Report referred to?**

22 A. Yes. TIRC funded the preparation of the Larson, Haag and Silvette
23 monograph, as well as several supplements to it, in the 1950s and 1960s.

1 **Q. Please look at pages CTR MIN-SAB 000075, CTR MIN-SAB 000077,**
2 **CTR MIN-SAB 000086-87 and CTR MIN-SAB 000093-94 of Exhibit JD-090960.**

3 **What do these pages show?**

4 A. These are portions of minutes of SAB meetings in May 1956, in
5 December 1956 and March 1957. These minutes show that the SAB voted to provide
6 financial support for the work by Larson, Haag and Silvette that led to the monograph
7 referred to in U.S. Ex. 64057, the 1964 Surgeon General’s Advisory Committee’s Report
8 on Smoking and Health.

9 **Q. Can you identify Exhibit JD-000500?**

10 A. Exhibit JD-000500 is a copy of the book – the SGAC called it a
11 monograph – titled *Tobacco: Experimental and Clinical Studies: A Comprehensive*
12 *Account of the World Literature* by Larson, Haag, and Silvette, published in 1961, which
13 TIRC supported.

14 **Q. Did the 1961 Larson, Haag and Silvette monograph acknowledge the**
15 **funding support of TIRC?**

16 A. Yes. If you turn to the preface on page vi of Exhibit JD-000500, it states:
17 “We gratefully acknowledge grant-in aid support from the Tobacco Industry Research
18 Committee during the final stages of this long project. We deem it only proper to inform
19 the reader that all responsibility for the data presented and views expressed herein, either
20 explicitly or implicitly, rests entirely upon the authors, the Tobacco Industry Research
21 Committee support having been in accordance with its established policy of leaving
22 complete freedom of planning and action to grant-in-aid recipients.”

23 **Q. Can you identify Exhibits JD-000501 through JD-000503?**

24 A. Exhibits JD-000501 through JD-000503 are three supplements to the 1961
25 Larson, Haag and Silvette monograph that were published, respectively, in 1968, 1971

1 and 1975. CTR continued to support the compilation of research articles contained in
2 these supplements.

3 **Q. Please take a look at pages CTR MIN-SAB 000240, CTR MIN-SAB**
4 **000258, CTR MIN-SAB 000277, CTR MIN-SAB 000288, CTR MIN-SAB 000310,**
5 **CTR MIN-SAB 000333, CTR MIN-SAB 000363, CTR MIN-SAB 000375, CTR**
6 **MIN-SAB 000382, CTR MIN-SAB 000402, CTR MIN-SAB 000405, CTR MIN-SAB**
7 **000423, CTR MIN-SAB 000426, CTR MIN-SAB 000432, CTR MIN-SAB 000442**
8 **and CTR MIN-SAB 000450 of Exhibit JD-090960. What do these pages show?**

9 A. These pages are the minutes of SAB meetings in March 1965,
10 March 1966, March 1967, March 1968, March 1969, March 1970, May 1971,
11 December 1971, March 1972, March 1973, March 1974, October 1974, March 1975 and
12 September 1975, showing the SAB's recommendations approving the funding of the
13 continuing work of Dr. Larson, Dr. Haag and Dr. Silvette on these three supplements and
14 the CTR Scientific Director's award of the grant funds, in accordance with those
15 recommendations.

16 **Q. Can you identify Exhibit JD-093079?**

17 A. Exhibit JD-093079 is a letter dated January 21, 1964 from Eugene H.
18 Guthrie, M.D., the staff director of the Surgeon General's Advisory Committee, to
19 Dr. Hockett of CTR.

20 **Q. Can you read the text of the letter into the record?**

21 A. "Dear Dr. Hockett:

22 "Under separate cover I am forwarding a copy of the Surgeon General's Advisory
23 Committee Report on Smoking and Health.

24 "The Report marks the completion of a difficult and complex study. It could not
25 have been done without competent professional assistance from a number of sources

1 outside the Committee membership. For your valuable services in this capacity, the
2 Surgeon General has asked that I express his appreciation and that of the Advisory
3 Committee.

4 “May I add my personal thanks for all that you have done.

5 Sincerely,

6 Eugene H. Guthrie, M.D.

7 Staff Director”

8 **Q. Please turn to the Acknowledgements section of the 1964 Surgeon**
9 **General’s Advisory Committee Report, U.S. Ex. 64057. Can you identify persons**
10 **affiliated with CTR who were acknowledged by the Surgeon General’s Advisory**
11 **Committee?**

12 A. The Surgeon General’s Advisory Committee acknowledged Dr. Julius
13 Comroe, who was a member of the original SAB and served on the SAB until 1960;
14 Dr. Kotin, who had served as a member of the SAB from 1954 and was still a member as
15 of 1964; Dr. Little; Dr. Hockett; and TIRC itself. The Advisory Committee also thanked
16 a number of scientists who had received research funding from TIRC or from CTR.
17 These grantees included Dr. William H. Carnes of the University of Utah School of
18 Medicine, Dr. Hans Falk of the University of Southern California School of Medicine,
19 Dr. Albert Damon of Harvard University, Dr. Russell Fisher of the University of
20 Maryland Medical School, Dr. Jerome Kleinerman of St. Luke’s Hospital in Cleveland,
21 Dr. Cecilie and Dr. Rudolf Leuchtenberger of the Centre Anticancereux Romand in
22 Lausanne, Switzerland, and Dr. John P. Wyatt of the St. Louis University School of
23 Medicine. Dr. Wyatt later became a member of CTR’s Scientific Advisory Board.

1 **D. Post-1964 Cooperation**

2 **Q. Do documents in CTR's files reveal contacts between CTR and the**
3 **federal government after the 1964 report of the Surgeon General's Advisory**
4 **Committee was issued and before you joined CTR in about September of 1983?**

5 A. Yes. The minutes of the meetings of the Scientific Advisory Board,
6 Exhibit JD-090960, show that the SAB urged that some proposed research projects be
7 referred to the NCI because they were closely related to work being done by scientists at
8 the NCI. A note in the minutes of the SAB meeting for December 8-9, 1968, for
9 example, suggests that a grant application by Dr. Daniel Roth, M.D. be "referred by staff
10 to Dr. Ian Mitchell of the N.C.I., who is involved in supporting similar studies." This
11 note appears in Exhibit JD-090960 on page CTR MIN-SAB 000307. The minutes of the
12 SAB meetings of September 18, 19 and 20, 1970, on page CTR MIN-SAB 000346 of
13 Exhibit JD-090960, refer to an upcoming joint meeting in October 1970 between
14 representatives of the NIH, the AMA-ERF, and the Planning Committee of the SAB.

15 **Q. Are you familiar with the Tobacco Working Group, or TWG?**

16 A. Yes, I am, generally.

17 **Q. What was the Tobacco Working Group?**

18 A. The Tobacco Working Group was a group of scientists, including some
19 from the government and some from the tobacco companies, formed in the late 1960s to
20 advise the National Cancer Institute's Smoking and Health Program. The TWG lasted
21 until at least the mid-1970s. I have read public reports about the TWG that are in CTR's
22 files. There also are a number of documents in CTR's files about meetings of the TWG.

23 **Q. Can you identify Exhibit JE-067628?**

1 A. Yes. This is a report of the NCI's Smoking and Health Program, probably
2 from the late 1970's. It refers to the TWG as an advisory group to the Smoking and
3 Health Program. We had a copy of this report at CTR.

4 **Q. On page ix of JE-067628, is there a list of the scientists who were**
5 **members of the TWG?**

6 A. Yes.

7 **Q. Were any members of the TWG then affiliated with CTR?**

8 A. No. Dr. Kotin, who had been a member of our SAB from 1954 until 1965,
9 was a member of the TWG. Another TWG member, Dr. Ros Boutwell of the University
10 of Wisconsin, later served as a member of our SAB. A number of tobacco company
11 scientists were members of the TWG, including Dr. Rodgman and Dr. Seligman from
12 Reynolds and Dr. Wakeham of Philip Morris. One of these company scientists, Dr. Alex
13 Spears of Lorillard, later was a director of CTR.

14 **Q. Did CTR have any contacts with the Tobacco Working Group?**

15 A. Yes. Documents from CTR's file show that Dr. Hockett, who was the
16 Research Director of CTR, and Dr. Vincent Lisanti, another member of CTR's scientific
17 staff, attended several meetings of the TWG. There are documents in CTR's files
18 showing that Dr. Hockett attended several meetings of the Tobacco Working Group,
19 which was sponsored by the federal government, in the 1970s.

20 **Q. Can you identify JD-013231, JD-013230 and JD-013229?**

21 A. Yes. JD-013231 is Dr. Lisanti's memorandum about a meeting of the
22 Tobacco Working Group that he attended in October 1973. Exhibits JD-013230 and JD-
23 013229 are Dr. Hockett's notes of two meetings of the TWG, held in September 1974
24 and July 1975. These are a few of the documents relating to TWG meetings that are in
25 CTR's files.

1 **Q. Can you identify JD-094397?**

2 A. Yes. JD-094397, which also is from CTR's files, is a presentation by Dr.
3 Hockett to the TWG describing the cancer segment of CTR's research program, which
4 apparently was given by Dr. Hockett at the September 10, 1974 meeting of the TWG.

5 **Q. Do the documents in CTR's files reveal any other contacts between**
6 **CTR and the federal government in this period?**

7 A. The 1965-66 TIRC Annual Report, Exhibit JD-090009, states on pages 22
8 and 23 that Charles L. Rose, Coordinator of the Normative Aging Study at the Veterans
9 Administration Outpatient Clinic in Boston, attended a conference on constitutional
10 factors as related to disease on April 6, 1966, and on pages 23-24 that Dr. S. Kreshover,
11 Associate Director of the National Institute of Dental Research, Dr. P. Person, Chief of
12 the Special Dental Research Laboratory of the Veterans Administration Hospital in
13 Brooklyn, Dr. Anthony Picozzi of the U.S. Army Reserve Dental Corps and Dr. Gordon
14 H. Rovelstad of the Dental Research Facility of the U.S. Naval Training Center in Great
15 Lakes, Illinois attended a conference on the role of oral cavity research in the study of
16 tobacco use and human health on October 16, 1965. The 1969-70 CTR Annual Report,
17 Exhibit JD-090012, states on pages 13-14 that Dr. Barbara B. Brown, Chief of
18 Experimental Psychiatry at the Veterans Administration Hospital in Sepulveda,
19 California, attended a CTR-sponsored conference on the effects of nicotine and/or
20 smoking on the central nervous system.

21 **Q. As a member of CTR's scientific staff beginning in 1983, did you**
22 **cooperate with agencies of the United States government with respect to issues**
23 **concerning smoking and health?**

24 A. Yes. In each year from 1983 to 1987, I attended the Interagency Forum on
25 Smoking and Health, which included representatives from the United States Department

1 of Agriculture and the NCI. At these meetings, each entity that was represented,
2 including CTR, reported on the research it was doing or supporting.

3 **Q. Did any other representatives of CTR attend these meetings?**

4 A. Dr. Hockett had attended them for a number of years before I did. Several
5 times, Dr. Hockett and I attended the Interagency Forum on Smoking and Health
6 together.

7 **Q. Did CTR send a representative to every meeting of the Interagency**
8 **Forum on Smoking and Health to which it was invited?**

9 A. To the best of my knowledge, it did.

10 **Q. Can you identify Exhibits JD-093117 through JD-093124 and Exhibits**
11 **JD-093126 and JD-093127.**

12 A. Exhibits JD-093117 through JD-093124 and Exhibits JD-093126 and JD-
13 093127 are letters from CTR's files, dated from 1980 through 1987, to and from Dr. T.C.
14 Tso of the United States Department of Agriculture, thanking CTR for sending a
15 representative to the meetings of the forum.

16 **Q. As a member of CTR's scientific staff, did you have other interactions**
17 **with the federal government?**

18 A. Yes. In the early part of my career at CTR, the Office of Smoking and
19 Health of the U.S. Department of Health and Human Services solicited information from
20 CTR about the research that CTR had funded. We provided this information, which was
21 incorporated into a publication entitled the Directory of On-Going Research in Smoking
22 and Health.

23 **Q. Can you identify Exhibit JD-093721?**

1 A. Exhibit JD-093721 is a letter, dated January 14, 1986, from Donald R.
2 Shopland, the Acting Director, Office of Smoking and Health, United States Department
3 of Health & Human Services, to me.

4 **Q. Can you please read the text of that letter?**

5 A. Yes.

6 “Dear Mr. McAllister:

7 “Please accept the enclosed hardbound edition of the 1984-1985 Directory of On-
8 Going Research in Smoking and Health as a small token of our appreciation for your
9 efforts in assisting with its compilation. This, the tenth edition in the Directory series,
10 contains more than 1,500 research projects from almost 50 countries. Thanks to your
11 efforts, it represents the largest and most comprehensive Directory published to date.

12 “The Directory is a significant undertaking by the Office on Smoking and Health
13 and involves numerous individuals, such as yourself, who take time from busy schedules
14 to provide us with printouts, summaries of research projects, or assist us in other ways.
15 Without your help the Directory would not be the valuable, biomedical research reference
16 tool it has become. If you would like additional copies of the Directory in the soft cover
17 edition, please contact my office at (301) 443-1575.

18 “Again, thank you for your involvement in the compilation of the Directory. If
19 there is anything we can do to assist you or your staff, please let us know.”

20 **VI. WAS THE RESEARCH FUNDED BY CTR**
21 **RELEVANT TO SMOKING AND HEALTH?**

22 **A. Dr. McAllister’s Beliefs**

23 **Q. During your tenure at CTR, did you consider it important whether**
24 **the research that CTR was funding through its grant-in-aid program was relevant**
25 **to issues of smoking and health?**

1 A. Yes, I did.

2 **Q. During that time, did you believe that the research that CTR was**
3 **funding through its grant-in-aid program was relevant to issues of smoking and**
4 **health?**

5 A. Yes, I did.

6 **Q. Can you explain why you considered that important?**

7 A. I understood CTR's mission to be the funding of high-quality biomedical
8 research related to smoking and health. When I was a member of the scientific staff, and
9 later the Scientific Director, I believed it was important for CTR to fulfill that mission.

10 **Q. Did anything ever cause you to believe that the research funded by**
11 **CTR was not relevant to smoking and health?**

12 A. No. I thought that the research funded by CTR was relevant to smoking
13 and health. I am sure there were individual projects that did not generate findings that
14 turned out to be directly relevant, as a result of the direction that the research took once it
15 got underway. That possibility is inherent in the funding of research through grants to
16 independent scientists who have scientific freedom: the researcher has to be free, up to a
17 point, to take the investigation where he or she wants to go and to write up and publish
18 those aspects of the results that the researcher thinks are most scientifically significant.

19 **Q. Who at CTR was responsible for seeing that the research funded by**
20 **CTR was relevant to smoking and health?**

21 A. The Scientific Director, with the advice of the Scientific Advisory Board.

22 **Q. In your years with CTR, did anything give you concern that the**
23 **Scientific Directors whom you worked with, Dr. Sommers and Dr. Glenn, believed**
24 **that the research CTR supported through the grant-in-aid program was not**
25 **relevant to smoking and health?**

1 A. No.

2 **Q. In your years with CTR, did anything cause you to become concerned**
3 **that members of the Scientific Advisory Board believed that the research CTR**
4 **supported through the grant-in-aid program was not relevant to smoking and**
5 **health?**

6 A. No.

7 **Q. When you were the Scientific Director of CTR, what standards did**
8 **you use when you determined whether a grant proposal was relevant to smoking**
9 **and health?**

10 A. I used the same standards that I used when I described the CTR grant-in-
11 aid program to prospective applicants who would call from time to time asking for
12 information about the CTR grant-in aid program. By the time I became Scientific
13 Director in 1991, CTR had made it fairly well known to much of the scientific research
14 community at large, and to many prospective grant applicants, that CTR would consider
15 proposals for high-quality biomedical research to study the disease processes that were
16 associated with smoking and other forms of tobacco use. These disease processes
17 included, but were not limited to, cancer, emphysema, chronic obstructive pulmonary
18 disease, coronary disease, atherosclerosis and stroke. CTR would also consider proposals
19 for high quality biomedical research into other biomedical aspects of tobacco use, such as
20 the effects of nicotine on the central nervous system. No topic related to smoking and the
21 causation of disease was off-limits. Whenever potential applicants called asking for
22 information about the CTR grant-in-aid program, that was how I explained it to them.
23 That is the standard of relevance that I used when I evaluated grant-in-aid applications as
24 Scientific Director and as a member of the SAB. I did not tell applicants that they needed
25 to use, or should use, cigarette smoke or tobacco products in their proposed experiments

1 because I did not believe that was necessary in order for them to formulate research
2 projects that would be relevant to smoking and health.

3 By the mid-1980s, and certainly in the 1990s, it was my opinion that the most
4 meaningful experiments, the ones that would provide the most insight would not involve
5 the use of tobacco smoke as an insult, but rather would explore the basic disease
6 processes themselves so that the role in disease processes of tobacco smoke constituents,
7 which were relatively well known by the time I became Scientific Director, could be
8 understood at the most basic level.

9 **Q. Did you find that the issue of whether a research project was relevant**
10 **to smoking and health was always clear-cut and unambiguous?**

11 A. No. In many instances, there were judgment calls involved in deciding
12 whether proposed research projects would be relevant to CTR's mission. It was the task
13 of the SAB, in the first instance, and of the Scientific Director, ultimately, to apply their
14 scientific judgment to whether a proposal for a grant-in-aid was relevant to smoking and
15 health.

16 **B. Disclosure of CTR's Funding Judgments**

17 **Q. Did CTR disclose to the public the kinds of research that it was**
18 **funding through grants-in-aid?**

19 A. It did. As I mentioned above, the CTR Annual Reports listed the projects
20 and the peer-reviewed research papers of which it was aware that published the results of
21 research that had been funded through CTR grants-in-aid. CTR also routinely sent
22 abstracts describing all research projects to the Smithsonian Institution's database known
23 as the Science Information Exchange. These abstracts were prepared by the grantees
24 themselves upon notification of their receiving an award. The information in that
25 database was freely available. In 1981, this project was abandoned by the Smithsonian.

1 **Q. Did CTR disclose to the public the kinds of research that it was**
2 **funding through research contracts?**

3 A. It did, in the same way. The projects funded through contracts were also
4 listed in the CTR Annual Reports. In addition, when a scientist funded by a CTR
5 research contract published in a peer-reviewed journal and CTR learned of the
6 publication, CTR published an abstract of that article in its Annual Report.

7 **Q. In addition to reading the Annual Reports, how else could scientists or**
8 **other interested persons find out about the research that CTR funded at any**
9 **particular time?**

10 A. They could read the publications themselves or hear about them through
11 word of mouth, or discuss the research with the scientists to which CTR provided
12 financial support or with others who might also know about the research CTR funded.

13 **Q. What about the research that CTR did not fund?**

14 A. Nothing prevented anyone from talking with scientists whose grant-in-aid
15 research proposals had been turned down by CTR. Nothing prevented a scientist whose
16 grant proposal had been turned down by CTR from complaining publicly about CTR's
17 decision.

18 **Q. Were there any disclosures to the federal government specifically**
19 **about the direction of CTR-funded research?**

20 A. Early on, as I mentioned, a representative of the NCI attended SAB
21 meetings for several years, and for most of the 20-plus years after that an NCI employee
22 was on the SAB. I also have mentioned Dr. Hockett's presentation to the Tobacco
23 Working Group in 1974, Exhibit JD-094397, which described in detail the areas of
24 cancer research that CTR was funding through grants-in-aid and research contracts. CTR

1 also had meetings in the late 1960s and early 1970s with a variety of groups, including
2 representatives of NIH, at which CTR described the research it was funding.

3 **Q. Can you identify Exhibits JD-001828 and JD-013247?**

4 A. Those are memos about two meetings during this period, at which CTR
5 representatives discussed CTR-funded research with representatives of the NIH. That
6 discussion is reflected on page 2, 3 and 4 of JD-001828 and on page 4 of JD-013247.

7 **C. Changes in CTR-Funded Research over Time**

8 **Q. Did the nature of the biomedical research that CTR funded with the**
9 **advice of the Scientific Advisory Board change over time?**

10 A. Yes. It changed very significantly over the 40-plus years of CTR research
11 funding.

12 **Q. As a starting point to a discussion about some of those changes, could**
13 **you briefly describe the kind of research CTR funded in its first decade, in the**
14 **period from 1954 to 1964?**

15 A. When TIRC was formed in 1954, there were two widely publicized lines
16 of evidence implicating cigarettes in the development of disease. One of these was a set
17 of experiments published in late 1953 by Wynder, Graham and Croninger, who reported
18 that they had produced carcinomas or papillomas on the shaved backs of mice that had
19 been painted with cigarette smoke condensate. They reported that two of these lesions
20 were malignant, that is, they had been successfully transplanted to other animals for at
21 least some period of time. On the other hand, Wynder, Graham and Croninger also
22 indicated that their background survey of the entire “skin painting” research literature up
23 to 1953 revealed that in dozens of studies, only seven epidermoid cancers (ones arising
24 from the epidermal tissue) had ever been detected.

1 The second line of scientific evidence, accumulated over the preceding decade,
2 consisted of results of several epidemiological surveys indicating that lung cancer and
3 other disorders (other pulmonary conditions, cardiovascular diseases, ulcers, etc.) were
4 found more often in smokers than in non-smokers. It was apparent that, as smoking had
5 increased during the first half of the 20th century, so had the diagnosed incidence of lung
6 cancer. The parallel increases were declared by some scientists to be causally related,
7 even though only a statistical association had been shown.

8 In the very first years of its existence, CTR funded research by scientists who
9 were attempting to confirm and better understand these reported findings, which had
10 prompted the January 1954 Frank Statement and the formation of the TIRC. At the
11 earliest meetings of the Scientific Advisory Board, each SAB member suggested areas of
12 research that he thought should be funded. These suggestions included expanded
13 experiments to test known components of cigarette smoke on animals, and the role of
14 nicotine in smoking-related heart disease. The TIRC also funded efforts to develop
15 standardized cigarettes and tobacco tars, so that the results of experiments could be
16 replicated as was required by standard scientific practice.

17 **Q. Please take a look at pages CTR MIN-SAB 000007 and CTR MIN-**
18 **SAB 000015 of Exhibit JD-090960. What do these pages show about CTR-funded**
19 **research?**

20 A. Page CTR MIN-SAB 000007 of Exhibit JD-090960 is from the minutes of
21 the August 16, 1954 SAB meeting, and it reflects the SAB's discussion of experiments
22 testing the components of cigarette smoke. Page CTR MIN-SAB 000015 of Exhibit JD-
23 090960 is from the minutes of the October 1954 SAB meeting. As shown on this page,
24 the TIRC funded efforts to develop standardized cigarettes and tobacco tars, so that the
25 results of experiments could be replicated, according to standard scientific practice.

1 **Q. Did CTR fund epidemiological studies in its early years?**

2 A. Yes. To take one example, from its earliest days the SAB was interested
3 in studies of the results of autopsies at a range of medical centers across the United
4 States, in an attempt to expand upon the investigations by Dr. Alton Ochsner of Tulane
5 University. This project developed into what was known at the TIRC as the Pathologic-
6 Anatomic project, and proceeded for a number of years.

7 **Q. Please take a look at pages CTR MIN-SAB 000010, 16, 25, 29, 33, 36,**
8 **40, 44, 50, 67, 72, 78, 83, 88, 95, 100, 104, 108, 115, 119-20, 129, 134, 149, 154 and 159**
9 **of Exhibit JD-090960. What do these pages show about CTR-funded research?**

10 A. These are all pages from the minutes of SAB meetings that refer to the
11 Pathologic-Anatomic project.

12 Page CTR MIN-SAB 000010 of Exhibit JD-090960 is from the minutes of the
13 SAB meeting on September 20, 1954, at which the SAB first discussed the Pathologic-
14 Anatomic project. It states in part: “Considerable discussion was devoted to the
15 application of Doctor Russell Weller covering a post mortem study of the bronchi, lungs
16 and heart correlated with inhaled substances related to occupation, residence and
17 smoking. A sub-committee composed of Doctor Reimann, Chairman, Doctor Lynch and
18 Doctor Kotin was appointed to study this and similar projects, and the sub-committee was
19 asked to return a report to the Advisory Board concerning such projects at the next
20 meeting.” Dr. Reimann, Dr. Lynch, and Dr. Kotin were members of the original SAB,
21 and each was involved in lung cancer research.

22 Page CTR MIN-SAB 000016 of Exhibit JD-090960, which is from the minutes of
23 the SAB meeting in October 1954, describes a report to the SAB by Dr. Reimann. It
24 states in part: “Doctor Reimann outlined the work which he has done and the conferences
25 he has held regarding the program which he had previously projected to study lung

1 cancer in ten to twelve major medical centers in the United States. This study is to be
2 concerned with the examination of lung tissue for evidences of the site and time of
3 beginning of lung cancer. All work will be predicated on comparable results and will be
4 conducted in a uniform manner to allow for such comparison. Factors such as length of
5 residence, geographic location of patients, occupational history, habits and associated
6 diseases will be reviewed for possible relation with cause and onset of cancer. This
7 project was unanimously approved by the Advisory Board with an estimated cost of
8 \$55,000 for one year covering not less than ten nor more than twelve institutions.”

9 The rest of these pages reflect subsequent discussions by the SAB of the
10 Pathologic-Anatomic project, which was funded by TIRC from 1954 to 1961.

11 **Q. Can you give an example of another kind of research that CTR**
12 **funded in the 1950s?**

13 A. Starting in 1954, TIRC supported scientists, including Dr. Bock and
14 Dr. Moore of Roswell Park Cancer Institute in Buffalo, New York, who tried to replicate
15 the results of the Wynder-Graham-Croninger mouse skin-painting studies. After several
16 unsuccessful efforts, Dr. Bock and Dr. Moore succeeded in 1958. When Dr. Bock and
17 Dr. Moore published their papers in the late 1950s, scientists had a stronger basis for
18 believing that the results that Dr. Wynder and Dr. Graham had reported were
19 scientifically reliable.

20 **Q. Please take a look at page 40 of Exhibit JD-090001, the 1957 TIRC**
21 **Annual Report; pages 29-31 of Exhibit JD-090002, the 1958 TIRC Annual Report;**
22 **page 56 of Exhibit JD-090003, the 1959 TIRC Annual Report; and page 24 of**
23 **Exhibit JD-090004, the TIRC 1960 Annual Report. What do these pages show**
24 **about CTR-funded research?**

1 A. These pages contain the abstracts of articles published by Dr. Bock and
2 Dr. Moore reporting on their TIRC-funded mouse skin-painting experiments. In the most
3 significant of these papers, titled “Carcinogenic Activity of Cigarette Smoke Condensate:
4 Effect of Trauma and Remote X-Irradiation,” which was abstracted at pages 29-31 of
5 Exhibit JD-090002, the 1958 TIRC Annual Report, the Annual Report summarized the
6 conclusions of Dr. Bock and Dr. Moore as including the finding that “[t]hese experiments
7 suggest that cigarette smoke condensate is a weak mouse skin carcinogen.”

8 **Q. Did CTR fund any other scientific research in its first decade that**
9 **used tobacco smoke condensates?**

10 A. Yes. CTR provided research grants-in-aid for experiments that involved
11 painting tobacco smoke condensates or components of smoke condensates on the skins or
12 tracheas of ducks, turkeys and dogs, as well as on the skins of mice.

13 **Q. Please take a look at pages 18-19 of Exhibit JD-090000, the 1956**
14 **TIRC Annual Report; pages 25 and 47 of Exhibit JD-090001, the 1957 TIRC**
15 **Annual Report; page 33 of Exhibit JD-090002, the 1958 TIRC Annual Report;**
16 **pages 21-22 of Exhibit JD-090003, the 1959 TIRC Annual Report; pages 31-32 of**
17 **Exhibit JD-090004, the 1960 TIRC Annual Report; pages 30-31 of Exhibit JD-**
18 **090005, the 1961 TIRC Annual Report; and pages 16-18, 29-30 and 32 of Exhibit**
19 **JD-090007, the 1963-64 TIRC Annual Report. What do these pages show about**
20 **CTR-funded research?**

21 A. These pages from CTR’s Annual Reports contain abstracts of the scientific
22 publications arising from these additional skin-painting and related studies that CTR
23 funded in its first ten years, as well as commentary by Dr. Little about the significance of
24 that research.

1 **Q. Please turn to the first of these references, pages 18-19 of Exhibit JD-**
2 **090000, the 1956 TIRC Annual Report, and read the heading for this section and**
3 **the last paragraph of the text.**

4 A. The heading of this section in the 1956 TIRC Annual Report is “Direct
5 Application of Tobacco Derivatives.” The last paragraph of the text stated: “At best,
6 work in animal exposure can produce only indirect evidence on the etiology of human
7 lung cancer. However, there is real value in animal work; it can and often does suggest
8 problems and pathways in clinical research.”

9 **Q. What other kinds of research did CTR fund starting in the 1950s?**

10 A. Exhibit JD-090000, the 1956 TIRC Annual Report, stated on page 19 that
11 animal inhalation studies, in which experimental animals such as mice, rats, dogs or other
12 animals were subjected to fresh whole cigarette smoke, were another kind of exposure
13 experiment, and that Dr. Kotin, one of the original SAB members, had been appointed
14 “as a subcommittee of one to review applications related to inhalation experiments.”
15 These kinds of experiments were intended to provide what is known in science as an
16 “animal model” for human smoking. The goal of these experiments was to have the
17 animals mimic human smoking behavior and thereby to test the hypothesis that smoking
18 caused specific kinds of lung cancers. CTR’s early research support for these
19 experiments proceeded in several steps and involved a number of grantees performing
20 research using different animals, different protocols, and different machinery to deliver
21 the smoke.

22 **Q. Please look at pages CTR MIN-SAB 000026, 33, 39, 41, 45, 71, 89, 120**
23 **and 221 of Exhibit JD-090960. What do these pages show about CTR-funded**
24 **research?**

1 A. These are pages from the SAB meeting minutes from 1954 to 1964 that
2 discuss the funding of animal smoke inhalation experiments that the SAB recommended.

3 **Q. Please take a look at pages 13-14, 19- 20 and 32-33 of Exhibit JD-**
4 **090002, the 1958 TIRC Annual Report; pages 18-19, 20-21 and 33 of Exhibit JD-**
5 **090003, the 1959 TIRC Annual Report; pages 15, 25-26 and 27-28 of Exhibit JD-**
6 **090004, the 1960 TIRC Annual Report; pages 14, 27 and 28 of Exhibit JD-090005,**
7 **the 1961 TIRC Annual Report; and pages 18 and 31 of Exhibit JD-090007, the 1963-**
8 **64 TIRC Annual Report. What do these pages show about CTR-funded research?**

9 A. These pages of TIRC Annual Reports show descriptions of research that
10 CTR funded from 1958 through 1964 in the area of animal smoke inhalation studies, as
11 well as abstracts of research papers that published the findings of those studies.

12 **Q. Did CTR fund epidemiological studies in this period in addition to the**
13 **Pathologic-Anatomic project, which you described earlier?**

14 A. Yes, it did. Among the other epidemiologic studies funded by CTR in the
15 1950s were a study by Dr. Caroline Bedell Thomas of Johns Hopkins medical students,
16 an analysis by Dr. Clark Heath of Harvard University of the differences between smokers
17 and non-smokers, and a study by Dr. Ancel Keys of the University of Minnesota and
18 colleagues in Finland of the differences between smokers and non-smokers in Finland
19 with respect to serum cholesterol levels, blood pressure and obesity. TIRC also funded
20 an analysis of personality traits of smokers and non-smokers, based on a study of Harvard
21 students by Dr. Carl Seltzer of Harvard, a study of the correlation between cigarette
22 smoking and the ingestion of nicotine and serum fatty acids by Dr. Alfred Kershbaum
23 and Dr. Samuel Bellett of Philadelphia General Hospital, an analysis of circulatory
24 measurements in smokers and nonsmokers by Dr. Henry Blackburn and Dr. Joseph
25 Brozek of the University of Minnesota, and an analysis of drinking habits, caloric intake

1 and serum cholesterol among smokers and nonsmokers by Dr. Albert Damon of the
2 Harvard School of Public Health.

3 **Q. Please look at pages 44 and 48 of Exhibit JD-090002, the 1958 TIRC**
4 **Annual Report; pages 45 and 46-48 of Exhibit JD-090003, the 1959 TIRC Annual**
5 **Report; pages 42-44 and 46 of Exhibit JD-090004, the 1960 TIRC Annual Report;**
6 **and pages 34, 40, 46-48 and 49-50 of Exhibit JD-090005, the 1961 TIRC Annual**
7 **Report. What do they show about CTR's funding of epidemiological studies?**

8 A. These pages of the 1958, 1959, 1960 and 1961 TIRC Annual Reports
9 contain abstracts of the scientific articles published by Thomas, Heath, Keys, Seltzer,
10 Kershbaum, Bellett, Blackburn, Brozek and Damon reporting on their TIRC-funded
11 studies, which I just referred to.

12 **Q. Please look at pages 8-9 and 11-12 of Exhibit JD-090004, the 1960**
13 **TIRC Annual Report. What do these pages show about CTR's funding of**
14 **epidemiological studies?**

15 A. Pages 8-9 and 11-12 of Exhibit JD-090004 are portions of a "Report by
16 the Scientific Advisory Board to the Tobacco Industry Research Committee" that
17 appeared in the 1960 TIRC Annual Report. On page 9 of the Report, the SAB stated
18 initially, "We are not satisfied to let the problem rest with statistical reports suggesting
19 that heavy smoking increases the risk of cancer of the lung; we are interested also in
20 knowing why the overwhelming majority of heavy smokers do not contract the disease
21 despite their smoking. We are also vitally interested in the meaning of the results,
22 derived from the same data, that only a small fraction of the reported excess deaths in the
23 heavy smoking group is attributable to cancer of the lung." The SAB report then stated,
24 on pages 11-12, that it was "exploring and, in some cases, plans are well along for
25 expanding, certain lines of work," including further epidemiological studies in relation to

1 ethnic, social, ecologic and cultural differences, as well as studies of human twins for the
2 purposes of analyzing hereditary and environmental factors in diseases and the
3 comparison of the physical, emotional and psychological characteristics of smokers and
4 of non-smokers.

5 **Q. Please take a look at page 6 of Exhibit JD-090008, the 1964-65 CTR**
6 **Annual Report. Could you read the second and third paragraphs of the text?**

7 A. “The research program of The Council received impetus from the
8 publication of several epidemiological studies that reported mortality from a score of
9 diverse diseases to be higher among cigarette smokers than among non-smokers; reports
10 which have been and still are the subject of much debate among statisticians on technical
11 grounds.

12 “However, such epidemiologic studies are helpful since they contribute hints and
13 leads for clinical and experimental investigators. The Council seeks to utilize such hints
14 and leads to a maximum degree in order to pursue the shortest and most realistic routes
15 toward the goal of practical prevention or control. This course, however, requires some
16 caution.

17 “The mathematical association of one variable with another typically raises a
18 number of alternative explanatory hypotheses. This is particularly true when the data
19 used have been gathered from nature by observation, without the intervention of
20 experimental planning and controls to minimize the effects of disturbing variables. The
21 establishment of any one possible explanatory hypothesis requires exclusion of all other
22 reasonable alternatives. This is often a difficult task.

23 “When an association between the incidence of some disease and cigarette
24 smoking is reported, three questions arise:

1 “1. Is cigarette smoking a cause of the disease, or does it contribute in some
2 way to its etiology, whether weakly, strongly, directly or indirectly?

3 “2. Is cigarette smoking an indicator or concomitant of congenital
4 characteristics that predispose to the disease or that engender a pattern of living habits,
5 one or more of which may cause, or predispose to the disease?

6 “3. Is the association fortuitous or an artifact due to technical operations? We
7 will leave this third question to the statisticians.

8 “If either of the first two questions could be answered definitely, the answer
9 would probably suggest measures for prevention or control of the disease. A positive
10 answer to the first might lead us eventually to some change in tobacco or tobacco smoke
11 that would have protective value. On the other hand, a positive answer to the second
12 question would suggest attention to the smoker rather than to the smoke.

13 “Each question suggests certain lines of research, quite different ones in each
14 case. If we knew for certain which hypothesis was correct, we could plan and guide
15 research much more efficiently and economically. Since we do not know, in the case of
16 any disease, we have little choice but to pursue studies suggested by each possibility.
17 This has been The Council’s policy.”

18 **Q. Did CTR support other kinds of research in its first decade?**

19 A. Yes. As I explained earlier, Dr. Little was one of the foremost cancer
20 researchers of his time. He repeatedly expressed the view, from the very first meeting of
21 the SAB in July 1954, that some of TIRC’s research funds should be used for research
22 into the basic etiology of the diseases associated with smoking. Dr. Little advocated
23 research that would look for answers to questions like: How does cancer start? What are
24 the steps in the formation of tumors? What are the body’s defenses to cancer cells? Why
25 do those defenses sometimes fail? What makes cancer metastasize? Why do some

1 tumors grow quickly and others slowly? What makes cells divide and multiply? These
2 kinds of questions involve what biomedical research scientists call basic science issues,
3 and the research into these questions is called basic research. The goal of basic research
4 is to understand the basic functioning of the organs and cells in both healthy and diseased
5 states.

6 **Q. Was Dr. Little's interest in basic research disclosed to the public?**

7 A. Yes. Dr. Little's views about the importance of basic research were
8 repeatedly expressed in public statements.

9 **Q. Can you identify U.S. Ex. 20278?**

10 A. U.S. Ex. 20278 is a transcript of a press conference on June 15, 1954, at
11 which Dr. Little described CTR and its mission. Right at the outset of this press
12 conference, Dr. Little stated his view that basic research, which he sometimes referred to
13 as "pioneer research," was very important and largely had been neglected in the U.S. in
14 favor of clinical and applied research.

15 **Q. Did the SAB express either agreement or disagreement with Dr. Little
16 about the desirability of funding basic research through grants from CTR?**

17 A. The SAB expressed agreement with Dr. Little on this point. If there was
18 disagreement with Dr. Little on this point by any SAB members, I am not aware of it.

19 **Q. Please look at pages 8-13 of Exhibit JD-090004, the 1960 TIRC
20 Annual Report, which is the report by the Scientific Advisory Board that you
21 mentioned. What did the SAB say in this report about the need for basic research?**

22 A. On page 13, the SAB stated: "We must continue to promote true basic
23 research in the intracellular processes of life and in the multicellular living organization
24 even though, in some instances, this will have no obvious or immediate connection with
25 the practical question of tobacco and health."

1 **Q. What were some of the early basic research projects funded by CTR?**

2 A. One of Dr. Little’s earliest basic research goals was to develop lung cell
3 tissue cultures that could be used to conduct experiments using cigarette smoke as well as
4 other insults, such as cigarette smoke condensates and components of cigarette smoke.

5 **Q. Please look at the SAB’s report on page 12 of Exhibit JD-090004, the**
6 **1960 TIRC Annual Report. What did the SAB’s report say about CTR’s support**
7 **for tissue culture research?**

8 A. The SAB report stated that TIRC had funded tissue culture experiments
9 and that the SAB was actively considering expanding the funding for these studies. On
10 page 64, the 1960 TIRC Annual Report stated that TIRC had provided fellowship support
11 for Dr. George Gey, Director of the Finney-Hewell Cancer Research Laboratory at Johns
12 Hopkins Hospital in Baltimore, on the subject of “the Culture of Human Lung Tissue and
13 the Effects of Known and Possible Carcinogenic Agents Upon Such Tissue.” Dr. Gey
14 had attended the January 1956 TIRC conference on tissue studies, according to the
15 documents in TIRC’s files that I mentioned. On page 68, the 1960 TIRC Annual Report
16 stated that TIRC had provided funding to Dr. Donald Pace at the University of Nebraska
17 for training in tissue culture techniques as well as a “Study of the Effects of Tobacco
18 Smoke Constituents on Various Strains of Tissue Cells Cultivated *In Vitro*.” The 1960
19 TIRC Annual Report also refers, on page 71, to TIRC support of the Tissue Culture
20 Association at Columbia University College of Physicians and Surgeons in New York.

21 **Q. Please look at pages CTR MIN-SAB 000080-82, 87-88, 93-95, 102-05,**
22 **106-07, 122-26, 127-28, 136-37 and 140-41 of Exhibit JD-090960. What do they**
23 **show about CTR’s support for tissue culture research?**

24 A. These are portions of the minutes of Scientific Advisory Board meetings
25 that reflect decisions to support tissue culture research through grants-in-aid. These are

1 minutes of the SAB meetings that took place in August 1956, December 1956,
2 March 1957, August 1957, November 1957, September 1958, December 1958, June 1959
3 and September 1959.

4 **Q. What happened to the focus of CTR-funded research after the 1964**
5 **Report of the Surgeon General’s Advisory Committee on Smoking and Health?**

6 A. CTR continued to fund studies concerning various aspects of lung cancer,
7 including basic questions such as why only a relatively small minority of heavy smokers
8 contract lung cancer and why some non-smokers contract lung cancer. CTR also
9 supported research into the relationships between smoking and other diseases, such as
10 cardiovascular disease, pulmonary diseases, and other forms of cancer. CTR also
11 supported research into smoking and women’s health, a topic that had been suggested by
12 the 1964 Report, which concluded only that cigarette smoking was causally related to the
13 increase in lung cancer in men. The CTR research program funded projects that
14 addressed these areas, as well as others related to smoking and health as new information
15 came to light, and as new techniques became available.

16 **Q. After the Surgeon General’s Advisory Committee Report was**
17 **published in 1964, were there aspects of CTR’s research focus that did not change?**

18 A. CTR’s focus always was on supporting advanced research in the field of
19 smoking and health that held the promise of advancing scientific knowledge, and that did
20 not change, then or at any time. CTR continued to provide grant support to many
21 scientists whose work it funded before the Surgeon General’s Advisory Committee
22 Report was published. As one prominent example, CTR continued to support the work of
23 Larson, Haag and Silvette, whose monograph compiling studies related to smoking and
24 health was discussed in the Surgeon General’s Advisory Committee’s 1964 Report on
25 Smoking and Health.

1 **Q. Can you give examples of the kinds of research CTR was funding**
2 **during the period from 1964 until you started at CTR in 1983?**

3 A. CTR continued to provide financial support for epidemiological research.
4 CTR continued to fund epidemiological studies by Dr. Carolyn Bedell Thomas of Johns
5 Hopkins. CTR also provided funding for an ongoing study of 2,000 male veterans by the
6 U.S.-Veterans Administration. CTR also provided funding for analyses of the Swedish
7 Twin Registry, through grants-in-aid to Dr. Lars Friberg. In the early 1970s, CTR
8 stepped in to provide financial support for the Framingham Heart Study, a landmark
9 epidemiological study, at a time when the United States government cut funding for that
10 study. CTR supported this epidemiological work through a grant-in-aid to Dr. Thomas
11 Dawber of Boston University School of Medicine.

12 **Q. Please look at pages CTR MIN-SAB 000227, 236, 249, 278, 280, 293-**
13 **94, 310, 334, 343, 345, 352 and 364 of Exhibit JD-090960. What do they show about**
14 **CTR’s research program?**

15 A. These are pages of the minutes from the May 1964, December 1964,
16 September 1965, March 1967, May 1967, May 1968, March 1969, March 1970,
17 September 1970 and January 1971 SAB meetings at which the SAB discussed and voted
18 after January 1964 whether to support grant-in-aid funding for Dr. Bedell Thomas.

19 **Q. Please take a look at pages 13, 18 and 19 of Exhibit JD-090013, the**
20 **CTR Annual Report for 1971. What did the 1971 CTR Annual Report say about**
21 **CTR’s support for epidemiologic research?**

22 A. Page 13 of Exhibit JD-090013 reported on CTR’s support of the
23 Framingham study. It states: “The Council has made a grant related to the Framingham
24 Heart Study, effective July 1, 1971. This study was to have been ended for lack of
25 federal funding, but its long-time director and several associates sought and obtained

1 outside support to keep it going. The Council’s grant is for an investigation of smoking
2 classes, risk factors and cardiovascular disease in the population being followed by the
3 project.”

4 Pages 18 and 19 of Exhibit JD-090013 reported on CTR’s participation in the
5 long-term study of veterans as well as support for the Swedish Twin Registry studies by
6 Dr. Lars Friberg.

7 **Q. Can you identify Exhibits JD-093613, JD-093614, JD-094386 and page**
8 **CTR MIN-SAB 000366 of Exhibit JD-090960?**

9 A. These are documents from CTR’s files, including the SAB minutes from
10 the May 1971 SAB meeting, showing that CTR provided funding support for the
11 Framingham heart study.

12 **Q. During the 1960s, did CTR fund epidemiological studies related to**
13 **lung cancer in women?**

14 A. Yes, it did. In 1968, two CTR grantees, Dr. Herbert Lombard and
15 Dr. Evelyn Potter Huyck published a paper entitled “An Epidemiological Study of Lung
16 Cancer Among Females,” which concluded that there is a positive relationship between
17 cigarette smoking and undifferentiated-epidermoid lung cancer among women.

18 **Q. During the 1960s, did CTR fund epidemiological studies related to**
19 **maternal smoking and fetal health?**

20 A. Yes, it did. CTR provided to two grantees, Dr. Laurence Hester and
21 Dr. B.V. Rama Sastry, extensive funding to study the phenomena of low-birthweight
22 babies born to mothers who smoked. Dr. Hester published some of the first papers on
23 this subject in the mid-1960s, years before the Surgeon General made note of the
24 phenomenon. Dr. Sastry also published extensively on this topic, and some of his work
25 later was cited in the Surgeon General’s reports on Smoking and Health.

1 **Q. Please take a look at page 69 of Exhibit JD-090011, the 1968-69 CTR**
2 **Annual Report. What appears on that page?**

3 A. This page contains the abstract of Dr. Lombard’s and Dr. Huyck’s article
4 entitled “An Epidemiological Study of Lung Cancer Among Females.”

5 **Q. Please take a look at pages 52-54 of Exhibit JD-090007, the 1963-64**
6 **CTR Annual Report and pages 57-58 of Exhibit JD-090009, the 1965-66 CTR**
7 **Annual Report. What appears on these pages?**

8 A. These pages contain the abstracts of Dr. Hester’s scientific publications
9 reporting on his research on maternal smoking and fetal health as a CTR grantee in the
10 mid-1960s.

11 **Q. Please take a look at pages 59-61 of Exhibit JD-090018, the 1976 CTR**
12 **Annual Report; pages 54-57 of Exhibit JD-090020, the 1978 CTR Annual Report;**
13 **pages 112-14 of Exhibit JD-090027, the 1985 CTR Annual Report; pages 80-81 of**
14 **Exhibit JD-090028, the 1986 CTR Annual Report; pages 150-51 of Exhibit JD-**
15 **090033, the 1991 CTR Annual Report; pages 104-06 of Exhibit JD-090034, the 1992**
16 **CTR Annual Report; and pages 146 and 176-77 of Exhibit JD-090035, the 1993**
17 **CTR Annual Report. What appears on these pages?**

18 A. These pages contain the abstracts of Dr. Sastry’s scientific publications
19 reporting on the research on maternal smoking and fetal health he conducted as a CTR
20 grantee in the 1970s and continuing into the 1980s and 1990s.

21 **Q. Can you identify Exhibit JD-043140?**

22 A. Exhibit JD-043140 is an article, published in 1968, by Dr. Lombard and
23 Dr. Huyck entitled “An Epidemiological Study of Lung Cancer Among Females.” At
24 page 54, this article concluded that, after 1956, cigarette smoking became an “important

1 factor” in the increase in lung cancer mortality among females studied in a sample of
2 death records in Massachusetts.

3 **Q. Can you identify Exhibits JD-043258, JD-093020, JD-094912, JD-**
4 **094914, JD-094915, JD-095269 through JD-095272 and JD-095274?**

5 A. Exhibits JD-043258, JD-093020, JD-094912, JD-094915, JD-095269
6 through JD-095272 and JD-095274 are publications by Dr. Sastry reporting on his CTR-
7 funded research on smoking and maternal and fetal health.

8 **Q. What were some of the other developments in the CTR research**
9 **program in the period from 1964 to the time you started at CTR in 1983?**

10 A. One research focus was the role of viruses in carcinogenesis. CTR had
11 funded research of this kind in the early 1960s. In the late 1960s there was a growing
12 belief that many cancers were caused by viruses, and CTR supported a significant amount
13 of research along these lines. Dr. Robert Huebner, who was Chief of the Viral
14 Carcinogenesis Branch of the National Cancer Institute and was a member of the SAB
15 from 1968 to 1982, was a proponent of this theory. A significant part of CTR-funded
16 research in this area was formulated to test the hypothesis that smoking might interact in
17 some way with viruses to lead to the increase in cancer associated with smoking.

18 Second, CTR expanded its support of research into the relationship of smoking
19 and cardiovascular disease, which statistically accounted for a larger share of the excess
20 mortality and morbidity attributable to smoking than lung cancer. CTR also expanded its
21 support of research into the relationships between smoking and other diseases, such as
22 chronic obstructive pulmonary disease and emphysema. From 1978 to 1981 CTR
23 provided grants to Dr. Aaron Janoff of the State University of New York at Stony Brook,
24 and from 1972 to 1983 to Dr. James Travis of the University of Georgia. These scientists

1 discovered what has been thought to be the principal mechanism by which oxidants in
2 cigarette smoke operate in the lungs to trigger emphysema.

3 Third, CTR moved forward with its efforts to develop an animal model for the
4 kind of lung cancer that was associated with smoking in human beings. If such a model
5 could be developed, constituents in cigarette smoke that might be causally involved in
6 smoking-related diseases might be identified. Genetic traits that made some individuals
7 more susceptible to disease might also be identified. In the 1970s and into the early
8 1980s, the SAB, with Dr. Huebner playing a leading role, focused its efforts to develop
9 an animal model using mice and specialized smoking machines developed under CTR
10 research contracts. As I discussed earlier, many of these animal inhalation studies and
11 related experiments were supported by CTR through research contracts with MAI in
12 Bethesda.

13 **Q. Were others involved in scientific research expressing an interest in**
14 **developing an animal model for lung cancer at that time?**

15 A. Yes. I have seen a number of references to that as a subject of scientific
16 interest in the late 1960s. By that time, there was much less interest among researchers in
17 the mouse skin-painting experiments of the kind pioneered by Dr. Wynder.

18 **Q. Can you identify Exhibit JD-000742?**

19 A. Yes. This is a copy of a book entitled *Tobacco and Tobacco Smoke:*
20 *Studies in Experimental Carcinogenesis*, by Dr. Wynder and Dr. Dietrich Hoffman,
21 published in 1967. We had a copy of this book in the CTR library, and I am familiar with
22 it.

23 **Q. What does the Wynder and Hoffman book, Exhibit JD-000742, say on**
24 **page 145 that relates to developing an animal model for lung cancer?**

1 A. Dr. Wynder and Dr. Hoffman said, under the heading Inhalation Studies,
2 “the bioassay for tobacco products on mouse epidermis,” and that refers to skin painting,
3 “have not answered questions on the problems of respiratory carcinogenesis. A bioassay
4 on the respiratory system of a laboratory animal should be useful provided that sufficient
5 smoke aerosols can be delivered to the bronchial epithelium.” This refers to attempting
6 to produce lung cancers in laboratory animals by having them inhale cigarette smoke –
7 that is, creating an animal model.

8 **Q. Do you know whether funding agencies other than CTR also**
9 **sponsored animal inhalation experiments in the 1970s?**

10 A. The March 1979 Status Report of the NCI’s Smoking and Health Program,
11 which is Exhibit JD-011826, referred to a number of research projects involving animal
12 smoke inhalation.

13 **Q. Did any agency or entity of the United States government have any**
14 **role in CTR’s efforts to develop an animal model during this period?**

15 A. Yes. In connection with developing and refining the smoking machines
16 that were used in the MAI mouse whole smoke inhalation experiments, CTR entered into
17 contracts with Oak Ridge National Laboratory, in Oak Ridge, Tennessee, which had
18 specialized knowledge in the science of analyzing the dispersion of particulates in air.
19 Oak Ridge National Laboratory is a nationally-known U.S. Government-owned facility.

20 **Q. Can you identify Exhibit JD-093855?**

21 A. Exhibit JD-093855 is a document from CTR’s files. It is a May 24, 1979
22 letter from Robert W. Holmberg of the Bio/Organic Analysis Section of Oak Ridge
23 National Laboratory to Dr. Gardner, who was then the Scientific Director of CTR,
24 enclosing copies of Oak Ridge National Laboratory’s Annual Progress Report.

1 **Q. Please read the last sentence of the second paragraph of Exhibit JD-**
2 **093855.**

3 A. “In essence, we shall give [Microbiological Associates, Inc.] our best
4 efforts toward getting the present exposure facilities operating properly and helping in the
5 acquisition of an expanded system.”

6 **Q. Was getting the exposure facilities to operate properly a problem in**
7 **the animal smoke inhalation experiments that were funded by CTR in the 1970s?**

8 A. That was one of many challenges in animal smoke inhalation research
9 from the 1950s right through the 1970s. If laboratory animals such as mice or hamsters
10 were placed in chambers and exposed to cigarette smoke in the atmosphere of the
11 chambers, as was done in some early experiments, the animals tended to bury their noses
12 in their fur and not inhale the cigarette smoke, or they would lick the smoke off of their
13 fur and get sick. On the other hand, if the animals were forced to breathe cigarette smoke
14 by, for example, having a tube inserted in their airways, they would be traumatized, and
15 the experimental results could be confounded by the effects of trauma.

16 **Q. Did the MAI scientists, working with scientists at Oak Ridge National**
17 **Laboratory, come up with a solution to this problem?**

18 A. Yes. Over several years, they developed a smoking machine in which
19 each experimental mouse that was exposed to cigarette smoke, as well as those that were
20 not exposed, was placed in a harness with a rubber cup that fit over its nose, through
21 which cigarette smoke was pumped. This achieved the result of depositing the smoke
22 into the animals’ lungs in a way that at least approximated the way humans inhale
23 cigarette smoke, and was not as traumatic as other ways of forcing the laboratory animals
24 to be exposed to the cigarette smoke.

25 **Q. What was the outcome of MAI’s animal inhalation experiments?**

1 A. After CTR spent nearly \$12 million on these research contracts, MAI did
2 not succeed in developing an animal model. The difference in the incidence of cancer
3 generated in the lungs of the experimental mice that were subjected to cigarette smoke,
4 compared to those mice that were not subjected to such smoke, was not statistically
5 significant.

6 **Q. When did CTR stop funding the mouse inhalation experiments by**
7 **MAI?**

8 A. On June 20, 1980, the Executive Committee of the Scientific Advisory
9 Board of CTR voted unanimously to let CTR Contract No. 30 with MAI expire on
10 December 31, 1980. Contract 30 involved the last of the attempts to use large-scale
11 inhalation experiments to come up with an animal model for lung cancer. The SAB
12 authorized the Scientific Director to contract with MAI for a phase-out period, and at this
13 meeting other contract funding with MAI for a total of \$145,000 was approved. At the
14 October 1980 SAB meeting, an additional \$931,000 in funding for the MAI experiments
15 was authorized, including termination costs. In June 1982, the Scientific Director,
16 Dr. Gardner, approved a payment by CTR of roughly \$38,000 to the MAI scientists to
17 enable them to complete their data analysis and prepare a final report.

18 **Q. Please take a look at pages CTR MIN-SAB 000563 through CTR**
19 **MIN-SAB 000661 of Exhibit JD-090960. What do these show about CTR-funded**
20 **research of animal smoke inhalation experiments?**

21 A. These are minutes of the meetings of the SAB Executive Committee in
22 1980, 1981, 1982 and 1983. The following pages in these exhibits contain the minutes of
23 the decisions related to the MAI mouse whole smoke inhalation contracts: CTR MIN-
24 SAB 000573 (June 20, 1980); CTR MIN-SAB 000576-84 (October 1980); CTR MIN-

1 SAB 000587-96 (April 1981); CTR MIN-SAB 000611-12 (December 1981); CTR MIN-
2 SAB 000625 (June 1982); CTR MIN-SAB 000626-36 (October 1982).

3 **Q. Did the MAI scientists prepare a final report on their mouse**
4 **inhalation experiments?**

5 A. Yes. After several years and much prodding by CTR, MAI submitted a
6 final report in 1984. CTR published that final report in book form, with a brief foreword
7 by Dr. Sommers summarizing MAI's findings. The two main investigators from MAI,
8 Dr. Richard Kouri and Dr. Carol Henry, also published their findings, including an article
9 in *The Journal of the National Cancer Institute* in 1986.

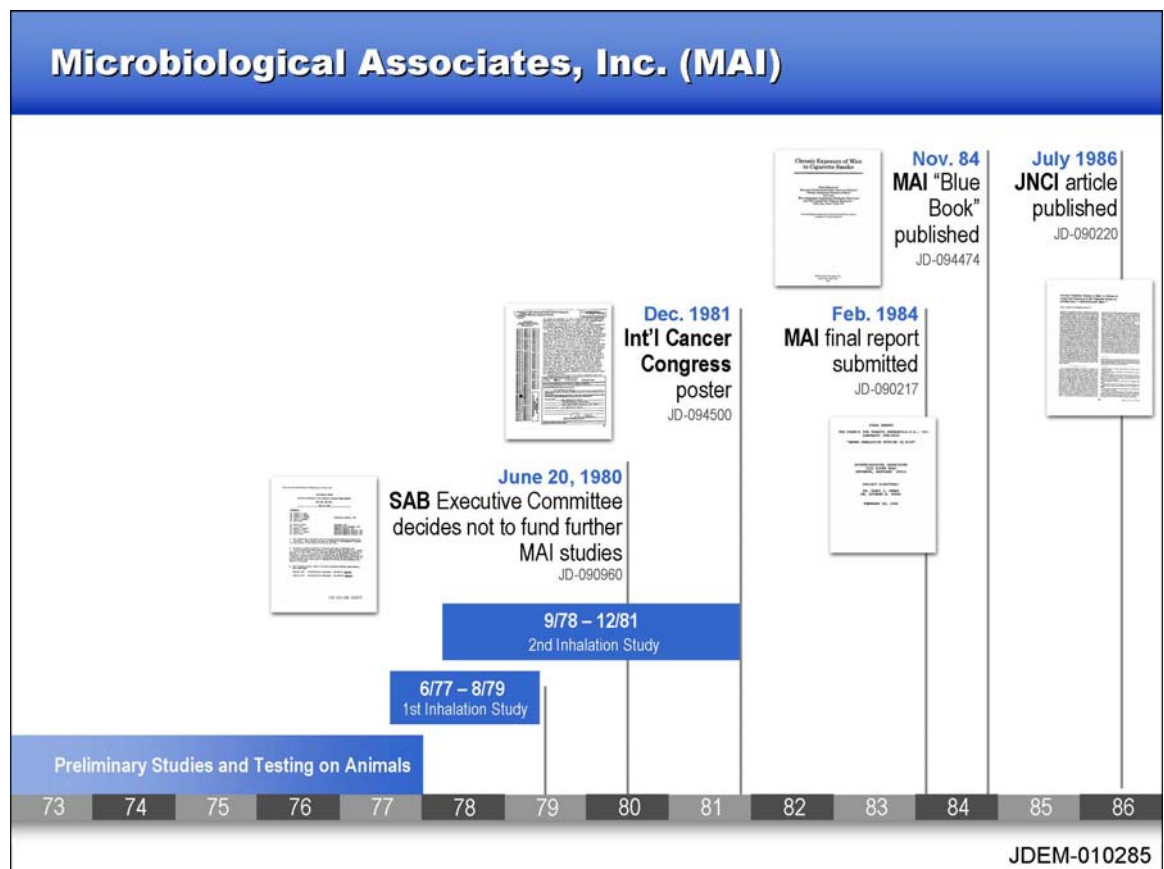
10 **Q. Can you identify Exhibits JD-046513, JD-094474, JD-090217, and JD-**
11 **094500?**

12 A. Exhibit JD-094474, which I discussed earlier, is the book published by
13 CTR that contains the final report submitted by the MAI researchers, with a brief
14 foreword by Dr. Sommers. Exhibit JD-090217 is the final report as it was submitted to
15 CTR by MAI in 1984. Exhibit JD-046513 is the 1986 JNCI article by Dr. Henry and
16 Dr. Kouri. Exhibit JD-094500 is a copy of a December 1981 abstract of a poster
17 presentation that the MAI scientists provided to the 13th International Cancer Congress,
18 reporting on their CTR-funded smoke inhalation research.

19 **Q. What is shown on Demonstrative Exhibit JDEM-010285, which is**
20 **reprinted below?**

21 A. This is a timeline of important events in the history of the animal
22 inhalation studies conducted by MAI pursuant to research contracts with CTR. The
23 information on the timeline comes from the underlying documents and the minutes of
24 meetings of the CTR Scientific Advisory Board. It shows the decision made in the early
25 1970s to utilize genetically pure strains of mice as the proposed animal model, the two

1 large-scale smoke inhalation studies that were conducted with the advice of the SAB, the
2 SAB Executive Committee's decision on June 20, 1980 not to fund further MAI studies.
3 It then shows some of the reports by the MAI researchers on the results of their studies, in
4 the poster presentation at the International Cancer Congress in December 1981, in the
5 final report published by CTR in 1984, and in the July 1986 article that the MAI
6 scientists published in *The Journal of the National Cancer Institute*.



7

8 **Q. After the inhalation experiments funded by CTR did not succeed in**
9 **developing an animal model for lung cancer, what did CTR do?**

10 A. After that point, and now we're in the early 1980s, just before I arrived at
11 CTR, CTR was increasingly funding what scientists usually call basic research. That

1 basic research sought to understand the mechanisms of the chronic diseases associated
2 with smoking, not necessarily by using cigarette smoke as an insult, but by using the
3 increasingly sophisticated techniques that were becoming available in the various fields
4 of biomedical research.

5 **Q. Was CTR's decision to focus on funding basic research consistent or**
6 **inconsistent with what was going on elsewhere in the scientific community with**
7 **respect to research on smoking and health?**

8 A. It was very much consistent with the scientific trends elsewhere.

9 **Q. How do you know that?**

10 A. Even after I went into university administration in the late 1970s until
11 1983, I kept up with and was very much aware of the major developments in biomedical
12 research. Increasingly, among sophisticated researchers, the focus was on basic research
13 using innovative techniques such as recombinant DNA and other technologies. As these
14 technologies became available, it made perfect sense for CTR to support research using
15 these new methodologies with respect to smoking and health.

16 **Q. Please take a look at page 218 of the 1982 Surgeon General's report**
17 **on Smoking and Health, U.S. Ex. 60598. Can you read the second paragraph?**

18 A. "Benign and malignant tumors have been induced in the larynx of
19 hamsters by long-term exposure to diluted cigarette smoke. Attempts to induce
20 significant numbers of bronchogenic carcinoma in laboratory animals were negative in
21 spite of major efforts with several species and strains. Neither rats nor hamsters nor
22 baboons inhale cigarette smoke as deeply and as intensely as the cigarette smokers who
23 have provided the data with the consequences of their 'experiment' in the form of clinical
24 evidence gathered by epidemiologists. In view of this compelling evidence, it appears

1 that the experimental induction of bronchogenic carcinoma should receive limited
2 priority as a research goal.”

3 **Q. Was CTR’s decision not to fund further experiments exposing**
4 **laboratory animals to whole smoke consistent with this statement?**

5 A. CTR’s decision was right in line with the Surgeon General’s statement.

6 **Q. When you were at CTR in 1983 and 1984, did you think CTR should**
7 **continue funding animal smoke inhalation tests at MAI or at other facilities?**

8 A. I thought the decision not to continue funding the MAI contracts was
9 absolutely the right decision. The experiments had not generated statistically significant
10 results, and other avenues seemed more likely to expand scientific knowledge and
11 understanding.

12 **Q. Have you heard allegations that CTR terminated certain contract**
13 **research by MAI because CTR was pressured to do so by the cigarette**
14 **manufacturers or their lawyers?**

15 A. Yes. I have read or heard that allegation a number of times since the early
16 1990s.

17 **Q. Have you seen anything to support the allegation that pressure from**
18 **those sources caused CTR to terminate any of MAI’s research?**

19 A. No. First of all, as far as I am aware, CTR never terminated any of MAI’s
20 research contracts. I believe all MAI’s contract research for CTR and all the MAI
21 scientists’ grants from CTR were carried out to their completion. The same is true of Dr.
22 Homburger’s contract research. The SAB decided at certain points that CTR should not
23 enter into additional contracts that were proposed by MAI, including contracts for
24 additional large-scale mouse inhalation experiments MAI proposed in 1980 and later. It
25 appears from CTR’s records that all these decisions were made by the SAB after

1 consideration of the scientific merits of the proposed research. That is what I learned
2 about the basis for these decisions after I joined CTR.

3 Over the years, I have been shown a number of memos in which lawyers,
4 scientists or others affiliated with the tobacco companies expressed a desire that CTR not
5 fund certain kinds of studies by MAI. All, or if not all virtually all, of those studies were
6 funded by CTR. If the tobacco companies were trying to stop CTR from funding
7 research by MAI that the SAB wanted to have CTR fund, the companies obviously had a
8 pretty poor record of success. The SAB's and the Scientific Director's scientific
9 judgments determined what did and did not get funded.

10 **Q. Did CTR stop funding animal inhalation research altogether in 1980?**

11 A. After 1980, CTR continued to fund some animal inhalation studies that
12 attempted to induce emphysema in experimental animals, and I agreed with the decisions
13 to do that. However, those experiments likewise did not succeed in producing an animal
14 model for human disease, because they did not result in the kind of emphysematic
15 changes in the lungs that are experienced by many long-term smokers. Although the
16 scientists conducting the experiments were able to induce emphysematic changes in the
17 lungs of animals by subjecting the animals to cigarette smoke or other challenges, the
18 changes were not permanent. When the scientists stopped subjecting the animals to that
19 challenge, the animals got better and their lung function returned to normal. CTR
20 ultimately decided, with the advice of the SAB, that this was not a good model for
21 smoking-related emphysema in humans, because smoking-related emphysema in humans
22 generally consists of permanent changes in lung function.

23 **Q. Do the CTR Annual Reports contain information about all of the**
24 **scientific research funded by CTR from 1964 to 1983 with the advice of the SAB?**

1 A. Yes. The CTR Annual Reports provide the best source of information.
2 Along with the SAB minutes, they are among the most informative and concise
3 documents describing the CTR research program funded with the advice of the SAB.

4 **Q. When you arrived at CTR in 1983, what kinds of research was CTR**
5 **funding?**

6 A. When I arrived at CTR in the fall of 1983, CTR was increasingly funding
7 basic research into the mechanisms of the diseases associated with cigarette smoking and
8 other forms of tobacco use. Instead of using smoke directly in their research, scientists
9 who received grant-in-aid funding from CTR were increasingly using the rapidly
10 emerging techniques of molecular biology.

11 **Q. Do you have personal knowledge of the reason CTR moved in this**
12 **direction?**

13 A. Yes. When I started with CTR in the autumn of 1983, the MAI inhalation
14 experiments had been completed and CTR was awaiting the final report from MAI.
15 These studies, as I described earlier, had failed to show that mice that had been required
16 to inhale cigarette smoke were statistically more likely than not to contract the type of
17 lung cancer associated with smoking in humans, or, for that matter, any type of lung
18 cancer. CTR had spent nearly \$12 million on these contracts.

19 **Q. Did you have concerns that CTR's increasing focus on basic research**
20 **was departing from CTR's mission to fund research related to tobacco and health?**

21 A. No, I did not.

22 **Q. Why?**

23 A. If an animal model for smoking-related disease in humans could not be
24 developed, the best way to learn about the relationship between tobacco use and disease
25 was to study the diseases themselves. If one could deconstruct the processes of diseases

1 such as cancer, heart disease and pulmonary disease, that would lead eventually to an
2 enhanced understanding of the relationships between smoking and disease and could
3 provide information that would be useful to the manufacturers of cigarettes, to
4 physicians, and to persons deciding whether to smoke.

5 **Q. Did anyone at CTR during the 1960s, 1970s and early 1980s refer in**
6 **writing to the changes in CTR's research focus that you have been describing?**

7 A. Yes. Dr. Leon Jacobson, who was an original member of the SAB and
8 served on it for 37 years. In 1981, when Dr. Jacobson became Chairman of the SAB, he
9 wrote a recollection of his years on the SAB, 27 of them at that point, which referred to
10 some of these changes.

11 **Q. Can you identify Exhibit JD-093895?**

12 A. Yes. Exhibit JD-093895 is Dr. Jacobson's recollection. Dr. Jacobson
13 referred on page 6 to the research problems focused on by the SAB in the early years, and
14 on pages 7 to 9, he discussed how basic research was coming to the fore, as was
15 occurring in 1981, when he wrote Exhibit JD-093895. As Dr. Jacobson said on page 8,
16 "we have entered the era of molecular biology and medicine."

17 **Q. Can you give some examples of the basic research projects funded by**
18 **CTR after you arrived in 1983, and describe how you understood that these**
19 **research projects related to smoking and health?**

20 A. Here are a few examples of basic research by scientists to whom CTR
21 provided grant-in-aid support during my tenure with CTR.

22 Dr. Howard Welgus at Washington University in St. Louis, who received funding
23 from CTR from 1985 to 1989 and from 1993 to 1999, studied how some types of
24 circulating cells in the blood that respond to inflammation are able to cause the
25 overproduction of an enzyme known as matrix metalloproteinase (MMP). Smokers'

1 blood vessels are more likely to have such inflammation and this research was relevant to
2 smoking and health, although it proceeded on a very basic level. MMP is known to be
3 responsible for severe tissue destruction both in chronic obstructive pulmonary disease as
4 well as in metastatic infiltration of cancer cells into normal tissues. This research was
5 thus relevant to two of the major diseases associated with smoking.

6 Dr. Stephen Sturley at New York University and the University of Wisconsin,
7 who received funding from CTR from 1995 to 1998, received a CTR grant-in-aid to
8 study a large protein, ApoB, a component of low density lipoprotein, or “bad”
9 cholesterol, which is predictive of increased susceptibility to coronary heart disease and
10 that is found at increased levels in both smokers and hypertensive individuals.
11 Dr. Sturley studied these relationships as well as the fact that after a high-fat meal, ApoB
12 rises much more in smokers than in non-smokers. Dr. Sturley’s research is highly
13 relevant to atherosclerosis and heart disease, two of the diseases that have been correlated
14 with cigarette smoking.

15 Dr. Reen Wu at the University of California at Davis, who received funding from
16 CTR from 1990 to 1993, conducted basic research related to squamous-cell carcinoma of
17 the lung, the most common form of lung cancer associated with heavy smoking.
18 Squamous cell carcinoma of the lung is characterized in its early stages by the loss of the
19 ability of some cells on the surface of the airway to produce mucus. These cells take on
20 what is characterized as a squamous or flattened appearance – hence the name squamous
21 cell carcinoma. Dr. Wu discovered that a particular gene in those cells directed the
22 synthesis of a unique squamous cell marker protein during the process of transformation
23 of those normal mucous-producing cells into squamous cells. This discovery could assist
24 in early detection of lung cancer.

1 Dr. Patrick Casey at Duke University was funded by CTR from 1995 to 1998 to
2 study a particular tumor promoter, or “oncogenic,” protein called “Ras.” This protein is
3 present in abundance in several types of cancer, including lung cancer, the type of cancer
4 most often associated with smoking. Ras must become anchored to the inner surface of a
5 cell’s membrane before it can participate in turning a normal cell into a cancerous cell.
6 Dr. Casey’s detailed study of this enzyme helped lead to the design and testing of several
7 chemical inhibitors of its activity that offer promise as therapeutic agents.

8 Another grantee, Dr. Avram Hershko at Technion University in Haifa, Israel,
9 received funding from CTR from 1992 to 1995 and from 1997 to 1999. He used these
10 funds to study the process of unregulated cell growth, which essentially is what cancer is
11 all about. The most universal characteristic of cancer is unregulated cell growth.
12 Normally, cells follow a highly complex set of obligatory instructions as they proceed
13 through the cell cycle process prior to division, stopping at appropriate check points for
14 various activities to occur. As part of this process, several very important control
15 proteins must be made quickly, perform their function, and then quickly be destroyed.
16 The timing of these processes is critical and when the process by which the control
17 proteins are destroyed goes awry, lung cancer as well as other diseases can result.
18 Dr. Hershko’s award-winning research, for which he was awarded the Nobel Prize and
19 the Lasker Award, elucidated exactly how those proteins are tagged for elimination,
20 helping us to understand how cancer might occur by that mechanism. That research was
21 funded, in part, by CTR.

22 Dr. Eric Tang at M.D. Anderson Cancer Center in Houston, Texas, received CTR
23 grant funds from 1995 to 1998. He helped to identify the way in which benzo-a-pyrene, a
24 constituent of cigarette smoke, inactivated genes that we call tumor-suppressor genes, in
25 particular one known as p53, and that are responsible for protecting the body against the

1 development of tumors. His work is part of a body of research that has been cited as
2 establishing a potentially precise mechanism by which smoking causes lung cancer.

3 Another example is CTR's funding of Dr. Murad and Dr. Ignarro, who won the
4 Nobel Prize in 1998. Dr. Murad received CTR grant-in-aid funding from 1978 to 1989
5 and Dr. Ignarro received CTR grant-in-aid funding from 1997 to 1999. Their work led to
6 discoveries about the role of nitric oxide, which is a component of cigarette smoke, in
7 hypertension, atherosclerosis and cardiovascular disease, which are chronic diseases
8 associated with cigarette smoking.

9 **Q. Did any of the CTR-funded research that you just described use**
10 **tobacco or tobacco smoke in the laboratory?**

11 A. No.

12 **Q. Did you believe, when CTR funded these research projects, that they**
13 **were relevant to smoking and health?**

14 A. Yes. I believed all of it was.

15 **Q. Why did you believe that?**

16 A. I viewed CTR's mission as funding research that was aimed at advancing
17 scientific understanding of diseases and disease processes associated with smoking. The
18 research that we funded was aimed at doing that, and that is why I think it was highly
19 relevant. It was not central to CTR's mission, as I understood it, to determine precisely
20 how these advances in scientific knowledge would be useful from a public health
21 perspective, but there were a couple of obvious possibilities. Publicly available scientific
22 information about precisely how smoking might be involved in a disease process could
23 be useful to cigarette manufacturers in designing cigarettes that would be less risky. New
24 scientific information could also help to identify those persons who are particularly
25 susceptible to adverse health effects from smoking.

1 **D. CTR-Funded Research Related to Nicotine**

2 **Q. Did CTR fund research concerning the effects of nicotine?**

3 A. Yes, it did, for many years. When TIRC was formed, little was known
4 about how nicotine was metabolized in the human body and the details of its
5 physiological actions other than the readily measured effects on heart rate and blood
6 pressure were poorly understood. In its early days, TIRC sponsored studies to investigate
7 the alleged role of nicotine in precipitating heart attacks. These studies generally showed
8 that the hypothesis that the nicotine in cigarettes caused heart attacks was unfounded.
9 However, other TIRC-funded studies in the 1950s and early 1960s found that nicotine
10 probably did play a role in reducing blood flow to the extremities, so individuals with
11 impaired peripheral circulation were adversely affected.

12 **Q. Did CTR do anything to publicize the results of these studies?**

13 A. TIRC held a conference on the Cardiovascular Effects of Nicotine and
14 Smoking at the New York Academy of Sciences in 1960, and that conference was
15 described in the 1960 TIRC Annual Report.

16 **Q. Please look at page 19 of Exhibit JD-090004, the 1960 TIRC Annual**
17 **Report. Could you read the first sentence of the sixth full paragraph?**

18 A. “It was generally agreed that smoking should be discouraged in patients
19 with peripheral vascular disease because, in many such persons, smoking may result in
20 vasoconstriction in the skin.” This statement summarized one of the conclusions of the
21 1960 CTR-sponsored conference at the New York Academy of Sciences.

22 **Q. Did CTR fund other kinds of nicotine-related studies?**

23 A. Yes. During the late 1970s and early 1980s, technical advances facilitated
24 an explosion of knowledge about central nervous system (CNS) neural circuits that were
25 directly or indirectly responsive to nicotine via specific receptors on the nerve cells.

1 Beginning in the late 1970s, CTR funded many grants that supported research about the
2 so-called nicotinic receptors in the CNS, including the so-called reward circuits of the
3 human brain, research related to addiction and dependence.

4 **Q. Did CTR fund additional kinds of nicotine-related studies?**

5 A. Yes. In the mid 1990s, CTR funded research by Dr. John Minna of the
6 University of Texas Southwestern Medical Center in Dallas, who hypothesized a novel
7 role for nicotine in carcinogenesis. Dr. Minna published several papers stemming from
8 his CTR-funded research that suggested nicotine has a possible role in lung cancer by
9 suppressing the process of apoptosis, or programmed cell death, which is one of the
10 body's principal defenses against cancer. If a cancer cell, which contains mutated DNA,
11 cannot self-destruct, then it will continue to multiply and metastasize. Dr. Minna's
12 research showed that nicotine and its metabolites had the potential to "turn off" one of the
13 body's key defenses to cancer.

14 **Q. Can you identify Exhibit JD-010296?**

15 A. Exhibit JD-010296 is Dr. Minna's article entitled "Opioids Induce While
16 Nicotine Suppresses Apoptosis in Human Lung Cancer Cells," which was published in
17 the October 1994 volume of *Cell Growth & Differentiation*. The article acknowledges
18 CTR's support.

19 **E. Proscribed Areas of Research**

20 **Q. Other than research related to product development, which you have**
21 **testified about earlier, were there any other areas of research related to smoking**
22 **and health that were proscribed – that is, that were "off limits" to CTR – based on**
23 **your experience at CTR?**

24 A. Again, other than the limitation that the research concern health effects of
25 smoking, there was nothing that the SAB would not consider.

1 **Q. I am showing you U.S. Ex. 35899, a letter dated March 31, 1980 from**
2 **Dr. Seligman at Philip Morris to Dr. Spears at P. Lorillard Tobacco Company.**

3 **Have you seen U.S. Ex. 35899 before?**

4 A. This document has been shown to me a number of times by plaintiffs'
5 lawyers in depositions or at trial.

6 **Q. Did CTR ever receive a copy of U.S. Ex. 35899?**

7 A. Not so far as I have been able to determine.

8 **Q. Page 3 of U.S. Ex. 35899 lists three “subjects to be avoided,” including**
9 **“[d]eveloping new tests for carcinogenicity,” “[a]ttempt[s] to relate human disease**
10 **to smoking,” and “experiments which require large doses of carcinogen to show**
11 **additive effect of smoking.” Have you seen any evidence that Dr. Seligman or**
12 **anyone else ever told CTR that it should avoid these subjects?**

13 A. No. A number of times when I have testified, I have been shown
14 documents in which company executives or scientists criticized CTR, sometimes because
15 they thought CTR was funding irrelevant research, other times because they did not like
16 the findings from that research. Few, if any, of these documents are in CTR's files. Even
17 when CTR did hear about criticisms from the member companies, it appears to be the
18 case that the Scientific Director and SAB did not change their decisions or approach as a
19 result, and that they continued to exercise their independent scientific judgment in
20 deciding what research CTR would fund.

21 **Q. After March 1980 did CTR fund research in any of the three subjects**
22 **listed as “subjects to be avoided” in U.S. Ex. 35899?**

23 A. CTR funded research projects in the first two categories and continued its
24 funding of previously-approved research in the third category. Both before and after
25 1980, CTR supported research attempting to develop new tests for carcinogenicity. For

1 example, CTR supported research by Dr. William Benedict at Children’s Hospital at the
2 University of Southern California on sister-chromatid exchanges, as well as the use of
3 Ames testing. These were new sensitive methods to test compounds for carcinogenicity
4 and mutagenicity. CTR funded Dr. H.Y. Reynolds at Yale through 1983 for his work in
5 this area, and in 1981 Dr. Reynolds published a review paper on the topic “Are Tumor
6 Markers Useful in Diagnosing Lung Cancer?” that cited the results of his and other
7 investigators’ research.

8 As for “attempt[s] to relate human disease to smoking,” CTR supported
9 pioneering research by Dr. Janoff and Dr. Travis, which I mentioned earlier, that led to
10 what is now accepted as the principal theory of how smoking contributes to emphysema.
11 In the mid-1980s, another CTR grantee, Dr. David Busbee at Texas A&M, found the
12 biologically damaging form of benzpyrene to negatively affect DNA production. In the
13 late 1980s, Dr. Leon Bradlow of Rockefeller University found an association between
14 cigarette smoking in women and significant anti-estrogenic effects. CTR also supported
15 a range of studies that moved forward our understanding about how smoking might
16 inactivate the body’s “tumor suppressor” genes. This theory of carcinogenesis involves
17 the idea that cancer is not caused exclusively by some outside insult that causes a direct
18 mutation of activated genes. Rather, “tumor suppressor” involvement in cancer relies on
19 the fact that such direct mutations occur constantly and that one way the body combats
20 cancer is through activation of built-in “self destruct” programs that are turned on when
21 those cells have suffered a mutation that would cause them to lose control of their growth
22 and thus become cancerous. CTR-funded scientists looked for changes in human tumor
23 suppressor genes that might be linked with smoking. They published their findings
24 starting in the mid-1990s, and this research received attention in the mass media,
25 including the *New York Times*.

1 As background for these studies, CTR had long funded investigations into the role
2 of “tumor promoter genes,” or “oncogenes,” typified by the work of Dr. Harold Varmus
3 of the University of California at San Francisco in the 1980s before he was awarded the
4 Nobel Prize in Medicine.

5 CTR also funded studies related to the role of oxidants, which are present in
6 cigarette smoke, and their role in cancer and other human diseases. Dr. John Repine, a
7 CTR grantee at Webb-Waring Lung Institute in Denver, was a very significant
8 contributor in this area.

9 **Q. What about the third category, “experiments which require large**
10 **doses of carcinogen to show additive effect of smoking”?**

11 A. CTR funded these kinds of experiments, known as co-carcinogenesis
12 studies, for a number of years, through research contracts with MAI as well as through
13 grants to Dr. Benedict. The results of these experiments were published by CTR in 1984
14 in the book that contained MAI’s final report as well as in research articles. This
15 research was conducted from 1977 to 1981, with the advice and approval of the SAB.
16 The experiments involved injecting the tracheas of cancer-susceptible mice with known
17 carcinogens such as benzpyrene or methylcholanthrene and then exposing the mice to
18 whole smoke. The SAB decided not to continue to fund these experiments after 1981,
19 partially because they were not representative of what occurred in human smoking. The
20 doses of co-carcinogen necessary to obtain tumors in these experiments were so high that
21 it was impossible to draw conclusions about the co-carcinogenicity of cigarette smoke.

22 **Q. In paragraph 1151 of the United States’ proposed findings of fact,**
23 **there is a reference to a January 1978 memorandum by Dr. Osdene of Philip**
24 **Morris, in which Dr. Osdene referred to “human studies involving aryl**
25 **hydrocarbon hydroxylase (‘AHH’)” and said, “It is my recommendation that CTR**

1 **cease work in this specific area of human studies.” Did CTR fund any human**
2 **studies involving AHH after January 1978?**

3 A. Yes. CTR funded research on AHH by a number of researchers. Those
4 studying the effects of AHH in humans after January 1978 included Dr. Marilyn Arnott at
5 M.D. Anderson Hospital in Houston, Hira Gortoo at Roswell Park Memorial Institute,
6 Dr. Kenneth Paigen, also at Roswell Park, Dr. Jacques Gielen of the University of Liege,
7 Dr. Franz Oesch at the University of Mainz, and Dr. Kouri at MAI. In March 1978, CTR
8 had a very disappointing experience with a scientific conference on AHH, which it
9 sponsored at Downstate Medical School in Brooklyn, and the SAB decided to make this a
10 very low priority going forward.

11 **Q. Can you identify Exhibit JD-090244 and U.S. Ex. 87,142?**

12 A. These documents show the reactions of SAB members to the meeting. In
13 Exhibit JD-090244, Dr. Hans Meier, an SAB member, told Dr. Gardner that he felt the
14 time for the use of AHH as a predictor of human sensibility to cancer was not feasible. In
15 U.S. Ex. 87,142 at page 5, Dr. Leake reported the comments of a number of SAB
16 members at the April 1978 SAB meeting. Among them was Dr. Sommers, the Chairman
17 of the SAB, who said that the AHH conference was the “worst scientific meeting I have
18 ever attended” and that “it’s foolish to spend any more money in this area.” The minutes
19 of the April 1978 SAB meeting said this about the AHH conference, as reflected on page
20 CTR MIN-SAB 000516 of Exhibit JD-090960: “The AHH meeting, held at Downstate
21 Medical School and supported by The Council, was discussed by those members in
22 attendance. The consensus was that the meeting had not lived up to expectations, and
23 that AHH measurements in human lymphocytes do not appear sufficiently promising as
24 an indicator of susceptibility to cancer to warrant more than minimal additional funding

1 for a few special purposes.” CTR did continue some funding of AHH research for
2 several years after January 1978, as I just said.

3 **Q. In paragraph 1150 of the United States’ proposed findings of fact,**
4 **there is reference to a concern within the tobacco companies about “certain short**
5 **term tests on smoke fractions,” and the United States quotes a December 1977**
6 **memorandum by Mr. Pepples of Brown & Williamson. Did CTR fund research into**
7 **smoke fractions of that sort after December 1977?**

8 A. I am not sure what is meant here by “short-term tests” with smoke
9 fractions. CTR did continue to fund research on smoke fractions or components after
10 1977. The principal CTR-funded research in the fractions area was Dr. William
11 Benedict, who was at the University of Texas and then at the University of Southern
12 California. CTR funded Dr. Benedict’s research on smoke fractions research for several
13 years after 1977, continuing into 1981. In continuing his research into smoke fractions,
14 Dr. Benedict worked closely with Dr. Kouri and Dr. Henry of MAI.

15 **Q. Can you identify Exhibits JD-091635 and JD-091636?**

16 A. These are grant summary sheets, from CTR’s files, that show CTR’s
17 funding of Dr. Benedict’s research on smoke fractions from 1975 until June 1981.

18 **F. Citations by the Surgeon General and FDA**

19 **Q. Did the Surgeon General’s Advisory Committee’s 1964 report on**
20 **Smoking and Health, U. S. Ex. 64057, cite the published results of any of the**
21 **scientific research that had been funded through TIRC grants-in-aid?**

22 A. Yes. The 1964 report of the Surgeon General’s Advisory Committee on
23 Smoking and Health cited 38 publications that presented results of research supported by
24 the Tobacco Industry Research Committee. Some of the articles were cited multiple
25 times. As I noted previously, the 1964 report also made use of, and expressly

1 acknowledged as “a basic reference source,” the Larson, Haag and Silvette monograph,
2 *Tobacco: Experimental and Clinical Studies*, which TIRC had funded.

3 **Q. Have you checked each of these 38 citations yourself?**

4 A. I have.

5 **Q. Did later reports by the Surgeon General on smoking and health cite**
6 **any scientific reports acknowledging funding by CTR?**

7 A. Yes. The reports of the U.S. Surgeon General from 1966 up to and
8 including 1994 cited articles that published the results of CTR-funded research
9 approximately 450 times.

10 **Q. Have you checked each of these 450 or so additional citations**
11 **yourself?**

12 A. I have, by comparing the titles of the articles cited at the end of each
13 chapter of the Surgeon General’s reports on smoking and health to the titles of the articles
14 appearing in the abstracts of CTR-funded publications in the CTR Annual Reports.

15 **Q. When the FDA asserted jurisdiction over cigarettes as purported drug**
16 **delivery devices in 1996, did it cite any scientific reports acknowledging funding by**
17 **CTR?**

18 A. Yes. The FDA in its jurisdictional statement in 1996 cited 114 scientific
19 publications by CTR-funded researchers in support of its conclusions. Many of these
20 articles were cited multiple times. In total, there were 198 citations of CTR-supported
21 scientific articles in the 1996 FDA jurisdictional statement.

22 **Q. Have you confirmed that the 114 articles cited by the FDA were in**
23 **fact supported by CTR?**

24 A. Yes. Again, I compared the titles of the 114 articles cited by the FDA in
25 its 1996 report with the titles of the articles in the CTR Annual Reports where the great

1 majority of them appeared. As to the others, I looked at reprints of the articles
2 themselves to confirm the authors' acknowledgement of CTR funding.

3 **Q. Can you identify Exhibit JD-090124?**

4 A. Yes. This is a summary exhibit that shows the citations in the 1964
5 Surgeon General's Advisory Committee Report as well as those in subsequent Surgeon
6 General's reports on smoking and health through 1994 to published reports of research
7 funded by CTR.

8 **Q. Can you identify Exhibit JD-093619?**

9 A. Yes. This exhibit shows the citations in the 1996 FDA jurisdictional
10 statement to published reports of research funded by CTR.

11 **G. Criticisms of Relevance of CTR Research**

12 **Q. Has anyone in the tobacco industry criticized CTR for funding**
13 **irrelevant research?**

14 A. In the 1960s and 1970s, a number of executives and scientists from
15 tobacco companies wrote memoranda in which they asserted that CTR's research was not
16 relevant to smoking or not relevant to the scientific problems facing the industry. These
17 documents are not in CTR's files, but I have seen a number of them in the course of
18 litigation. From the documents I have seen, the most prolific of the company executives
19 who criticized CTR was Mr. Yeaman of Brown & Williamson, and the most prolific of
20 the company scientists who criticized CTR was Dr. Wakeham of Philip Morris.

21 **Q. Did reading any of those criticisms cause you to question the**
22 **relevance of CTR-funded research?**

23 A. Not at all. Many of these criticisms were either expressly based on a
24 scientifically unsophisticated, or at least superficial, analysis of the titles or subjects of
25 CTR grants or the titles of articles published by grantees, or appear to have been the

1 result of analysis on that level. As I have tried to explain, I did not, and it was clear to me
2 that the other Scientific Directors of CTR and the SAB did not, consider that scientific
3 relevance could be determined in that way. Insofar as these criticisms were based on any
4 real analysis of the research that CTR was funding, they appear to me to reflect at most
5 merely disagreements in scientific judgment about what research related to smoking and
6 health should be funded. The SAB and the Scientific Directors of CTR made their
7 judgments as scientists. Others might have chosen to fund different projects. These are
8 judgment calls about which scientists and others can reasonably and legitimately
9 disagree.

10 **Q. Can you identify U.S. Ex. 86005?**

11 A. U.S. Ex. 86005 is a December 11, 1975 letter from Mr. Yeaman to
12 Mr. Clements of The Tobacco Institute, attaching some comments that Mr. Yeaman said
13 he had just made at a meeting of CTR members. Mr. Yeaman recently had become the
14 Chairman of CTR.

15 **Q. In U.S. Ex. 86005, did Mr. Yeaman criticize the relevance of the**
16 **research funded by CTR, as he did in some other documents?**

17 A. No. To the contrary, Mr. Yeaman said on page 3 of U.S. Ex. 86005 that
18 when he was at Brown & Williamson he was “a very glib critic” of CTR. One of the
19 things he criticized CTR for was the lack of relevance of its research. On this issue,
20 Mr. Yeaman said in 1975, on page 2 of this exhibit, “I have sat through a two-day
21 conference of very distinguished scientists on a scientific problem so esoteric that this
22 layman didn’t understand a word of it. But what I did understand was that it was a
23 discussion totally germane to our problems, conducted by highly qualified people in an
24 air of complete respect for their host, the CTR.”

1 **Q. Since you have been with CTR, has any member of the SAB criticized**
2 **CTR for funding research that was not relevant to smoking and health?**

3 A. To the best of my knowledge, no SAB member has done that. Certainly
4 no SAB member has made such a criticism at any SAB meetings that I have attended.

5 **Q. Who was Dr. John Craighead?**

6 A. Dr. Craighead, a pathologist at the University of Vermont, was a member
7 of the SAB for a brief period, in 1976 and 1977. Dr. Craighead served as an outside
8 reviewer of grant applications to CTR on a number of occasions after that.

9 **Q. Are you aware of any criticism by Dr. Craighead of the relevance of**
10 **CTR-funded research?**

11 A. I have read Dr. Craighead's deposition from a case in the 1990s, in which
12 he testified that he resigned from the SAB in 1977 because the research being funded by
13 CTR at that time put too much emphasis on the basic causes of smoking-related diseases
14 and not enough on tobacco itself. However, so far as I can tell, Dr. Craighead never said
15 any of those things while he was on the SAB. There is correspondence from Dr.
16 Craighead to CTR, but it doesn't mention the concerns that he testified about 15 or 20
17 years later.

18 **Q. Can you identify Exhibits JD-046447, JD-046467, JD-090763, JD-**
19 **090767, JD-090769, and JD-090774?**

20 A. These are letters between and to Dr. Craighead and Dr. Gardner in CTR's
21 files, written in 1976, 1977, 1979, 1980 and 1984. In the later letters, Dr. Craighead
22 expressed an interest in re-joining the SAB.

23 **Q. In any of these documents, did Dr. Craighead tell CTR why he was**
24 **resigning from SAB?**

1 A. Yes, in Exhibit JD-090767, which is dated October 26, 1977, he
2 mentioned other commitments and time conflicts. He made no mention of his views
3 about the relevance of CTR-funded research.

4 **Q. Moving forward to 1986, when Dr. DeVita of the NCI instructed**
5 **Dr. Howley that he no longer could serve on the SAB, did he communicate to CTR**
6 **that NCI's position was that CTR was funding scientific research that was**
7 **irrelevant to smoking and health?**

8 A. No. In fact, in Exhibit JD-093887, Dr. DeVita's June 13, 1986 letter that I
9 discussed earlier, Dr. DeVita said nothing about the lack of relevance of the research
10 funded by CTR. Dr. DeVita said only that the reason Dr. Howley could not serve on the
11 SAB was that the NCI was opposed to having Dr. Howley serve on a board that could
12 benefit the tobacco industry.

13 **Q. Other than Dr. DeVita, have there been scientists employed by the**
14 **U.S. Government who were familiar with the kinds of research CTR was funding?**

15 A. Yes, quite a few. Each of the four SAB members who worked for NCI
16 certainly was very familiar with the research CTR was funding. Before them, Dr. Heller
17 and Dr. Ray of the NCI were familiar with the research program. I would add the many
18 scientists from the NCI who attended CTR conferences as well as those who reviewed
19 applications for grants-in-aid; the staff and members of the 1962 Surgeon General's
20 Advisory Committee; the authors of the other Surgeon General's reports on Smoking and
21 Health from 1966 to 1994, who cited hundreds of CTR-funded scientific articles; the
22 authors of the FDA jurisdictional statement on nicotine and cigarettes, who did the same;
23 Dr. David Kessler, who was FDA Commissioner at the time that statement was
24 promulgated; Dr. Shopland of the Office of Smoking and Health of the U.S. Department
25 of Health & Human Services; and Dr. Tso of the U.S. Department of Agriculture.

1 **Q. Are you aware of any scientist employed by the United States who,**
2 **other than in the course of litigation, has criticized CTR’s research program as**
3 **irrelevant?**

4 A. No.

5 **Q. During the time that you were with CTR and Dr. Howley was on the**
6 **SAB, did Dr. Howley ever say, to your knowledge, that the research that CTR**
7 **funded was irrelevant to smoking and health?**

8 A. No, he did not.

9 **Q. Can you identify Exhibit JD-094003?**

10 A. Exhibit JD-094003 is a review from CTR’s grant files written by
11 Dr. Howley in connection with a grant application submitted to CTR by Dr. Harold
12 Varmus of the University of California at San Francisco Medical School, later a Nobel
13 Prize winner. Dr. Varmus sought a grant to study the role of tumor-promoter genes,
14 known as oncogenes, in the formation of cancer. According to the SAB meeting minutes,
15 Exhibit JD-090960, Dr. Varmus’s grant application was considered at the SAB meeting
16 held on March 28-30, 1984, and so this memorandum was written sometime shortly
17 before those dates. In this memorandum, Dr. Howley gave Dr. Varmus’s grant
18 application an “A” for merit and an “A” for relevance and said “[t]he work is highly
19 relevant to the research interests of the CTR.” So Dr. Howley had an understanding, or
20 believed he had an understanding, of what was relevant from CTR’s point of view, and
21 his view that Dr. Varmus’s research was relevant was a factor in Dr. Howley’s high
22 rating of the application. CTR funded this grant application at the level of \$120,000, the
23 funding level that Dr. Howley recommended.

1 **Q. Please take a look at pages CTR MIN-SAB 000662 through CTR**
2 **MIN-SAB 000672 of Exhibit JD-090960. What do these pages show about the grant**
3 **application that is discussed by Dr. Howley in Exhibit JD-094003?**

4 A. Pages CTR MIN-SAB 000662 through CTR MIN-SAB 000672 of Exhibit
5 JD-090960 are the minutes of the SAB meeting in March 1984, at which Dr. Varmus's
6 grant application, No. 1687, was discussed and voted upon by the SAB. Pages CTR
7 MIN-SAB 000666 and CTR MIN-SAB 000667 contain the favorable SAB vote on
8 Dr. Varmus's application. Page CTR MIN-SAB 000671 contains a record of the
9 Scientific Director's decision to fund Dr. Varmus's grant application, No. 1687.

10 **Q. Was the research proposed by Dr. Varmus's grant application basic**
11 **research?**

12 A. Definitely. Dr. Varmus's grant proposal involved a basic study of the
13 genetic control of cell division that goes awry in cancer.

14 **H. Dr. Glenn's 1994 Congressional Testimony**

15 **Q. Have you read Dr. Glenn's 1994 testimony before the House**
16 **Committee on Commerce Subcommittee on Energy and the Environment?**

17 A. Yes, I have.

18 **Q. Doesn't Dr. Glenn's statement that no more than 10 percent of CTR's**
19 **grants had anything to do with smoking or tobacco at least suggest to you that**
20 **Dr. Glenn did not believe that the research CTR supported had anything to do with**
21 **smoking and health?**

22 A. No, it does not.

23 **Q. Why not?**

24 A. Dr. Glenn's testimony on this point pertained to such matters as whether
25 the kinds of experiments CTR funded used cigarette smoke or tobacco smoke

1 constituents, or whether CTR was funding epidemiological studies that compare the
2 health of smokers to that of nonsmokers. That kind of research was done decades ago by
3 scientists both supported and not supported by CTR. It did not surprise me that
4 Dr. Glenn in 1994 said that CTR was no longer funding much of that kind of research.

5 **VII. DID CTR SPECIAL PROJECTS AFFECT**
6 **THE SAB GRANT PROGRAM?**

7 **A. Dr. McAllister's Personal Knowledge**

8 **Q. What are CTR Special Projects?**

9 A. From about 1966 until 1991, at the request of CTR's member companies,
10 CTR acted as the administrative vehicle for the funding of scientific research projects that
11 were not part of the CTR grant-in-aid program that I have been testifying about. These
12 research projects were called CTR Special Projects. The procedures for review and
13 evaluation of research proposals by the Scientific Advisory Board did not apply to CTR
14 Special Projects.

15 **Q. How do you know about CTR Special Projects?**

16 A. Either when I interviewed for the position of Associate Research Director,
17 or shortly after I arrived at CTR in 1983, someone with CTR that I spoke to —
18 Dr. Sommers, Dr. Gardner, Mr. Hobbs (the Chairman of CTR) or Mr. Gertenbach (the
19 Vice President of CTR) — explained that, in addition to CTR grants-in-aid that were
20 awarded on the basis of peer review by the Scientific Advisory Board, CTR handled the
21 funding arrangements for some scientific research projects at the request of its member
22 companies, and that they were called CTR Special Projects. In the 1980s and early
23 1990s, I heard occasional references to CTR Special Projects. So far as I can recall,
24 during that period I did not learn anything about any specific CTR Special Projects. But I
25 was aware at that time of some of the basic facts about CTR Special Projects: that CTR

1 Special Projects were not part of CTR's grant-in-aid program, that CTR performed a
2 limited role with respect to the administration of CTR Special Projects, that they were not
3 reviewed by the Scientific Advisory Board, and that the funds provided for CTR Special
4 Projects were obtained and disbursed completely separately from those provided by
5 CTR's members for use in the CTR grant-in-aid program.

6 In February 1992, Judge Sarokin wrote an opinion that was widely reported in the
7 media, in which he discussed CTR Special Projects. In February 1993, an article about
8 CTR in *The Wall Street Journal* extensively discussed CTR Special Projects. Beginning
9 in December 1993, I was deposed numerous times in smoking and health cases. In most
10 of these depositions, the plaintiffs' lawyers asked me lots of questions about CTR Special
11 Projects, and most of what they asked about was not familiar to me. In September 1994,
12 CTR responded to inquiries by a subcommittee of the United States House of
13 Representatives Committee on Commerce, chaired by Representative Henry Waxman.
14 CTR prepared and submitted to the subcommittee a list of all the CTR Special Projects it
15 had any information about, with the publications resulting from each CTR Special Project
16 that had been identified. I reviewed CTR's response to Representative Waxman's
17 subcommittee, including the list of CTR Special Projects, after it was submitted to the
18 subcommittee.

19 In an effort to learn more about CTR Special Projects, I began in 1997 to review
20 CTR's files on specific CTR Special Projects and the published findings of CTR Special
21 Project research that had been identified. Since 1997, I have reviewed all the documents
22 relating to CTR Special Projects that were in CTR's files, and I have become familiar
23 with the work of many of the scientists who received funding support through CTR
24 Special Projects. Based on this knowledge, beginning in 1997 I have testified several
25 times in depositions and at trials about CTR Special Projects.

1 **Q. Can you identify U.S. Ex. 53303?**

2 A. U.S. Ex. 53303 is the list of CTR Special Projects that CTR submitted to
3 Representative Waxman’s subcommittee in September 1994. It lists the title and
4 principal investigator for each CTR Special Project, the dates and amounts of funding
5 that were provided, and the scientific publications and presentations resulting from each
6 CTR Special Project.

7 **Q. According to CTR’s records, how many CTR Special Projects were**
8 **funded?**

9 A. The first page of U.S. Ex. 53303 says that CTR has in its files information
10 about 120 CTR Special Projects. That is about 9% of 1,335, which is the number of CTR
11 grants-in-aid. Some 69 researchers were funded through CTR Special Projects. That is
12 less than 6% of 1,190, which is the approximate number of principal investigators who
13 were funded as part of CTR’s grant-in-aid program.

14 **Q. What was the total amount of funding provided for CTR Special**
15 **Projects?**

16 A. Approximately \$18 million. That is just under 6% of \$317 million, the
17 approximate total funding provided to researchers in the CTR grant-in-aid program,
18 including CTR’s research contracts.

19 **Q. What is shown in Demonstrative Exhibit JDEM-010286?**

20 A. This exhibit summarizes some of the basic statistics about CTR Special
21 Projects and compares them to the corresponding statistics about CTR grants-in-aid and
22 research contracts.

23 **Q. Can you identify Exhibit JD-090143?**

24 A. Exhibit JD-090143 is a handwritten document entitled “Procedure for
25 Special Projects.” Exhibit JD-090143 came from a file at CTR that was maintained by

1 Lorraine Pollice, a long-time CTR employee who helped administer CTR Special
2 Projects. It explains the fundamentals of how CTR Special Projects were administered. I
3 recognize the writing as that of Mr. Hoyt, who was CTR's President from 1981 to 1984.

4 **Q. Can you read CTR's procedure for initiating CTR Special Projects**
5 **that is set forth in Exhibit JD-090143?**

6 A. "1. A description of the proposed project and its cost is presented to CTR
7 by X for appraisal by the Scientific Director.

8 "2. If approved by the Scientific Director the person who presented it is
9 responsible for obtaining its approval by the General Counsel of the participating
10 companies.

11 "3. When approved by the participating companies X advises us and
12 arranges for the investigator to apply for funding at which time the investigator provides
13 CTR with a protocol and budget request.

14 "4. CTR writes a letter of approval after checking with the Scientific
15 Director.

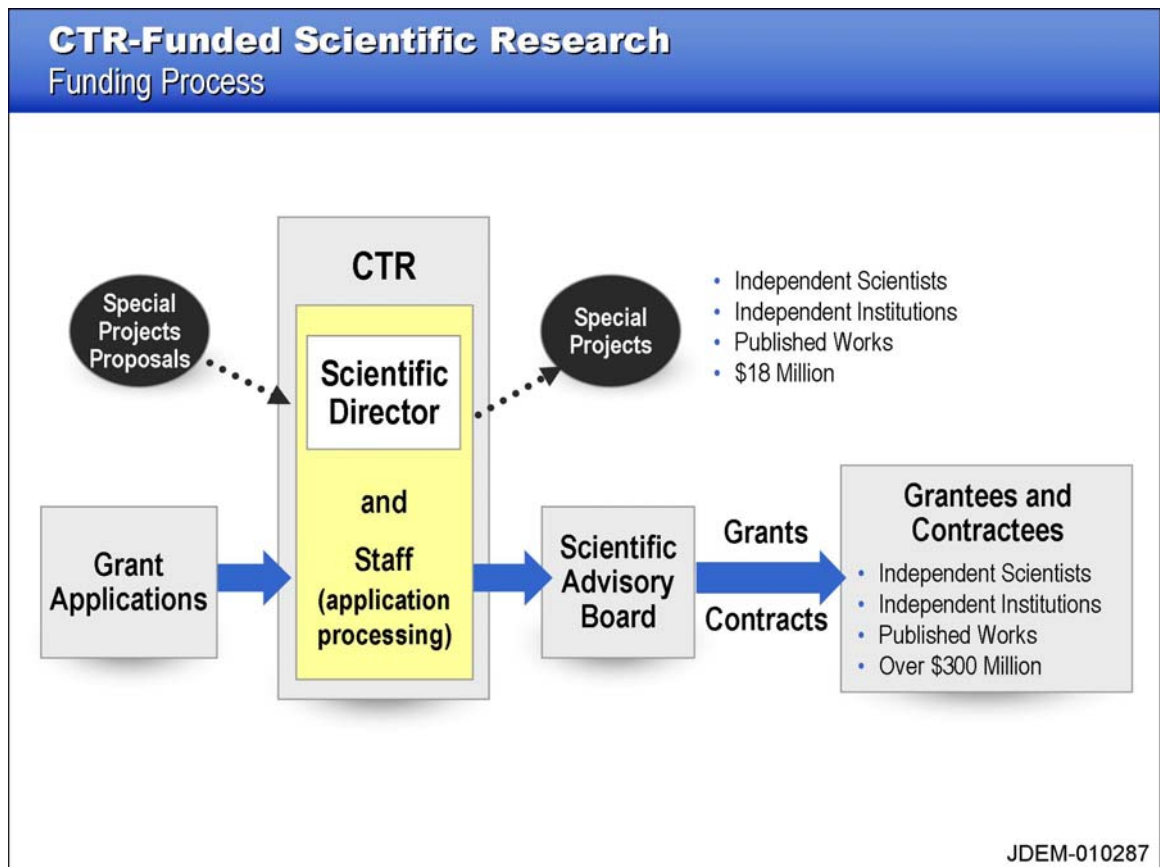
16 "5. Funding for Special Projects is accomplished by submission of a
17 request for funds, based on Maxwell figures, as needed, together with a Special Project
18 Fund Summary, a detailed compilation of outstanding commitments."

19 **Q. Can you identify Exhibit JD-093897?**

20 A. Exhibit JD-093897 is a memorandum dated June 1, 1976 from
21 Dr. Gardner, CTR's Scientific Director, to Dr. Hockett, CTR's Research Director, and
22 Mr. Hoyt, CTR's Executive Vice President. This memorandum reflects Dr. Gardner's
23 review and approval of a renewal of CTR Special Project No. 71. It is illustrative of the
24 documents in CTR's files that show how the CTR Scientific Director reviewed CTR
25 Special Projects under the Procedure for Special Projects discussed above.

1 **Q. What is shown on Demonstrative Exhibit JDEM-010287, which is**
2 **reprinted below?**

3 A. This exhibit includes what is shown in Demonstrative Exhibit JDEM-
4 010280, which showed the general process for approval of grants and contracts reviewed
5 by the SAB, and puts that next to an illustration of the general way in which CTR Special
6 Projects were funded.



7

8 **Q. While you were the Scientific Director of CTR from 1991 to 1999, did**
9 **you ever review an application for a CTR Special Project?**

10 A. No. By the time I became Scientific Director in 1991, there no longer
11 were any CTR Special Projects. According to CTR's files, the last CTR Special Project

1 was approved in 1986, and CTR's last payment to a CTR Special Project researcher was
2 made in April 1990.

3 **Q. Is the procedure described in Exhibit JD-090143 consistent or**
4 **inconsistent with what you know about CTR Special Projects?**

5 A. It is completely consistent.

6 **B. CTR Special Projects and the Grant Program**

7 **Q. What was the relationship between CTR Special Projects and CTR's**
8 **funding of research as part of its grant-in-aid program?**

9 A. The two programs were completely separate. As I explained earlier, the
10 budget for the CTR grant-in-aid program was set each year by the Board of Directors
11 after the directors heard the recommendation of the Scientific Director and CTR's
12 Chairman. The funds were then provided to CTR by the cigarette manufacturers based
13 on their shares of the U.S. cigarette market. None of this money was used to fund CTR
14 Special Projects. Funds for CTR Special Projects also came from CTR's manufacturer
15 members, but were provided through an entirely separate process, based on the
16 expenditures for individual CTR Special Projects that were approved by the companies.

17 **Q. When CTR listed or described CTR-funded research projects in press**
18 **releases and in its Annual Reports, did those lists and descriptions include CTR**
19 **Special Projects?**

20 A. No, they did not. The subject of the Annual Reports and press releases
21 was research funded through CTR's grant-in-aid program and research contracts, and it
22 was limited to that research. Similarly, the statistics about numbers of projects and
23 researchers funded and the amounts of total funding in CTR's press releases and Annual
24 Reports did not include CTR Special Projects.

1 **Q. What effect, if any, did CTR Special Projects have on the CTR grant-**
2 **in-aid program?**

3 A. To the best of my knowledge, they had no effect. I say that based on my
4 involvement in the grant-in-aid program from 1983 to 1991 as an Associate Research
5 Director. Even though CTR Special Projects were still being funded at that time, so far
6 as I could tell that did not have any impact on the grant-in-aid program. The amount of
7 funding budgeted by the Board of Directors for the CTR grant-in-aid program increased
8 over the years, irrespective of whether CTR Special Projects also were being funded, and
9 those annual budget amounts do not appear to have been affected by expenditures on
10 CTR Special Projects. After I arrived at CTR in 1983, I heard numerous discussions
11 about CTR's annual research budget. I never heard any suggestion that the amount of
12 that budget was affected by amounts spent on CTR Special Projects. CTR Special
13 Projects had no effect on the SAB's review or evaluation of grant applications since the
14 SAB was not involved in CTR Special Projects. My extensive review of CTR's files,
15 including the minutes of SAB meetings and hundreds of grant files, leads to the same
16 conclusion: CTR Special Projects had no effect on CTR's funding of research grants-in-
17 aid.

18 **C. CTR Special Projects Attributions**

19 **Q. Could you turn to page CTR SP-FILES 025224 of Exhibit JD-093722,**
20 **which is a letter to Dr. Alvan R. Feinstein, M.D., dated May 5, 1988, and read the**
21 **third paragraph of that letter?**

22 A. “Our records will again designate this undertaking as a Special Project of
23 The Council for Tobacco Research – U.S.A., Inc. rather than a grant-in-aid. If a credit
24 line should be inserted in any future publications, it should be so worded to avoid its

1 being confused with the grant program of the Scientific Advisory Board.” The emphasis
2 was in the original letter.

3 **Q. Was similar language contained in each of the letters CTR sent to the**
4 **scientists who received CTR Special Projects funding?**

5 A. Yes. In all of them, CTR said that the research project was being
6 designated as a “Special Project of the Council for Tobacco Research” and instructed the
7 researcher that this wording should be used in the credit line in any publication that
8 results from the research. Most of these letters explained that the purpose of CTR’s
9 instruction to identify the research as a Special Project of CTR was to avoid any
10 confusion with the grant-in-aid program of CTR.

11 **Q. Are you aware of any instructions ever being given by CTR or anyone**
12 **else to any CTR Special Projects recipient not to include this funding**
13 **acknowledgment in his or her publications?**

14 A. To the best of my knowledge, that never happened.

15 **Q. Have you reviewed the funding acknowledgment portions of the**
16 **scientific articles resulting from CTR Special Projects that are cited in U.S. Ex.**
17 **53303?**

18 A. Yes.

19 **Q. In the acknowledgment portions of those articles, did the CTR Special**
20 **Projects recipients who published their research findings include the**
21 **acknowledgement wording that was requested by CTR for papers that reported on**
22 **research that was funded through CTR Special Projects, as reflected in the letters in**
23 **Exhibit JD-093722?**

24 A. They did not do that consistently. Some of these acknowledgments are the
25 same as, or very similar to, the one that CTR instructed the scientists to use in

1 Exhibit JD-093722. Some of the acknowledgments do not mention CTR at all. Some of
2 the acknowledgments changed the wording that CTR requested. In the same way, a
3 number of the scientists who were funded through the grant program neglected to identify
4 the research they published as supported by CTR, or got the wording garbled.

5 **D. Disclosures about CTR Special Projects**

6 **Q. Did anyone ever tell you that there was anything secret about CTR**
7 **Special Projects?**

8 A. No.

9 **Q. Were the members of the Scientific Advisory Board of CTR told of**
10 **the existence of CTR Special Projects?**

11 A. Yes. The minutes of the SAB meeting in December 1965 reflect that the
12 members of the SAB were informed about plans to initiate CTR Special Projects.

13 **Q. Were any of the NCI scientists who served as members of the SAB**
14 **present at that meeting?**

15 A. Yes. Dr. Andervont was present, according to the minutes.

16 **Q. Can you identify pages CTR MIN-SAB 000251-255 of Exhibit JD-**
17 **090960?**

18 A. These pages are the minutes of the SAB's meeting on December 10-12,
19 1965. The first page lists Dr. Andervont as one of the members who was in attendance.

20 **Q. Would you please turn to page 5 of the minutes, which is at CTR**
21 **MIN-SAB 000255, and read paragraph number 11?**

22 A. "The Scientific Director discussed with the Board plans for additional
23 contract and special projects research, to be instituted at the discretion of the scientific
24 staff. He anticipated these to be pilot studies, short-term projects and others of a
25 character which may not suit themselves to grants-in-aid. These projects would be

1 budgeted separately from the grants-in-aid program of the Board, and any publication
2 resulting would bear an imprimatur distinct from that of the Scientific Advisory Board's
3 program. He explained that the Board would be kept informed of work going forward
4 under this program."

5 **Q. Are there other documents in CTR's files that show that members of**
6 **the SAB were aware of CTR Special Projects?**

7 A. Yes. Members of the SAB were informed from time to time about
8 specific CTR Special Projects when they reviewed grant applications submitted by
9 former or current recipients of CTR Special Projects funding. The application forms for
10 grants-in-aid changed over time; many of those forms required the scientists applying for
11 CTR grants to disclose their current funding sources. In addition, in providing
12 information or evaluation opinions to the SAB about grant-in-aid applicants who had
13 received CTR Special Projects funding, CTR's Scientific Director, members of the
14 scientific staff and SAB members on occasion mentioned that a CTR grant applicant had
15 received CTR Special Projects funding.

16 **Q. Can you identify Exhibits JD-013234, JD-013235, JD-013236, U.S.**
17 **33,048, JD-013238, JD-001767, and JD-013239 through JD-013244?**

18 A. These are documents from CTR's files that show that a number of
19 members of the SAB were informed, at various times, of the fact that some applicants for
20 CTR grants-in-aid had previously received funding pursuant to CTR Special Projects.

21 Exhibit JD-013234 is a 1971 memorandum from Dr. Hockett to four SAB
22 members (Dr. Bing, Dr. Cattell, Dr. Jacobson and Dr. Sommers) about the CTR grant-in-
23 aid application of Dr. Clifford Barger of Harvard Medical School. In Exhibit JD-013234,
24 Dr. Hockett stated, "This application has a considerable history, beginning insofar as the
25 Council is concerned, with a small Special Project Grant to explore the effect of

1 continuous stimulation of the renal sympathetics in producing persistent hypertension in
2 dogs.”

3 Exhibit JD-013235 is a 1972 application for a CTR grant-in-aid submitted by
4 Dr. Jerome Kleinerman of Case Western Reserve University, in which Dr. Kleinerman
5 stated at page 2c, TIF number 50094097, that he had recently “been awarded funds from
6 the Council for Tobacco Research U.S.A., Inc.” The same page contains a handwritten
7 note by Dr. Hockett, then the Acting Scientific Director of CTR, explaining that
8 Dr. Kleinerman was referring to a “‘Special Project Grant’ financed by the principals [of
9 CTR] apart from the C.T.R. budget.” Exhibit JD-013236 is a cover memorandum from
10 Dorothea Cohen to four SAB members (Dr. Loosli, Dr. Gardner, Dr. Lynch and
11 Dr. Rienhoff), to which she attached Dr. Kleinerman’s application containing
12 Dr. Hockett’s note.

13 U.S. Ex. 33,048 is a memorandum, dated March 5, 1975, from Dr. Gardner to two
14 SAB members (Dr. Huebner and Dr. Sommers), as well as to Dr. Hockett and Dr. Stone
15 of CTR’s scientific staff, regarding a CTR grant-in-aid application from Dr. George Wolf
16 of the Massachusetts Institute of Technology. In U.S Exhibit 33,048, Dr. Gardner stated,
17 “This proposal results from a special project that was supported last year at the instigation
18 of the industry.”

19 Exhibit JD-013238 is a memorandum, dated March 11, 1980, from Dr. Gardner to
20 three SAB members (Dr. Feldman, Dr. Heubner and Dr. Hans Meier), as well as to
21 Dr. Hockett, Dr. Donald Ford, and Dr. David Stone of the CTR scientific staff) on a CTR
22 grant-in-aid application from Dr. Stewart A. Lonky of the University of California, San
23 Diego. In Exhibit JD-013238, Dr. Gardner stated that the preliminary work for
24 Dr. Lonky’s proposal “has already been done and is reported in a preprint (supported by
25 CTR Special Project # 87 [K.M. Moser]).” Exhibit JD-001767 is a copy of Dr. Hockett’s

1 notes of the April 1980 SAB meeting, in which he stated at page 9, that the “special
2 project history” of Dr. Lonky’s grant application was discussed.

3 Three of these documents pertain to a 1981 application for a CTR grant-in-aid by
4 Dr. Lawrence Kupper of the University of North Carolina. Exhibit JD-013239 is the
5 application submitted by Dr. Kupper, in which he stated at page 9, TIF number
6 50149146, that his “[o]ther sources of financial support” included “Council for Tobacco
7 Res. Special Projects # 101” and “Council for Tobacco Res. Special Projects # 102R1.”
8 Exhibit JD-013240 is a memorandum from David Stone of CTR, which shows that
9 Dr. Kupper’s grant application was sent to a committee of the SAB consisting of
10 Dr. Gardner, Dr. Huebner, Dr. Jacobson and Dr. Lynch. TIF 50149101. Exhibit JD-
11 013241 is a memorandum, dated March 10, 1981, from Dr. Gardner to four SAB
12 members (Dr. Huebner, Dr. Jacobson, Dr. Lynch and Dr. Sommers), in which
13 Dr. Gardner stated that Dr. Kupper’s assistant, Dr. Joseph Janus, “had been supported by
14 a Special Project administered by The Council.”

15 Exhibit JD-013242 is a 1987 application for a CTR grant-in-aid from Dr. William
16 Gutstein of New York Medical College, in which Dr. Gutstein stated at page 6, TIF
17 number 40430643, that he was receiving support through “Council for Tobacco Research
18 SP#122.” Exhibit JD-013243 is a memorandum from Dr. Stone, which shows that
19 Dr. Gutstein’s application was forwarded to SAB members Dr. Bing and Dr. Jacobson for
20 their review.

21 Exhibit JD-013244 is a memorandum, dated June 19, 1981, from Dr. Gardner to
22 the other members of the Executive Committee of the SAB (Dr. Bing, Dr. Feldman,
23 Dr. Jacobson and Dr. Sommers), in which Dr. Gardner said that an application from
24 Dr. Gerhard Schrauzer of the University of California, San Diego, might be outside the
25 scope of the CTR grant program and that “[t]his came in as a special project.”

1 A. I know a couple of them by reputation. Dr. Alvan Feinstein, an
2 epidemiologist, was a professor at the Yale School of Medicine. As I mentioned earlier,
3 Dr. Feinstein won the Gairdner Award in 1993 for his leadership role in establishing
4 clinical epidemiology as a scientific discipline. Dr. Hans Selye is someone whose
5 reputation I learned of when I was in graduate school, where his work was a standard part
6 of the physiology curriculum. He was one of the most famous physiologists of recent
7 times. His theory on the general adaptation to stress was widely studied for decades, and
8 lay the groundwork for how the body responds to stress.

9 **Q. Are you familiar with the reputations of any of the research**
10 **institutions with which the scientists who received funding support through CTR**
11 **Special Projects were affiliated?**

12 A. Yes. Many of these scientists were affiliated with institutions that had
13 outstanding reputations for biomedical research, including Harvard Medical School, Yale
14 Medical School, the medical schools of the University of California at San Francisco and
15 at San Diego, the Karolinska Institute, the Massachusetts Institute of Technology, Baylor
16 College of Medicine, Georgetown University Medical Center, Harvard University School
17 of Public Health, Washington University School of Medicine, the University of Southern
18 California School of Medicine, the University of London, M.D. Anderson Cancer Center
19 at the University of Texas, Case Western Reserve University, Tulane Medical Center,
20 Louisiana State University Medical Center, Emory University, and the University of
21 North Carolina School of Public Health. Two of the commercial laboratories where
22 scientists received CTR Special Projects funding, Battelle Laboratories and Oak Ridge
23 National Laboratory, also had outstanding reputations for biomedical research. A
24 number of CTR Special Projects recipients were affiliated with specialized research
25 institutions, which appear to have been for-profit operations that I am not familiar with.

1 **Q. Can you identify Exhibit JD-095522?**

2 A. Exhibit JD-095522 is a contract between CTR and Martin Marietta Energy
3 Systems, Inc, which is denominated CTR Special Project No. 132. The first few
4 paragraphs explain that Martin Marietta entered into the contract with CTR pursuant to
5 Martin Marietta's contract with the United States Department of Energy, and that the
6 work under the contract would be performed by Oak Ridge National Laboratory. As I
7 explained earlier, Oak Ridge was a U.S. Department of Energy facility. At the time that
8 CTR Special Project No. 132 was in effect, Oak Ridge was operated by Martin Marietta.

9 **Q. Are you familiar with any of the scientific journals in which CTR**
10 **Special Projects researchers published their findings?**

11 A. Yes. Some of these findings were published in very highly respected
12 peer-reviewed journals, such as *The Journal of the National Cancer Institute*, *The*
13 *Journal of the American Medical Association*, *The British Medical Journal*, *Lancet*,
14 *Science*, *Cancer*, *Nature*, *Virology*, *Cancer Research* and *Proceedings of the National*
15 *Academy of Sciences*.

16 **Q. Did any of the scientists who received CTR Special Projects funding**
17 **publish scientific results that linked cigarette smoking to various diseases in**
18 **humans?**

19 A. Yes. Dr. John Carter of Case Western Reserve University and
20 Dr. Feinstein of Yale were CTR Special Projects recipients. Both published research
21 demonstrating that the association of smoking and lung cancer was not, as some had
22 suspected, an artifact of interview bias. Dr. Lars Friberg of the world-renowned
23 Karolinska Institute in Stockholm used his CTR Special Projects funding to publish a
24 lengthy monograph based on analysis of the Swedish Twin Registry. He reported strong
25 correlations between smoking and both lung cancer and heart disease. Dr. John

1 Salvaggio of Tulane Medical School in New Orleans was a CTR Special Projects
2 recipient who published results indicating that smoke-sensitive subjects with asthma
3 experienced a significant decline in pulmonary function when exposed to environmental
4 tobacco smoke. Dr. Charles D. Puglia, of the Medical College of Pennsylvania published
5 research findings deriving from his CTR Special Projects research showing that, in
6 animals, cigarette smoke exposure challenged the antioxidant defense systems of the
7 lung.

8 **Q. What is shown in Demonstrative Exhibits JDEM-010288 and JDEM-**
9 **010289?**

10 A. These exhibits have excerpts from the articles of CTR Special Projects
11 recipients that I just identified.

12 **Q. Can you identify Exhibits JD-094633, JD-094503, JD-094639, JD-**
13 **094746, JD-010268, JD-094750, JD-094684 and JD-094685?**

14 A. Exhibits JD-094633, JD-094503, JD-094639, JD-094746, JD-010268, JD-
15 094750, JD-094684, and JD-094685 are the published articles and abstracts by CTR
16 Special Projects recipients that I just referred to.

17 **Q. Were any of the research findings by CTR Special Projects recipients**
18 **cited in reports of the federal government on smoking and health?**

19 A. Yes. The reports on Smoking and Health of the Surgeon General of the
20 United States cited 21 CTR Special Projects publications from 1979 to 1990.

21 **Q. Can you identify Exhibit JD-090124, and, in particular, the footnotes**
22 **and accompanying text that appear at pages 8, 11, 14-16, 19, 22-23, 25, 30, 33, 37, 43,**
23 **45-46 and 50.**

24 A. This exhibit shows the citations U.S. Surgeon Generals' reports to
25 publications of research funded by CTR. This exhibit, and, in particular the footnotes

1 and accompanying text, identify 21 papers reporting upon CTR Special Projects that were
2 in turn cited by the Surgeon General in one or more reports on smoking and health.

3 **F. Federal Government Contacts**

4 **Q. Did any recipients of CTR Special Projects funding also receive**
5 **funding from federal government agencies for their scientific research?**

6 A. Many of them did. At least 40 of the scientific articles that resulted from
7 CTR Special Projects funding acknowledged funding from United States agencies,
8 including the NCI, the NIH, the National Heart and Lung Institute, and the United States
9 Public Health Service.

10 **Q. Did any CTR Special Projects recipients have other connections with**
11 **the federal government?**

12 A. Yes. Some of them held prominent positions within funding agencies of
13 the government.

14 **Q. Can you identify Exhibits JD-093467 and JD-093514?**

15 A. Exhibits JD-093467 and JD-093514 are the c.v.'s of Dr. Hugh H.
16 Fudenberg and Dr. John Salvaggio, two researchers who received CTR Special Projects
17 funding.

18 **Q. What do these documents show with respect to Dr. Fudenberg's and**
19 **Dr. Salvaggio's connections with the federal government?**

20 A. Dr. Fudenberg was a member of the NIH's National Task Force on
21 Multiple Myeloma and Chronic Leukemia as well as a member of the NIH's Committee
22 on Immunologic Standardization. Dr. Salvaggio was an NIH fellow, a member of the
23 NHLBI Pulmonary Disease Advisory Council as well as chairman of the NHLBI's
24 Immunologically Mediated Pulmonary Diseases Council.

1 **Q. How do you know about the relationships between CTR Special**
2 **Projects recipients and the federal government?**

3 A. This information came from a number of sources. Some of the scientific
4 publications cited in U.S. Ex. 53303 state that recipients of CTR Special Projects funding
5 also received funding from federal government agencies.

6 There are documents in CTR's files, including c.v.'s submitted to CTR by CTR
7 Special Projects researchers, that show connections with the federal government such as
8 the ones we just discussed.

9 Several years ago, I discovered that one of the websites of the NIH contains what
10 it calls the CRISP database, which lists grant projects funded by the NIH. The database
11 is searchable by the name of the principal investigator. We have searched that database
12 for listings of NIH grants to CTR Special Projects recipients.

13 There are other sources of publicly available information, such as the websites at
14 these researchers' institutions that refer to the fact that some of them received funding
15 from the U.S. government agencies.

16 **Q. Can you identify Exhibits JD-094600, JD-094641, JD-094642, JD-**
17 **094679, JD-094691, JD-094697, JD-094700, JD-094740 and JD-094793?**

18 A. Yes. Each of these exhibits is a scientific article that acknowledges
19 funding of research by a CTR Special Projects recipient by one or more federal
20 government agencies.

21 **Q. Can you identify Exhibits JD-093438, JD-093450, JD-093452, JD-**
22 **093457, JD-093458, JD-093459, JD-093460, JD-093467, JD-093470, JD-093473, JD-**
23 **093477, JD-093479, JD-093481, JD-093482, JD-093484, JD-093486, JD-093488, JD-**
24 **093491, JD-093493, JD-093494, JD-093497, JD-093500, JD-093501, JD-093503, JD-**

1 **093504, JD-093508, JD-093509, JD-093513, JD-093514, JD-093517, JD-093519, JD-**
2 **093522 and JD-093524?**

3 A. Each is a c.v. from CTR's files that shows that the CTR Special Projects
4 recipient received funding from an agency of the federal government, was employed by
5 the federal government, or served as a consultant to an agency of the federal government.

6 **Q. Can you identify Exhibits JD-093439, JD-093443, JD-093445, JD-**
7 **093449, JD-093454, JD-093456, JD-093461, JD-093463, JD-093464, JD-093466, JD-**
8 **093469, JD-093472, JD-093476, JD-093480, JD-093487, JD-093489, JD-093490, JD-**
9 **093492, JD-093495, JD-093498, JD-093499, JD-093502, JD-093505, JD-093507, JD-**
10 **093510, JD-093515, JD-093516, JD-093518, JD-093520, JD-093523 and JD-093525?**

11 A. Each is a printout from the NIH's CRISP database that shows that an
12 agency of the federal government provided funding support for scientific research by a
13 CTR Special Projects recipient.

14 **Q. What is shown in Demonstrative Exhibit JDEM-010292?**

15 A. This exhibit lists a number of the other agencies that provided research
16 funding to scientists who received funding through CTR Special Projects. It includes
17 agencies of the United States government as well as institutions such as the World Health
18 Organization, the American Cancer Society, the American Heart Association, and the
19 Medical Research Council of Canada.

20 **G. CTR Special Projects and CTR's Stated Purpose**

21 **Q. From your perspective as a member of CTR's scientific staff from**
22 **1983 on, and as CTR's Scientific Director from 1991 until 1999, was CTR's role in**
23 **administering CTR Special Projects inconsistent with the statement in CTR's**
24 **certificate of incorporation that CTR's purpose was to "aid and assist research into**
25 **tobacco use and health?"**

1 A. I viewed CTR's role in administering CTR Special Projects as entirely
2 consistent with that purpose. CTR Special Projects were scientific research conducted by
3 investigators at highly reputable research institutions who were not affiliated with the
4 tobacco companies. I am aware of nothing showing that this was not bona fide,
5 legitimate research. The legitimacy of the research is confirmed by the fact that it
6 resulted in more than 300 publications in the scientific literature. And, as I said before,
7 administering this research did not affect, so far as I can tell, the aid to scientific research
8 provided through the SAB grant program.

9 H. Alleged Racketeering Acts

10 Q. Have you reviewed the Appendix to the Amended Complaint, in
11 which the United States has listed alleged racketeering acts?

12 A. Yes, I have.

13 Q. In some of those alleged racketeering acts, has the United States
14 claimed that CTR or other defendants, through CTR, sent, delivered, or received
15 certain documents through the United States mails?

16 A. Yes.

17 Q. Have you read any interrogatory answers in which the United States
18 has alleged additional racketeering acts that make such claims as to CTR?

19 A. Yes.

20 Q. Have you looked into any of the facts surrounding these alleged
21 racketeering acts?

22 A. Yes. I have reviewed the documents that are referred to in the United
23 States' allegations about CTR. In a number of instances, I have reviewed additional
24 documents pertaining to these allegations.

1 **Q. Do some of these alleged racketeering acts relate to scientists who**
2 **received funding for their research through CTR Special Projects?**

3 A. By my count, fourteen of these racketeering acts relate to one of seven
4 scientists who received CTR Special Projects funding. They are Racketeering Acts No.
5 9, 15, 17, 31, 38, 44, 66, 67, 70, 73, 77, 88, 98 and 123. The seven scientists are Dr.
6 Feinstein, Dr. Selye of the University of Montreal, Dr. Richard J. Hickey of the
7 University of Pennsylvania, Dr. Hans Eysenck of the Institute of Psychiatry in London,
8 Dr. Domingo Aviado of the University of Pennsylvania, Dr. Theodor Sterling of Simon
9 Fraser University in Canada and Dr. Carl Seltzer of Harvard.

10 **Q. Have you looked into the circumstances surrounding CTR Special**
11 **Project funding of those seven scientists as it generally relates to the alleged**
12 **racketeering acts you just listed?**

13 A. I have. I looked at the underlying documents and at the CTR Special
14 Projects that they related to. For two of the scientists, Dr. Eysenck and Dr. Aviado, the
15 alleged racketeering acts appear to have nothing to do with research that CTR funded.
16 For the other five scientists, the allegations involve discussions of research that was
17 funded through CTR Special Projects. That research fits the general pattern of CTR
18 Special Projects. It was research conducted by scientists at reputable research
19 institutions, all of whom published their findings as shown in CTR's list of CTR Special
20 Projects, U.S. Ex. 53303. I have looked at many of those publications. They show that
21 each of these five scientists received research funding from other reputable agencies,
22 including funding of all five scientists by agencies of the federal government. The
23 publications I reviewed showed that these scientists were inconsistent about
24 acknowledging funding support through CTR Special Projects, but a number of their
25 published articles did acknowledge that support.

1 **Q. Do alleged Racketeering Acts No. 22 and 25 relate to CTR?**

2 A. Yes. These racketeering acts refer to the possibility of CTR funding, as a
3 CTR Special Project, of a scientific conference.

4 **Q. Did CTR sponsor the conference that is referred to in Racketeering**
5 **Acts No. 22 and 25?**

6 A. Yes. These allegations refer to a conference that was held in St. Martin in
7 January 1972. According to CTR's list of CTR Special Projects, U.S. Ex. 53303, at page
8 40, the conference was funded through CTR Special Project No. 64.

9 **Q. Were the proceedings of the conference published?**

10 A. Yes They were published in book form.

11 **Q. Can you identify Exhibit JD-040795?**

12 A. Exhibit JD-040795 is a copy of a book entitled *Smoking Behavior:*
13 *Motives and Incentives*. It was published in 1973, and is the book I just referred to.

14 **Q. Please turn to page ix of Exhibit JD-040795 and read the heading on**
15 **that page.**

16 A. “List of Contributors.”

17 **Q. Are the contributors' institutional affiliations identified on the list?**

18 A. Yes. The largest number of contributors, six of them, were affiliated with
19 Columbia University. Two were from Harvard, and two were from the University of
20 Pennsylvania. Others were from Johns Hopkins, Rockefeller University, UCLA, the
21 University of Michigan and the U.S. Veterans Administration. There were a few other
22 institutions as well. The summary chapter, Chapter 21, was written by Dr. Seymour
23 Kety. Dr. Kety was then at Harvard Medical School. Before that, he had been the
24 Scientific Director of the National Institute of Mental Health, which is part of the NIH.
25 After he retired from Harvard, Dr. Kety returned to the NIH.

1 **Q. What is in the 21 chapters in this book?**

2 A. Each chapter is a presentation of one or more of these listed contributors,
3 describing their research findings or aspects of smoking motivation, including the effects
4 of nicotine.

5 **Q. Was the research described in these chapters funded by CTR?**

6 A. Some of it was. Some of the research was funded by the American Cancer
7 Society, which is acknowledged on page 33 of Exhibit JD-040795; the Office of Naval
8 Research, NASA and The National Science Foundation, which is acknowledged on page
9 171; and the U.S. Public Health Service, which is acknowledged on page 209.

10 **Q. Do alleged Racketeering Acts No. 13 and 14 relate to CTR?**

11 A. Yes. These allegations relate to efforts to identify potential witnesses to
12 testify on behalf of the tobacco companies at Congressional hearings, and to evaluate the
13 progress of research projects in relation to their potential use at Congressional hearings.

14 **Q. These allegations refer to CTR's Ad Hoc Committee. Did CTR or**
15 **TIRC have an Ad Hoc Committee?**

16 A. During the time I was with CTR, it had no Ad Hoc Committee. I have
17 never heard or seen anything to suggest that such a committee ever existed at CTR or
18 TIRC. I have seen documents in the course of litigation referring to an Ad Hoc
19 Committee, whose members were attorneys for the various cigarette companies. In the
20 references to an Ad Hoc Committee I have seen, that committee was not part of CTR or
21 TIRC.

22 **Q. Did CTR have any role in deciding what scientists would serve as**
23 **witnesses on behalf of the cigarette companies at Congressional hearings?**

24 A. Not as far as I I know. Over the years, a few individuals affiliated with
25 CTR have testified at hearings before committees of Congress about CTR's research

1 program, but I am not aware of any involvement by CTR in identifying potential
2 witnesses to testify at Congressional hearings on behalf of CTR's member companies.

3 **VIII. DID PUBLIC RELATIONS CONSIDERATIONS**
4 **AFFECT THE SAB GRANT PROGRAM?**

5 **Q. During your years with CTR, did CTR issue press releases?**

6 A. Yes. CTR issued a total of about 20 press releases from 1983 until 1997.

7 **Q. What were the subjects of these CTR press releases?**

8 A. Each year a press release announced the issuance of CTR's Annual
9 Report. Most of the other press releases during those years announced personnel changes
10 at CTR: for example, the appointment of a new member of the scientific staff or a new
11 member of CTR's SAB. CTR also issued a press release when it published MAI's final
12 report in 1984.

13 **Q. While you were with CTR, did the press releases that accompanied**
14 **the issuance of the Annual Report discuss the findings from the research that was**
15 **summarized in the Annual Report?**

16 A. No. Those press releases typically set out the dollar amount of funds
17 provided by CTR to its grantees and the number of grants supported during the year
18 covered by the Annual Report.

19 **Q. Did those press releases discuss smoking and health?**

20 A. No.

21 **Q. Have you read the press releases in CTR's files that were issued by**
22 **CTR prior to your years as a member of its scientific staff?**

23 A. Yes.

24 **Q. What subjects were covered in those press releases?**

1 A. In its early years, CTR issued a number of press releases about smoking
2 and health. Most of those press releases presented in one way or another Dr. Little's
3 position that the hypothesis that cigarette smoking was causally related to certain diseases
4 or conditions, which had been based largely on statistical data, was not borne out
5 scientifically by subsequent experiments despite a variety of efforts to do so. Some of
6 these early press releases conveyed similar statements by Dr. Hockett or Mr. Hartnett.
7 Some press releases covered the same kinds of events that I just mentioned, personnel
8 changes or the issuance of an Annual Report, and others announced the awarding of CTR
9 grants-in-aid.

10 **Q. Have you seen any published comments from this period about the**
11 **sincerity of Dr. Little's views on smoking and health?**

12 A. One such comment that I am aware of was published in *The New England*
13 *Journal of Medicine*.

14 **Q. Can you identify Exhibit JD-020447?**

15 A. Yes. This is a page from the June 15, 1961 *The New England Journal of*
16 *Medicine*, describing a recent program on smoking and health at which Dr. Wynder and
17 Dr. Little had presented their differing views on smoking and lung cancer. Their talks
18 were published in this edition of *The New England Journal of Medicine*.

19 **Q. Can you read the last sentence of the second paragraph of the text in**
20 **Exhibit JD-020447?**

21 A. "Both authors," referring to Dr. Wynder and Dr. Little, "are dedicated,
22 sincere proponents of their points of view, each upholding what he believes to be the
23 truth and nothing but the truth, each ready to admit that the whole truth has not yet been
24 revealed to aspiring man."

1 **Q. Did any of the press releases in CTR’s files that were issued by CTR**
2 **prior to your years as a member of its scientific staff state positions or comment on**
3 **whether cigarette smoking is addictive?**

4 A. No. The focus was on smoking and disease, especially lung cancer, not on
5 addiction or the effects of nicotine.

6 **Q. During your years with CTR, did any of the press releases issued by**
7 **CTR state positions or comment on whether cigarette smoking is addictive?**

8 A. No.

9 **Q. You said that in CTR’s “early years,” CTR issued press releases**
10 **about smoking and health. What did you mean by CTR’s “early years?”**

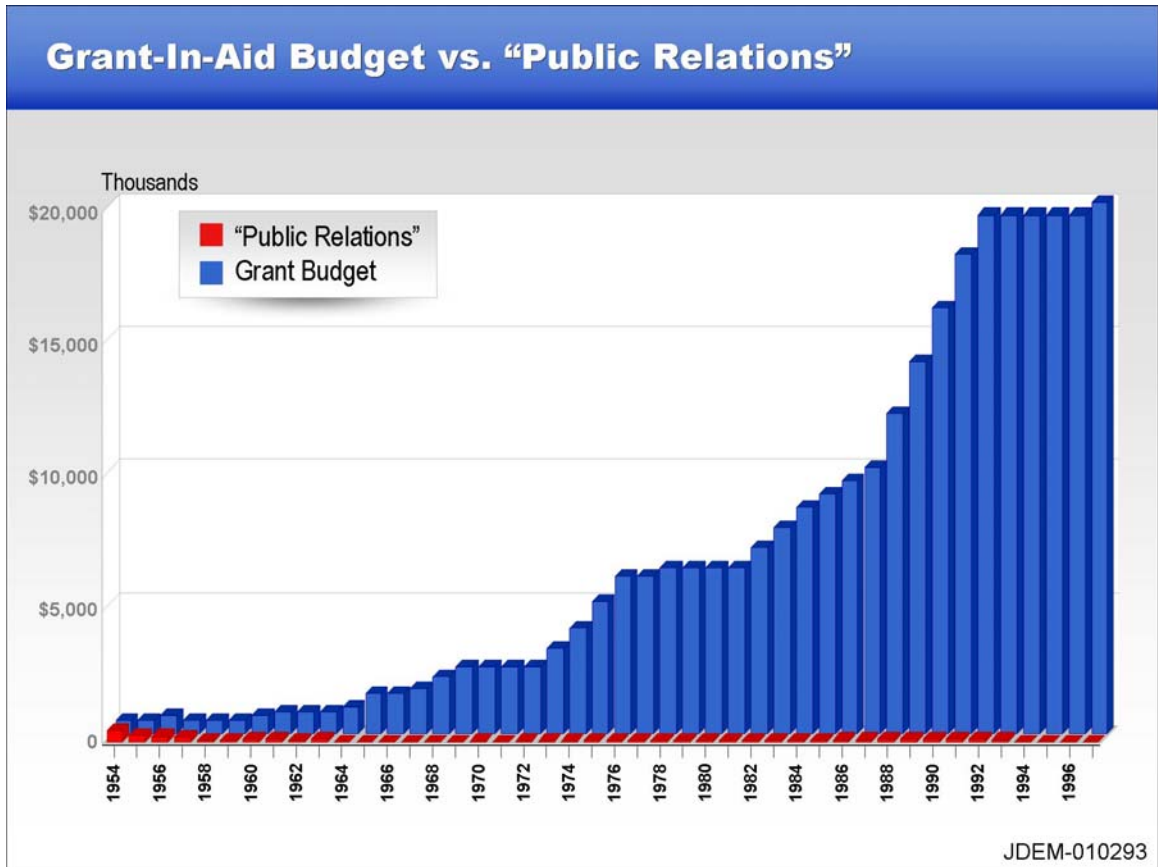
11 A. Principally from 1954 to 1958. In 1958, the cigarette manufacturers
12 formed the Tobacco Institute, and after that the public relations aspect of CTR’s activities
13 declined. After the Surgeon General Advisory Committee’s Report was issued in
14 January 1964, the frequency of CTR’s press releases diminished further. During the
15 remaining seven years of Dr. Little’s tenure as Scientific Director, there were additional
16 CTR press releases expressing his views on the state of smoking and health research.
17 After Dr. Little passed away in 1971, the number of press releases by CTR expressing
18 any viewpoint on smoking and health issues declined still further. By the early 1970s,
19 CTR had ceased issuing press releases expressing views on smoking and health.

20 **Q. Did any of the press releases issued during your time at CTR, from**
21 **1983 through the dissolution of CTR, discuss the extent to which any research**
22 **findings, individually or collectively, did or did not implicate smoking as a cause of**
23 **disease?**

1 A. No. Those kinds of things had been the subject of TIRC press releases in
2 the 1950s and, to a lesser degree, in the 1960s. By the time I arrived in 1983, CTR's
3 press releases did not deal with those issues.

4 **Q. What is shown in Demonstrative Exhibit JDEM-010293, which is**
5 **reprinted below?**

6 A. In this exhibit, I have compared the amount of money spent by CTR on
7 public relations from 1954 through 1998, when CTR was dissolved, to the amount of
8 each year's research budget for grants-in-aid and contracts. I took the data in this exhibit
9 from the minutes of meetings of the members and the Board of Directors of CTR. It
10 shows that, except for 1954, CTR's first year of existence, public relations expenditures
11 were always less than those for the grant program. In 1954, CTR began the funding of
12 grants in the latter part of the year, and its public relations expenditures included
13 significant one-time expenses, including those connected with the publication of the
14 Frank Statement. This shows that after the early 1960s, CTR's public relations
15 expenditures were a very small percentage of the amounts disbursed for research.



1

2 **Q. Did the Scientific Advisory Board of CTR ever object to the issuance**
 3 **of these statements to the public?**

4 A. In one situation that I am aware of, the members of the SAB wanted to
 5 ensure that statements made by CTR’s staff were distinguished from their views. In 1957
 6 and 1958, a committee of TIRC published two issues of a newsletter, called “Tobacco
 7 and Health,” collecting previously published statements that a causal connection between
 8 smoking and lung cancer had not been proven. When advance copies were provided to
 9 the SAB members, at least two of them expressed their concerns to CTR.

10 **Q. Can you identify Exhibit JE-031476 and U.S. Ex. 31474?**

11 A. These are letters from two SAB members in 1957, Dr. Edwin Wilson and
 12 Dr. McKeen Cattell, expressing concerns about whether the information contained in

1 advance copies of the publication “Tobacco & Health” could be misconstrued as having
2 the approval of the SAB.

3 **Q. Look at page CTR-TIRC MN 000132 of Exhibit JD-093292. What**
4 **does this reflect about “Smoking and Health?”**

5 A. Shortly after receiving the letters from Dr. Wilson and Dr. Cattell, a
6 decision was made to issue the pamphlet under the imprimatur of the newly formed
7 Tobacco Information Committee rather than TIRC. This step satisfied the SAB that there
8 would be no impugning of the SAB’s scientific integrity. After the publication of the
9 first two issues of Tobacco and Health, the Tobacco Institute was formed and it took over
10 the publication of the pamphlet.

11 **Q. Can you identify Exhibits JD-093610 and JD-093608?**

12 A. Exhibit JD-093610 is a letter dated October 2, 1957 from Mr. Hartnett, the
13 Chairman of TIRC, to Dr. Julius H. Comroe, a member of the SAB. In the letter,
14 Mr. Hartnett explained to Dr. Comroe the changes that were made to the publication
15 “Tobacco and Health” after the advance copy that Dr. Comroe had seen and prior to its
16 publication. Exhibit JD-093608 is a letter dated October 8, 1957, in which Dr. Comroe
17 responded to Mr. Hartnett’s letter. Dr. Comroe stated that he was satisfied with the
18 solution of printing the publication “Tobacco and Health” under the name of a committee
19 that did not identify the publication with the SAB.

20 **Q. Can you identify Exhibit JD-093609?**

21 A. Exhibit JD-093609 is a memorandum dated October 16, 1957 from W.T.
22 Hoyt, the Executive Secretary of TIRC. In it, he discusses the need that was felt to
23 establish a separate subcommittee of TIRC to distribute “Tobacco and Health,” in order
24 to maintain the scientific autonomy of CTR’s SAB.

1 **Q. You mentioned that the SAB said it wanted to avoid having its**
2 **integrity “impugned” in this particular situation. Have you seen other examples of**
3 **that?**

4 A. Yes. At the May 1958 SAB meeting, SAB members expressed concern
5 that statements about smoking and health by Dr. Little might be misconstrued as
6 statements by the SAB. Dr. Julius H. Comroe, an SAB member from the University of
7 Pennsylvania Medical School, suggested that it would be helpful if Dr. Little did not
8 serve as both the Chairman of the SAB and the Scientific Director of CTR. Later in
9 1958, the two positions were separated. Dr. Little retained his position as Scientific
10 Director, and a new Chairman of the SAB was selected.

11 **Q. Can you identify JD-093292 at CTR-TIRC MIN 000141-148 and**
12 **CTR-TIRC MIN 000149-156?**

13 A. Yes, they are reports of the TIRC meetings held in May and
14 November 1958. They repeat comments by members of the SAB that there needed to be
15 a clearer line between TIRC and the SAB of TIRC especially with respect to public
16 statements. This is apparent from page 000142 of the May meeting. The suggestion was
17 made to have Dr. Little relinquish his chairmanship of the SAB but maintain his position
18 as Scientific Director. The report of the November 1958 meeting makes it clear that this
19 suggestion was implemented.

20 **Q. During your years with CTR, did CTR retain a public relations**
21 **consultant?**

22 A. Yes. From the time of my arrival until the early 1990s, CTR retained
23 Leonard Zahn & Associates, Inc. CTR originally had retained Mr. Zahn long before I
24 arrived in 1983.

1 **Q. What services did Leonard Zahn & Associates, Inc. perform for**
2 **CTR?**

3 A. During my tenure, the majority of services provided by Leonard Zahn
4 involved attendance at, and reporting to CTR on, scientific conferences, and the
5 coordination of the publication of CTR's Annual Reports.

6 **Q. Can you identify Exhibit JD-093894?**

7 A. Exhibit JD-093894 is a letter from Dr. Glenn to Mr. Zahn, dated June 13,
8 1991. Exhibit JD-093894 clarifies that Mr. Zahn cut back on his work for CTR in 1991
9 and stopped performing services for CTR in 1993.

10 **Q. Have you previously seen U.S. Ex. 55,955, which is a June 24, 1974**
11 **memorandum from Dr. Spears of Lorillard?**

12 A. Yes. This document is not in CTR's files, but I have been shown this in
13 depositions.

14 **Q. On page 3 of U.S. Ex. 55,955, Dr. Spears said, "Historically, the joint**
15 **industry funded smoking and health research programs have not been selected**
16 **against specific scientific goals, but rather for various purposes such as public**
17 **relations, political relations, position for litigation, etc." Was the research funded**
18 **through CTR grants-in-aid and contracts selected for various purposes such as**
19 **public relations, political relations, position for litigation?**

20 A. Certainly they were not during my time at CTR, and I don't believe they
21 ever were.

22 **Q. In your years with CTR, did public relations ever take priority over**
23 **CTR's scientific program?**

24 A. No. Absolutely not.

1 **Q. Do any of the racketeering acts alleged by the United States involve**
2 **CTR press releases?**

3 A. Yes. Two of them do, Racketeering Acts No. 2 and No. 120.

4 **Q. What is the press release at issue in Racketeering Act No. 2?**

5 A. That allegation concerns a CTR press release, dated July 15, 1957, which
6 was entitled “Scientist Comments on Benzpyrene Report”. The Government alleges, in
7 racketeering act number 2, that this press release “disputed the United States Surgeon
8 General’s report that Benzpyrene had been identified in cigarette smoke, and stated that
9 scientists had ‘generally concluded’ that Benzpyrene in cigarette smoke cannot be a
10 cause of cancer in smokers.”

11 **Q. Can you identify U.S. Ex. 77558?**

12 A. U.S. Ex. 77558 is a press release entitled “Scientist Comments on
13 Benzpyrene Report,” issued for TIRC for release on July 15, 1957. It appears to be the
14 press release referred to by the United States in racketeering act number 2.

15 **Q. This 1957 TIRC press release, U.S. Ex. 77558, set forth a statement**
16 **made by Dr. Hockett, the associate research director of TIRC, “in connection with**
17 **today’s news reports from Washington quoting the U.S. Surgeon General as saying**
18 **benzpyrene had been found in cigarette smoke.” Have you seen any statement by**
19 **the U.S. Surgeon General about benzpyrene in cigarette smoke at that time?**

20 A. I have seen newspaper articles that reported statements by the U.S.
21 Surgeon General, Dr. Leroy Burney that mentioned benzpyrene on July 15, 1957. That is
22 the date of the TIRC press release, U.S. Ex. 77558.

23 **Q. Can you identify U.S. Ex. 76,446?**

24 A. U.S. Ex. 76,446 is a copy of the front page and page A3 of the July 16,
25 1957 *Washington Post and Times Herald*. An article on page A3 with the headline

1 “Senate Speech Cites Smoking Peril,” refers to statements made by Dr. Burney the day
2 before, which was July 15, 1997, the date of the TIRC press release.

3 **Q. Can you identify Exs. U.S. 76,662 and 76,444?**

4 A. U.S. Ex. 76,662 is a copy of the front page and a part of an inside page of
5 the *New York Post*, dated July 16, 1957. There is an article on the inside page with the
6 headline “Health Chief Urges More Study of Cigaret Link to Lung Cancer.” The bottom
7 of the page is cut off and, as a result, part of the article is missing. U.S. Ex. 76,444 is a
8 copy of the front page of the *New York Post*, dated July 15, 1957, along with part of an
9 inside page from the July 16, 1957 issue of the newspaper, which is not cut off at the
10 bottom as it was in U.S. Ex. 76,662. The full article is there.

11 **Q. According to these articles, what did Dr. Burney say on July 15, 1957**
12 **about the presence of benzpyrene in cigarette smoke?**

13 A. He did not say anything about the presence of benzpyrene in cigarette
14 smoke. He said that some studies had indicated the presence of benzpyrene in tobacco
15 tars, which refers to the material that is retained on a very fine filter when smoke is
16 passed through it.

17 **Q. Did the TIRC press release, U.S. Ex. 77558, dispute Dr. Burney’s**
18 **statement that benzpyrene was present in cigarette tars?**

19 A. Not really. Dr. Hockett’s statement about the presence of benzpyrene in
20 tobacco smoke said, “Scientists have not actually succeeded in isolating the substance,”
21 referring to benzpyrene, “from tobacco smoke. Some feel that they have identified the
22 substance by means of extremely sensitive, indirect measurements as probably present in
23 smoke. Several chemists have not been able to detect benzpyrene in smoke at all, so
24 elusive is this substance.”

1 **Q. Have you seen anything to suggest that Dr. Hockett’s statements**
2 **about whether benzpyrene had been isolated from tobacco smoke or was present in**
3 **tobacco smoke were not accurate in July 1957?**

4 A. No, I have not.

5 **Q. Have you seen anything to suggest that Dr. Hockett did not believe**
6 **these statements about benzpyrene and tobacco smoke were accurate in July 1957?**

7 A. No, I have not.

8 **Q. Did the July 16, 1957 press release, U.S. Ex. 77558, state that**
9 **“scientists ‘generally concluded’ that benzpyrene in cigarette smoke cannot be a**
10 **cause of cancer in smokers,” as alleged in paragraph 2 of the Appendix?**

11 A. No. The press release said that benzpyrene “has been widely discounted
12 as a significant factor in connection with lung cancer by scientists,” and it provided
13 several reasons in support of that discounting. One reason was uncertainty about the
14 presence of benzpyrene in tobacco smoke. The second reason related to the quantities of
15 benzpyrene that might be present. The press release said, “The general conclusion is that
16 if benzpyrene is actually present in cigarette smoke, it occurs in such minute quantities it
17 could not even account for such biologic activity as has been reported for tobacco smoke
18 in some experiments on sensitive mouse skin.” Dr. Hockett referred to the highly
19 publicized mouse skin painting experiments by Dr. Ernst Wynder and others, in which
20 tobacco tars were painted on the shaved backs of mice. The press release quoted Dr.
21 Wynder as saying, “The benzpyrene content of tobacco tar is not more than 2 parts per
22 million which, according to our experiments, is not sufficient to produce the type of
23 activity noted in our animals painted with tobacco tar.” Finally, the press release cited
24 the fact that benzpyrene had not been shown to cause cancer in humans.

1 **Q. Have you seen anything suggesting that anything Dr. Hockett said in**
2 **support of his view that benzpyrene had been widely discounted as a significant**
3 **factor in lung cancer was not true?**

4 A. No, I have not.

5 **Q. Have you seen anything to suggest that Dr. Hockett did not believe**
6 **any of these statements about the role of benzpyrene?**

7 A. No, I have not. I have checked the reference to the statement attributed to
8 Dr. Wynder, and it is accurate.

9 **Q. According to the newspaper accounts that you have seen, did Dr.**
10 **Burney say anything on July 15, 1957 about the quantity of benzpyrene in tobacco**
11 **tars?**

12 A. Yes. According to the *Washington Post and Times Herald* article, U.S.
13 Ex. 76,446, Dr. Burney “said in an interview that the presence of benzpyrene might be a
14 contributing factor to the increase in lung cancer among smokers.” The article adds that
15 Dr. Burney “issued a ‘clarifying’ statement later saying ‘there are some scientific studies
16 which indicate benzpyrene has been identified in cigarette tars. There is no evidence to
17 indicate, however, that benzpyrene in itself is present in sufficient quantities in cigarette
18 tars to cause human lung cancer.’” The New York Post article, U.S. Exs. 76,662 and
19 76,444, also reported both Dr. Burney’s first statement and his later, “clarifying”
20 statement, July 16, 1957.

21 **Q. Did the TIRC press release, U.S. Ex. 77558, disagree with Dr.**
22 **Burney’s statement he made clarifying the possible role of benzpyrene in cigarette**
23 **tars?**

24 A. The press release and Dr. Hockett’s statement did not disagree with, and
25 were consistent with, Dr. Burney’s reported, “clarifying” statement about the small

1 quantities of benzpyrene that had been found in tobacco tars. Compared to Dr. Burney’s
2 statement, Dr. Hockett’s statement was a more limited, precise statement about scientists
3 believing that in the context of skin painting experiments the quantities of benzpyrene in
4 tobacco smoke were insufficient to have significant biological activity.

5 **Q. What press release is involved in Racketeering Act No. 120?**

6 A. This involves a CTR press release, dated April 22, 1970, entitled “Studies
7 Raise Questions About Smoking As Health Hazard.” The Government alleges that this
8 press release “was issued to identify studies supported by the Council for Tobacco
9 Research that call into question whether ‘smoking has actually been shown to be a health
10 hazard,’ or that there is a link between smoking and diseases such as lung cancer and
11 emphysema.”

12 **Q. Can you identify U.S. Ex. 47,778, which is in evidence?**

13 A. U.S. Ex. 47,778 is a press release entitled “Studies Raise Questions About
14 Smoking As Health Hazard,” which says that it was issued for the Council for Tobacco
15 Research – U.S.A. It appears to be the document referred to in racketeering act number
16 120. I could not determine whether this press release was ever distributed outside of
17 CTR.

18 **Q. Did the 1970 CTR press release, U.S. Ex. 47,778, say that studies
19 supported by CTR called into question the link between smoking and diseases such
20 as lung cancer and emphysema?**

21 A. No. The April 22, 1970 press release, U.S. Ex. 47,778, did not dispute
22 that a link had been shown between smoking and diseases such as lung cancer and
23 emphysema. What it said was that certain scientific studies supported by CTR, which
24 were listed in the press release, raised questions as to whether smoking “has actually been
25 shown” to be a health hazard.

1 **IX. DID CTR SUPPRESS OR CENSOR**
2 **REPORTS OF SCIENTIFIC RESEARCH?**

3 **A. CTR's Policy Toward Publication**

4 **Q. What was CTR's policy toward the publication of research results by**
5 **the researchers who received grant-in-aid funding from CTR?**

6 A. Throughout its history, going back to 1954, CTR permitted and
7 encouraged the publication of reports of grantees' final research results in peer-reviewed
8 scientific journals.

9 **Q. During the 45-year period, when CTR-funded grantees published**
10 **more than 6,400 scientific articles, did any CTR grantee ever claim that CTR**
11 **blocked, or had tried to block, the publication of CTR-funded research results?**

12 A. Not to the best of my knowledge.

13 **Q. To the best of your knowledge, did CTR ever suppress the publication**
14 **of any research results by any of its grantees?**

15 A. No.

16 **Q. When you were CTR's Scientific Director from 1991 to 1999, could**
17 **CTR have stopped publication of a grantee's work if it had wanted to do that?**

18 A. As a practical matter, I don't see how CTR could have done that. Year
19 after year, CTR repeatedly stated in no uncertain terms, in writing and to the public, that
20 it awarded research grants-in-aid with no strings attached, except that the scientist was
21 required to perform the work set forth in the grant application and to report the results
22 honestly and in the conventional manner. I don't believe CTR had any legal right to
23 block publication by the recipient of a grant-in-aid, particularly one in a peer-reviewed
24 journal, or a presentation of findings at a scientific conference. Once a research paper

1 has been accepted for publication by a peer-reviewed journal, there is nothing that a
2 sponsoring agency can do to stop the publication.

3 **Q. Can you identify Exhibit JD-093918?**

4 A. Exhibit JD-093918 is a letter from CTR's files dated April 9, 1973 from
5 Dr. Cecile Leuchtenberger, a Swiss cancer researcher and a then-longtime CTR grantee,
6 to Dr. Hockett, who was then the Associate Scientific Director of CTR. In her letter,
7 Dr. Leuchtenberger enclosed her final progress report after more than 15 years as a CTR
8 grantee and stated in her closing words to Dr. Hockett, "I would like to take this
9 opportunity to thank once more the Scientific Committee of the Council for Tobacco
10 Research for the confidence and generous financial support extended to me over the
11 many years. I especially appreciated your help, your constructive attitude, and the liberty
12 which was given to me in carrying out the research, and in publishing the results."

13 **Q. Please take a look at pages 31-32 of Exhibit JD-090002, the 1958**
14 **TIRC Annual Report; page 27 of Exhibit JD-090004, the 1960 TIRC Annual**
15 **Report; pages 26-28 of Exhibit JD-090005, the 1961 TIRC Annual Report; pages 30-**
16 **32 of Exhibit JD-090007, the 1963-64 TIRC Annual Report; pages 44-45 of Exhibit**
17 **JD-090008, the 1964-65 CTR Annual Report; page 41 of Exhibit JD-090009, the**
18 **1965-66 CTR Annual Report; page 15 of Exhibit JD-090010, the 1966-67 CTR**
19 **Annual Report; pages 26, 65-66, and 91-92 of Exhibit JD-090011, the 1968-69 CTR**
20 **Annual Report; pages 29-31 and 55 of Exhibit JD-090013, the 1971 CTR Annual**
21 **Report; pages 23-24 and 62-63 of Exhibit JD-090014, the 1972 CTR Annual Report;**
22 **and pages 17-19 of Exhibit JD-090016, the 1974 CTR Annual Report. What do**
23 **these pages contain?**

24 A. These pages contain abstracts of Dr. Cecile Leuchtenberger's scientific
25 publications reporting the findings of her CTR-funded research. Dr. Leuchtenberger's

1 research was on cancer, and much of her work was in the area of animal smoke inhalation
2 studies.

3 **Q. Can you identify Exhibit JD-011509?**

4 A. Exhibit JD-011509 is one of Dr. Leuchtenberger's last scientific
5 publications reporting on her CTR-funded studies, an article entitled "Differential
6 Response of Snell's and C57 Black Mice to Chronic Inhalation of Cigarette Smoke,"
7 which was published in 1974 in the research journal *Oncology*.

8 **B. CTR's Statement of Policy**

9 **Q. Can you identify Exhibits JD-043287, JD-093054, JD-094138, JD-**
10 **094155, JD-094012, JD-091193, JD-090200 and U.S. Ex. 87531?**

11 A. These exhibits are different versions of the CTR Statement of Policy
12 Containing Conditions and Terms under Which Grants Are Made. These versions are not
13 dated, but I have been able to place them in time from the names of SAB members and
14 CTR scientists, and the names and addresses of the organization that are on them.

15 The first exhibit, Exhibit JD-043287, is the original Statement of Policy as
16 adopted by the original Scientific Advisory Board of TIRC on September 20, 1954. It is
17 attached to the minutes of the meeting of the Scientific Advisory Board. Those minutes
18 are in Exhibit JD-090960, at pages CTR MIN-SAB 000009-10. The original Statement
19 of Policy, JD-043287, appears at pages CTR MIN-SAB 000011-13.

20 The second exhibit, Exhibit JD-093054, is a printed version of that original
21 Statement of Policy. Because it shows Dr. Little as both Scientific Director of TIRC and
22 Chairman of the SAB, it dates from 1954 to September 1958, when Dr. Kenneth Lynch
23 became the Chairman of the SAB.

24 The third exhibit, Exhibit JD-094138, is a Statement of Policy that shows Dr.
25 Lynch as the Chairman of the SAB. It dates from about September 1958 to 1960.

1 The fourth exhibit, Exhibit JD-094155, is a Statement of Policy that shows Dr. J.
2 Morrison Brady as a member of the scientific staff of TIRC, which he joined in May
3 1960, and lists Dr. Kotin's faculty position at the University of Southern California,
4 which he left in 1962. It appears that this Statement of Policy dates from about 1960 to
5 1962.

6 The fifth exhibit, Exhibit JD-094012, is a Statement of Policy that shows the
7 change in name from TIRC to The Council for Tobacco Research – U.S.A., which
8 occurred in January 1964. Based on that and the SAB members who are listed, it appears
9 to date from 1964 to 1968.

10 The sixth exhibit, Exhibit JD-091193, is a Statement of Policy that shows the
11 incorporation of CTR, which occurred in 1971, and the address where CTR had its office
12 from 1972 to 1984. It therefore dates from that period.

13 The seventh exhibit, Exhibit JD-090200, is a Statement of Policy that shows the
14 address of CTR's next office, where it moved in 1984. It dates from 1984 to the earlier
15 1990s.

16 The eighth exhibit, U.S. Ex. 87531, is a slightly shorter version of the Statement
17 of Policy. This is the version that was sent out to prospective grant applicants and others
18 in the 1990s, when I was the Scientific Director of CTR.

19 **Q. Over the 45 years that CTR funded biomedical research, were there**
20 **changes in the CTR Statement of Policy Containing Conditions and Terms Under**
21 **Which Project Grants are Made?**

22 A. CTR's Statement of Policy stayed pretty much the same, as one can tell
23 from reading the versions we just went through. There were wording changes, some of
24 which reflected modifications in CTR's administrative procedures. The key provision
25 was that "The Council desires to have scientists work with the greatest freedom, without

1 domination of any kind. It will make no attempt to direct the administration of a project
2 once started, to influence its course or to control its results, other than to assure itself that
3 funds are properly expended for the purposes of the grant and that all findings are
4 reported in accordance with the best scientific practice.” Those words remained
5 unchanged in CTR’s Statement of Policy for 45 years.

6 **Q. When did you first read the CTR Statement of Policy?**

7 A. I was shown a copy of the Statement of Policy when I interviewed for the
8 position of Associate Research Director, and it was one of the first documents I reviewed
9 after I started at CTR in 1983.

10 **Q. What was the function of CTR’s Statement of Policy, as you**
11 **understood it as a member of CTR’s scientific staff and as CTR’s Scientific**
12 **Director?**

13 A. This was the basic document that identified the terms and conditions under
14 which grants were made by CTR. It was the principal policy that governed CTR’s
15 conduct towards its grantees and also identified the responsibilities that grantees had with
16 respect to the monies that they received from CTR.

17 **Q. Was the Statement of Policy sent to the scientists who applied for**
18 **grant-in-aid funding from CTR?**

19 A. That was CTR’s practice when I was at CTR. I believe that also was the
20 practice before I arrived.

21 **Q. Did the Statement of Policy, as reflected in Exhibits JD-043287, JD-**
22 **093054, JD-094138, JD-094155, JD-094012, JD-091193, JD-090200 and U.S. Ex.**
23 **87531, say anything about the publication of research findings by CTR’s grantees?**

24 A. Yes. There was the overall promise of scientific freedom that I read a
25 moment ago. There was also in each Statement of Policy a provision on publication. The

1 earlier formulation said that CTR approved publication by grantees in the scientific
2 literature. As reflected in U.S. Ex. 87531, that formulation ... was changed in the 1990s
3 to read: “The Council advocates that investigators present their research results only in
4 accepted medical and scientific journals or before accepted medical or scientific societies.
5 It has no objection to dissemination to the public of any or all final conclusions from
6 projects in these ways. Published reports emanating from Council-supported projects are
7 expected to carry acknowledgement of that support.”

8 **Q. While you were CTR’s Scientific Director, what was CTR’s purpose**
9 **in saying that CTR “advocates that investigators present their research results only**
10 **in accepted medical and scientific journals or before accepted medical or scientific**
11 **societies?”**

12 A. We wanted to tell our grantees that they would have the same freedom to
13 publish their findings that they would have if they received grants from any of the other
14 recognized funding agencies. The reference in CTR’s Statement of Policy to “accepted
15 medical and scientific journals” refers to peer-reviewed publications whose editorial
16 boards act as a check on the quality and reliability of the research whose findings are
17 being presented. Likewise, the reference to presentations before “accepted medical or
18 scientific societies” referred to the standard methods of presenting medical and research
19 results at scientific or medical conferences. The reference to the presentation of “final
20 conclusions” referred to a well-understood and accepted concept that research findings
21 should be reported only after the final data have been assembled and fully analyzed,
22 rather than on an interim basis subject to revision and update.

23 **Q. Can you identify Exhibit JD-094461?**

1 A. Exhibit JD-094461 is a document entitled “Important Procedural
2 Information for Applicants.” It was sent to applicants for grant-in-aid funding from CTR,
3 along with the Statement of Policy.

4 **Q. Were recipients of CTR grants-in-aid required to agree that they**
5 **would adhere to CTR’s Statement of Policy?**

6 A. Yes. In Exhibit JD-094461, the document entitled “Important Procedural
7 Information for Applicants,” CTR stated that “[s]igned applications constitute an
8 agreement to abide by the stipulations on the sheet entitled ‘Statement of Policy.’”

9 **Q. Did language similar to that in the Statement of Policy appear in any**
10 **other documents that were sent to CTR grantees?**

11 A. Yes. Each of CTR’s Annual Reports prominently featured a statement
12 very similar to the Statement of Policy. As I testified earlier, the Annual Reports were
13 widely distributed to the scientific community, including CTR’s grantees and applicants
14 for CTR grants-in-aid.

15 **Q. Where was this statement made in CTR’s Annual Reports?**

16 A. The 1956 Annual Report, Exhibit JD-090000, stated on page 7: “It is, and
17 will continue to be, the established policy of the Scientific Advisory Board to permit each
18 investigator to publish his findings independently when he feels he is ready to report his
19 work.”

20 The 1957 Annual Report modified this language so that it tracked more closely
21 the language of the Statement of Policy. The 1957 Annual Report, Exhibit JD-090001,
22 stated at page 4: “Recipients of Tobacco Industry Research Committee grants are assured
23 complete scientific freedom in conducting their investigations and reporting the results of
24 their research in the accepted scientific manner through medical and scientific journals

1 and societies. The investigators receiving grants from the Committee are alone
2 responsible for publishing or reporting their research results.”

3 With minor variations, this statement appeared in each of the CTR Annual
4 Reports, usually on the inside front cover. Similar language appears on the following
5 pages of these CTR Annual Reports: Exhibit JD-090002, the 1958 Annual Report, on
6 page 1; Exhibit JD-090003, the 1959 Annual Report, on page 1; Exhibit JD-090004, the
7 1960 Annual Report, on page 1; Exhibit JD-090005, the 1961 Annual Report, on page 1;
8 Exhibit JD-090006, the 1962 Annual Report, on page 1; Exhibit JD-090007, the 1963
9 Annual Report, on page 1; Exhibit JD-090008, the 1964 Annual Report, on page 1;
10 Exhibit JD-090009, the 1965 Annual Report, on page 1; Exhibit JD-090010, the 1966-67
11 Annual Report, on page 1; Exhibit JD-090011, the 1968-69 Annual Report, on page 1;
12 Exhibit JD-090012, the 1960-70 Annual Report, on page 1; Exhibit JD-090013, the 1971
13 Annual Report, on page 1; Exhibit JD-090014, the 1972 Annual Report, on page 5;
14 Exhibit JD-090015, the 1973 Annual Report, on page 1; Exhibit JD-090016, the 1974
15 Annual Report, on page 1; Exhibit JD-090017, the 1975 Annual Report, on page 1;
16 Exhibit JD-090018, the 1976 Annual Report, on page 1; Exhibit JD-090019, the 1977
17 Annual Report, on page 1; Exhibit JD-090020, the 1978 Annual Report, on page 1;
18 Exhibit JD-090021, the 1979 Annual Report, on page 1; Exhibit JD-090022, the 1980
19 Annual Report, on page 1; Exhibit JD-090023, the 1981 Annual Report, on page 1;
20 Exhibit JD-090024, the 1982 Annual Report, on page 1; Exhibit JD-090025, the 1983
21 Annual Report, on page 1; Exhibit JD-090026, the 1984 Annual Report, on page 1;
22 Exhibit JD-090027, the 1985 Annual Report, on page 1; Exhibit JD-090028, the 1986
23 Annual Report, on page 1; Exhibit JD-090029, the 1987 Annual Report, on page 1;
24 Exhibit JD-090030, the 1988 Annual Report, on page 1; Exhibit JD-090031, the 1989
25 Annual Report, on page 1; Exhibit JD-090032, the 1990 Annual Report, on page 1;

1 Exhibit JD-090033, the 1991 Annual Report, on page 1; Exhibit JD-090034, the 1992
2 Annual Report, on page 1; Exhibit JD-090035, the 1993 Annual Report, on page 1;
3 Exhibit JD-090036, the 1994 Annual Report, on page 1; Exhibit JD-090037, the 1995
4 Annual Report, on page 1; Exhibit JD-090038, the 1996 Annual Report, on page 1; and
5 Exhibit JD-090039, the 1997 Annual Report, on page 1.

6 **Q. To the best of your knowledge, did any of CTR's 1,200 or so grantees**
7 **ever complain to CTR that CTR did not live up to its Statement of Policy, or that**
8 **CTR interfered with their scientific freedom in connection with scientific research**
9 **supported by a CTR grant-in-aid?**

10 A. No.

11 C. CTR Site Visits

12 **Q. What is a site visit?**

13 A. A site visit occurs when a representative of a funding organization that is
14 supporting (or considering supporting) a researcher goes out and personally meets with
15 the researcher at his or her laboratory.

16 **Q. Do most scientific research-funding organizations conduct site visits?**

17 A. A. Yes, they do. All of the NIH institutes that fund biomedical
18 research, and many of the principal private organizations such as the American Heart
19 Association, the American Cancer Society, the Damon Runyon Foundation, the Howard
20 Hughes Charitable Trust, and others, conduct site visits to the laboratories to which they
21 provide funding.

22 **Q. Did CTR conduct site visits?**

23 A. Yes. As I mentioned before, this was something that generally was done
24 by members of CTR's scientific staff. CTR tried to send a staff scientist to visit the
25 principal investigator of each grant at least once during the course of the project.

1 A. No. We asked the grantees to acknowledge CTR's funding support if they
2 published. That implication was clear, but each grantee made his or her own decision
3 whether to acknowledge CTR funding, and if so in what form.

4 **Q. In the articles they published in the scientific literature, did CTR**
5 **grantees identify their funding source as CTR?**

6 A. Yes, when they felt it was appropriate. Certain types of articles such as
7 reviews sometimes carry no acknowledgement. If a grantee did acknowledge CTR's
8 support but did not send us a copy, we may or may not have become aware of the
9 publication. As a result, we don't know the full universe of articles from CTR-funded
10 research.

11 **E. Sample Award Letter**

12 **Q. Can you identify Exhibit JD-093612?**

13 A. Exhibit JD-093612 is a sample grant-in-aid award letter and a packet of
14 materials that were used during my tenure at CTR.

15 **Q. Can you identify Exhibits JD-043299, JD-092866, JD-092868, JD-**
16 **092872 and JD-093190?**

17 A. These are documents from CTR's files. The first of these, Exhibit JD-
18 043299 is a CTR grant award letter dated March 29, 1973 to Dr. Benacerraf. The second,
19 third, and fourth of these exhibits, Exhibits JD-092866, JD-092868 and JD-092872, are
20 CTR grant award letters dated November 15, 1977, December 21, 1976, and
21 December 18, 1975 to CTR grantee Dr. Georg Neurath, of Microanalytical Laboratory in
22 Hamburg, West Germany. The fifth of these exhibits, Exhibit JD-093190, is a CTR grant
23 award letter dated January 12, 1979 to Dr. Kjell Fuxe of the Karolinska Institute in
24 Stockholm, Sweden.

1 more time to provide comments if they were sought by the grantees. Dr. Hockett, who
2 was then CTR's Research Director, was a prolific correspondent and thoughtful editor
3 and he sometimes provided comments on and suggestions about draft articles that were
4 sent to him for such comment.

5 **Q. Did any CTR grantee ever say that CTR interfered with his or her**
6 **scientific freedom when Dr. Hockett provided those comments and suggestions?**

7 A. Not to the best of my knowledge.

8 **Q. To the best of your knowledge, did any grantee who submitted draft**
9 **articles reporting on scientific research funded by CTR ever complain about the**
10 **comments that were provided by CTR on the proposed scientific publication?**

11 A. No.

12 **Q. To the best of your knowledge, did CTR ever share drafts of articles**
13 **submitted by grantees with its Board of Directors or any other representatives of its**
14 **member companies?**

15 A. No.

16 **G. Publication of Contract Research**

17 **Q. Were the publication rights of CTR's contract researchers identical to**
18 **those of its grantees?**

19 A. No, but that is characteristic of the publication rights under scientific
20 research contracts generally. When scientific research is funded through a grant-in-aid, it
21 usually is the researcher's own proposal that is being funded. The research findings and
22 data belong to the researcher and the researcher is free to publish or not. In contract
23 research, on the other hand, the researcher enters into a legal agreement to conduct the
24 research on behalf of the funding agency. The research findings and data belong to the

1 agency that commissioned the work. This does not necessarily mean that contractees
2 cannot publish the results. They just have to get authorization from the agency.

3 **Q. Can you identify Exhibit JD-095546?**

4 A. Exhibit JD-095546 is a document in CTR's files dated March 9, 1972. It
5 is a letter from Dr. Hockett to Dr. A.P. Wehner of Battelle Pacific Northwest
6 Laboratories, a CTR contractee, and it explains CTR's policy with respect to publication
7 of findings derived from research performed under contracts with CTR. Dr. Hockett said
8 that, in the case of contract research, "[u]ltimate publication of all scientifically
9 significant findings is contemplated" and "[t]he only difference is that, with contracts, the
10 Council retains the privilege of reviewing and commenting upon all manuscripts prepared
11 for publication and of exercising a limited control over the timing of their release."
12 Dr. Hockett explained: "The purpose of timing control is to avoid premature publications
13 of findings of such limited scope that they could easily be misinterpreted if seen apart
14 from the context to be expected from the further extensions and ramifications of still
15 uncompleted studies." He stated: "This is essentially the same policy, I believe, as that
16 which governs contract research sponsored by the government agencies, which is
17 similarly understood to be in the public domain."

18 **Q. Were the results of CTR contract research published?**

19 A. Yes. In most instances, the results were published in peer-reviewed
20 journals. The MAI scientists published at least 88 articles acknowledging CTR funding,
21 and in 1984 CTR itself published MAI's Final Report. Dr. Homburger published at least
22 a half dozen articles reporting on the results of his CTR contract research.

23 **Q. Can you identify Exhibits JD-091196 and JD-094474?**

24 A. Exhibit JD-091196 is a list of 88 scientific publications that acknowledge
25 funding support under CTR's contracts with MAI. The list includes the book that CTR

1 published reporting the results of some of MAI's contract research. Exhibit JD-094474 is
2 a copy of the book that CTR published, which is entitled "Chronic Exposure of Mice to
3 Cigarette Smoke: Final Report of Research Performed Under Contract entitled 'Smoke
4 Inhalation Studies in Mice.'"

5 **Q. Can you identify Exhibits JD-090160, JD-090218, JD-090233, JD-**
6 **090234, JD-090263, JD-090272, JD-092803, JD-093110, JD-093112, JD-093113, JD-**
7 **093114, JD-093115, JD-093611, JD-094488, JD-094500, JD-094501, JD-095376, and**
8 **JD-095448 through JD-095462?**

9 A. These exhibits are some of the articles published by MAI researchers
10 reporting on the results of the research that was funded through the contracts with CTR.

11 **Q. Did all of these articles acknowledge funding support from CTR?**

12 A. Not all of them, but nearly all of them did. A few of the articles, primarily
13 abstracts, did not note the source of the funding for the research that was discussed in the
14 articles, but it is clear from the content that the research being reported on is the work that
15 was done pursuant to MAI's contacts with CTR.

16 **Q. Can you identify Exhibits JD-061179, JD-091243, JD-091246, JD-**
17 **091248, JD-091252, JD-092756 through JD-092764, JD-094477 and JD-094486?**

18 A. These exhibits are articles that Dr. Homburger published, reporting on the
19 results of his CTR contract research at Bio-Research Consultants, in which hamsters were
20 exposed to smoke.

21 **Q. Are you familiar with U.S. Ex. 85,934?**

22 A. I have seen it only recently. It is not from CTR's files. It appears to be
23 the first page of a longer document.

24 **Q. Do you see the reference to an "assumption that work should be self-**
25 **serving to the industry?"**

1 A. Yes.

2 **Q. Was CTR's or Dr. Homburger's contract research for CTR "self-**
3 **serving" to the tobacco industry?**

4 A. I am not sure what is meant by "self-serving," in this context, but this was
5 "self-serving" research only in that it was good research directed at an important issue.
6 The goal of producing an animal model for lung cancer was widely considered to be an
7 important one. The CTR contract research was approved by the SAB. It was conducted
8 by competent scientists, out in the open, and the results were often published. These
9 extensive efforts to produce an animal model, like other efforts, just did not succeed.

10 **Q. Do you see that it says in U.S. Ex. 85,934 that "contract work" means**
11 **that "disposition of the results will be under complete control of the industry?"**

12 A. I do.

13 **Q. For CTR's research contracts, was the disposition of research results**
14 **within the control of the tobacco industry?**

15 A. No. CTR's contractees published their research findings in the scientific
16 literature. The terms of CTR's research contracts gave CTR the right to approve
17 publication, and in a number of instances CTR reviewed contract researchers' articles
18 before they were published. But if these researchers wanted to publish their findings, I
19 don't see how CTR could have prevented that. And they did publish.

20 **H. Publications Showing Disease Links/Addiction**

21 **Q. Did the scientists funded through CTR grants and contracts publish**
22 **research results that showed a link between the use of tobacco products and disease**
23 **in humans?**

24 A. Yes. There were many such publications. For example, CTR funded
25 epidemiological studies that reported new or stronger statistical associations between

1 smoking and disease than had been reported before. CTR funded mouse skin painting
2 studies to replicate the Wynder-Graham-Croninger findings. There were papers that
3 identified potential mechanisms for smoking-related disease, including lung cancer, heart
4 disease, and emphysema. There were papers that identified links between smoking
5 among pregnant women and low birth weight.

6 **Q. Can you describe Demonstrative Exhibits JDEM-010294 and JDEM-**
7 **010295?**

8 A. These exhibits show a few of the research findings reported by CTR-
9 funded scientists linking smoking to disease. They summarize the published findings of
10 eight different CTR-funded grantees, and, specifically the following eight publications:
11 H.R. Pratt Thomas (1957), “Observations Concerning the Bronchi Relative to Smoking
12 and Environment”; E.D. Warner (1961), “A Study of the Tracheobronchial Epithelium
13 and Changes Related to Smoking”; Samuel Bellett and Alfred Kershbaum (1963),
14 “Physiologic Basis for Prohibition against Smoking”; Laurence Hester (1965), “The
15 Relationship of Smoking to the Outcome of Pregnancy”; Aaron Janoff (1978), “Possible
16 Mechanisms of Emphysema in Smokers” and (1979), “Cigarette Smoke Inhalation
17 Decreases Alpha-Antitrypsin Activity in Rat Lung”; Hojnacki (1981), “Cigarette Smoke-
18 Induced Depression in LCAT Activity” and “Cigarette Smoking Impairs Hepatic Uptake
19 of High-Density Lipoproteins”; Research Group of Raymond Bosse (1982), “Influence of
20 Cigarette, Pipe, and Cigar Smoking, Removable Partial Dentures, and Age on Oral
21 Leukoplakia”; Ake Wennmalm (1992) “Tobacco Use and Urinary Excretion of
22 Thromboxane A(2) and Prostacyclin Metabolites in Women, Stratified by Age.”

23 **Q. Can you identify Exhibits JD-095249, JD-095317, JD-094871, JD-**
24 **095083, JD-095076, JD-095086, JD-095064, JD-095062, JD-094926 and JD-095323?**

1 A. These are the published articles that are referred to in Demonstrative
2 Exhibits JDEM-010294 and JDEM-010295.

3 **Q. Did CTR-funded grantees publish research findings about smoking
4 and “dependence” or “addiction”?**

5 A. CTR funded many grants for research into the pharmacological effects of
6 nicotine and many publications resulted from that research. I will mention three
7 significant examples. In 1963, 25 years before the 1988 Surgeon General’s report said
8 that smoking was addictive, Dr. Peter Knapp, a CTR grantee at Boston University School
9 of Medicine, published an article reporting on his CTR-funded research in which he
10 described heavy smokers as “true addicts.” In 1988, Dr. Torgny Svennson, another CTR-
11 funded grantee, published “Selective Stimulation of Limbic Dopamine Activity by
12 Nicotine,” which illustrated some of the chemical bases for claims that smoking
13 cigarettes is an addictive activity. In 1995, CTR grantee Lorna Role of Columbia
14 University published an article entitled “Nicotine Enhancement of Fast Excitatory
15 Synaptic Transmission in CNS by Presynaptic Receptors.” Dr. Role’s article was
16 reported widely in the general media, including *The New York Times* and *USA Today*.
17 CTR grantees have published dozens of additional papers on nicotine’s effects on the
18 body, including nicotine’s effects on the central nervous system.

19 **Q. Can you identify Exhibit JD-095549?**

20 A. Exhibit JD-095549 is a document from CTR’s files containing the records
21 of grant-in-aid funding payments to Dr. Role. Exhibit JD-095549 shows that Dr. Role
22 received funding from CTR from 1990 through 1999. In total, Dr. Role’s laboratory
23 received approximately \$500,000 from CTR for nicotine-related research.

24 **Q. Can you identify Exhibits JD-093891 and JD-090203?**

1 A. Exhibit JD-093891 is a printout of the text of a September 22, 1995 *USA*
2 *Today* article entitled “Nicotine’s power on brain tied to smokers’ alertness.” Exhibit JD-
3 090203 is a September 23, 1995 *New York Times* article entitled “Researchers Discover
4 Feel-Good Spot for Nicotine.” These newspaper articles reported on the findings of
5 Dr. Role’s CTR-funded nicotine research.

6 **Q. Can you identify Demonstrative Exhibits JDEM-010290 and JDEM-**
7 **010291?**

8 A. These are documents that I prepared in about 2002 to illustrate some of the
9 findings that CTR grantees published on the subject of cigarette smoking, dependence
10 and addiction. They summarize the findings of five different CTR-funded grantees,
11 specifically, the following six publications: Knapp (1963), “Addictive Aspects in Heavy
12 Cigarette Smoking”; Abood (1978 and 1979) “Electrophysiological, Behavioral, and
13 Chemical Evidence for a Noncholinergic, Stereospecific Site for Nicotine in Rat Brain”
14 and “Evidence for a Noncholinergic Site for Nicotine’s Action in Brain:
15 Psychopharmacological, Electrophysiological and Receptor Binding Studies”; Fuxe
16 (1981), “Effects of Acute Central and Peripheral Administration of Nicotine on
17 Ascending Dopamine Pathways in the Male Rat Brain”; Svennson (1988), “Selective
18 Stimulation of Limbic Dopamine Activity by Nicotine”; and Role (1995), “Nicotine
19 Enhancement of Fast Excitatory Synaptic Transmission in CNS by Presynaptic
20 Receptors.”

21 **Q. Can you identify Exhibits JD-004658, JD-094832, JD-094833, JD-**
22 **095005, JD-095301 and JD-095351?**

23 A. These are the articles that are referred to in Demonstrative Exhibits
24 JDEM-010290 and JDEM-010291.

1 **Q. Did CTR's Annual Reports refer to research findings linking smoking**
2 **to disease and discussing cigarette smoking and addiction?**

3 A. Yes. In its Annual Reports, CTR summarized the results of each of the
4 papers that it became aware had been published and that attributed support to CTR. For
5 example, the Knapp article is cited on pages 48-49 of Exhibit JD-090007, the 1963-64
6 CTR Annual Report; the Abood articles are cited on pages 40-42 of Exhibit JD-090021,
7 the 1979 CTR Annual Report; the Fuxe article is cited on pages 89-90 of Exhibit JD-
8 090027, the 1985 CTR Annual Report; the Svennson article is cited on pages 117-118 of
9 Exhibit JD-090030, the 1988 CTR Annual Report; and the Role article is cited on page
10 207 of Exhibit JD-090037, the 1995 CTR Annual Report.

11 **Q. Dr. McAllister, are you familiar with Dr. Neil Benowitz of the**
12 **University of California at San Francisco Medical School?**

13 A. I don't know Dr. Benowitz personally, but I know him by reputation.

14 **Q. Was Dr. Benowitz ever a CTR grantee?**

15 A. He was not. He submitted a CTR grant application quite a few years ago,
16 but did not receive funding from CTR.

17 **Q. Please look at pages CTR MIN-SAB 000566 and CTR MIN-SAB 570**
18 **of Exhibit JD-090960. What do these pages show?**

19 A. Pages CTR MIN-SAB 000566 and CTR MIN-SAB 000570 are the pages
20 of the minutes of the CTR SAB meeting of April 9-11, 1980, at which Dr. Benowitz's
21 grant application was considered. The first page, CTR MIN-SAB 000566, shows that
22 Dr. Benowitz's grant application was rated for approval by the SAB, which meant that it
23 met the minimum standards for funding. The second page, CTR MIN-SAB 000570,
24 shows the 30 grant applications that were ultimately funded. Based on CTR's grant

1 review procedures about which I have testified, Dr. Benowitz's grant application was not
2 rated quite highly enough by the SAB to be funded by CTR.

3 **Q. Are there other documents in CTR's files that may help to explain**
4 **why Dr. Benowitz's grant application was not ultimately funded by CTR?**

5 A. The written reviews of the grant application by the SAB members
6 assigned to write those reviews help to explain those reasons.

7 **Q. Can you identify Exhibit JD-013232?**

8 A. Exhibit JD-013232 is the review of Dr. Benowitz's CTR grant application
9 that was prepared by Dr. Richard Bing, a cardiologist on the SAB. The title of
10 Dr. Benowitz's grant application was "the Role of Cotinine in the Pharmacology of
11 Chronic Nicotine." Cotinine is a metabolite of nicotine, and Dr. Benowitz had proposed
12 to study the effect of this metabolite on the body. Dr. Bing had himself conducted
13 extensive research into nicotine. Dr. Bing's review said, "I am not too impressed by this
14 application, the main reason being that the evidence of the chronic effects of cotinine so
15 far are minor, making it doubtful that cotinine itself contributes much to the effect of
16 nicotine. The authors are certainly well qualified pharmacologists, and their paper on the
17 effect of Disulfiram (antibuse) is important. Nonetheless I find this application as not
18 contributing to the pharmacology of nicotine. Their grants on the effect of nicotine are
19 already in progress, and my reason for stating that cotinine itself is not a contributor to
20 this is borne out by much of what they say. Therefore, I am doubtful about this
21 application, although it is carried out by competent people and with competent
22 techniques."

23 **Q. Does Dr. Benowitz's name appear on any later documents in CTR's**
24 **files?**

1 A. Yes. In the 1990s, Dr. Benowitz and Dr. Jon Levine, a CTR grantee who
2 was a colleague of Dr. Benowitz at the University of California at San Francisco Medical
3 School, collaborated on research related to nicotine and jointly reported their findings.
4 Dr. Benowitz and Dr. Levine appeared as co-authors of at least two scientific articles
5 reporting on CTR-funded research.

6 **Q. Can you identify Exhibit JD-053337?**

7 A. Exhibit JD-053337 is a copy of a scientific article entitled “Neural and
8 Endocrine Circuits Mediating Inhibition of Bradykinin-Induced Plasma Extravasation by
9 Subcutaneous and Spinal-Intrathecal Nicotine,” and it appeared in 1996 in *The Journal of*
10 *Pharmacology and Experimental Therapeutics*. The authors are listed as Frederick Jai-
11 Pei Miao, Neal Benowitz, and Jon D. Levine.

12 **Q. Does this article, Exhibit JD-053337, acknowledge CTR’s funding**
13 **support?**

14 A. Yes, it does. It states on page 1515, under the acknowledgements section,
15 “This work was supported by a grant from the Council for Tobacco Research,” referring
16 to CTR’s grant to Dr. Levine.

17 **Q. Can you identify Exhibit JD-013233?**

18 A. Exhibit JD-013233 is a scientific article entitled “Contribution of Adrenal
19 Hormones to Nicotine-Induced Inhibition of Synovial Plasma Extravasation in the Rat,”
20 which appeared in 1997 in *The British Journal of Pharmacology*. The authors are
21 Frederick Jia-Pei Mia, Neal L. Benowitz, Philip H. Heller and Jon D. Levine.

22 **Q. Does this article, Exhibit JD-013233, acknowledge CTR’s funding**
23 **support?**

24 A. Yes, it does. It states on page 303, “This work was supported by a grant
25 from the Council for Tobacco Research,” again referring to CTR’s grant to Dr. Levine.

1 **Q. Are there abstracts of these two articles in CTR Annual Reports?**

2 A. No. We received copies of these articles too late to include the abstracts
3 in our last CTR Annual Report.

4 **I. Publication of CTR Special Projects Research**

5 **Q. Did recipients of CTR Special Projects funding publish their research**
6 **results?**

7 A. Most of them did. U.S. Ex. 53303, which CTR submitted to
8 Representative Waxman's subcommittee in September 1994, lists more than 300
9 publications and public presentations by the scientists who were funded through CTR
10 Special Projects. So far as I can determine, there was no procedure for CTR Special
11 Projects recipients to submit copies of their published articles to CTR, but some of them
12 did submit copies that are in CTR's files. In the 1990s, CTR and the member companies
13 collected the publications they could find in the scientific literature by CTR Special
14 Projects recipients that acknowledged CTR funding, or that otherwise appeared to have
15 resulted from CTR Special Projects funding.

16 **Q. Did every CTR Special Project result in one or more publications in**
17 **the scientific literature?**

18 A. No, but that is not surprising. At least 25 of the 120 CTR Special Projects
19 did not support original scientific research, but instead were used to provide funding for
20 scientists to review the existing scientific literature, for scientists' attendance at
21 conferences, or for other activities that one would not expect to lead to publications in the
22 scientific literature. Not every original research project results in publication; sometimes
23 research does not yield publishable results. That's the nature of scientific research.
24 Likewise, it was not unusual for CTR grants-in-aid to not result in publication for that
25 same reason. In fact, the proportion of research projects that did not result in publications

1 was roughly the same – approximately one-third – for research funded by CTR Special
2 Projects and for research funded by CTR grants-in-aid.

3 **Q. Did CTR tell recipients of CTR Special Projects funding anything**
4 **about publishing their research findings?**

5 A. Yes. There are in CTR’s files numerous letters to CTR Special Projects
6 recipients that refer to the prospect that they would publish, with no reference to any
7 limitation on their right to publish.

8 **Q. Can you identify Exhibit JD-093722?**

9 A. Exhibit JD-093722 is a compilation of 183 letters to CTR Special Projects
10 researchers that I just referred to. The letters notify the researchers of the approval of
11 their initial or renewal funding requests, and each of them refers to the prospective
12 publication of the recipient’s research.

13 **Q. Can you identify Exhibit JD-093792?**

14 A. Exhibit JD-093792 is an August 29, 1985 letter from Mr. Gertenbach, the
15 President of CTR, to Edgar Bowers, Associate Counsel of Martin Marietta Energy
16 Systems, regarding CTR Special Project No. 132 with the U.S. Department of Energy. In
17 the letter, Mr. Gertenbach said he wished to emphasize that not only did Martin Marietta
18 Energy Systems, the Department of Energy, and the Government have the right to
19 publish or disclose any data arising from the Special Project, but that “they should have
20 the intention to publish such data.”

21 **Q. Are you aware of any evidence that any recipient of CTR Special**
22 **Projects funding was told not to publish his or her research results?**

23 A. No, I am not.

1 **Q. Are you aware of any evidence that any recipient of CTR Special**
2 **Projects funding was told what to say, or what not to say, in any publication of his**
3 **or her research findings?**

4 A. No, I am not.

5 **X. WHEN DID CTR CEASE ITS ACTIVITIES?**

6 **Q. According to the information in CTR's files, when did CTR stop**
7 **supporting CTR Special Projects research?**

8 A. After 1986, no new CTR Special Projects were begun, but the funding of a
9 half dozen or so CTR Special Projects continued. The last check appears to have been
10 written to Dr. Feinstein in 1990.

11 **Q. When was CTR's last Annual Report issued?**

12 A. In the spring of 1998. That was the Annual Report for 1997.

13 **Q. When did CTR issue its last press release?**

14 A. In 1997.

15 **Q. When did CTR stop funding all scientific research?**

16 A. In around March 1999, six years ago.

17 **Thank you, Dr. McAllister. No further questions.**