UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, Plaintiff, v. PHILIP MORRIS USA INC., f/k/a PHILIP MORRIS INC., et al., Defendants.	Civil Action No. 99-CV-02496 (GK)

UNITED STATES' WRITTEN DIRECT EXAMINATION

OF

WILLIAM A. FARONE, Ph.D.

SUBMITTED PURSUANT TO ORDER #471

I. Preliminary Introduction and Summary of Opinions

Q: Please state your name for the record, Dr. Farone.

A: My name is William A. Farone.

Q: You hold a Ph.D. in physical chemistry, correct?

A: Yes.

Q: What is your current occupation?

A: I am President and Chief Executive Officer of a company called Applied Power Concepts, Inc.

Q: Did you found Applied Power Concepts?

A: Yes.

Q: What does Applied Power Concepts do?

A: Our company develops chemical technology and biotechnology related to energy generation and environmental remediation. For example, we develop processes to remove toxic materials from the atmosphere and environment. We do that through making chemicals that treat pollution on sites or by replacing toxic materials with other materials that are environmentally more friendly, such as creating sugar and fat-based insecticides and fungicides. The chemical we use to make one insecticide has even been approved for use as a food additive by the Food and Drug Administration, so it is a much safer and environmentally friendly alternative to other insecticides.

Q: Have some of your concepts or inventions been used to alleviate environmental pollution?

A: Yes, we have two products that were used at over 8,000 sites around the United States.

Q: When did you form Applied Power Concepts?

A: In 1987.

Q: Prior to forming Applied Power Concepts, you worked at Philip Morris from 1976 to 1984, correct?

A: Yes.

Q: So the record is clear, when I refer to Philip Morris throughout this direct examination, do you understand that I am referring to Philip Morris USA Inc., the Defendant in this case formerly known as Philip Morris Incorporated?

A: Yes.

Q: During the entire time you were there, what was Philip Morris Incorporated's basic corporate structure as it pertained to its cigarette business?

A: Philip Morris Inc. had two divisions, Philip Morris USA and Philip Morris International.

Q: During that time did Philip Morris Inc., now known as Philip Morris USA Inc., have any parent company?

A: No.

Q: What was your position at Philip Morris?

A: For the last seven of the eight years I was there, I was the Director of Applied Research.

Q: Dr. Farone, you have been retained as an expert by the United States in this action, correct?

A: That is correct.

Q: Before getting into a more detailed review of your background and your work at Philip Morris, can you please summarize your conclusions about which you are prepared to testify?

A: Yes. My conclusions cover six main areas:

1. A cigarette is a complex device engineered to deliver nicotine via cigarette smoke, and that what a smoker gets from puffing on a cigarette is determined by how a cigarette is made, what is used to make it, and how the smoker smokes it. It is my opinion that the cigarette company Defendants have designed and sold their brands of cigarettes to intentionally exploit their sophisticated understanding of all three – the manufacturing process, the components of a cigarette, and smoker behavior.

2. The tobacco industry recognized, even during the time that the companies were publicly denying that the smoke from cigarettes caused disease, that the evidence linking smoking and disease was sufficient to conclude scientifically that inhaling cigarette smoke was a cause of disease.

3. Defendants have long understood that cigarettes are addictive and that nicotine is the agent in cigarette smoke primarily responsible for addiction; and that in light of this knowledge, they have designed and manufactured their cigarettes to ensure that smokers can obtain enough nicotine to satisfy their addiction. As a result of these design choices to facilitate nicotine delivery, the major brands of cigarettes sold by Defendants as "light" or "low tar" do not significantly change the chemistry or composition of cigarette smoke compared to their "full flavor" counterparts. Therefore, from a chemist's perspective, I would not expect such cigarettes to present any meaningful reduction in harm. In fact, at least some designs features as used in "light" cigarettes make the smoke more toxic than the smoke from their "full flavor" versions.

4. Defendants' product research and development activities reflect an agreement not

to perform certain biological research on commercially marketed products in their domestic facilities. I first learned of the existence of such an agreement during my time at Philip Morris. As a result of this agreement, Defendants failed to perform meaningful tests on their as marketed products indicating biochemical differences in toxicity that have a bearing on the safety of their products.

5. Defendants' research and development activities demonstrate substantial understanding of which chemicals in cigarette smoke were overwhelmingly likely to contribute to causing the harms of smoking. Defendants in fact knew of and have developed technologies that reduced or eliminated harmful agents from smoke that were technically and commercially feasible, but did not meaningfully test them, did not incorporate them into marketed products in meaningful fashion, and did not assess how cigarettes with these features performed on standard toxicological tests as compared to commercially sold brands. It is my conclusion that Defendants did not want to generate comparative scientific data that could show some cigarettes likely to be less harmful than others, since their official position was that no cigarettes had been proven unsafe. Defendants' scientific documents show that Defendants have endlessly studied and restudied scientific issues and problems, inevitably concluding that there was insufficient data to support fully implementing changes with potential safety advantages.

6. Defendants continue to obfuscate the science and technology of cigarettes and cigarette smoke, as it relates to their research on the chemicals in smoke and tobacco, the harm caused by the chemicals, and thus the products. In my view, the "reduced risk" products that Defendants have recently begun to market, or say

they intend to market, represent technologies available to them for decades.

Q: On what do you base these conclusions?

A: All of these opinions derive from my scientific education, training, and work experiences, including my eight years working in applied research in the Research & Development Department at Philip Morris; my contact with others who worked in the tobacco industry; review of the pertinent published scientific literature; and from my review of industry documents. These industry documents include (1) documents that concern research on cigarette design and manufacture for which I received copies while at Philip Morris, (2) Philip Morris documents created both during and after my employment at Philip Morris to which I first gained access well after I left Philip Morris, and (3) other industry documents, including large numbers of documents showing similar technical results as the PM documents.

II. <u>Education, Training, and Work History</u>

Q: Dr. Farone, when you went to work for Philip Morris in 1976, what were you hired to do?

A: I was hired for two main reasons: to help Philip Morris develop a less hazardous cigarette product, and to help Philip Morris diversify its business to reduce its economic dependency on cigarettes.

Q: Did you have any prior experience working in the tobacco industry or with cigarette technology before you went to Philip Morris?

A: No.

Q: Taking your main objectives one at a time, what was your background that qualified you to work on developing technologies to reduce the hazards of cigarettes at Philip Morris?

A: I had studied and worked extensively in two areas very important to cigarette design and technology. First, I had studied the chemistry and biochemistry of a group of chemicals called alkaloids, which include nicotine. I had studied nicotine specifically. Second, I had studied and worked on the chemistry and physics of smoke, including tobacco smoke, as part of my study of colloidal systems. Colloidal systems are things like clouds or aerosols, which have particles suspended in them. Tobacco smoke is an aerosol. I also had management experience with direct responsibility for the development of new consumer products and testing those products for their safety.

A. Education

Q: Dr. Farone, please briefly recount your educational background and training, beginning with your college studies.

A: I went to Clarkson University in northern New York, and graduated in 1961. I majored in electrical engineering, chemical engineering, and chemistry, and graduated with a degree in chemistry in 1961. I then went on to receive my Masters of Science in 1962 in chemistry from Clarkson. I then pursued a Ph.D., and received a Ph.D. in Physical Chemistry, also from Clarkson, in 1965.

Q: Please describe generally the field of physical chemistry.

A: Physical chemistry is the field that concerns the intersection between physics and chemistry.

Most broadly, it's the understanding of chemistry as it applies to and interacts with physical and living systems, including humans, animals, plants, and bacteria. We also studied how chemicals are created in plants, and how one can synthesize and extract chemicals. We also studied chemistry dealing with combustion and pyrolysis, which is related to what happens chemically

when things burn or become heated to high temperature.

Q: What are combustion and pyrolysis?

A: Both basically concern the degradation of chemicals in the presence of high heat. Most generally, combustion involves the burning of matter in the presence of oxygen, such as the burning of gasoline in your car. Pyrolysis involves the burning of matter in the absence of oxygen, such as burning food in a closed container such as a roast in a pot where air cannot access the burning material.

Q: Can you give a real-world example of where both combustion and pyrolysis occur?

A: Yes. Both combustion and pyrolysis occur in a burning cigarette.

Q: We will discuss how that occurs in a cigarette in more detail later on. Do you know what natural product chemistry is?

A: Yes. Natural product chemistry is the study of the chemicals and their reactions that are normally found in nature, either in plants or in mammals or bacteria or even in soil. Natural product chemistry is a subset of chemistry in that all the products being studied are found in natural products whereas chemistry in general concerns any interaction between the 118 elements currently known, no matter where they are found. In physical chemistry, we add the dimension of the physical interaction of the chemical compounds formed from the elements, no matter where they are found, including how energy is given off or taken up when they interact.

Q: Did you study natural product chemistry when you were in school?

A: Yes, I did.

Q: How long did you study natural product chemistry?

A: It began in my senior year in college, a full year, and then extended into my graduate studies.

Q: Was your understanding and study of natural product chemistry relevant to your later work at Philip Morris?

A: Yes.

Q: How was your understanding and study of natural product chemistry relevant to your later work at Philip Morris?

A: Tobacco and cigarettes contain nicotine, which is a natural alkaloid. As part of studying the chemistry of how chemicals interact with human cells, we studied all of the major alkaloids known at the time and even some of the synthetic ones. When I was in college, there was a major problem with "designer drugs" being produced that were related to ones you find in nature. The ones you find in nature are things like nicotine, cocaine, heroin, peyote, mescaline, and caffeine. There are also a lot of beneficial drugs that are found in nature that are used to treat diseases or in chemotherapy. The purpose of this course was to study those chemicals, understand how they interact with humans or how they are synthesized in plants, with the idea that as a chemist you might be involved in projects to make synthetic chemicals of similar type like pharmaceutical companies do. At the time I was at Clarkson we had a major program in designing chemotherapeutic agents, many of which were derived form natural products.

Q: What is an alkaloid?

A: Alkaloid is a term applied to a very broad class of chemicals that have a nitrogen compound that causes the chemical to act as an organic base.

Q: What do you mean by base?

A: A basic substance is one that if you put it in water, it has a high basicity or alkalinity – most technically, a relative dearth of hydrogen ions. On the pH scale which measures how acidic or basic something is, a base has a pH greater than 7. The pH scale is open ended, but generally

things in nature are in the range of 0 to 14, with values over 7 being more basic and those below 7 being more acid. Things like lemon juice and vinegar are acidic and taste sour while things like lye-soap, alkaloids like caffeine and nicotine, and garden lime are basic and taste bitter.

Q: Are there alkaloids in tobacco other than nicotine?

A: Yes. Nicotine is certainly the major alkaloid, but tobacco also has minor alkaloids, including nornicotine, cotinine, and anabasine. For the purposes of this discussion, when I say alkaloid in tobacco chemistry, I am referring to nicotine, nornicotine and the other compounds that provide a similar pharmacological effect as nicotine.

Q: Are the alkaloids in tobacco the only ones delivered to smokers in cigarette smoke?

A: No, additional alkaloids are formed during pyrolysis. These include pyridine and pyridine derivatives. Some alkaloids such as theobromine occur in smoke because they are associated with additives used in making cigarettes, such as cocoa products.

Q: Is nicotine is an alkaloid that you specifically studied?

A: Yes.

Q: What area within the field of physical chemistry did you focus on during your Ph.D. studies?

A: My Ph.D. studies focused on colloids, which is a state of matter where things are finely divided and suspended. For example, smoke is a colloid. Clouds are colloids. Milk, blood and the inside of bacterial cells are all colloids.

Q: What was your doctoral dissertation project about?

A: My dissertation was about using electromagnetic radiation, light radar, and infrared to determine the physical and chemical properties of these suspended materials, either an aerosol like smoke or a hydrosol like milk. The method allowed you to simply shine different kinds of

radiation on it without actually disturbing the system and determine both its physical makeup and its chemical composition.

Q: Did you actually study smoke as part of your Ph.D. work?

A: Yes.

Q: What kinds?

A: Many different kinds, including smoke from burning cigarettes and smoke from wood fires. The instruments and techniques we used allowed us to study the colloidal state of matter and we used the instruments on a wide variety of products and problems – everything from clouds in the sky to long thin fibers made from glass or metal to things like cigarette smoke and suspensions of gold particles.

Q: Was your doctoral study of aerosols used in your later work at Philip Morris?

A: Yes.

Q: How so?

A: It was actually one of the reasons they were interested in hiring me, because there are not too many people that understand the physical chemistry of aerosols. Tobacco smoke is an aerosol, which is a colloidal system. And prior to the time I went to work for Philip Morris I had spent a considerable portion of my professional career understanding and publishing on things like smoke. For example, I had studied the way that one can control the particle size distribution of an aerosol and the means in nature whereby particles could become easier or more difficult to inhale.

B. Pre-Philip Morris Employment (1964-1975)

Q: We will discuss your work at Philip Morris in more detail shortly. Let's first review your work before you went to Philip Morris. What was the work you first did that applied

your knowledge of physical chemistry?

A: Between 1964 and 1965, I worked as an atmospheric physicist for the Department of Defense at White Sands Missile Range.

Q: What did you do at White Sands?

A: The aerosol we were interested in there was the atmospheric aerosol, such as clouds in the atmosphere and dust. This had application to understanding things like chemical agents in warfare and radar. The military was very interested at that time in technology related to being able to sense things in the environment using radiation like multiple wavelength radar without actually taking samples. Some of the projects, for example, that I dealt with involved determining the colors of the rainbow and that had to do with, from a military perspective, how different wavelengths of light were scattered off clouds. It was related to classified technology related to the Stealth Bomber.

Q: Did you publish papers describing your work at White Sands?

A: I was allowed to publish some of my work conducted while at White Sands, including papers on the rainbow, tables to help in determining smoke particle size, and a paper on radar UFOs that were called radar "angels," which are things that you see on a radar screen even though the sky is clear.

Q: Can you please identify these on U.S. Ex. 78,530, which is a recent version of your curriculum vitae?

A: They include publications numbered 7, 8, 12 and 13 on the CV.

Q: You indicate that you were employed at White Sands Missile Range as a physicist. Could you explain your background in terms of how it would allow you to serve as a physicist as well as a chemist?

A: Physical chemistry is a cross-over between physics and chemistry. And in some areas things related to aerosols and clouds and radar are considered physics. When you start talking about the chemical composition of those clouds and how it affects the radiation, then it is chemistry. So it is a cross-over discipline.

Q: Are you a member of any professional societies?

A: Yes, I belong to professional societies for both physics, chemistry, and chemical engineering.

Q: Have you published in both physics and chemistry peer-reviewed journals?

A: Yes. I have over 75 peer-reviewed publications, including patents.

Q: Are some of these publications listed on your CV (U.S. Ex. 78,530)?

A: Yes.

Q: What did you do after your work at the White Sands Missile Range?

A: I taught college for two years at Virginia State University in Petersburg, Virginia.

Q: What courses did you teach there?

A: I taught advanced chemistry courses, physical chemistry, thermodynamics, biochemistry, statistics, and a course in mathematics.

Q: Did you continue to work with aerosols while you were teaching at Virginia State University?

A: Yes.

Q: Did you work extensively with any particular aerosol?

A: Yes.

Q: Which one?

A: Tobacco smoke.

Q: Was this the first time you had studied tobacco smoke as an aerosol?

A: No. When I was in college, we used tobacco smoke in our light scattering systems because it was more complex than the aerosols we made synthetically, so we would try and extend what we were doing with our synthetic aerosols to tobacco smoke.

Q: At Virginia State, what work did you do that involved tobacco smoke?

A: I had a National Institutes of Health grant to study atmospheric pollution, which included tobacco smoke.

Q: When was the first time you had any contact with any of the scientists from Philip Morris?

A: It was during that period, around 1965 or 1966.

Q: How did you have contact with them?

A: The American Chemical Society section that I belonged to when I taught college was the same one that the chemists at Philip Morris belonged to, and several times during the course of my teaching career we were invited actually to go to Philip Morris for talks concerning chemistry topics.

Q: What did you do after your teaching experience?

A: I went to work for Lever Brothers Company in Edgewater, New Jersey.

Q: What did you do there?

A: I had a series of positions at Lever Brothers. When I first went in, I was a scientist involved in their programs on Close-Up toothpaste. Later, the part I was involved in was transitioning Close-up to another toothpaste you may have heard of, Aim toothpaste. The difference is that Aim is a drug because it contains fluoride, and Close-Up was a regular toothpaste at that time. So they hired me to help them develop the formulations and the

chemistry that was used to support Aim toothpaste; that was the first job I had.

Q: What did you do after that?

A: I went through a series of jobs. In 1969, I became a manager of New Product Development.

Q: What did that position entail?

A: I reported to the vice president of R & D and in that job I was responsible for all the new products that Lever Brothers would make. That includes food, cosmetics, toiletries, detergents, household products, including over-the-counter drugs.

Q: When you say responsible for them, what do you mean?

A: Well, I would work with the scientists in the development part. I would interface with attorneys that were involved in FTC claims support, with the marketing people, with attorneys involved in patenting the products and financial analysis for the company on which of these products may be successful and which ones might not be.

Q: What was your next job at Lever?

A: The next job was manager of Detergent Evaluation, and specifically there I was responsible for FTC claim support on all of the household products.

Q: And what was your next job at Lever Brothers after that?

A: In 1972, I became Director of Scientific Research, responsible for the entire Research Division at Lever Brothers.

Q: Please generally describe your responsibilities in that position.

A: That job entailed supervision of the Toxicology Department, the Microbiology Department, organic chemistry, physical chemistry, analytical chemistry and engineering. All of the work that was done relating to government regulatory bodies, including the Food and Drug

Administration, Environmental Protection Agency, and the Consumer Product Safety Commission, went out over my signature. I also reviewed and approved the science behind advertising claims before they were made.

Q: Please explain further your work in reviewing potential advertising claims.

A: When you make an advertising claim, you have to have evidence to support the claim. For example, one product I worked with was Promise Margarine, which Lever claimed lowered your blood level of cholesterol. To make sure that claim was accurate, we actually ran clinical trials, several hundred people in each set, where we had them use Promise Margarine. Margarine in general will not lower your blood level cholesterol; however, you can make it in a specific way by using certain kinds of fats, so that it can lower blood cholesterol. In order to say it does in an advertisement, you have to run clinical trials. So we hired physicians. These were clinical trials like one would do for a drug, and we were able to establish a lowering of blood level cholesterol over a period of a couple of years, and then we could advertise that product for that purpose.

Q: Did you undertake these testing procedures for all of the products that Lever was manufacturing and selling?

A: Yes. Not only for claim support, but also for consumer interactions. For example, I was also the person that was on the call-up for the Poison Control Center in case someone accidentally ingested a bottle of dishwashing liquid; and we would also monitor consumer complaints and would attempt to change products to make them so the complaint rate would decrease, that is, the company would not receive complaints.

Q: What type of complaints are you referring to?

A: I'm talking about complaints related to physical effects of products, not situations where people call and say things like, "Your detergent didn't wash my clothes as well." I'm talking

about consumers reporting things like, "I got a rash," "I got a mouth irritation," or "I got sick from eating your product."

Q: For these types of physical complaints, what complaint rate would Lever Bros. recognize as a significant problem when you were there?

A: We kept track of the number of problems per million units sold or ten million units sold. And I think in the case of toothpaste, for example, we didn't like to see irritation complaints of more than one in fifty million tubes sold.

Q: What did you do if you did see complaints that exceeded the threshold of one in fifty million tubes sold?

A: We would try to talk to the people who had complained to determine if there was a problem and what it was. I remember in one case we saw some two hundred complaints in a year, and we were able to establish through going back and looking at our records testing that the problem was chemical. One of the flavors – cinnamon added to Close-Up toothpaste – was responsible for the excess irritation. We had to devise a new test that was more sensitive than the previous one to make sure that all new batches of cinnamon that we put in toothpaste would not cause irritation.

Q: Can you briefly explain how just adding something like cinnamon could cause the rate of irritation-related complaints to rise?

A: Yes. Adding a new chemical, even something that might be benign on its own, can alter the effects of the formulation considerably. In consumer products like the ones we were dealing with there in toothpaste, for example, we might put three flavors in toothpaste, we might use spearmint, cinnamon and peppermint combined, and if we tested them all individually, we might find they are all okay. But when we put them together, we might find out they are very irritating.

That is called synergy – when two or more interacting chemicals cause a reaction that was greater than the sum of the parts that were put together.

Q: And did that play a role in your work at Lever in terms of assessing the effects when you would put together the components, for example, of a bar of soap?

A: Absolutely. We tested not only the individual chemicals that went into the product but then we would test exactly the final exact formulation that we would sell to consumers to make sure that there were no synergistic problems.

Q: Could you tell us what whole product testing is?

A: It is the testing of the product exactly as the consumer is going to come in contact with it. Typically, you either remove those products from the production line to test or you go out into the market and you buy back products that are on store shelves, both ways are used.

Q: Why are you interested in doing that if you are a manufacturer?

A: That's the product the consumer interacts with, and so that's the product that you want to test, to find out if it has a hazard or a problem.

Q: When did you leave Lever Bros.?

A: In 1975.

Q: Where did you work next?

A: I went to work for a company called Pacific Vegetable Oil International (PVO). The headquarters was in San Francisco, California. The production facilities and Research & Development Department was in New Jersey. I became the Vice President of Research and Development.

Q: What did PVO do while you were Vice President of R&D?

A: PVO actually is doing similar things to what my company is doing today. We were

making products from natural products such as vegetable oil that could be used by consumer product companies. PVO sold products to Lever; that's how I first became aware of them. PVO also sold products to other pharmaceutical companies and consumer product companies.

Q: What was your next job?

A: I was then hired by Philip Morris.

III. Employment at Philip Morris, 1976-1984

A. Hiring

Q: How did you come to work for Philip Morris in 1976?

A: In late 1975, I was approached by an executive search firm – a headhunter – sent out by Philip Morris looking for someone that had experience in dealing with regulatory authorities for consumer products and that had a background in colloidal systems to join their company for the two purposes: number one, of helping them diversify into other areas and, second, to help them develop less hazardous products.

Q: How did you learn that these were the two primary goals for the position about which you were contacted?

A: I learned this from Robert Seligman during my initial interview. He was then a staff Vice President in the New York office of Philip Morris, but he was going to become the Vice President of Research and Development in Richmond sometime early in 1976. He was looking to augment his staff with someone with my kind of background because of concerns over the future direction of the company.

Q: How and from whom did you learn of these concerns?

A: From Dr. Seligman during this initial interview.

Q: How extensive was the interview and hiring process?

A: Quite involved. The interview process extended over about three months.

Q: And what, to your understanding, was it about your training and experience that made you a favorable candidate to Philip Morris at that time?

A: I think it was several different things. As we have discussed, I have a background in the kind of chemistry that is important for tobacco smoke. I had studied aerosols; I had studied combustion and pyrolysis. I also worked for a consumer product company and was in charge of getting new products to market. I had also been the chairman of Unilever's Patent Committee, so I understood how to develop and patent new technologies. I also was not a tobacco company insider at that time and thus would bring a different perspective.

Q: Did Philip Morris offer you a position?

A: Yes.

Q: Why did you take it?

A: Because I believed I could help Philip Morris design and manufacture safer, and could help them lessen their corporate dependence on cigarettes by diversifying into new product areas.

Q: When did you start with Philip Morris?

A: I started working April 1, 1976.

Q: What was your first job title at Philip Morris?

A: Associate Principal Scientist.

Q: What did you do in that position?

A: For approximately the first year I traveled around different parts of the company, learning about the business and how cigarettes were made. I visited all of the manufacturing plants, all of their operations facilities, and interviewed the scientists in the lab to develop my ideas, based on my background, about what areas Philip Morris should focus on with regard to both

diversification and production of safer cigarette products.

Q: How did you go about doing that?

A: My boss, Dr. Seligman, arranged for me to spend a period of time, like a week, at the different facilities, for example the manufacturing facility and the reconstituted leaf factory. I even went out in the field and saw how tobacco was grown. I went with the leaf buyers, bought tobacco at auction, saw how tobacco was stored. After each of those episodes, I would come back and talk about how, given my own background, to improve or change some of those processes.

Q: Prior to coming to Philip Morris, were you aware of how a cigarette was manufactured?

A: No.

Q: During that first year at Philip Morris, when you visited the different facilities throughout Philip Morris, did you learn how a cigarette is made?

A: Yes.

Q: Did you have access to documents and materials recording previously done research at Philip Morris?

A: Yes.

Q: Was your access limited to research of a particular subject area or department at Philip Morris?

A: No. However, I could not have access to certain of the research reports related to smoking and health issues without permission, usually from Dr. Tom Osdene.

Q: Were you encouraged to learn and understand those documents?

A: Yes, I was. Some of the people, such as Dr. Helmut Wakeham, were very helpful in

terms of providing me historical documents. I had access to all of his files related to earlier technical work to reduce the risks of the products as provided by him or his secretary. Also, Philip Morris had an excellent library where scientists could have access to research reports. I also had access to other people's previous files. They would provide me with earlier reports they had written in many cases.

Q: Were the reports regularly prepared and kept in a systematic fashion?

A: Yes.

Q: Please describe how research reports were prepared and kept.

A: Each part of the R&D Department did an annual or semi-annual report on their work. They would submit the report with a cover sheet bearing the authors, the supervisor who approved the report, and the distribution list. These are the project reports I am talking about. All of the work was divided by projects and assigned a budget number.

Q: Where were the reports kept?

A: People on the distribution lists each received one, and at least one copy was stored in Philip Morris's research library, called "Central Files."

Q: Was access to prior research conducted at Philip Morris important to your job?

A: Yes.

Q: In what way?

A: If I had an idea about how to change or research something, it was important for me to learn whether people at Philip Morris had had the same idea before, and if so, how much had they thought about or pursued the idea. In science, the next level of scientific progress depends on what you know about the past. Scientists formulate a hypothesis based on observations of what has happened in the past. So I was able to determine what they had done in the past and

thereby help me develop new ideas.

Q: Did you have access to everything in Central Files?

A: It depends on the type of document and the kind of project. Projects that were normally confidential, but not top secret, were maintained in the library, and there was a distribution list that they went to. And when you were finished with that document, you had to return it. There were other documents that required permission of a particular person, most cases it was Dr. Osdene, to have access to that document. And then that was to be returned immediately. Those were documents related to smoking and health that had to do with things that were being done that weren't generally available to the scientists below manager level.

Q: You mentioned diversification as one of the objectives that Philip Morris identified when hiring you. What did you do in this area?

A: During my eight year career there, I proposed areas of interest that they should consider to achieve the goal of diversifying the product portfolio beyond just cigarettes. I visited companies that we thought about purchasing or investing in and showed Philip Morris how that would interact with their current cigarette business and help them change their business.

Q: Were any of those companies involved in the manufacture of cigarettes?

A: No. Most of the ones I suggested were pharmaceutical companies.

Q: What was your next position after Associate Principal Scientist?

A: I became Director of Applied Research in 1977. That was the position for which I was hired, so the change in position was planned when I was hired.

Q: You said that you had access to an excellent library of previous research. How did you gain access to specific documents and research memoranda?

A: For most of the documents dealing with cigarette technology or tobacco technology,

Philip Morris had an index that could be searched. Also, every week one of the projects would be presented at a meeting, and even in my first year I went to all of those, and as a director you go to them. At the meeting, the scientists involved in that project would report on everything they did for the last year. In the written reports, there would be references to prior scientific work, just as in most scientific publications, so scientists could go back and look up that previous work. For the documents related to smoking and health, access could be more restrictive, depending upon the document.

Q: How did your position, Director of Applied Research, fit into the organizational structure of the R&D Department?

A: When I was at Philip Morris, the lowest level of organizational unit was a "project"; a project might involve, for example, attempting to research a filter that selects out particular toxic chemicals. Those projects were organized into divisions. Divisions were organized into directorates, headed by Directors. I was the head of the Applied Research Directorate. While I was at Philip Morris, there were initially four, and later five, directorates. The Directors reported to the Vice President of Research & Development, the top employee in the R&D Department. The Vice President of R&D of Philip Morris reported to a Senior Vice President for Operations, who then reported to the President of Philip Morris USA.

Q: To whom did you report as Director of Applied Research?

A: Over the time that I was at Philip Morris, there were two Vice Presidents of R&D to whom I reported. For the first approximately four years it was Dr. Robert Seligman. The second four years it was Dr. Max Hausermann.

Q: How many divisions did you supervise?

A: It ranged from three to five or six divisions, depending on the time frame, because we

would reorganize periodically and change things around.

Q: How many employees in total would you estimate were under your supervision in the Applied Research Directorate?

A: It started out at about 40 and increased to about 150-200 by the time that I left Philip Morris.

Q: Could you explain briefly what work you actually did as Director of Applied Research? A: The two major job tasks that I had were first, mergers and acquisitions, which accounted for about twenty percent of my actual time that I spent while I was there. And about eighty percent of the time was spent on overseeing the development of technology that could be used in less hazardous cigarette products.

Q: Was that the allocation of time you expected when you started at Philip Morris?

A: Not at all. I thought that I would spend much more time working on diversification and acquisitions, to lessen Philip Morris's reliance on the cigarette business. However, over time it became apparent that Philip Morris remained committed to cigarettes as its primary business, so much more of my time ended up being spent working on cigarette technologies.

This point was made by Mr. McDowell, Senior Vice President of Operations during a discussion I had with him at the time of the change in Vice President of R&D from Dr. Seligman to Dr. Hausermann. Mr. McDowell was explaining the focus of the company in terms of my future and he used an analogy comparing Hercules and Atlas as counterparts to the cigarette business. The question was whether the cigarette business would be like Atlas, who had to bear the weight of the business forever, or like Hercules, who could rest after completing his defined set of tasks. Given what I was hired to do, I saw my job and responsibilities, and future at Philip Morris, as tied to the latter philosophy.

Q: The second responsibility you mentioned was developing technologies for potentially less hazardous products. What did you do in this area?

A: Different directorates within R&D contributed to the development of new cigarette prototypes. My directorate, Applied Research, devised new or improved technologies or processes that we believed could potentially reduce the harmfulness of the product. These technologies were based on the chemistry of specific chemicals in the smoke or on using physical design characteristics to change these chemicals. We would give instructions to another part of R&D, which would have the cigarettes incorporating the new technology manufactured at a small on-site facility, known as the semi-works, which can make small batches of cigarettes specially for research. Then another directorate, run by Dr. Thomas S. Osdene, would oversee the testing of the prototype cigarette. That information would come back to us in various ways depending on where the testing was done and what type of testing was done. And we would then use whatever was transmitted back to us to go to the next step and change the research we were doing.

Q: We will come back to the testing done under Dr. Osdene's direction. Dr. Farone, did you have a say in the final decision as to which technology would ultimately be used, and to what extent, for a particular brand to be commercially sold by Philip Morris?

A: No.

Q: When did you leave Philip Morris?

A: In 1984.

Q: To summarize this portion of your testimony, Dr. Farone, did you apply your training and experience in physical chemistry in your work as Director of Applied Research?

A: Yes.

Q: Did your work at Philip Morris expand your understanding of cigarette smoke from a physical chemistry perspective?

A: I did not learn new scientific principles relating to smoke, but I learned how to apply those principles more specifically to cigarette smoke and to particular components of cigarette smoke in different types of cigarettes.

Q: Was any of your research involving cigarette smoke ever published in a peer-reviewed scientific journal?

A: Yes.

Q: Are those publications listed on your CV, which is U.S. Ex. 78,530?

A: Yes.

Q: In the period of time since you left Philip Morris, have you continued to study the chemistry and biochemistry of toxic chemicals?

A: Yes.

Q: Since leaving Philip Morris, have you continued to work with aerosols and colloidal systems?

A: Yes.

Q: Since leaving Philip Morris, have you continued to work with or study toxic chemicals and their interaction with living systems?

A: Yes. My company deals with all of these things very directly, since we design products and technology that can neutralize or eliminate toxic chemicals from the atmosphere and environment.

Q: Since leaving Philip Morris, have you continued to keep abreast of scientific

developments related to cigarette technology and the chemistry and physics of cigarette smoke?

A: Yes.

Q: How have you kept abreast of such developments?

A: My main source has been through reading the published literature and documents provided to me to review in tobacco cases. I am also on the advisory board to the Transdisciplinary Tobacco Use Research Center (TTURC), a tobacco research organization located at the University of California at Irvine. It has performed some scientific research on cigarettes, including duplicating research involving nicotine pharmacology and acetaldehyde that was done at Philip Morris in the early 1980s. I have suggested some of this work to the group.

Q: In addition to TTURC, have you contributed to public health studies or reports about cigarettes and smoking?

A: Yes.

Q: In what way?

A: I assisted FDA with their studies on cigarette and nicotine from 1994 to 1997. I have also reviewed papers and books chapters for NIH/NCI, and provided technical information to the Centers for Disease Control. In addition, I have given many invited presentations to medical, state governmental and academic organizations.

Q: Dr. Farone, have you ever testified in tobacco litigation as an expert on cigarette design issues and on the chemistry, biochemistry and physics of tobacco smoke?

A: Yes.

Q: Has a court ever precluded you from testifying as an expert witness on these areas based on a finding that you lack sufficient expertise in these areas?

A: Not to my knowledge. I believe that there may have been a case where I was not allowed to testify as an expert because the scope of my expertise was not relevant to the case.

Q: Dr. Farone, have you testified numerous time in lawsuits involving the Defendants in this case?

A: Yes.

Q: How did you come to be involved in matters related to the tobacco industry as a witness?

A: Around Christmas in 1993, an investigator for FDA contacted me out of the blue and asked if I would provide information to FDA about how cigarettes are made, because they were investigating whether to assert regulatory jurisdiction over cigarettes.

Q: That was about 10 years after you left Philip Morris, right?

A: Yes.

Q: Why did you agree to speak to the FDA investigators?

A: I realized that I possessed important information that could potentially contribute to the goal that I had when I was at Philip Morris – to reduce the harms caused by smoking – though obviously in a different setting. There were two parts to the information. One part is the fact experiences of how the Industry worked. This was not my main interest. My scientific experience in the area was very complete and I felt that I could help teach public health officials and interested parties about tobacco technology.

Q: Did you also see it as an opportunity to supplement your income?

A: No. I did not charge FDA anything and I didn't charge plaintiffs anything for the first 4 years after that.

Q: You served as an expert witness for free?

A: Yes.

Q: Why did you start seeking compensation after those first four years?

A: The demand on my time had reached a point that by 2000 my company could no longer provide this pro bono service. I am President and CEO and also function as Chief Scientist for my company, so my absence is a problem. I do own a controlling share of the corporation, although now there are only two shareholders and we each own 50%. The other shareholder felt that I should charge to reimburse the company for the time spent. The money goes to the general revenues of the corporation and not to me personally.

Q: Are you being compensated by the United States for your time working on this case?

A: Yes.

Q: What is your fee?

A: I charge $250/hour while giving testimony. For other expert work I performed in the case, I charged $150/hour. These rates were decided by the corporation as being a fair rate for the corporation.

Q: Have you only testified in cases where Philip Morris was a defendant?

A: No, I have testified in cases that didn't involve Philip Morris, where Brown & Williamson or Reynolds was the only defendant.

Q: How many depositions would you estimate you have given in smoking and health-related cases involving these Defendants?

A: About 60 transcripts of deposition covering about 80 days worth of testimony.

Q: In how many trials have you given testimony?

A: I would estimate about 25 trials, although I am unsure of the precise number.

Q: Did you prepare an expert report that was filed by the United States on November

15, 2001 in this case?

A: Yes.

Q: How did you select the documents that you relied on in support of the opinions expressed in that report?

A: I have maintained a set of reliance materials that consist of publicly available materials over the years. I relied upon the set as it existed at the time I prepared the report.

Q: How did you identify the documents to rely upon in preparing your expert report in this case?

A: I have tried to select documents that I consider to be typical from among the many thousands of documents I have reviewed.

Q: Were the conclusions you identified in your expert report in this case the same basic conclusions as in other reports you have filed?

A: Yes.

Q: Did you review additional documents after the filing of your expert report in November 2001?

A: Yes.

Q: What types of additional documents did you review?

A: I reviewed compilations of Defendants' summary reports and plans from their Research and Development departments, and also documents that describe some of the more recent research and development activities of Defendants.

Q: Is the testimony you are offering today substantially identical to that you have offered in other cases on the same topics?

A: Yes. While the particular words I use to relate my testimony probably varies slightly

from case to case, sometimes depending on what questions are asked and how they are asked, I certainly intend it to be substantively the same.

Q: You testified that you left Philip Morris in 1984. Why did you leave?

A: I was fired.

Q: Have Defendants questioned you about your termination in previous cases in which you've testified?

A: I cannot recall a case in which they have not asked me about it.

Q: What was the reason given at that time for your termination?

A: The reason given by the Human Relations person was insubordination. At the time, my immediate supervisor, Dr. Max Hausermann insisted that I was resigning under mutual agreement with the company.

Q: Did your termination relate to your job performance in any way?

A: Both Human Relations and Dr. Hausermann agreed at the time that the termination was not related to my work performance in any way.

Q: How long after your termination was it before you found and began another job?

A: While I was technically "fired" on July 6, 1984, a settlement was reached with Philip Morris that allowed me to remain employed until September 1984. In July I formed a Virginia corporation, I started discussion with several potential clients, and began work for one of those clients, Dean Witter Reynolds, immediately after the official Philip Morris termination date in September. I moved to the West Coast in October 1984 to carry out this work. When I formed Applied Power Concepts in 1987, it purchased the corporation I had formed in 1984.

B. Philip Morris Structure and Organization

Q: Can you please explain how the Research and Development Department where you

worked operated, and how it interacted with other parts of Philip Morris?

A: Yes. There were different formal and informal structures at Philip Morris. I mentioned that I traveled around to the different areas of the research and manufacturing departments during the first year I was there. Also, every Friday we would have a project review. The lowest level unit organization was the project. Every Friday all of the managers and directors and senior scientists from Research & Development would get together and review the projects that were being done. So, as is typical in scientific meetings, the scientists could hear about different projects and ask the other scientists questions about what they were doing.

At the next level the Directors, myself for example, would have a weekly meeting with our managers. Managers are the people to whom these different projects report. The purpose of those meetings was also to review progress on the projects that weren't up for review at that point, to change direction of projects if necessary, and to discuss budgets to figure out what we were going to do next year.

The next level of meeting was Directors' meetings. I would go to meetings with my fellow Directors. For example, when I was there the other Directors were Dr. Frank Gannon, myself, Dr. Osdene and Mr. Thomson; the four of us would meet with Dr. Seligman, the Vice President of R&D, once a week.

Then once a month we would have what were termed the "Richmond meetings."

Q: What was the general purpose of the monthly Richmond meetings?

A: The purpose of the Richmond meetings was to exchange information among senior management of the company – the chairman, the president, officers, chief financial officer, the general counsel, the Research & Development Department. Everybody who was in senior management, including marketing, management, vice-presidents, marketing directors, and

research and development people, would attend if the issues being discussed related to their interests and if they were invited. It was basically a show-and-tell for R&D.

There were two parts – a technical general meeting and a products meeting. The general meeting would discuss technology in general while the product meeting discussed new products, changes in existing products, product testing and issues with competitive products.

Q: Did all of these people come to every Richmond meeting?

A: No. It depended upon the subject matter of the particular meeting.

Q: Who are some of the people whom you remember coming to Richmond meetings?

A: Several executives from New York came to Richmond meetings, including:

– Mr. Cliff Goldsmith. When he interviewed me he was president of the Philip Morris USA. He then became president of Philip Morris Inc., and then became chairman.

– Hugh Cullman, senior executive in Philip Morris Inc. He was the chairman of Philip Morris USA; and he attended these meetings regularly.

– Joseph Cullman, III, attended several of them that I can recall. He was the chairman of Philip Morris Inc. for the earlier part of my career there.

– Alexander Holtzman, who was general counsel of PM USA, also attended some of the meetings.

– Bill Campbell, who was then a vice president of marketing and marketing director.

– James Morgan, who later became president of PM USA. He was marketing vice president and senior executive vice president at the time I was there.

– Ross Millhiser, who was co-chairman of Philip Morris Inc.

– Shep Pollack who was president of Philip Morris USA for most of my career there.

– Frank Resnik, who used to be Senior Director of Research under Dr. Wakeham when I

was first hired. He became a senior executive in Philip Morris USA and later in 1984 became president of Philip Morris USA.

There were several marketing people, including Mr. Fitzmaurice, John Zoler and several brand managers came from time to time. The marketing personnel from New York came and took part in these discussions when Myron Johnston, Jon Tyndall, Dr. William Dunn, and Dr. Dunn's colleagues in behavioral research would describe in detail how people interacted with nicotine and cigarette products. Since R&D performed the product opinion tests and various internal Philip Morris cigarette-use tests, and coordinated analysis of product tests conducted outside the company, the marketing department also attended some of the Richmond meetings.

Q: How was the business of the Richmond meetings conducted?

A: From the R&D perspective, we in R&D would propose topics ahead of time, and we would make presentations to the attendees and have interactions with them.

Q: What do you mean by interactions?

A: Outside the meeting itself, there would always be a lunch before or after, so we had a chance to eat with and talk to the senior executives in a more informal way.

Q: Did you have interaction with other divisions of the company outside of the Richmond meetings?

A: Yes. Our main interaction with the marketing department was generally done at Richmond meetings. The other departments like leaf department, manufacturing, engineering department – those we didn't have formal meetings but we had joint projects, especially in my area. One of the reasons my area was called Applied Research was that we were trying to get the technology into the production facilities and help the people in the production facilities as best we could. I would meet regularly with the vice president of engineering, vice president of

operations, but those weren't formal meetings, just whenever it was required.

Q: Did the R&D Department ever interact with the Philip Morris Board of Directors?

A: Yes.

Q: Please describe how those interactions occurred.

A: Every year, just before the annual shareholders meeting in the Spring, the Operations Department – which included the R&D, Leaf, and Manufacturing Departments – usually through the Vice President of R&D, would make a presentation to the Board of Directors to update the Board on the work of the past year and what upcoming plans were.

Q: Did you ever personally participate?

A: I did not personally make presentations to the Board, although I was very involved in preparing the presentations that were delivered by other people, like Max Hausermann when he was Vice President for R&D.

Q: You also mentioned that people within R&D interacted and communicated through informal structures. What do you mean by that?

A. By that I mean the types of interactions that occur regularly in any office environment. I would regularly eat lunch with other scientists, or people would drop by my office, and we would talk about what we were working on, what other people were working on, scientific problems, and so forth. For example, I informally assisted with some work on the behavioral psychology work being conducted by Carolyn Levy and Bill Dunn, so I often had coffee with them to discuss their projects.

IV. <u>Opinion No. 1 – Cigarette Design and Technology</u>

A. Manufacturing Process

Q: Dr. Farone, at the outset of your testimony, you summarized your first opinion as

follows:

> **A cigarette is a complex device engineered to deliver nicotine via cigarette smoke, and that what a smoker gets from puffing on a cigarette is determined by how a cigarette is made, what is used to make it, and how the smoker smokes it. It is my opinion that the cigarette company Defendants have designed and sold their brands of cigarettes to intentionally exploit their sophisticated understanding of all three – the manufacturing process, the components of a cigarette, and smoker behavior.**

I will now ask you some questions to assist the Court's understanding of how a cigarette is made, what is in it, and what happens when it is smoked. Focusing first on the manufacturing process, what is the first step in the making of a cigarette?

A: The first step in the making of a cigarette is the growing of the tobacco.

Q: When you were at Philip Morris, did Philip Morris generally grow its own tobacco for its cigarettes?

A: No. It is possible that some of the tobacco grown by subsidiaries outside the U.S. could be imported but basically Philip Morris buys its tobacco on the open market either in the U.S. or foreign markets. Sometimes they bought tobacco directly and other times they bought through a company such as Universal Leaf.

Q: What happens after it is harvested?

A: It is treated or handled in a process known as curing. How it is cured depends upon what type of tobacco it is, as well as the particular curing technology used by the curer.

Q: When you were at Philip Morris, did Philip Morris cure its own tobacco?

A: Not commercially. Experimentally we grew and cured tobacco, and in my Directorate we even leased farms to perform some of the work that we did to study growing, harvesting and curing to improve the tobacco, that is to reduce the harms from smoking it when it was burned.

Q: We will discuss the different types of tobacco and the various curing methods shortly. After the tobacco is cured, what happens to it next?

A: The next step is the purchase of tobacco by the tobacco companies, which mainly occurs at auction. In some case, tobacco can be purchased by direct contract.

Q: At the time of purchase, what information do the companies have about the particular tobacco they are buying?

A: In the U.S., tobacco comes in bales. Generally it comes in some kind of container that has a defined amount of a certain type of tobacco. The bales come with sheets that provide a lot of information about the chemical composition of the tobacco. For example, the companies learn what the total alkaloid content is of the tobacco that is available for purchase. The sheets list the "grade" of the tobacco and some information about where it was grown, etc. Experienced leaf buyers can connect the grade with the approximate nicotine or alkaloid content by knowing the strains used that year and the nicotine yields expected from earlier testing. Since the two – nicotine and alkaloids – are related for any type of tobacco, they provide essentially the same information. Buyers can also pick up and smell the tobacco. For each type of tobacco a buyer learns how to associate the smell with the degree of curing, the amount of volatile materials in the tobacco and thus relate this to the alkaloid content. This is a check on what the other information tells the buyer.

Q: Where does the tobacco go after purchase?

A: The first place it goes is to the stemmery. At the time I was there, Philip Morris owned

its own stemmeries.

Q: What happens at a stemmery?

A: Tobacco is a leaf. It has veins in the leaf that are sometimes referred to as ribs or midribs. So the first thing to do is beat the leaf to break out the mid-ribs from the tobacco leaf from what is then called the stem. The leaf is the part in between the mid-rib. If you think of a maple leaf, remember the ribs going out. If you dry that down and bang on it, the rib comes out. We call those stems. The chunks of lamina or leaf in between, we call tobacco leaf. So that work is done at the stemmery.

Q: What happens next?

A: Those different parts of the tobacco plant are segregated for most types of tobacco. Once separated, the next step is to "age" the tobacco leaf. The parts go into storage or aging areas where they may be held for up to five years. They are stored in different kinds of containers. One large wooden keg is called a hog's head historically. Imported tobacco, called oriental or Turkish tobacco, doesn't need to be stemmed because it is a different form of the plant that has tiny leaves. They are put in there. They are all held in storage until they are needed either directly to make cigarettes or for other processes to change the form of the various parts of the tobacco.

Q: What happens at this stage to the stem and the other pieces that were separated from the tobacco leaf?

A: Those parts, including left-over pieces that are too small to make cigarettes and the stems, are sent off to other processing facilities. Philip Morris had two such processes where they are converted in two different types of "reconstituted" tobacco. One type was called "blended leaf," referred to as BL or RCB in the older literature when these terms referred to using primarily

Burley tobacco. The second type was called reconstituted leaf or RL.

Q: What do these processes do?

A: These are processes for taking tiny bits and scraps of tobacco, turning them back into a sheet of paper. After it is made, it is broken up, chopped up, and put in cigarettes. When I was there, Philip Morris had facilities for manufacturing this reconstituted tobacco only in Richmond but we also had manufacturing plants in Kentucky and one in North Carolina.

Q: Are there any other processes Philip Morris uses to change tobacco from its natural form as part of the manufacturing process?

A: Yes. In the making of cigarettes, we also used a material called expanded tobacco where you take tobacco and impregnate it with a liquid and evaporate that liquid.

Q: What does the impregnating and evaporation process do?

A: Tobacco leaves shrink when they are dried or cured as with the curing processes for Bright and Burley tobaccos, performed before the tobacco is sold at auction. Adding a material in the tobacco like carbon dioxide or Freon, usually after the tobacco is cut up into the shreds used in filler, causes the tobacco pieces to expand. When the material is heated and expanded, it puffs back up to about the size of that chunk of tobacco as it was originally on the plant.

Q: How are these different types of processed tobacco – reconstituted leaf, blended leaf, and expanded tobacco – used in cigarettes?

A: When the time comes to make cigarettes, the manufacturer picks certain quantities of those materials, according to the formula for the particular brand.

Q: Is the chemical composition of the tobacco and these processed tobaccos always the same?

A: No.

Q: Why not?

A: Because they are made from tobacco, and as a natural agricultural product, the tobacco varies from year to year, from type to type. Even within a plant, the chemical composition of the plant differs in various parts of the plant. For example, the amount of nicotine varies by the stalk position, as does the amount of protein.

Q: So how do tobacco companies use this information?

A: Their knowledge of the tobacco plant, and the particular tobacco crop helps them determine what to put in a particular tobacco blend. Philip Morris, for one, separated leaf according to different parts of the plant during the aging and storage process.

Q: How did that affect the manufacturing process?

A: Philip Morris had what are called blend sheets – like a recipe – to select the desired mix of all tobacco-based components of the cigarette, including the cut leaf and the reconstituted tobaccos.

Q: Let's go back to discussing the tobacco leaf. What happens to the tobacco after it has been selected according to the blend sheet?

A: It is sprayed with a material called a "casing" to make it more supple.

Q: Please explain that a little bit more.

A: The tobacco is eventually going to be chopped up into fine thin pieces, and if it is too dry when you start hitting it real fast with the knives, it just turns into dust. If the pieces are too small, pieces will fall out of the cigarette. Over the decades cigarette making machines have gotten faster and faster. So what they have found is by spraying the tobacco blend with things like glycerin or other sugar solutions, you can moisten it, and so when you cut it, it doesn't break apart into tiny pieces. The casing can also contain other chemical additives that can impart

various flavors or other chemicals to the smoke when it is burned. Chemicals are also added in the reconstituted tobacco process.

Q: What happens to the mixed blend after it has been sprayed with the casing chemicals?

A: Then it is cut up and mixed with chemicals that make up the "aftercut." "Aftercut" is exactly what it says. After the tobacco is cut up, the flavors and the other ingredients that we are going to use are put on it. Aftercut is basically the mix of flavorings. That's spread around real well, and then the tobacco blend – which after all its chemical treatment is called "filler" – goes to the cigarette making machine.

Q: What happens at the cigarette making machine?

A: The filler is rolled up in the wrapping paper into an extremely long tobacco rod. It is actually being made continuously. The rod is the front part of the cigarette cut up into lengths.

Q: We are going to use the demonstrative aid that helps with the explanation at the point of actual construction of the cigarette. What happens to the long rod of filler next?

A: That's attached to the filter. There are several ways of doing that. One of the popular ones at the time I was there was to actually make two filters back to back as one filter. You stick a cigarette rod on each end; when the filter is cut in half, it makes two cigarettes. The machine that performed these functions is what is referred to as a cigarette making machine which comes in various designs. At the time I was at Philip Morris the machines could make from 8,000 to 16,000 cigarettes per minute. There is something called a combiner; which combines the rod with the filter; then you have packers of different size, and the cigarettes are packed into the packs or boxes and boxes are packed into cartons. Cartons are packed into the shipping containers.

B. Cigarette Components and Parameters

Q: Now that you have discussed the basic manufacturing process, I want to go back and talk about some of the different components and ingredients of the cigarette, to further explain your conclusions about Defendants' cigarette design. I have provided a basic diagram, U.S. Ex. 17,346, to assist your testimony on this point. To start this discussion, Dr. Farone, can you give a brief description of the major physical parts of the cigarette?

A: The part of the cigarette that contains the tobacco filler is generally referred to as the cigarette rod. Most of the cigarette is the filler – which contains the tobacco blend, the different kinds of reconstituted tobaccos, the flavors, and other chemical additives – wrapped inside the cigarette paper. At the other end from the filler is the filter, which is also wrapped in paper. The filter is attached to the filler rod by glued paper known as the overwrap. Most cigarettes have one or two rows of holes in a circle around the filter some distance from the end of the filter. These are known as ventilation holes, and enable air to be drawn into the filter when a cigarette is puffed on, in order to dilute the cigarette smoke.

Q: Focusing on the filler first, what are the main types of tobacco that American manufacturers use to make up the blend for their cigarette brands?

A: The three major types that are used are Burley, Bright, and oriental. There are other types of tobacco, but those are the main ones used in American-style cigarettes.

Q: Can you describe some of the chemical differences among the three major strains of tobacco?

A: Yes. The different strains have different chemical compositions. For example, the three major strains each have generally different nicotine levels that occur naturally. Burley tobacco naturally contains much higher levels of tobacco-specific nitrosamines. Chapter 5 of Monograph

13, U.S. Ex. 58,700, has a good summary of the different types of tobacco and their chemical composition.

Of course, even within a strain there are variations. There are varieties just like there are with corn or any other product. Each one of those varieties will have slightly different nicotine alkaloids. Different chemical properties. Just like corn would have different levels of sugar or starch. In addition to that, it depends a lot on the weather. If it rains a lot, the plant has one level of nicotine. If it is drier, the plant will have another level of nicotine. The manufacturers keep track of all of this.

Q: How does the variety among types and strains of tobacco affect the manufacture of cigarettes?

A: The manufacturers blend not only across types of tobacco, but also across years, in order to compensate for the year-to-year variations in the tobacco crop. So, for example, the tobacco blend for 2004's cigarettes contains tobaccos not just from the 2003 crop year, but from the several years before that.

Q: You also mentioned that even within a single plant, the nicotine content varies. Can you explain that further please?

A: Yes. Nicotine is synthesized in the root of the plant and varies within the plant by the age and positions of the leaves. The tobacco companies keep track of tobacco also by the stalk position in the plant. The bottom of the plant has dried out and some of those leaves are ready to fall off; they are called lugs. These leaves have lost most of their nicotine to the air. As you go up the plant, the nicotine increases, and then towards the top it goes back down again, since these leaves are still growing and have not reached maximum nicotine or alkaloid content yet. There is a leaf section in the plant that has the highest level of nicotine. And those are sold separately and

kept track of separately because the alkaloid content varies.

Q: Let's discuss the major varieties of tobacco one at a time. What is Bright tobacco?

A: Bright tobacco is a variety grown in Southern Virginia and across the southeast United States.

Q: Is Bright tobacco also referred to by a different term?

A: Yes. Bright is also known as flue-cured tobacco.

Q: What is flue curing?

A: Flue curing is one of the main methods of curing tobacco that has been used in American-style cigarettes over the years. Before Philip Morris or any other tobacco company buys tobacco, it is processed by the farmer or by some independent agency that processes it for the farmer. There are several ways of curing that have grown up over the decades. The typical way Bright tobacco is cured is by putting it in a hothouse where either hot gases or heat is applied in some manner, and that's called flue curing.

Q: What are the other main ways of curing tobacco?

A: Other types of tobaccos have historically been cured simply by hanging it up to dry either in the shed or in the sun. If the tobacco is hung outside in the sun, it's called sun-cured; if you do it in a shed where the sun doesn't hit it, it is called air-cured. Eastern European countries also use a type of tobacco typically referred to as oriental tobacco, which is also known as Turkish tobacco. That is a smaller plant. Oriental tobacco leaves are packed moist into stacks, and are slightly fermented; that's a different type of curing.

Q: What is the purpose of curing tobacco?

A: The main purpose of curing is to dry the tobacco. What you are actually doing is taking the tobacco from the plant-like green state and converting it to a dry leaf that has the properties

that people have known for a couple of hundred years or at least a hundred and fifty as tobacco. Before that it is sort of a tobacco plant. Curing makes the tobacco more uniform and allows it to be stored for longer periods.

Q: What effect does curing have on the tobacco?

A: Curing causes chemical changes in the tobacco. Basically, the more heat present, the greater the chemical changes. During curing, various reactions change the chemistry of the tobacco leaf – for example, minor amounts of cellulose are degraded to sugars, minor amounts of sugars are oxidized to aldehydes, etc.

Q: Do the changes that occur as a result of the curing process ultimately affect the content of the smoke delivered to the smoker?

A: Yes, the chemical reactions that occur during the curing process have a significant effect on the smoke composition – to a much lesser degree than the reactions that occur during combustion and pyrolysis – but that are still important in influencing the state of the "raw material" that ends up in the cigarette. The way you cure tobacco affects the chemicals that are produced when you actually burn the tobacco. For example, the traditional method of flue-curing greatly increased the level of tobacco-specific nitrosamines (TSNAs) in the bright tobacco, meaning that TSNA levels in the smoke also increased. Similarly, the sugar content can increase during curing if cellulose is degraded more than the sugar reacts with proteins, and when sugar is burned it raises the level of aldehydes. The curing reactions with proteins create compounds that the cigarette companies desire for their contribution to aroma and flavor, but which unfortunately also have undesirable effects. For example, curing traditionally increases the level of nitrogen compounds in the tobacco, which when burned result in smoke that is more mutagenic.

Q: What does mutagenic mean?

A: Mutagenicity is the capacity for a compound or agent to induce mutations in cells. The more mutagenic a substance is, the more it has been shown to cause genetic alterations in cells or cause abnormal cell growth.

Q: How are substances tested for mutagenicity?

A: The principal test is the Salmonella/Microsome Plate Incorporation Assay. It is commonly known as the Ames test because it was developed by Bruce Ames and co-workers at the University of California, Berkeley. This test was developed in order to detect mutagenic agents that are potential carcinogens, and is still considered a reliable test today.

Q: Is the Ames test commonly used by cigarette manufacturers?

A: Yes, the Ames mutagenicity test is a widely used and reproducible test for the safety evaluation of products. In fact, the development of the assay was considered a breakthrough because of its ease of use and biological relevance. It was rapidly incorporated into the toxicology testing of governmental agencies, the scientific community, and many industries, including the tobacco industry. It has been the principal screening test used by the tobacco companies to test their cigarettes for at least the past 25 years.

Q: We will come back to this issue later. Another of the major types of tobacco you mentioned is Burley tobacco. What are its distinctive properties?

A: Burley is a strain of tobacco that naturally has a higher alkaloid content, which means more nicotine but also more nitrosamines. It is higher in nitrates and higher in protein than other tobacco strains. Burley is air-cured.

Q: You have mentioned the terms "nitrosamines" and "TSNAs" a few times. What are nitrosamines?

A: They are a family of chemicals that are generally very toxic and in tobacco some of them

are modified alkaloids, so they have some chemical relationship to nicotine. The tobacco-specific nitrosamines, or TSNAs, are found naturally in tobacco, especially in Burley. Volatile nitrosamines, or VNAs, also form during combustion and pyrolysis. I mentioned earlier that nitrogen compounds generally correlate with increased toxicity in smoke and the nitrosamines are one of the reasons. Nitrates and ammonia both contribute to the formation of nitrogen compounds. In the case of nitrates, they form oxides of nitrogen which then react with the alkaloids and amino acids from the proteins to make toxic materials.

Q: And the third major strain of tobacco that you said is in cigarettes is oriental tobacco. What are its distinguishing characteristics?

A: Oriental/Turkish is imported tobacco. We also import some Burley and Bright from other countries too. Historically, Turkish is all imported.

Q: You mentioned that oriental tobacco is cured by fermentation. How does the fermentation process affect the chemistry of oriental tobacco?

A: It causes a greater degree of degradation of certain materials; for example, more sugars are lost in that process, while the chemical processes that occur during the fermentation makes some other chemicals from sugar which then give a different starting point for the combustion process.

Each process gives a different smoke, results in smoke that has different chemical properties and, therefore, because it has different levels of different kinds of chemicals that are either mutagenic or carcinogenic or whatever, it has different properties in terms of its potential consequences for harm.

Q: You have now described the main types of tobacco. You described the tobacco-based fillers like reconstituted tobacco earlier when describing the manufacturing process.

I will now ask some questions about some of the other major physical design features. First, what other design features do you consider to be important?

A: Each of the major categories of design parameters on the demonstrative is very important – the filler, the filter, the paper, the ventilation. A modern cigarette is an extraordinarily complex device, and there are literally dozens of physical and chemical parameters that influence the delivery and content of smoke delivered to the smoker.

Q: How many different physical and chemical design parameters can affect the performance of a typical cigarette?

A: When I was at Philip Morris one of the things I participated in was building a model of how the cigarettes delivered different chemicals based on engineering parameters. We determined that they had 15 years of smoke data that had been collected over many different cigarettes. So one of the fellows working for me had an interest in modeling it. We bought a very large computer system in order to do this. It turned out there were about 57 different things that we tracked. A person from the product development area could go in and if they wanted, for example, to make a cigarette which delivered ten milligrams of tar and one milligram of nicotine under Federal Trade Commission conditions, they could type in different parameters – the kind of filter, the diameter, the kind of tobacco they used, etc. – and obtain an estimate of whether the desired tar and nicotine levels would actually result from selection of different parameters.

Q: How many of these 57 cigarette features influence the amount and type of toxic chemicals delivered to the smoker in smoke?

A: All of them. They also affect the amount and type of toxic chemicals that come off the cigarette into the air around the smoker.

Q: Have you listed those parameters on a document anywhere?

A: Yes. A few years ago I prepared a short document that lists the physical and chemical parameters.

Q: Directing your attention to U.S. Ex. 61,160; is this the document you prepared listing the different design parameters?

A: Yes.

Q: We will focus on a few major parameters. Is there one part of a cigarette that is the most important factor in determining the chemicals a smoker gets?

A: Yes. The filler.

Q: Why is the filler most important?

A: The filler is comprised of the tobacco and the additives. It is the most significant part of the mass that is burned to make all of the chemicals that are in the smoke. The paper also contributes to those chemicals, of course, and burning paper also contains toxic chemicals but biological testing shows that the filler smoke is much more toxic.

Q: You also identified filters as very important. Can you please explain that further?

A: Yes. A range of different materials are available to make the filter, such as paper, tobacco, or cellulose acetate, which is the most common filter material. Filters can have different densities, and be made up of fibers of different width. The shape and length of the filter can also vary.

Q: What is the effect on the smoker of changing the filter's characteristics?

A: It depends upon what the change is. Increasing the density of a cellulose acetate filter, for example, increases something called the "resistance to draw."

Q: What is "resistance to draw?"

A: "Resistance to draw" describes how hard the smoker has to suck on a cigarette to get the

smoke. The smoker has to light a conventional cigarette. He or she has to suck on it, draw on the filter and some of the air may come through those ventilation holes. Some of it's going to come down the burning rod and carry smoke along with it. A filter increases the resistance to draw compared to an unfiltered cigarette. A pressure gauge can actually measure it.

Q: How does a filter affect the amount of smoke a smoker gets?

A: Again, many parts of the filter can affect that. For example, where and how the filter material is located has a huge effect. By bunching it up ahead of where the filter ventilation holes are, I could actually construct a cigarette that when smokers draw on the filter end, 99 percent of what they take into their mouths is air that will come through those holes. If I put it on the other side of the ventilation holes I can get a different mix between the smoke coming down the rod and the air coming through the ventilation holes.

Q: You also mentioned cigarette paper. How does that influence the chemistry of the smoke?

A: The type of paper and the porosity of the paper – how much air can pass through the paper – changes the chemistry of will be in the smoke when the cigarette burns. A change in the paper type or porosity alters the chemistry because of the chemical composition of the paper itself and because the porosity changes the speed at which the cigarette burns. By manipulating these parameters, I can increase the level of certain chemicals and decrease the levels of certain chemicals.

Q: You have "filler cut size" listed up there as another important physical parameter. What do you mean by that?

A: Many years ago the size of each piece of tobacco used in a cigarette was bigger than it is now, because they didn't have machines in the early days to cut it up very fine. If you think

about burning things in a fireplace even, if you wad up paper, for example when you burn it, it burns entirely different than if I shred it up into confetti and burn that. The rate at which something burns depends on the surface area. As a matter of aerosol chemistry, generally speaking, burning finer cut materials creates a smaller particle size aerosol. Changing the filler cut width can change the size distribution of the aerosol and chemistry.

Q: How does the cut width affect the smoke delivery?

A: An aerosol with smaller particles is easier to inhale. So, especially compared to cigarettes made before the advent of high-speed cigarette making machinery, smokers of fine-cut tobacco get smoke further in their lungs, inhaling more and more of it. In my opinion – and when we were at Philip Morris, I discussed it with scientists there – the reduction in cut width appears to be one of the things that led to the cigarette as an inhalation device, as something that was routinely deeply inhaled. Obviously, in order to have chemicals cause lung cancer they have to get into the lungs, not always, but the vast majority has to get into the lungs, and that's what these aerosols are doing. It has been accepted that the association between lung cancer and smoking related to changes that were made in the 1910 to 1920 area of cigarette making. Between 1900 and 1910, in the period leading up to World War I cigarette making by machine became more and more prevalent. Additives began to be used and tobacco was cut into thin strips to keep it from falling out of the paper as the pieces would interlock better. Inadvertently at first, the cigarette was made more inhalable as the smoke was sweeter, not as bitter, and smaller particles. By World War I, machine-made, easily inhalable cigarettes had taken over the market. In the late 1920s and early 1930s, lung cancer rates began to rise precipitously and by the late 1930s it became apparent that there was a relation to the greatly increased amount of smoking as well as the products themselves.

From my perspective as a physical chemist, it makes sense that the changes in technologies and how cigarettes were made affected the chemistry and physics of cigarettes and cigarettes smoke, and thereby contributed to the rapid increase in lung cancer deaths in the mid-20th century.

Q: Turning to some of the chemical parameters now, please give an example of chemical parameters that affect the chemistry of smoke delivered to the smoker.

A: I consider the tobacco blend to be a chemical parameter, since the tobacco and the reconstituted tobaccos are responsible for most of the chemicals in cigarette smoke. The other main categories of additives can be used to change the chemistry of what's in the smoke are casings and aftercut flavors.

Q: Would you go into greater detail with respect to casings and additives?

A: I pointed out earlier the casings, the chemicals you put on before the tobacco is cut up, and the aftercut flavorants that are put on after the tobacco is cut up, but before it ends up in the cigarette. You can put different materials in either one of those.

Q: Can chemical additives also affect the physical parameters that you have identified?

A: Yes. Chemicals also affect the performance of some of the physical parameters. For example, flavors can be put in the filter, flavors can be put in the paper. Chemical burn enhancers can be used in the paper to make it burn faster. Things like menthol, which is a local anesthetic and helps mask the harshness of inhaling cigarette smoke, can be used so that the smoke is easier to inhale. So there are all of these "degrees of freedom," as it is called in science and engineering, things that the cigarette designer can do to change the way the cigarette delivers smoke and the way it delivers different chemicals.

Q: How many chemical additives are used in making a cigarette?

A: The tobacco companies have used up to 600 different chemicals in these processes although not all companies use all 600. In 1986 and 1994 they provided a list of such chemicals that contained 599 chemicals each although the two lists are not identical.

Q: Was it your experience that Philip Morris considered all of these parameters in designing cigarettes?

A: Absolutely. That's why we created the computer modeling program I described earlier. This model was based on 15 years of empirical data at that time. And that was carried out during my career while I was there. That model helps people understand what you can do to a cigarette to change nicotine, tar, carbon monoxide and even specific chemicals.

Q: Did you personally review this data used to create the computer modeling program while you were at Philip Morris?

A: Yes. They actually had data before that, but the data that was considered useful for cigarettes in 1976 went back about 15 years.

Q: From your personal experience at Philip Morris, and your review of documents created before, during, and after the time you worked there, does Philip Morris have extensive understanding of how altering these design parameters changes the amount of the smoke delivered to the smoker?

A: Yes. For example, in the original Cambridge cigarette in 1980, we designed one that was very difficult to suck harder on and get more tar out of. That product delivered almost no tar under the FTC machine conditions or less than a tenth of a milligram. So we knew all these parameters and how to adjust them to pretty much provide a cigarette of any tar delivery that we wished.

Q: Does Philip Morris have extensive understanding of how varying these design

parameters affects the composition of the smoke that are delivered to the smoker?

A: Yes.

Q: In your view were the cigarette companies other than Philip Morris also aware of the effect that these different design parameters had on the amount and chemical composition of smoke delivered to the smoker?

A: Yes.

Q: Where does your understanding about the cigarette design technologies and knowledge of Defendants other than Philip Morris come from?

A: A few different sources. The main source is from my time at Philip Morris, when scientists working for me in the Applied Research directorate regularly purchased and dissected other companies' products. We examined all the different components – filter characteristics and design, contents and density of the rod, the tobacco blend. We performed chemical tests to find out the smoke components. We tracked other companies' patents, which provided detailed information about some of their work. Looking at the products of other companies in your industry is considered essential.

Also, in the last 10 years I have been able to see many documents from the tobacco industry and place the information in the documents in perspective with my previous knowledge.

Q: What are the other sources of your knowledge of the cigarette designs and technologies of defendants other than Philip Morris?

A: I also went to meetings, like the Tobacco Chemists Research Conference or the American Chemical Society, where scientists from other companies would make presentations. I have also reviewed many patents issued to tobacco industry scientists or agents, because they are great evidence of the state of knowledge. I've also reviewed thousands of industry documents that

have been released in litigation. Finally, reports of the public health community have also provided information about the design and composition of cigarettes made by companies other than Philip Morris.

C. The Burning Cigarette

Q: Now that you have described how a cigarette is made and how it is designed, I will ask you some questions about what happens when a cigarette is smoked. Let's look at U.S. Ex. 17,348, a basic picture of a cigarette, to aid your explanation. What happens when a cigarette is lit?

A: The lighting of the cigarettes triggers the formation of the cigarette smoke aerosol. As you draw on the lighting puff, the glowing zone called the coal is formed and the reactions take place.

Q: Can you describe what is going on in a burning cigarette, and how the smoke aerosol is formed?

A: Yes. The burning part of the cigarette is called the coal. The temperatures in the coal and around the coal get up to between 1,500 and 1,700 degrees Fahrenheit. Paper burns at about 450 degrees Fahrenheit. Sugar starts to decompose at about 220 degrees, just above the boiling point of water for those of you who ever made caramel. As the temperature goes way up, different chemistry occurs, but what is basically happening is that a solid material is turning into vapor.

So that process creates a lot of gas. As this vapor of all the different chemicals in smoke, 4,000 or more chemicals, start to condense. That's what makes the smoke. Some of the chemicals do actually stay in the gas phase, which is also called the "vapor phase." One example of a chemical in smoke that does not condense is carbon monoxide.

So it starts out all in vapor and condenses into what are called particles. Usually the

particles in tobacco smoke are little liquid droplets. They are not particles like solid particles. At the center of each of those liquid particles, however, there is in a little bit of inorganic material, which starts the process of condensing the gas. All those chemicals that make up cigarette smoke condense. So when we talk about the "particulate phase" that's the aerosol of smoke liquid, the "particles," that we normally refer to as smoke. This process occurs both in the side stream smoke, before puffs, and in the mainstream smoke, which is what the smoker gets when they draw on cigarettes.

Q: What is happening chemically during in this process?

A: Chemically there are two processes – combustion and pyrolysis. As a reminder of what I said earlier, combustion is the reaction of oxygen from the air with materials in the tobacco to make a different set of chemicals; that's what people normally think of as burning. Pyrolysis occurs when something is heated up in the absence of oxygen. Pyrolysis is the thermal degradation of material heated to high temperature in the absence of oxygen. As the smoker you draws or sucks on the cigarette, the temperature of that coal goes way up. It gets so hot that the gases and radiation coming off the coal keeps the oxygen from getting in there. So when something is burned very rapidly at high temperature, pyrolysis is the reactions that occur inside that coal where the air can't get in; combustion is what occurs on the outside where the air can mix.

Q: What are the effects of the different processes?

A: Most basically, different sets of chemicals are formed by the combustion and pyrolysis reactions.

Q: What happens to the smoke after it is formed by combustion and pyrolysis?

A: The mainstream smoke – the smoke taken in by the smoker – is drawn through the

cigarette rod, through the filter, and into the smoker's mouth.

Q: Does the smoke change in chemical composition as it travels through the cigarette rod and filter?

A: Yes. Chemical reactions continue to occur, and the particles in the aerosol change in size as they move through the rod.

Q: Do ventilation holes in the filter affect the smoke chemistry?

A: Yes. Ventilation changes the chemistry of the smoke by adding in more air, and, since it is entering closer to the filter end, it slows down the smoke behind it, giving that smoke more time to undergo further chemical changes.

Q: Does ventilation reduce the toxicity of the smoke?

A: It depends how much ventilation. Relatively low levels of ventilation – 30-40% – actually increase the toxicity of the smoke according to Ames test mutagenicity studies. However, higher levels of ventilation – getting up to 70-90% – reduce the toxicity because the smoke is so diluted with air.

Q: How much ventilation is used in commercial cigarette products?

A: Brands vary. For example, Marlboro Reds – the regular, full-flavor Marlboro – have one row of ventilation holes, so it is on the order of 10% dilution. Marlboro Lights have two rows of ventilation holes, causing about 30-40% dilution. In 1980, I helped with the design of the Cambridge "lowest tar" cigarette, which was introduced with over 95% dilution.

Q: How does the mutagenicity of the smoke from Marlboro Reds compare to that of Marlboro Lights?

A: Marlboro Lights have more mutagenic smoke on a per milligram of tar basis.

Q: Is it generally true that "light" cigarettes have more mutagenic tar than their full-

flavor counterparts?

A: Again, brands vary. However, where a "light" cigarette is largely identical to its full flavor counterpart – as is the case for Marlboro and Marlboro Lights, except that the "light" has dilution levels in that middle 30-40% range – the tar from that light cigarette is likely more mutagenic.

Q: What is your support for this conclusion?

A: Some of it is the physical chemistry and biochemistry of the process. I personally know a lot about ventilation, because when I was at Philip Morris my group developed a laser perforation system that was implemented. The laser system made much higher levels of ventilation, and thus smoke dilution, possible. However, except for the 1980 Cambridge, Philip Morris didn't commit to the very high dilution that, in my opinion, can substantially decrease the toxicity of smoke. Further, the documents demonstrate that Philip Morris and other companies have long understood the potential of dilution technology, and its pitfalls as actually used. Philip Morris, at least, did not test with branded cigarettes until recently, but Ames mutagenicity studies run on prototype cigarettes with different levels of variation yielded these findings by the time I was there.

Q: We will revisit this issue later in your testimony. When mainstream cigarettes smoke reaches the smoker, is it still in both particulate and vapor phases?

A: Yes.

Q: Are the particles uniform in size?

A: No. This smoke coming out the back end has what we call particle size distribution. What

we mean by that is we have all different sizes of particles, but there's not equal amounts of all

particles.

Q: Does the fact that particles are different sizes affect what happens to the smoke when it enters the body?

A: Yes, it has a very great effect because the particle size influences first where it gets absorbed, as it needs to be of a certain size to get into the lung. For example, the particles in cigar smoke are much bigger than the particles in cigarette smoke, so cigar smoke – which also has a high pH, and is thus more bitter than cigarette smoke – generally does not get down to the lungs. In addition, the particle size influences how fast chemicals will be transferred to the tissue.

As particles get smaller, in the range below 10 microns they can go into the lungs but the maximum penetration of particles that go into the lungs is below 0.3 microns. Below 0.3 microns the absorption increases very rapidly. In fact below 0.1 microns filtration devices like the Cambridge pad used in the FTC test is not of much value and these particles, right down to the gas phase, are those most retained by the lung.

Q: To your knowledge, was the issue of particle size and its importance known at Philip Morris by the time you arrived in 1976?

A: Yes. Philip Morris documents from the late 1950s recognized the role and importance of particle size in cigarette smoke. U.S. Ex. 20,123, a Philip Morris research plan from 1957, is such a document. At page 21, Bates number ending in 5534, the Philip Morris researcher discussed the potential value of controlling the particle size of smoke to avoid retention of smoke particles in the lung.

Q: Are all the smoke particles that are not exhaled eventually absorbed, whatever their size?

A: Yes. However, the particle size affects whether and where the particles are absorbed. Particles above three-tenths of a micron are more likely to be absorbed in the mouth and throat.

Q: What are the toxic constituents of the smoke delivered by a cigarette?

A: As I have explained, the exact composition of the smoke varies depending upon the many design parameters. Generally, however, smoke contains several different categories of toxic constituents, many of them formed by combustion and pyrolysis. For example, there are irritants, there are carcinogens. Of course, even among the carcinogens, there are different types, depending upon the state of knowledge about them. There are ones that are known to be carcinogens in man, ones that are suspected to be carcinogens in man. There are others that are known in animal systems to cause cancer.

Q: Can you please identify the major categories of smoke constituents that you believe contribute to smoking causing cancer and other serious diseases?

A: Yes. The major categories are nitrosamines, aldehydes, polycyclic aromatic hydrocarbons, monocyclic aromatic hydrocarbons, aza-arenes, aromatic amines, carbon monoxide, and heavy metals.

Q: Where does this list come from?

A: You can find it in many places. Most of these groups of compounds were known to and acknowledged at Philip Morris by 1963.

Q: Dr. Farone, you have been shown U.S. Ex. 20,088. What is this document?

A: This document is a 1961 presentation made by Helmut Wakeham to the Philip Morris Board of Directors.

Q: Did you see first this document while you were at Philip Morris?

A: Yes.

Q: What information in this document do you consider significant with respect to the issue we are discussing, the constituents in cigarette smoke?

A: There are important chemicals identified in various places in this document, but on the page with Bates number ending in 7183, Wakeham has a list titled "Partial List of Compounds in Cigarette Smoke Also Identified As Carcinogens." This shows that by 1961, Philip Morris had identified most of the same basic classes of chemical compounds that were considered to be the most harmful substances in cigarette smoke when I arrived at Philip Morris in 1976.

Q: Looking now at U.S. Ex. 22,894, can you please describe the significance of this document for the Court, as it pertains to the issue of constituents in cigarette smoke?

A: This is a September 25, 1963 letter to Helmut Wakeham from Peter Waltz at FTR, which was Philip Morris's Swiss facility. This document describes the reported carcinogenic and significant toxic properties of nitrosamines. While this document does not state that nitrosamines were definitely in cigarette smoke, that link was well established soon after that, and known to Philip Morris.

Q: When you arrived at Philip Morris, was the list of known toxic constituents of cigarette smoke significantly different from the compounds identified in U.S. Ex. 20,088 and U.S. Ex. 22,894?

A: No. When I was at Philip Morris and during the interview before I became employed there, since I was going to be charged with the responsibility of reducing toxic chemicals in smoke, one of the things that we discussed deeply was how one might go about reducing the various classes and the relevant toxicity of the classes.

Even before I arrived at Philip Morris, I already had concluded scientifically that chemicals in tobacco smoke must be responsible for causing cancer. Exactly which chemicals in

exactly which quantities, I did not know – and still no one knows the exact answer to that question. But I did know that if you could prevent the formation of known carcinogens and toxins in the first place, you'd probably be pretty far along in reducing the harm from smoking cigarettes. Once things are in the smoke, it is a lot harder to figure out ways to remove or reduce them.

When I was at Philip Morris, our activities were focused on these same classes of chemicals, which we thought we had to reduce to have a chance of reducing the disease associated with smoking. We knew that they must be reduced to very low levels – different levels for each chemical depending on its toxicity – and we knew that quantities in the nanograms per cigarette smoked range were enough to cause disease due to the continued and repeated exposure. My work as a chemist and all of my work before coming to Philip Morris related to the exposure levels of chemicals that in turn produced toxic effects. The idea that the levels were "small" is not a scientifically valid response to these dangers, since it was well known that low levels of all of these chemicals were enough to cause diseases.

Q: Is the list of known carcinogenic and toxic compounds in cigarette smoke significantly different today from the ones known to Philip Morris by the early 1960s?

A: No, these same chemicals generally remain the substances of primary concern today.

Q: Dr. Farone, I have shown you with U.S. Ex. 58,700, which is a copy of Monograph 13, the National Cancer Institute's 2001 Report on cigarettes with low machine-measured yields of tar and nicotine. Are you familiar with this report?

A: Yes, I was a peer reviewer for the Monograph.

Q: Please direct your attention to Table 5-4 on pages 163 to 165, title "Carcinogens in Cigarette Smoke." From your review of the classes of compounds identified, are the

compounds on this 2001 list different from the ones that you were aware of and focused on when you were at Philip Morris from 1976-1984?

A: No. As a matter of fact the list hasn't changed since I went there and the list as I understand it from documents and my colleagues was pretty much the same since the early to mid-1960s. Note that the last category, inorganic materials, are the so-called heavy metals – including chromium, nickel, arsenic, cadmium, lead, and polonium-210, which is a radioactive isotope. Many of the heavy metals are confirmed human carcinogens.

Q: How is it that a radioactive isotope finds its way into a cigarette?

A: In the case of polonium it's a degradation product from uranium. Uranium is found in conjunction with phosphate. Phosphate is used in fertilizer. Plants need nitrogen, phosphorus and potassium to grow. And incidently, the fertilizer may contain some tiny amounts of degradation products of uranium if it was mined from certain places in the world. Fertilizer on the ground mixes with the dust and gets on the leaves of the tobacco plant and it sticks there because the leaves are kind of waxy. About half of it is on the plant and about half is inside the plant. And it can stay there during the time the tobacco is cured, ground up, and cooked. Particularly when these inorganic heavy metals are inhaled as during smoking, as opposed to consumed by eating, the body's clearance mechanisms to get such metals out of the body are not very good.

Q: Does Monograph 13 also identify other classes of substances on this list that may not have been found to be carcinogens, but that have toxic properties?

A: Yes, in Table 5-3 on page 163. Carbon monoxide is listed first, followed by several others.

Q: Which family of compounds in cigarette smoke do you consider the most toxic?

A: The nitrosamines. The nitrosamines are made because of the reactions with the alkaloids in the tobacco. For example, nicotine and nornicotine are alkaloids that are found in tobacco. One of the nitrosamines, NNK, is nicotine nitrosamine ketone and it is essentially made from nicotine. The one above it, NNN, is called nitroso nornicotine and it is made from nornicotine.

In other words, if you didn't have any nicotine in tobacco you wouldn't have any NNK because it's made from the nicotine. Some of the others will form in the combustion processes. Every one of the compounds in this list say "nitro," so N, they all have nitrogen in them. That is an important piece of information about the most toxic class. They are all derived from nitrogen.

Q: What do you consider to be the next most important toxic compounds in cigarette smoke?

The next class of compounds are the aldehydes. These are products of combustion. Formaldehyde and acetaldehyde, these are both carcinogens by inhalation. Formaldehyde and acetaldehyde, however, are very easily formed from the combustion of sugars and other starches and other carbohydrate materials.

Q: Will you explain how the sugars are involved in this process?

A: As you heat up a sugar, sugar contains a lot of carbon, hydrogen and oxygen in its chemical makeup. It is a structure which allows the pieces to fall apart easily as it is heated higher than about the boiling point of water. Sugars and similar carbohydrates lead to a series of compounds and among the more toxic are the aldehydes such as formaldehyde or acetaldehyde. It's a very well known combustion reaction in sugars.

Q: Have these categories of smoke constituents, nitrosamines and aldehydes, been found to be carcinogens?

A: Yes, they have. While I was at Philip Morris, aldehydes, after nitrosamines, were

considered the second most important class to remove to make a safer cigarette.

Q: What is the next group of toxic constituents in cigarette smoke that you want to identify?

A: The polycyclic aromatic hydrocarbons. They are also referred to as polynuclear aromatic, the "polynuclear" simply means that these are compounds that have ring-shaped chemical structures, where there is more than one ring. Many of the ones on this list that you see here, like benzo(a)pyrene, the second one on the list, are known carcinogens and the mechanism of those carcinogens are known. All of them typically exhibit similar properties.

Q: What is another type of toxic constituent delivered in cigarette smoke?

A: There is a group of other compounds like the aza-arenes, monocyclic aromatic hydrocarbons, aromatic amines, they are in the same level. Some of these are more toxic than. Most of these compounds are the products of pyrolysis, whereas the aldehydes are products of combustion.

Q: Can you explain how each of the processes influences the formation of chemicals?

A: The ones that are the products of pyrolysis are formed in that coal in the absence of oxygen. All of those polycyclic aromatic hydrocarbons, if you look at the structure they have very little oxygen in the structure. Same is true in the monocyclic aromatic hydrocarbons, there's no oxygen incorporated in the chemical structure. Whereas in the aldehydes in the combustion process you incorporated oxygen in the structure.

V. Opinion #2 – Defendants' Scientific Conduct Demonstrates Widespread Internal Understanding That Smoking Causes Disease

Q: Dr. Farone, I want to turn now to Defendants' positions on smoking and health issues. When you were at Philip Morris, did you ever discuss with other scientists whether smoking was a cause of lung cancer and other diseases?

A: Yes.

Q: With whom did you discuss this issue?

A: People throughout the Philip Morris R&D department – from the Vice President, Dr. Seligman, to my fellow directors, including Dr. Osdene, and many others, including Jim Charles, Cliff Lilly, who worked in my directorate, and Bob Pages.

Q: What was the view among Philip Morris scientists on the question of whether smoking cigarettes is a cause of lung cancer and other diseases?

A: There was widespread acceptance that smoking caused disease. I never talked with a scientist at Philip Morris who said that smoking doesn't cause disease.

Q: What was the basis for this understanding, if you know?

A: The compelling epidemiology such as that recounted in the Surgeon's General's reports, and our knowledge about the chemicals that were created by cigarettes and what was delivered to the smoker, hundreds of times per day on average.

Q: Looking at U.S. Ex. 35,239, can you tell the Court what it is?

A: It is a September 1969 technical report titled "The Current Status of Gas Phase Composition Control: A Summary Statement" written by Philip Morris scientist Tibor Laszlo, approved by Helmut Wakeham, and copied to many scientists throughout the R&D department, including Mr. Goldsmith, Mr. Seligman, and Dr. Osdene.

Q: Have you seen this document before?

A: Yes. I saw it when I was at Philip Morris and discussed it with Laszlo. In fact, I updated the kinds of information in it, based on 1978 data, and discussed it with Dr. Osdene as part of our efforts to reduce carbon monoxide and nitric oxide.

Q: What, if anything, do you consider significant in this document to your opinion about the widespread acceptance within Philip Morris R&D that smoking causes disease?

A: On page 3, Laszlo states: "The short range, acute toxicity of nearly all compounds identified so far in the gas phase are known." The report refers to Appendix I at the back, where Laszlo shows that in 1969, Philip Morris was using known industrial exposure limits, known as "threshold limit values," which set occupational exposure thresholds for various toxic chemicals that workers can be exposed to in their work environment. You can see from Appendix I, Bates Nos. 1000345230-5232, that the levels of certain toxic chemicals in cigarette smoke – acetaldehyde, acrolein, formaldehyde, carbon monoxide, hydrogen cyanide, and nitrogen dioxide – far exceed the industrial TLV.

Q: What was the source of the smoke levels of these chemicals Laszlo used in this document?

A: The 1964 Surgeon General's Report.

Q: Is the reference to exposure limits in this document significant to your opinions?

A: Yes.

Q: How so?

A: This document shows that Philip Morris recognized the toxicity of chemicals in part of the smoke as compared to accepted quantitative exposure benchmarks. In my view, one significant failing in Defendants' statements about their potentially less hazardous cigarettes is

that they don't measure the claimed reductions in delivery of the harmful compounds against quantitative limits. Instead, they focus on "percentage reductions" without any communication about whether the reduction – even if successful – is likely to be biologically meaningful. Exposure limits are a target to aim for, so that you have an idea about the likely risk associated with the product.

This document also shows that Philip Morris accepted and used in its own research the scientific data about smoke chemistry put forth by the 1964 Surgeon General's Report. It also shows that this was understood widely at Philip Morris among the scientific staff, even outside of Dr. Osdene's group of scientists, and that this information was part of the day-to-day science done at Philip Morris.

Q: During your years at Philip Morris, did you ever hear or participate in discussions involving PM executives about the health effects of smoking?

A: Yes.

Q: Who participated in the discussions?

A: Ross Millhiser, Hugh Cullman, Joe Cullman, Cliff Goldsmith, Alexander Holtzman, and Tom Ahrensfeld, among others. I mentioned all but Mr. Weissman and Ahrensfeld earlier. Mr. Weissman was Chairman of Philip Morris USA, and Mr. Ahrensfeld was the General Counsel for Philip Morris Inc.

Q: Where did you hear such discussions?

A: Mostly at the Richmond meetings, and the lunches or dinners that Philip Morris held on the day of the Richmond meetings.

Q: Did discussions about whether smoking causes adverse health effects occur frequently in and around the Richmond meetings?

A: I wouldn't necessarily say it was frequently discussed, because it was so well accepted internally. At the Richmond meetings and other meetings internally, the issue for the company was not whether smoking caused disease, but how the company should respond to that fact.

Q: Did any of these executives, in your discussions with them, challenge the validity of the scientific evidence that smoking caused disease?

A: No. Their comments generally focused on how the company could or should respond, not to whether the scientific evidence was valid. Remember, a main reason why they hired me in 1976 was to help develop a less hazardous cigarette. It seemed to me at the time I was hired, and certainly was the case during my entire time there, that hiring me for that job was itself implicit recognition that the cigarettes that were out there being sold were causing disease.

Q: As a scientist, do you need irrefutable scientific proof of exactly how one thing causes a particular effect before you can conclude, as a scientist, that one thing "causes" another?

A: No.

Q: Why not?

A: Because all of science and scientific conclusions involve judgment based on probabilities, and you look at all the evidence to decide whether the evidence is strong enough to support that conclusive scientific judgment. There are fundamental physical laws such as the Laws of Thermodynamics and the Laws of Quantum Mechanics that preclude an exact knowledge of things. These laws have never been violated in all of the years they have been tested and they indicate that you cannot know something "exactly" but you can always calculate a probability based on the data and then you can do more experiments to refine the estimate.

Q: Do you have a view about whether the other tobacco companies Defendants – R.J.

Reynolds, Brown & Williamson, Lorillard, Liggett, and BATCo. – each internally also had an understanding, contemporaneous to Philip Morris's, about the chemical toxicity of cigarette smoke?

A: Yes.

Q: What is that view?

A: My review of other companies' documents shows me that they recognized and understood that tobacco smoke delivers many toxic and carcinogenic chemicals to the smoker. The documents show that the other companies recognized and accepted that the great weight of evidence -- epidemiological, toxicological, biological, chemical -- justified a scientifically valid conclusion that smoking causes disease.

Every company had an understanding that cigarette smoke delivered harmful and carcinogenic substances, and thus smoke's role in disease, going back into the 1950s.

Q: Can you please identify and describe some of the documents that you rely upon for this conclusion?

A: Yes. These are in addition to the Philip Morris documents previously discussed, and are examples from among the hundreds of documents that support my view on this issue. U.S. Ex. 22,887 describes Lorillard's hiring of a well known physician to conduct clinical trials on the reduction of disease through the use of their filtered cigarettes in 1955. Dr. Woldbott stated that there was "evidence" that smoker's emphysema, respiratory infections, bronchitis, and other conditions "were due to the irritating action of certain chemicals in the cigarettes."

U.S. Ex. 21,369 is a 1958 report from scientists for Defendant BATCo on their visit to representatives of tobacco companies in the United States, including Liggett and Philip Morris. They wrote:

> With one exception (H.S.N. Greene) the individuals whom we met believed that smoking causes lung cancer if by 'causation' we mean any chain of events which leads finally to lung cancer and which involves smoking as an indispensable link. In the U.S.A. only Berkson, apparently, is now prepared to doubt the statistical evidence and his reasoning is nowhere thought to be sound. . . .
>
> The majority of individuals whom we met accepted that beyond all reasonable doubt cigarette smoke most probably acts as a direct though very weak carcinogen on the human lung. The opinion was given that in view of its chemical composition it would indeed be surprising if cigarette smoke were <u>not</u> carcinogenic.

In U.S. Ex. 20,735, a longtime scientist for RJR, Alan Rodgman, stated in 1962 that "The cigarette smoke-lung cancer problem has been investigated epidemiologically, pathologically, biologically, and chemically. Each discipline has yielded pertinent information." Dr. Rodgman also wrote that "the amount of evidence accumulated to indict cigarette smoke as a health hazard is overwhelming. The evidence challenging this indictment is scant. Attempts to shift the blame to other factors, e.g., air pollutants, necessitates acceptance of data similar to those denied in the cigarette smoke case."

Q: Are these statements consistent with your conclusions about the health effects of smoking from the perspective of biochemistry, natural product chemistry, and the physics and chemistry of cigarettes and smoke?

A: Yes. the Lorillard, BATCo, and RJR documents all recognize the presence of chemicals in smoke as the likely reasons smokers develop cancers and other diseases.

Q: Are these the only documents you have seen that support your opinion on this point?

A: Not at all. In total, I have seen hundreds, perhaps thousands, of documents from the different tobacco companies that support my view on this issue. Many of these are on my reliance list.

VI. Opinion No. 3 – Addiction and Its Role in Cigarette Design

Q: Dr. Farone, we are now going to shift to discuss the issue of nicotine and addiction. Will you please restate your conclusion regarding Defendants' understanding about the addictiveness of smoking and nicotine?

A: Yes. Defendants have long understood that cigarettes are addictive and that nicotine is the agent in cigarette smoke primarily responsible for addiction; and that in light of this knowledge, they have designed and manufactured their cigarettes to ensure that smokers can obtain enough nicotine to satisfy their addiction. As a result of these design choices to facilitate nicotine delivery, the major brands of cigarettes sold by Defendants as "light" or "low tar" do not significantly change the chemistry or composition of cigarette smoke compared to their "full flavor" counterparts. Therefore, from a chemist's perspective, I would not expect such cigarettes to present any meaningful reduction in harm. In fact, at least some designs features as used in "light" cigarettes make the smoke more toxic than the smoke from their "full flavor" versions.

Q: What are the bases for your opinion that Defendants have understood internally that smoking and nicotine are addictive?

A: There are several bases. The most obvious is that when I was at Philip Morris, there was widespread acceptance internally throughout the company – among executives, scientists, and marketing people – that nicotine was the primary component of tobacco and cigarette smoke

responsible for smoker's addiction to smoking.

From my background and training in chemistry and biochemistry, and from my understanding of cigarette design and technology obtained from 8 years at Philip Morris, the documents show that defendants well understood the physiological effects that nicotine had on the body, and that Defendants designed their products to deliver enough nicotine to satisfy smoker's need for it.

My understanding of this goes back to my college training in 1960 where nicotine based on the definition of addiction at the time was identified as an addictive drug from a biochemical perspective.

Scientific papers from the early 1940s had supported this and it met the parameters we discussed at the time – it is intoxicating when first used, because new smokers often experience dizziness and nausea; smokers build up tolerance to non-toxic amounts very rapidly, wherein the toxic effect becomes pleasant but still elevates bold pressure by constricting the veins and increases the heart rate by about 6 beats per minute; and finally, smokers experience withdrawal when you try to stop.

Also, in the tobacco companies' documents there are hundreds of references to the importance of nicotine in maintaining the use of the product of the majority of smokers. To be clear, all smokers are not dependant on nicotine. Based on the studies cited by the Food and Drug Administration, the percentage of smokers that are dependent on nicotine ranges from 77% to 92% of smokers.

Another basis for my view of Defendants' understanding of nicotine's role is that no product has ever been continued as a marketed product that was basically a nicotine-free cigarette. When Sano and King Sano cigarette failed to sell in the 1950s, the truth of the nicotine

requirement was apparent to everyone in the business. U.S. Ex. 20,352, for example, shows that Philip Morris had available to it two nicotine-reduction processes by March 1961, one of which it had developed that could reduce the nicotine by 90%.

Q: You said nicotine is the "primary component" responsible for addiction to smoking. Are there others?

A: Yes. Tobacco and cigarette smoke contain other nicotinic alkaloids besides nicotine. Nicotine is the main one, but there are other alkaloids that affect the central nervous system, as well as chemicals like pyridine and pyrazines. There are also chemicals in smoke, like acetaldehyde, that appear to enhance the reinforcing effects of nicotine.

Q: Dr. Farone, when you were at Philip Morris, did you ever discuss with other scientists whether smoking was addictive?

A: Yes.

Q: With whom did you discuss this issue?

A: All the same people I mentioned earlier, the people with whom I discussed causation. In addition, I informally worked with some of the people working on smoking behavior research, including Dr. William Dunn, Dr. Jim Charles, Dr. Carolyn Levy, Dr. Frank Gullotta, Dr. Victor DeNoble, Dr. Paul Mele and others – and I also talked to them about nicotine's role in smoking.

Q: What was the general view of Philip Morris scientists about whether smoking cigarettes is addictive?

A: There was widespread agreement among scientists in R&D that smoking is addictive. I never heard someone make substantive remarks to the effect that it was not addictive. The scientists did, however, talk about ways to provide information that could criticize what outside scientists had concluded.

Q: What was the general view of Philip Morris scientists about what was responsible for smoking addiction?

A: Among the scientists, there was widespread conviction that nicotine is the chemical agent delivered by cigarettes that is primarily responsible for addiction to smoking. The other alkaloids and similar agents as well as modifiers were also believed to play a role, especially in increasing or reducing the rate of delivery. But the view was that the main agent is nicotine.

Q: Did you hear people use the word "addiction" in relation to smoking and nicotine?

A: On many occasions. Around 1980 when the American Psychiatric Association published new criteria for addiction, Dr. William Dunn advised a group of us, including Dr. Osdene, Dr. Fagan and Dr. Eichorn, that while earlier definitions may have allowed us to argue that nicotine was not addictive based on a definition of intoxication that required the intoxication to impair judgment under the older definition, the new definition made it impossible for the tobacco industry to continue to say it is not addictive. Of course the industry did continue to say it is not addictive up though the year 2000. For some companies, including Brown & Williamson and R.J. Reynolds, I still have not seen a clear statement that they agree that nicotine delivered by cigarettes is addictive, although they pose no science to support any alternative.

Q: What was the basis for this widespread conviction about smoking and nicotine being addictive?

A: Our understanding came from both internal and external research, about nicotine and its primary role in keeping people smoking. For example, we knew that nicotine binds to the cholinergic receptors in the brain and stimulated the release of dopamine, which makes one feel alert yet appear relieved of stress because dopamine is a significant chemical in regulating body functions. A natural chemical, acetylcholine, in your body normally performs this function.

Q: Please review U.S. Ex. 61,329. What is this?

A: It is an excerpt from the 1976 edition of "Essentials in Medicinal Chemistry," a reference textbook I used at PM. The excerpt, in technical fashion, describes this biochemical effect I just described. One of the diagrams of the nicotinic receptors in the brain, Figure 15.5 on the second-to-last page, is a 1959 reference.

Q: How did this widespread internal conviction that smoking and nicotine are addictive manifest itself at Philip Morris?

A: Just as the nature of certain research projects at Philip Morris was itself implicit recognition that smoking causes disease, the research related to nicotine similarly rested on the accepted premise that nicotine was the reason people were addicted to smoking.

Q: Please review U.S. Ex. 37,314. Can you please describe this document?

A: It is an August 1989 memorandum by Philip Morris's Frank Gullotta and others titled "When Nicotine is Not Nicotine." It is among my reliance materials. Dr. Gullotta performed extensive research on nicotine's brain effects, measuring how the administration of nicotine influenced brain patterns with an EEG machine. This report stated that he studied the differences between nicotine's effects on the central nervous system when the nicotine was in either acidic or basic form. The conclusion on the last page states that the magnitude of the CNS effects was twice as big when the nicotine in the cigarettes was a base than when it was in its more acidic form. He then recommended that cigarettes using the basic form of nicotine be further tested.

Q: What, if anything, is significant about this document?

A: Along with all the other reports from Dr. Gullotta's nicotine and EEG projects, and the behavioral pharmacology rat and nicotine analog research conducted by Victor DeNoble and Paul Mele, this document shows that Philip Morris's interest in nicotine was in learning about and

exploiting its brain effects.

Q: Does this document refer to or concern the flavor or taste of nicotine?

A: No.

Q: Did this understanding of nicotine influence the design and manufacture of cigarettes at Philip Morris?

A: Yes.

Q: In what way?

A: In terms of designing cigarettes, it was clear that for any cigarette – other than very low delivery cigarettes that Philip Morris referred to as "exit brands" because they believed that smokers of those brands were on the road to quitting – the design had to ensure that the cigarette could deliver enough nicotine to keep the smoker addicted.

For example, from the late 1970s, when I was there, Philip Morris had a program where we were trying to develop a chemical relative to nicotine, called an analog, as a substitute for nicotine that had the same brain effects as nicotine. Nicotine has some negatives of its own. It's implicated in cardiovascular disease. So we were trying to find an analog that did not have the negative peripheral nervous system effects such as increased heart rate and blood pressure. From the documents, such as U.S. Ex. 34,404, which is a 1978 Lorillard document which states that analog research might lead to information that could help Lorillard "adjust physiological impact in our cigarettes," one can see that some of the other cigarette companies were interested in the nicotine analogs, too.

The nicotine analog program and the interest in these compounds in all companies is evidence of the degree of understanding of what nicotine is and how it works. For example, can one imagine trying to develop a substitute for aspirin without knowing that it is a pain reliever?

The same concept is true for any drug development. You relate the chemical structure to the desired biochemical activity to create analogs with similar structure and similar activity.

Q: Did you personally work on the effort to find a replacement for nicotine?

A: Yes. Initially I was personally involved with Dr. Seeman and Dr. Sanders in understanding the chemistry of nicotine binding to receptors in the brain. I solved a series of equations for them that described how the binding site kinetics for nicotine could work in a detailed way. You can use other chemical reactions as surrogates for the receptor reaction, and that was done. There are two papers on my resume from that direct involvement. In my capacity as Director I arranged for the Computer Applications Division to assist Dr. Seeman with molecular modeling calculations on the analog structures. I have used such quantum mechanical calculations my entire career and still do. They are an indispensable tool in designing chemical to have specific structures such as the requirements for nicotine to match the receptor for acetylcholine in the brain.

Q: You mentioned "external" research. What do you mean by that?

A: Research conducted by non-Philip Morris scientists and published in the scientific and medical literature.

Q: You have been shown J.D. Ex. 00972. What is this document?

A: It is the famous 1942 Lancet article by Lennox Johnston that found that, based on the different physical reactions that nicotine injections had on smokers and nonsmokers, "Nicotine usually gives rise to toxic symptoms in a non-smoker," "A considerable tolerance to nicotine is . . . acquired as a result of smoking." Johnston also found that "Smokers could tolerate considerably larger doses than non-smokers."

Q: Was Philip Morris aware of this article when you were there?

A: Certainly.

Q: How do you know that?

A: Well, for one, I was the Director of Applied Research, and I first became aware of it when I was in college, because it was one of the bases for my understanding that nicotine satisfied at least two characteristics of some addictive drugs – intoxication and tolerance. In addition, Philip Morris scientists – especially people working in the behavioral research group – were familiar with the relevant literature related to nicotine.

Q: What is U.S. Ex. 22,848?

A: It is a draft 1969 presentation titled "Why One Smokes" presumably, as it states, to be given to the Philip Morris board of directors by the Vice President of Research & Development.

Q: What about the document is significant to you with respect to addiction?

A: It shows both considerable sophistication about the role of nicotine in smoking and its physiological effects on the smoker. For example, the second page states:

> We share the conviction with others that it is the pharmacological effect of inhaled smoke which mediates the smoking habit. . . .
>
> We have then as our first premise, that the primary motivation for smoking is to obtain the pharmacological effect of nicotine. . . .
>
> In the past we at R & D have said that we're not in the cigarette business, we're in the smoke business. It might be more pointed to observe that the cigarette is the vehicle of smoke, smoke is the vehicle of nicotine, and nicotine is the agent of a pleasurable body response.

And the third page states:

> This primary incentive to smoking gets obscured by the overlay secondary incentives, which have been superimposed upon the habit. Psychoanalysts have speculated about the importance of the sucking behavior, describing it as oral regression. Psychologists have proposed that the smoker is projecting and ego-image with puffing and his halo of smoke. One frequently hears "I have to have something to do with my hands" as a reason. All are perhaps operative motives, but we hold that none are adequate to sustain the habit in the absence of nicotine. In product tests, low nicotine cigarettes are repeatedly rejected in preference for higher levels. Intravenously injected nicotine was found to be an acceptable substitute for smoking in a study with 35 smokers (Johnston, 1942).

So not only does the document acknowledge Philip Morris's conviction that nicotine is the most important component of cigarette smoke, this 1969 document also relies on the 1942 Johnston Lancet article I just referred to.

Q: Did you ever hear PM executives discuss addiction?

A: Yes.

Q: Who?

A: Again, the same group I mentioned before, including the Cullmans, Ross Millhiser, George Weissman, Cliff Goldsmith, and Alexander Holtzman.

Q: In what circumstances?

A: Mostly at and around the Richmond Meetings, when they would come down from New York to talk about activities, developments, and plans for all aspects of the cigarette business.

Q: So you had personal discussions, and were present at meetings when such

discussions occurred?

A: Yes.

Q: What was their view about smoking and addiction?

A: They candidly acknowledged smoking's addictiveness. Hugh Cullman and Ross Millhiser were always praising the addictive nature of the product for maintaining sales. When I came to PM, I occasionally smoked a pipe, which I started doing while I taught college. I smoked "Bond Street" pipe tobacco and it said on the can it was made by Philip Morris. When I was asked what brand of cigarettes I would like – employees were allowed a free pack a day – I indicated I would like the Bond Street tobacco instead, like a can a week. I was told that PM no longer made the pipe tobacco or "smoking tobacco" as they called it. At a subsequent Richmond meeting with senior executives I had lunch at a table with Mr. Hugh Cullman. I asked about the history of the "smoking tobacco" business and he indicated that they had sold it to U.S. Tobacco under license because pipe and cigar smokers do not attain the level of addiction of cigarette smokers and Philip Morris did not want to be bothered with that level of business.

Q: Are there documents you have relied upon and considered that further support your testimony about Philip Morris's internal understanding of nicotine and addiction?

A: Yes.

Q: Can you please identify a few for the Court?

A: These documents include U.S. Ex. 20,177; U.S. Ex. 20,376; U.S. Ex. 20,491; U.S. Ex. 20,509; U.S. Ex. 22,029; U.S. Ex. 22,285; and U.S. Ex. 22,967.

Q: Dr. Farone, to your knowledge, did Philip Morris ever inform the public what they knew and accepted internally about nicotine – that smoking was addictive and the nicotine delivered by cigarettes was the primary reason for that addiction?

A: No. To my knowledge Philip Morris in their official statements did not provide any admission that cigarette smoking was addictive until around 2000.

Q: Can you describe U.S. Ex. 21,239?

A: It is a May 16, 1988 press release from the Tobacco Institute.

Q: What was the Tobacco Institute?

A: A trade organization of the tobacco industry.

Q: To your knowledge, were the Defendants in this case – Philip Morris, RJR, B&W, Lorillard, Liggett, and American Tobacco – members of the Tobacco Institute?

A: Yes.

Q: Let me read to you portions of this press release.

> **CLAIMS THAT CIGARETTES ARE ADDICTIVE CONTRADICT COMMON SENSE . . . Smoking is truly a personal choice which can be stopped if and when a person decides to do so. . . . The claim that cigarette smoking causes physical dependence is simply an unproven attempt to find some way to differentiate smoking from other behaviors. In fact, any feelings persons might have upon giving up smoking are those that would be expected when one is frustrated by giving up any desired activity . . . . The claims that smokers are 'addicts' defy common sense and contradict the fact that people quit smoking every day.**

Based on your personal knowledge, training and experience, including your knowledge of and participation in work related to nicotine-related smoking behavior at Philip Morris, in your opinion is that a true statement?

A: No.

Q: In your opinion, based on your personal knowledge, training and experience, including your knowledge of and participation in work related to nicotine-related smoking behavior at Philip Morris, and your review of Defendants' internal documents from the perspective of your scientific and professional background, training and experience, is that statement inconsistent with Defendants' own understanding of smoking, addiction and nicotine?

A: Yes.

Q: Do you have an opinion about whether other tobacco companies had the same internal understanding as Philip Morris's scientists, that smoking is addictive and that nicotine is the main thing responsible for causing and maintaining addiction?

A: Yes.

Q: What is your opinion about the other Defendants' views on nicotine and addiction?

A: My opinion is that all the Defendant manufacturers believed that smoking and nicotine were addictive whether or not it satisfied a specific technical definition that they chose to adopt for the purposes of confusing the public.

Q: On what do you base that opinion?

A: I base that opinion on my personal experience, my review of the documents, and my knowledge of industry terminology and manufacturing processes.

Q: You have been shown U.S. Ex. 20,928. Have you seen this document before?

A: Yes, it is on my reliance list.

Q: What is the document?

A: It is a 1963 document titled "A Tentative Hypothesis on Nicotine Addiction" from

BATCo. The first sentence states "The physiological action of nicotine consists in the liberation of catecholamines both in the brain and in the muscle tissue." The first sentence of the next paragraph states, "the hypothalamus-pituitary stimulation of nicotine is the beneficial mechanism which makes people smoke." This is consistent with what I learned in 1960 about nicotine's effects.

Q: Are there other documents that you have relied upon or considered in forming this opinion about other companies' internal views about nicotine and addiction?

A: Yes.

Q: Please identify some of those documents for the Court.

A: These documents include the BATCo-sponsored HIPPO studies of the early 1960s (U.S. Ex. 20,247 and U.S. Ex. 38,486); U.S. Ex. 20,659, a 1972 memorandum by R.J. Reynolds's Claude Teague; U.S. Ex. 21,485, a 1978 B&W document that states that "very few consumers are aware of the effects of nicotine, i.e., its addictive nature and that nicotine is a poison"; and U.S. Ex. 22,012, a 1976 Lorillard document that acknowledges a consensus that "the most probable reason for the addictive properties of the smoke is the nicotine."

Q: Dr. Farone, I now want to ask you some questions about how Defendants' understanding of nicotine, and its importance to smoking, has affected how they design and make cigarettes. In your view, have the Defendants' cigarette design and manufacturing activities taken account of their internal understanding of nicotine's primary role in maintaining smoking behavior?

A: Yes.

Q: How so?

A: Most generally, it is my personal experience, as well as my conclusion from reviewing

documents and from my chemistry background, that the tobacco companies have long understood the need to have a cigarette that delivered sufficient nicotine to the smoker. This understanding influences the selection and combination of design parameters and technologies, both physical – like the cigarette length, circumference, and density, the filter composition and design – and chemical – such as the blend selection, cigarette paper composition and porosity, and the choice of additives.

Q: Is the aim simply to deliver as much nicotine to the smoker as possible?

A: No. With nicotine, more is not always better because too much nicotine is unpalatable to the smoker. Too much nicotine is usually aversive to the smoker, because, as a base, it has a bitter taste and makes the smoke harsh and irritating to inhale. Research at Philip Morris and other Defendants has shown this to be true. One document I just identified, U.S. Ex. 22,029, is a 1980 William Dunn memo that states that one challenge in designing a high nicotine, low tar cigarette was "to overcome the taste problem typically reported with such a preponderance of nicotine." So part of the cigarette design involves figuring out how to balance the many different components and variables to get a smokable cigarette that enables the smoker to get enough nicotine without being too harsh.

Q: I have provided you U.S. Ex. 48,335 for review. What is this document?

A: It is a July 27, 1978 internal report on research at RJR from Charles Rix, titled "The Taste of Nicotine II."

Q: Why is this document relevant to your opinion about nicotine and "taste"?

A: It says in several places that nicotine is "irritating and harsh." The conclusion on page 5, Bates ending in 7765, states that "nicotine itself was quite irritating." So again, this shows that "taste" is not the reason why nicotine delivery is so important to cigarettes.

Q: What is the main component of a cigarette that contributes to nicotine delivery?

A: The tobacco blend.

Q: Why?

A: Because the amount and types of tobacco determine how much nicotine will be in the unsmoked rod. As I mentioned earlier, different types of tobacco naturally have different alkaloid content, and because nicotine is an alkaloid, different nicotine levels. Also, different parts of the tobacco plant have different levels of nicotine.

Q: Is all of the nicotine that is in an unsmoked cigarette delivered in the smoke to the smoker?

A: No. An unsmoked cigarette has many times the amount of nicotine than that actually delivered to the smoker. A cigarette that delivers about 1 mg of nicotine in smoke by the FTC test has about 14-20 milligrams of nicotine in the unsmoked rod. So there is a tremendous reserve of nicotine. To Philip Morris and the other Defendants, a critical part of cigarette design is first ensuring that enough nicotine is available in the unsmoked rod, and then making sure that the design enables the smoker to get enough of the nicotine out to maintain his or her addiction.

As I said earlier, burley tobacco is naturally highest in nicotine, so the Defendants have used extra burley in some of its lower FTC yield blends to maintain those cigarettes' ability to provide the "impact" – nicotine effects – for addicted smokers. Philip Morris did this with its Merit brand.

Q: Have you seen other documents where Defendant tobacco companies other than Philip Morris also use blending techniques to maintain adequate nicotine levels, even in lower FTC yield products?

A: Yes.

Q: Please review U.S. Ex. 34,293, a Lorillard document dated February 8, 1971. Do you see that it was written to Alexander Spears and another Lorillard employee?

A: Yes.

Q: Who was Alexander Spears?

A: He was a top researcher at Lorillard.

Q: On Bates page ending in 6196, the memo states that "[t]he ratio of nicotine to tar can be controlled by blending high nicotine and tar grades with low ones resulting in a net gain of nicotine delivery over tar level." How if at all does this relate to what you have been testifying about with respect to the role of the blend in controlling nicotine levels?

A: This supports exactly what I've been discussing, which is that Defendants know how, and do, substantially determine the nicotine level in the cigarette through blend selection. At Philip Morris, we altered the nicotine-to-tar ratio by using more Burley tobacco in the blend.

Q: You have been shown U.S. Ex. 56,269. Have you seen this document before?

A: Yes, it is part of my reliance set. It is a 1981 paper by Alexander Spears and another Lorillard scientist.

Q: What about this document do you consider significant to your opinion about the role of the tobacco blend in nicotine levels?

A: On page 24 of the publication, Bates number ending in 8495, Spears states: "Higher nicotine levels can be achieved by decreasing Oriental and the stem and the tobacco sheet and increasing the Burley and upper stalk positions of both the Flue-cured and the Burley tobacco." This simply confirms again that Lorillard knew, as we did at Philip Morris, that nicotine levels could be controlled by selection of tobacco – by type and stalk position – and total composition of the blend.

Q: Are you aware that the tobacco companies have made statements about the nature of the nicotine-to-tar ratio in cigarettes?

A: Yes.

Q: Can you describe the nature of these statements?

A: The tobacco companies have always argued publicly that the nicotine level is determined by the tar level, that they don't keep track of nicotine levels in the manufacturing process, and that the nicotine level is fixed.

Q: And are those statements true?

A: No, for several reasons. As this Lorillard document shows, the nicotine-to-tar ratio in cigarettes is variable, depending upon the blend of tobaccos chosen. More Burley in the blend causes a higher nicotine-to-tar ratio. As I said before, the use of a tobacco blend with a higher percentage of Burley tobacco was one of the key design features of Merit cigarettes at Philip Morris in the 1970s. The nicotine-to-tar ratio can also be intentionally altered by other design features.

Q: What other design features can be used to alter the nicotine-to-tar ratio?

A: Ventilation holes in the filter can dilute the smoke in a way that alters the ratio, too.

Q: You have been shown U.S. Ex. 35,572. What is this document?

A: This is a March 24, 1969 document titled "Factors Affecting Nicotine Concentration in FTC Tar." The memo is from W.E. Claflin to R.M. Ikeda.

Q: Did you know either of these people?

A: I knew them both very well. Warren Claflin was an engineer in Process Development at Philip Morris. Employees in the Applied Research Directorate interacted with him frequently. Bob Ikeda was one of the key, if not the key, flavor chemist. My personnel worked with Bob

Ikeda on many projects such as making an inhalable nicotine aerosol generator that was not a cigarette.

Q: How does this document support your testimony?

A: The second sentence in the "Summary" states that "There does appear to be a definite increase in nicotine concentration as the percentage dilution increases" and that while "the nicotine concentration increases as total delivered tar decreases," "[t]he dilution effect is the greater of the two." Then, on the next page, the report says: "The basic conclusion to be reached from this data is that as delivery is reduced, a lower percentage of nicotine is filtered out than of FTC tar in general. This reduction is enhanced if the reduction is accomplished by dilution rather than improved internal filtration."

Q: What is significant about this for your opinion on this issue?

A: It shows that Philip Morris found from its research that it could increase the nicotine-to-tar ratio by increasing the amount of dilution from ventilation.

Q: Why else do you conclude that the Defendants' statements about not tracking nicotine levels is not true?

A: The statement about not tracking nicotine during the manufacturing process is misleading, because tobacco is analyzed for alkaloids, which is the same thing for all practical purposes because nicotine is the majority of the alkaloids. For the tobaccos Philip Morris used, the two track so closely that if you know the alkaloid content you know the nicotine content. In chemistry we use the idea of one thing being a measure of another. Alkaloids are a measure for nicotine and the reverse is also true. The tobaccos that Philip Morris purchased were all analyzed for alkaloid content and then blended accordingly. So Philip Morris already knew how much nicotine was going to end up in the cigarette. For example, in U.S. Ex. 37,130, a 1977

presentation to the Philip Morris Board of Directors, Wally McDowell stated, on page 5, Bates number ending in 1003, that

> the accurate control of the chemical composition of our tobacco blends becomes critical. As you can see, the compositions vary significantly by stalk position. In addition, they change from year to year and vary widely by tobacco type. Our analysis techniques have developed to the point that we can determine the presence of these critical components in the blend with a high degree of accuracy. From this data, the tar generated by a particular blend can be predicted.

I would add that nicotine could be accurately predicted for the same reasons.

Q: You have been shown U.S. Ex. 34,293 for review. Please describe this document.

A: It is a Lorillard document on my reliance list, and is a February 8, 1971 memo to Alexander Spears and a Mr. Tucker from S. Jones. It discusses how Lorillard predicted tar and nicotine levels, and even smoke levels, by analyzing the tobaccos bought by Philip Morris, RJR, and B&W.

Q: Are there any other reasons that you find Defendants' statements about nicotine-to-tar ratios to be inaccurate?

A: Yes. The companies definitely know how much nicotine is in the reconstituted tobaccos like reconstituted leaf and blended leaf, and use that to fine tune the nicotine levels to ensure consistency. Finally, the companies have full capability to change the ratio however they want, because they have the ability to remove all nicotine from cigarettes. Even before I got to Philip Morris, they had at least one method for removing virtually all nicotine.

Q: You have been shown U.S. Ex. 20,352. Have you seen this document before?

A: Yes, I saw it when I was at Philip Morris because I had access to the Wakeham files. Also, it is part of my expert reliance set.

Q: What is this document?

A: It is a March 1961 memo from Wakeham to Hugh Cullman that advises that "[W]e have available in Research and Development two processes for reducing nicotine in smoke. . . ." So that is 1961, and Philip Morris already has multiple ways to control nicotine levels – and nicotine-to-tar ratios – in cigarettes.

While I was at Philip Morris we were working on another nicotine-removal process – called "supercritical fluid extraction" – that Philip Morris eventually used to make the denicotinized cigarettes it briefly test-marketed in the late 1980s. That cigarette had virtually no nicotine, but about 14 mg. of tar by the FTC method.

Q: How does cut width affect nicotine delivery?

A: Again, cut width affects the particle size of the liquid drops in the smoke aerosol. The finer the cut width, the faster the cigarette burns and the smaller the particles in the smoke. Particle size in turn influences the kinetics of absorption – the rate and location of where the particles are absorbed. Further, the cut width influences how fast the tobacco will burn. Rapid burning tobacco also creates smaller particles and facilitates rapid, repeated use of the product, thereby increasing nicotine delivery to the smoker. Cut width also influences how much of the nicotine that is in the tobacco will get into the mainstream. Nicotine is essentially distilled from the tobacco, and greater surface area from smaller cut width will let nicotine volatilize more depending on some other parameters such as resistance to draw. Thus, one can change the nicotine-to-tar ratio with cut width as well as influencing the aerosol particle size. With smaller particles in the aerosol, cut width can influence how much nicotine is inhaled into the lungs and

how fast it is absorbed into the bloodstream.

Q: Have you seen documents where Philip Morris discusses particle size and inhalation?

A: Yes. Dr. Osdene had a whole program on this which I was participating in with my diagrams and expertise. Before I arrived at Philip Morris, papers were published that are on my reliance documents, including U.S. Ex. 61,129, a paper about measuring particle size by Carter and Hasegawa, two Philip Morris scientists. I had scientists in Applied Research building light scattering instruments for measuring the particles sizes.

Q. Would these principles have application in the area of cigarette design and nicotine inhalation?

A. Yes, that is one of the things I was doing at Philip Morris.

Q: You have been shown U.S. Ex. 70,839. Please describe what the document is.

A: It is a 1999 status report on smoke research from Ken Shafer of Philip Morris.

Q: Have you seen this document before?

A: Yes. I reviewed it after it was produced in this case.

Q: What about this document bears on your testimony about nicotine and particle size?

A: This document is discussing one of Philip Morris's recent research initiatives – development of a non-cigarette "aerosol generator" – basically, a means of generating and delivering an aerosol of known chemical composition. At the top of page 2 of the document, Bates number ending in 1519, the document describes the objective of the project: "Develop a drug inhalation device for non-tobacco applications which is based on capillary aerosol generator (CAG) technology."

It shows that Philip Morris is applying its sophisticated understanding of aerosol

formation and particle size to develop new technologies. They could be developing this technology as a means of delivering nicotine and flavor without the carcinogens in smoke. This technology could yield the ideal less harmful product as we all knew in the 1960s and as was discussed in the 1970s when I was there.

Q: Do added chemicals like casing or flavorants affect nicotine delivery?

A: They can, depending upon the type of chemical and the amount used.

Q: Are there particular chemical additives that have particular importance to nicotine delivery, in your view?

A: Yes. One important flavorant is menthol, which as anyone who has sucked on a menthol cough drop knows can act as a local anesthetic in the throat. Menthol thus can help override the irritation that naturally comes from the inhalation of cigarette smoke.

Second, additives like ammonia, other ammonia-related compounds, and other flavor components can also mediate the harshness of nicotine, thereby facilitating inhalation. They can also make the tobacco smoke more acidic or more basic, which in turn affects the form of nicotine delivered in cigarette smoke.

Third, compounds like pyridine and synthesized chemicals know as "reaction flavors" made from the reaction of sugars and proteins or amino acids can also have effects on the central nervous system. Many of the chemicals made in these reactions have structural similarity to nicotine as well as being flavorings and finding classes of chemicals that are both nicotine analogs and accepted flavors was a major project at PM. RJR also has developed these "cooked flavors" or "reaction flavors."

Q: You mentioned that certain additives affect the "form" of nicotine. What do you mean by the form of nicotine?

A: Nicotine in cigarette smoke is found primarily in two different chemical states: either the protonated form or the unprotonated "free" form. Most nicotine in cigarette smoke is protonated – that is, it carries a positive chemical charge. As the smoke becomes more basic – that is, the pH rises – more of the nicotine that is delivered is in its "free" chemical form. At a given pH, there is a given ratio of free to protonated nicotine. Also, as more nicotine is delivered in the free, unprotonated form, a greater proportion of the nicotine is also delivered in the gas phase of smoke.

Q: How can a cigarette designer raise the pH of cigarette smoke?

A: The pH can be altered in more than one way. Again, the tobacco blend is important, because Burley tobacco is naturally higher in alkaloids and nitrates, and therefore yields a higher pH of smoke. Another way of raising pH is to mix more basic substances, like ammonia (or substances that convert to ammonia upon burning) into the filler.

Q: Can you explain more about the role ammonia can play in a cigarette's nicotine delivery?

A: Yes. First, ammonia can alter the impact of smoke and nicotine because it is not as bitter as nicotine and thus "smoothes" the smoke. Second, ammonia – and other chemicals, like urea, which convert to ammonia when burned – raise the pH level, and therefore causes more of the nicotine to be in the unprotonated form and in the gas phase of smoke. Third, the way ammonia actually works is also important. When ammonia is released during combustion it sweeps along the remaining tobacco, which has been moistened by water of combustion replacing nicotine and causing the nicotine to be released in gas phase from the tobacco.

Q: On what do you base these statements about ammonia's different characteristics?

A: Some of it is fundamental chemistry. This is also what I learned while at Philip Morris.

Patents going back to the 1920s discuss how ammonia can be used to extract nicotine from tobacco. The effects of pH on the form of nicotine have been discussed for decades as with any of the alkaloids such as cocaine.

Q: Did Philip Morris actually use ammonia to exploit its properties?

A: Yes. As I heard at many Richmond meetings, speeches, and discussions when I was there, Philip Morris considered its blended leaf, or BL, to be a secret to Marlboro's success, because of the ammonia added to the BL.

Q: What is the significance of delivering more of the nicotine in its "free" form?

A: Two things about this are important. First, the tobacco companies' documents show their conclusion, by the 1970s, that smokers found cigarettes with more of the nicotine delivered in "free" form to have greater impact than cigarettes with the same total amount of nicotine, but less free nicotine.

Q: You have been shown U.S. Ex. 35,109 for review. What is this document?

A: This is a June 18, 1975 report titled "Manipulation of Nicotine Delivery by Addition of Acids to Filler" by Joseph Cipriano at Philip Morris, and distributed to over 20 people in the R&D department.

Q: Have you seen this document before?

A: Yes, I saw it when I was at Philip Morris, and it is part of my reliance set.

Q: Did you discuss this document with personnel who were involved in it when you were at Philip Morris?

A: Yes.

Q: What part of this document do you consider important?

A: This document reports on a Philip Morris experiment with lowering pH by adding acids,

but found that while nicotine delivery actually increased by 25%, test smokers found that the "impact" did not change. What is significant is the researcher's conclusion that

> These subjective results seem to be consistent with the theory that smoke impact (inhalibity [sic]) is not so much related to total nicotine as to the level of unprotonated nicotine. As pH falls, the nicotine equilibrium shifts more toward the protonated (less active form).

Q: Have you considered other documents that support your testimony that the tobacco companies have known since the 1970s that cigarettes with a greater percentage of the nicotine in the free form give smokers greater physiological effect than cigarettes with the same amount of nicotine but less of it in the free form?

A: Yes.

Q: Can you identify those for the Court?

A: Yes. Lorillard had a series of research projects, mostly in the 1980s, called the Nicotine Augmentation Project that looked at ways to increase the delivery and effects of nicotine. Related documents include: U.S. Ex. 20,025; U.S. Ex. 20,029; U.S. Ex. 20,043; U.S. Ex. 34,191; U.S. Ex. 34,192; U.S. Ex. 34,197; U.S. Ex. 34,205; U.S. Ex. 34,207; U.S. Ex. 34,209; U.S. Ex. 34,217; U.S. Ex. 34,269; U.S. Ex. 34,296; U.S. Ex. 34,311; U.S. Ex. 46,443; U.S. Ex. 47,720; U.S. Ex. 47,721; U.S. Ex. 47,723; U.S. Ex. 54,377; U.S. Ex. 55,938; U.S. Ex. 56,825; U.S. Ex. 85,456; U.S. Ex. 85,457; U.S. Ex. 85,459; U.S. Ex. 88,771; and U.S. Ex. 88,772.

An R.J. Reynolds document, U.S. Ex. 48,662, provides a very good summary of pH, free nicotine, and the state of industry knowledge about the chemistry of tobacco smoke as related to these things. It talks about the different approaches Philip Morris was using to raise pH, with the conclusion that the increase in free nicotine in Marlboro had corresponded to Marlboro's increase

in sales in the late 1960s and early 1970s.

Similarly, U.S. Ex. 20,669 shows that by 1973, Reynolds found that Marlboro cigarettes delivered more free nicotine than Winston, Salem, and Kool, and that Marlboro's sales compared to those brands correlated significantly with the amount of free nicotine delivered by the brands, and that "our emphasis should be directed toward nicotine." So they also knew that "pH was a measure of or tool to effect free nicotine."

Another document, U.S. Ex. 37,312, is a handwritten memo from Philip Morris's Frank Gullotta, who researched the brain response to smoking using an EEG instrument that records brain wave patterns and found that adding ammonia to cigarettes resulted in the smoker experienced brain effects faster. This document, titled "The Effects of Cigarette Smoke 'pH' on Nicotine Delivery and Subjective Evaluations" states, on the second page that "the higher the pH the more rapidly nicotine enters the blood stream. . . . rate of entry is pH dependent."

The Brown & Williamson Leaf Blenders Manual, which is U.S. 86,908, says similar things about pH, ammonia, and free nicotine as the Lorillard and RJR documents.

Q: Are the statements and conclusions in these documents consistent with your understanding, from a biochemistry perspective, of the role of ammonia and pH on the formation and delivery of nicotine in its free form?

A: Yes.

Q: Did any companies, other than R.J. Reynolds, study Marlboro and reach the same conclusion about its use of ammonia in that brand?

A: Yes. Brown & Williamson did an extensive analysis of Marlboro over a number of years, as shown in U.S. Ex. 25,418. As shown at page 14 of the document, Bates number ending in 0020, B&W also found that ammonia and/or diammonium phosphate that produces ammonia

when burned were used to "Enhance nicotine availability (free nicotine)."

Q: Dr. Farone, have you seen any documents that confirm that RJR actually used methods to increase free nicotine in their cigarettes?

A: Yes. I have a series of so-called RJR black book analyses of their cigarettes over a period of years. Their own analysis gives the pH of the smoke delivered by their products and as the delivery of the amount of tar in a product decreased over time the pH of the smoke was increased. Thus, for example, the pH of NOW cigarettes was much higher than the pH of Winston. Thus, even though NOW may deliver less nicotine, more of it is in the free base form.

Q: Dr. Farone, you said there were two reasons why delivery of nicotine in its unprotonated form is important. What is the second reason that delivery of free nicotine is important to your opinion?

A: The second reason is that gas phase nicotine – which goes up as free nicotine increases – is not "captured" by the filter pad used to collect tar and nicotine in the FTC machine test to determine the FTC tar and nicotine yields. Thus, even before figuring in the differences in delivery to human smokers as opposed to the FTC smoking machine, cigarettes with more gas phase nicotine deliver regularly deliver more nicotine than their FTC rating would suggest.

Q: Is this all information that you were aware of at Philip Morris?

A: Absolutely.

Q: And is it your opinion that Philip Morris used its knowledge of design parameters to control the amount and form of nicotine delivered to smokers?

A: Yes.

Q: I have provided you U.S. Ex. 20,371 for review. Have you seen this document before?

A: Yes, it is part of my reliance set of documents that I have considered.

Q: What is it?

A: It is a March 22, 1996 newspaper ad from the Tampa Tribune titled, "What does Philip Morris have to say about the allegation of 'nicotine manipulation'? Plenty."

Q: The last sentence in the first paragraph states that "quality control . . . does not constitute 'manipulation.'" In your view, Dr. Farone, from what you saw, what you learned, and what you did when you were at Philip Morris, and from your review of Philip Morris documents, were Philip Morris's manufacturing processes that you described earlier solely for "quality control" and "consistency"?

A: No. Cigarettes are designed to give a desired tar and nicotine level for each member of any brand family. They are designed into the product and they are not a matter of random variation. The manipulation starts at the design stage and then it is maintained. The statement focuses on maintaining the manipulated design, but leaves out the entire idea of how it got to be that nicotine and tar level in the first place. Every cigarette on the market has been manipulated to be what it is and then they use the "quality control" and "quality assurance" to keep it that way or deliberately change it. Manipulation is not solely for quality control. It is also for design and making of the products in the first place.

Q: Similarly, from what you saw, what you learned, and what you did when you were at Philip Morris, and from your review of Philip Morris documents, were Philip Morris's research and development of methods for controlling the amount and form of nicotine in cigarettes and cigarette smoke, methods you have described in your testimony today, solely for "quality control" and "consistency"?

A: No. Cigarettes were designed to provide the levels of nicotine and tar desired by the

companies. The nicotine was and is manipulated to keep the smokers addicted. No cigarette without nicotine has ever been a marketing success, since nicotine provides a biochemical effect that overcomes the natural disinclination to deliberately inhale smoke into the lungs.

Q: What percentage of nicotine delivery occurs in the "free" particulate form or in the gas phase of smoke?

A: Recent research confirms what Tom Osdene reported in 1975 – that up to 14% of the nicotine can be delivered in the gas phase of smoke.

Q: You have been shown U.S. Ex. 61,368. What is this document?

A: It is the 1975 Osdene paper in which he reports the conclusion about the percentage of gas-phase nicotine.

Q: Where in the document is that information?

A: On the page with Bates number ending in 2275, in Table VIII, the first line, fifth column over reports the ratio for nicotine of MS Gas (Mainstream Gas) to MS TPM (Mainstream Total Particulate Matter) as .14. MS refers to the smoke a smoker gets, as opposed to SS, or sidestream smoke, the smoke that comes directly off the lit cigarette into the air.

Q: You have been shown U.S. Ex. 88,093. What is this document?

A: This an article by James Pankow published in 2003 in the peer-reviewed Journal of Chemical Research and Toxicology. You can see on the third page of the document, in the "Results and Discussion" section, Pankow states: The results here indicate that significant amounts of the nicotine in smoke PM [particulate matter] from some cigarettes can be in the free base form" and that, on the next page, "for a given cigarette smoke, the presence of significant PM phase free base nicotine will lead to increased nicotine RT [respiratory tract] deposition efficiency" as compared to cigarettes with more of the nicotine in its regular, protonated form.

Basically, Pankow shows that prior measurements of smoke pH – including measurements published by the tobacco companies – give incorrectly "low" pH ratings, that is, suggest that cigarette smoke is less basic, more acidic, than it actually is. And, since more free and therefore gas phase nicotine is produced at higher pH levels, Pankow's research shows that previous statements have presented free nicotine measurements that understate the actual amount in cigarette smoke.

Q: Are you aware, from personal experience or your knowledge of documents, whether tobacco companies other than Philip Morris were similarly committed to designing cigarettes that ensured that a smoker could obtain sufficient nicotine?

A: Yes.

Q: You have been shown U.S. Ex. 34,706, a June 1985 BATCo document entitled "Nicotine Transfer Efficiency." Have you reviewed this document?

A: Yes.

Q: Do you see the first main paragraph on page 2 of the document that says, "Nicotine transfer efficiency will be affected by various design aspects of a cigarette – paper permeability, filtration, ventilation, pressure drop (filtration in the rod), pH of tobacco etc."?

A: Yes.

Q: What do you interpret nicotine transfer efficiency, and this passage, to mean?

A: This document is talking about how the cigarette design affects "the nicotine transfer efficiency," that is how much of the nicotine in the original unsmoked cigarette ends up getting delivered in smoke to the smoker. It is discussing the exact same types of design parameters that I was discussing for Philip Morris, and shows BATCo's identical interest in ensuring adequate

nicotine delivery to the smoker.

Q: While you were at Philip Morris, were you aware of whether Philip Morris was conducting research into how people smoke cigarettes of varying nicotine levels?

A: Yes, and I was personally involved in the analysis of some of those tests.

Q: Can you briefly explain how it is you were aware of this research?

A: As a Director, I was copied on the research results and plans and was present at the presentations of the work. Additionally, because of my mathematics background and my work at Lever Brothers in consumer product testing, I was consulted on ways to plan the experiments and analyze the data. The computer analysis of the data was under my Directorate and in the later years the Consumer Testing group under Colon Rowe reported to me.

Q: What do you know about what that research found?

A: We were aware that if we adjusted the design to reduce the nicotine delivery, or if people were given a cigarette of lower nicotine delivery than their usual brand, smokers would "compensate" – change how they smoked – to get the amount of nicotine they need.

Q: What do you mean when you say that smokers will compensate to get the amount of nicotine they need?

A: Well, the general consensus as I've been involved in it and understand it scientifically is that when one starts to smoke, one builds up a tolerance, if you will, for nicotine. That level varies from smoker to smoker. Some people develop higher tolerances, some people have lower tolerances. Eventually, that tolerance becomes the amount needed by the smoker. And it becomes sort of a required amount to sustain the dependence on nicotine.

Q: How does a smoker achieve their tolerance level of nicotine?

A: Smokers will modulate their smoking behavior in different ways to obtain that required

amount of nicotine. These behaviors include smoking more cigarettes per day; puff compensation (the strength of the puff, which is sometimes referred to as puff volume); number of puffs taken in a single cigarette; and blocking ventilation holes. Compensation is largely an unconscious act. These are examples of compensation, that is, these are ways in which a smoker compensates to achieve the needed level of nicotine.

Q: Does the method and degree of compensation vary, depending upon the differences in the cigarette design and yields between the two cigarettes?

A: Yes. If the differences between the two cigarettes are relatively minor, smokers can just draw a little harder on the cigarette. There is published literature and evidence that if a smoker who is accustomed to a cigarette with one level of nicotine is given a cigarette with another level of nicotine, within the smoking of that one cigarette – because nicotine gets to your brain so quickly – the smoker will adjust the way they smoke to try to make the level of nicotine that they receive the same as they are used to.

In the context of "light" cigarettes and their full flavor counterparts, the major means of compensation is simply to draw a little harder on the cigarette. If you puff longer or take a deeper puff on such "light" cigarettes you are essentially defeating the filter when ventilation is used.

Q: Dr. Farone, are there circumstances in which a smoker simply may not be able to obtain the needed dose of nicotine via compensation?

A: In my view, a smoker dependent upon the level of nicotine associated with full flavor cigarettes like Marlboro Red may not be able to get enough nicotine out of an ultra-low delivery product like the original Cambridge. If a smoker drew very hard on that cigarette one could get 1-3 mg of tar, but not enough nicotine to satisfy most smokers' need for the drug on a per

cigarette basis. Of course, that smoker could always smoke more cigarettes.

Q: So what happens when a smoker simply cannot obtain the desired dose of nicotine via compensation?

A: If it is not possible to get the desired dose of nicotine via compensation then a smoker will do one of the following: become tolerant of the new, lower level of nicotine (and thus tar); quit smoking; or revert to higher tar cigarettes.

Q: Was Philip Morris aware of the phenomenon of compensation when you were there?

A: Yes.

Q: How do you know?

A: From conversations that I had with many of my colleagues at Philip Morris while I was working there, including people working under Dr. Dunn in his behavioral research group. It is evident from the company's own documents.

Q: Are these documents included in your list of reliance materials in this case?

A: Yes.

Q: Dr. Farone, looking at U.S. Ex. 34,674, please explain its significance to the Court.

A: U.S. Ex. 34,674 is a memo dated March 24, 1961, from Helmut Wakeham to Hugh Cullman. The subject of the memo is "Trends of Tar and Nicotine Deliveries over the last 5 Years." Dr. Wakeham reports that he and others had reviewed preliminary charts of nicotine and tar deliveries data.

Q: What if anything in this document supports your testimony about Philip Morris's awareness of compensation?

A: Dr. Wakeham stated: "The King non-filter smokers and the regular non-filter smokers

may actually be smoking to a comparable delivery, the former group, omitting the last puff or two and the latter group smoking down to the bitter end." This describes puff compensation.

Then, in the next paragraph, Wakeham wrote: "As we know, all too often a smoker who switches to a hi-fi [highly filtered] cigarette, winds up smoking more units in order to provide himself with the same delivery which he had before." In this statement, Dr. Wakeham acknowledged a different type of compensation – simply smoking more cigarettes.

Q: Did this research into and understanding of compensation influence how Philip Morris designed cigarettes?

A: Yes.

Q: Dr. Farone, you have referred at various points to the "FTC test," "FTC machine," and "FTC yield." Can you please briefly describe what these terms refer to?

A: Yes. These terms refer to a standardized machine smoking test that the FTC instituted in 1967. The FTC test was intended to give smokers a standardized measurement of tar levels on which to base their choice among the existing brands.

In the test, many cigarettes, typically 200 or so are placed in a machine that draws on the cigarette in uniform puffs at planned intervals. The machine draws a given volume of smoke – and air when the cigarette is diluted – for a given time. The mainstream smoke from this smoking regimen is collected on a filter pad that can collect 99% of the particles over 0.1 micron. The filter pad does not collect the gas and it misses the very small particles. The material on the pad is called "total particulate matter" or TPM. It is analyzed for water and nicotine. The nicotine and water are subtracted from the TPM to give a "tar" value. The exact regiment – things like puff volume, and puff duration, and total smoking length – is in Chapter 5 of Monograph 13.

Q: In your view, do smokers generally receive tar and nicotine in the quantities reported by the FTC for a particular brand?

A: No.

Q: Why not?

A: Because the machine smokes in a uniform way, and human smokers smoke to get varying amounts of nicotine that they need at varying times, and in different situations.

Q: What is the basis for your testimony on this point?

A: Both personal knowledge gained from when I was at Philip Morris, and the literature which I became more aware of in the years since I left. Even at the time I went to Philip Morris there was literature on this, and it was part of general reference texts that discussed smoking and health. In some of the references of the 70's the term titration is used to describe the idea that the smoker is trying to get his or her desired amount of nicotine. Compensation is the way smokers smoke that allows them to titrate for nicotine.

Q: You have been shown U.S. Ex. 21,487 for review. What is this document?

A: It is a 1966 Report, titled "Market Potential for a Health Cigarette," written by Myron Johnston, a PM researcher.

Q: Did you know Myron Johnston?

A: Yes. He and I had dozens and dozens of conversations. He worked for Colon Rowe who reported to me for a time near the end of my tenure at Philip Morris.

Q: Have you seen this document before?

A: Yes. I saw it when I was at Philip Morris.

Q: As Director of Applied Research, how would you have had occasion to see this document?

A: During my time at Philip Morris until the end of my career there I actually was involved in the chain of supervision related to consumer perceptions where the facility called the subjective evaluation facility or the testing facility, consumer testing, and they reported to me.

Q: In what forum or types of meetings did you participate where you learned about this type of market and planning information?

A: These types of issues were discussed at the Richmond meetings with senior executives on a monthly basis but also in between at R&D as part of our reaction to the decision made at the Richmond product meetings. One of the major focuses on research at Philip Morris was behavioral research. Why and how people smoke. The person who is signing this, not the person who wrote it, is Dr. William Dunn, who headed that from long before the time I got there through the time that I was there. Dr. Dunn and his group did the vast majority the research on how and why people smoke.

Some of the most senior executives would always come to the monthly Richmond meetings when any presentation was given by Mr. Johnston or Mr. Dunn relative to this topic because there was a general recognition within Philip Morris that what we were doing was selling a nicotine delivery device. People smoke for the nicotine. So topics like how much nicotine smokers need, how much they want, how much they can tolerate, how little they can accept, were all topics that were discussed frequently. This is one of probably several dozen documents on this same subject that I have seen.

Q: The page ending in Bates No. 8646 shows the report was approved by Dr. Dunn and distributed to H. Wakeham and R. Seligman. Do you see that?

A: Yes.

Q: Please identify any portions of U.S. Ex. 21,487 that you consider significant to your

opinions about cigarette design and explain the significance.

A: There are several important statements in this document. The first, on page 3 of the document, Bates number ending in 8650, is Johnston's recommendation that "we not introduce another health cigarette unless there is another health scare or additional restrictive legislation is passed." That is important because it expresses Philip Morris's attitude not to do anything to proactively develop and sell a potentially less hazardous product, but rather to develop and introduce such products only defensively.

The second part is on page 2 of the document, listed as point number 10, where Johnston says "the illusion of filtration is as important as the fact of filtration," and then in the next point where he says that any novel filter method "need not be any more effective" than current filters. This again shows that Philip Morris's product development was not genuinely aimed at making products that meaningful testing showed likely to be less hazardous, but rather products that would imply safety but didn't actually offer any advantage.

The third part is on page 5, where it says: "A cigarette that does not deliver nicotine cannot satisfy the habituated smoker and cannot lead to habituation, and would therefore almost certainly fail." This reflects the view – understood in 1966, and certainly when I was there – that nicotine delivery was the most important thing for a cigarette to do.

A fourth important statement, again on the page with Bates ending in 8650, is that

> [i]n the event of a resumption of the tar derby or the passage of legislation requiring a statement of 'tar' and nicotine content on the pack, the delayed dilution cigarette could be a formidable entry as a full tobacco flavored cigarette. It could compare favorably with any health cigarette currently on the market yet deliver full flavor throughout the crucial first 40 mm of

the rod. I am of the opinion that we should press development of this concept.

Q: What does "passage of legislation requiring a statement of 'tar' and nicotine content on the pack" mean?

A: Johnston wrote this memo in anticipation of the introduction of the FTC testing method.

Q: What, if anything, does this paragraph reveal about Philip Morris's cigarette development plans in anticipation of the FTC method?

A: That paragraph shows that Philip Morris was planning to develop cigarettes that would generate low tar and nicotine numbers on the FTC machines, but the cigarettes would actually deliver much higher levels when smoked by humans.

Q: Do you want to identify and explain any other significant statements in this document?

A: Yes. Page 4 of the document, ending in Bates 8651, states: "If we could develop a . . . 'healthy' cigarette that tasted exactly like a Marlboro, delivered the nicotine of a Marlboro, and was called Marlboro, it would probably become the best selling brand." This shows that Philip Morris believed that a cigarette that could actually marketed as less hazardous – in contravention of the industry agreement – could be an economic success.

Q: I will return a little later to the subject of the industry agreement to which you just referred. In your personal experience, from your employment at Philip Morris and your participation in the Richmond meetings, and your knowledge of the documents, did the sentiments expressed in U.S. Ex. 21,487 extend beyond just Myron Johnston?

A: Yes.

Q: On what do you base that?

A: Johnston was generally acknowledged to be the guru on market analysis within the R&D Department, and he was well-regarded and influential among Philip Morris executives, so his research and recommendations shaped their views and decisions. While I was there I found, over and over, these attitudes reflected openly in meetings and, more importantly for consumers, in decisions about what to market and what not to incorporate into marketed cigarettes.

Q: Can you identify some of the other documents that support your testimony about Philip Morris's awareness and understanding of compensation, and explain their significance to the Court?

A: Yes. U.S. Ex. 36,855 is a memo dated September 2, 1970 from Dr. Ray Fagan to Dr. Wakeham. The second page, in the middle, states: "Smokers determine how much smoke they take in, not the cigarette." Here, Dr. Fagan recognizes puff adjustment – where the smoker draws harder on the cigarette. Dr. Fagan also acknowledges another form of compensation, smoking more cigarettes: "The number of cigarettes per smoker has increased. With certain kinds of cigarettes the compensation is by increasing number."

U.S. Ex. 20,176 is a special research report that Tom Schori wrote in November 1971. The abstract reveals that the test here was to look at cigarettes of different tar levels and different nicotine deliveries within those tar levels. U.S. Ex. 20,176 speaks in terms of the levels at which smokers were accustomed. When the smokers were switched between these various cigarettes, as tar delivery decreased from that to which the smokers were accustomed, cigarette consumption increased. This resulted in a tendency for the smokers' daily intake of tar to remain constant even though the tar deliveries of the cigarettes he smoked differed markedly. Again, this document relates to the compensation phenomenon. The last sentence of the abstract reads: "These findings support the hypothesis that the smoker does have daily intake quotas for tar

and/or nicotine and that he titrates his smoke intake to meet his quotas." U.S. Ex. 20,159 is a very similar document that concluded that smokers adjust their consumption in order to maintain their "daily nicotine intake quota," but that "No support was found for the analogous notion of a daily tar intake quota."

U.S. Ex. 35,224 is a memo from Helmut Wakeham to Paul Smith, dated August 11, 1967. This memo concerns plastic dilution tipped Parliament. Specifically, Wakeham is reporting the results of two tests conducted at Product Opinion Laboratories. On the first page of Exhibit 35,224, Bates number ending in 7719, Dr. Wakeham says:

> Two tests conducted at Product Opinion Laboratories demonstrate that in smoking a dilution filter cigaret [sic.], the smoker adjusts his puff to receive about the same amount of 'undiluted' smoke in each case. . . . In the smoking machine the puff volume is constant so that with dilution the quantity of 'equivalent undiluted smoke' delivered to the Cambridge filter is reduced. Not so with the human smoker who appears to adjust to the diluted smoke [now we're talking about dilution, filtered ventilation] by taking a larger puff so that he still gets about the same amount of equivalent undiluted smoke.

Wakeham is talking about the smoker adjusting his puff.

Q: So, what, if anything, does this show about Philip Morris's understanding of the puff compensation phenomenon?

A: It shows that Philip Morris understood the puff compensation phenomenon. This document shows that by 1967, Philip Morris recognized that when you have dilution or ventilation, the mechanism for compensation is puff adjustment.

Q: Is there any other part of this document significant to your opinions about the effects of cigarettes as designed by Philip Morris?

A: Yes. On the second page of this document, Bates number ending in 7720, there is a further conclusion that relates to the compensation phenomenon:

> The smoker is, thus, apparently defeating the purpose of dilution to give him less 'smoke' per puff. He is certainly not performing like the standard smoking machine; and to this extent the smoking machine data appear to be erroneous and misleading. It has probably always been so for diluted smoke cigarettes, whether dilution is obtained by porous paper or holes in the filter.

So this document shows that Philip Morris knew in 1967 that human smokers compensated by increasing their smoke intake when switching from non-filter to filter cigarettes, and in doing so, smokers received the same amount of tar and nicotine from filter cigarettes as from non-filter cigarettes. It also shows Wakeham's understanding that the FTC tar and nicotine yields for low tar cigarettes are erroneous and misleading.

Q: In your opinion, does a smoker receive the same amount of tar and nicotine, whatever the cigarette?

A: No, for the reasons I stated before. In my view, a full flavor smoker could probably not achieve full compensation on a per cigarette basis by smoking a highly diluted cigarette with a high resistance to draw, such as the original, lowest tar version of Cambridge, which I sometimes refer to as "Cambridge lowest." So, in my opinion, U.S. Ex. 35,224 relates only to mildly diluted cigarettes such as Marlboro Lights, as compared to Marlboro.

Q: To your knowledge, was there any effort on the part of your co-workers at Philip

Morris, including your supervisors, to restrict any public acknowledgment on the part of Philip Morris of the phenomena of compensation?

A: Yes, there was.

Q: Please explain that to the Court.

A: Yes. I remember papers on hole occlusion, which is when a smoker covers up the holes on the filter by fingers as a method of achieving compensation. Some of the scientists wished to publish a paper on that topic, but their request was denied several times until it was worded in such a way that one could assert that the problem was in the statistical significance level of the experiment. There is a reference to this paper in U.S. Ex. 35,966, which is a memorandum written by Max Hausermann to company counsel.

Q: You have been shown U.S. Exhibit 20,348. Please describe this document for the Court.

A: U.S. Exhibit 20,348 is an inter-office memorandum from Barbro Goodman to Leo Meyer dated September 17, 1975. It discusses research done regarding Marlboro and Marlboro Light delivery. The data revealed that the Marlboro smoker "did not achieve any reduction in smoke intake by smoking a cigarette (Marlboro Light) normally considered lower in delivery." This memo shows that Philip Morris recognized that Marlboro Light cigarettes were not smoked like regular Marlboro cigarettes. It supports my point – shown in other documents as well – that where a "light" version of a brand varies in limited ways from its full flavor counterpart, compensation will cause the smoker to take in basically the same amount of toxins.

Q: What, if any, are the differences in design between Marlboro and Marlboro Lights?

A: The principal difference is that Marlboro Lights has extra ventilation holes, raising its dilution levels to 30-40%. All other major design parameters – tobacco blend, nicotine-to-tar

ratio, filter material – are essentially the same.

Q: Has Philip Morris, including during your time there, exploited its knowledge of compensation phenomenon in its design and manufacture of cigarettes?

A: Yes. Philip Morris exploited knowledge of compensation phenomenon by designing low tar cigarettes to register low tar and nicotine yield values under the FTC method testing protocol, while at the same time enabling smokers to compensate. When I was there, it was a key consideration in every product development.

Q: Did Philip Morris ever inform the FTC that cigarettes were being designed to take advantage of the particular design and protocol of the FTC testing method?

A: While I was at Philip Morris, I was involved in helping Philip Morris develop the grounds for its complaint to the FTC about Brown & Williamson's Barclay cigarette. The Barclay filter, when placed in the FTC machine, gave a normal reading, but when you smoked the cigarette, it was very easy to occlude, or block, the ventilation holes, giving you a much higher yield. Philip Morris complained about that to the FTC in 1981.

Q: Was Barclay the only cigarette manufactured and sold by the tobacco companies that was designed in a way to deliver higher tar and nicotine levels to human smokers than to the FTC smoking machine?

A: No. The argument against Barclay also applies to Marlboro Lights and other similar products – simply a different mechanism. Artificially low FTC ratings is an inherent characteristic that occurs in the design of cigarettes with low resistance to draw as manufactured by all the companies. It is predominantly puff volume compensation in Marlboro Lights compared to predominantly filter hole occlusion in the case of Barclay.

Q: Dr. Farone, you indicated earlier that you had discussions with your colleagues at

Philip Morris about topics of smoking that dealt in any way with this compensation phenomenon or related issues?

A: Yes.

Q: Was there discussion at Philip Morris as to whether or not compensation was an unconscious act?

A: Yes, it was acknowledged by my colleagues at Philip Morris that compensation was an unconscious act.

Q: Would you explain that to the Court, please.

A: Well, these topics were discussed among the management of the company. There were a lot of Philip Morris employees with whom I discussed compensation, such as Joe Cullman, Hugh Cullman, Cliff Goldsmith, Shep Pollack, Frank Resnik, Helmut Wakeham, Hamish Maxwell, Bill Campbell, James Morgan, Wally McDowell, Ross Millhiser, Alex Holtzman, Tom Ahrensfeld, just to name a few. I was there eight years, and we had meetings every month, and these topics were discussed several times a year at these meetings. Not only was everyone aware of the compensation phenomena, but they were very interested in that subject, and they understood how compensation worked and these issues that we have been talking about were the subject of our meetings within the research and development department at Philip Morris, and between the R&D people, the marketing people, and the senior management of the company.

Q: What about a cigarette design facilitates compensation?

A: Basically, a cigarette where the difference in FTC tar delivery between two cigarettes is relatively small and the filter presents only a minor obstacle to receiving the nicotine. In short, it is a cigarette where a smoker has to draw only a little harder to get the necessary nicotine.

Q: Does this continue today?

A: Sure. Marlboro Lights, Virginia Slims Lights, and Winston Lights, just to name a few, are all cigarettes that are designed to facilitate compensation.

Q: Dr. Farone, can you define what a "Light" cigarette is?

A: I cannot provide you with a definition because "Light" is a meaningless term used by tobacco companies.

Q: Can you define "Low Tar" as used by tobacco companies?

A: Again, I cannot because it is an arbitrary term used by the tobacco company Defendants in this case.

Q: Why do you say these terms are meaningless?

A: Because there are lights of certain brands with higher tar levels than regulars of other brands from the same company, and there are also lights and regulars of the same brand that have the same FTC tar rating. So therefore the term "light" is not related to tar or taste. For example, according to the most recent FTC report of tar and nicotine yields, Philip Morris sells versions of Virginia Slims and Virginia Slims Lights that both deliver 15mg of tar by the FTC method.

Q: Dr. Farone, you have been shown U.S. Ex. 85,073. Have you seen this document before?

A: Yes. This is a Philip Morris document that I was aware of at the time I was there. It is titled "Some Unexpected Observations on Tar and Nicotine and Smoker Behavior," and is dated March 1, 1974. It is a document that talks about changes in how people smoke given the tar delivery of the cigarette that they're given. This was done to show how Philip Morris obtained information, what is called a puff report, to determine how people smoke as contrasted to the Federal Trade Commission method.

Q: What is the significance of this document, if any, to your opinions?

A: Yes. On the last page of the document, Bates number ending in 3493, this presentation concludes that "The FTC standardized test should be retained. 1) It gives low numbers. 2) It permits comparison between brands." The last sentence states: "Meanwhile, we are reviewing our own program in the light of these observation[s] to design cigarettes for improved acceptance." Like the other documents, this has to do with the knowledge of compensation, which is the subject of this document, and designing the cigarette so that the FTC tar number is lower, but the amount of nicotine that can be extracted by the smoker relatively easily by changing their habits would be equal to the one of higher tar delivery.

Q: When you were at Philip Morris, from 1976 though 1984, was this compensation phenomenon known in the scientific community?

A: The idea that people did not smoke like the machine was known for years and it was even pointed out by the tobacco companies to the FTC in 1966. By 1977, textbooks such as "The Pharmacological Basis of Therapeutics" by Goodman and Gilman had a section on nicotine use that discussed titration and thus compensation.

Q: During your time at Philip Morris, Dr. Farone, did Philip Morris have a greater understanding of compensation than the outside scientific community?

A: Yes.

Q: Is it your opinion that the same is true for the other tobacco company Defendants?

A: Yes.

Q: Please explain these last two answers further.

A: What was closely held within Philip Morris and the tobacco industry was the knowledge of exactly how compensation occurred, that it was easily done. Unless the smoker was educated on how to smoke a cigarette, they would inadvertently compensate. Also withheld was the

information that cigarettes were designed to make such "misuse" easy, and that there were designs that would greatly reduce the possibility of compensation. These other designs would have greatly benefitted from an educational campaign as to how and why smokers should use these designs even if they were different and possibly less "comfortable" in the beginning. Consider the analogy that many drivers did not like seat belts when they first came out. But even before they were mandated, they were being explained to people and sold as a benefit – something for which one would even want to pay extra. Seat belts were not made so loose that they were ineffective which is the analogy to making a filter that is easy to compensate.

Q: Looking back at U.S. Ex. 36,855, the September 2, 1970 memo from Dr. Fagan to Dr. Wakeham, how, if at all, does this document bear on Philip Morris's understanding of the effects of cigarette design?

A: This memo appears to have been prompted by the FTC's proposed requirement that the tar and nicotine deliveries of cigarettes be displayed in advertising. The beginning of the second paragraph states:

> There is a second assumption which is implicit in the FTC's requirement for the revelation of tar and nicotine content. This assumption is that 'tar' is 'tar' is 'tar.' Although superficially this seems like a reasonable assumption, there is little evidence to validate it. As a matter of fact, much of the evidence available seems to point in the opposite direction."

Q: Can you explain Dr. Fagan's statement?

A: Dr. Fagan is saying that there is chemical distinction between the tar in different cigarettes. This true for the reasons I stated earlier, when describing how the different processes and design parameters influence the composition and carcinogenic potential of cigarette smoke.

Q: Dr. Farone, can you briefly summarize your earlier testimony on the effect that use of ventilation holes to dilute the cigarette smoke has on the toxicity of cigarette smoke?

A: Yes. It is my testimony that, holding all other design parameters constant, dilution levels in the range of 30-40% – the levels used on many best selling "lights" brands – results in tar that is likely more mutagenic on a per milligram of tar basis. This is compared to the tar from cigarettes from either higher or lower dilution levels.

Q: Do manufacturers of cigarettes typically test their products for mutagenicity?

A: Yes. It is common practice to test for mutagenicity at least using the Ames test.

Q: What does it mean if an agent yields a high rating using the Ames test?

A: A mutagenicity test that yields a high Ames score indicates there is a potential risk that the tested chemical or chemical mixture can cause cancer. Material that tests positive on an Ames test is usually a candidate for further testing for carcinogenicity, using studies that are considered better predictors of cancer risk. The subsequent testing should take into account both the dosage of the materials and the route of administration of exposure.

Q: Do you know whether Philip Morris tests its products for mutagenicity?

A: Yes. A review of documents produced by Philip Morris reveals that for approximately the past 25 years, Philip Morris has consistently used the Ames test to test for specific mutagenicity of cigarette smoke condensate in various forms – such as whole smoke condensate (WSC), total particulate matter (TPM), or "tar."

Q: How would you describe Philip Morris's level of acceptance of the Ames test?

A: I believe it is fair to say that Philip Morris has concluded that Ames test predicts carcinogenicity. Philip Morris's own documents also demonstrate Philip Morris's belief that the Ames assay test for biological activity is predictive of carcinogenicity. For example, Philip

Morris's documents and the depositions of many of its employees that I have read establish that the goal of creating a less harmful cigarette is demonstrated at the first level by decreasing mutagenicity scores. The Ames assay was consistently used and widely accepted by Philip Morris when I was there, as a screening mechanism for cigarette design and parameter changes, because of its predictive qualities for determining carcinogenesis. Documents show that Philip Morris has continued to use the Ames test for the same reason.

Q: What, if anything, have Philip Morris's mutagenicity test results revealed about its cigarettes?

A: Well, in the case of Marlboro Lights, the Philip Morris test data I have reviewed on that level of dilution for equivalent blends indicated that the product design for their Light cigarettes was more mutagenic than the full flavor Marlboro, Marlboro Reds, and therefore predictive of more potential cancer risk. These studies were repeated multiple times over the past 20 years and continue to be repeated to this day. The Philip Morris data, as was used by Philip Morris, was a strong warning that their product design change between a Marlboro Red and a Marlboro Light – increased ventilation – resulted in a potentially more dangerous product.

Q: You have been provided U.S. Ex. 35,635. What is this document?

A: It is a November 1977 Philip Morris memorandum to Dr. Robert Pages about Ames testing on some prototype cigarettes.

Q: Please identify what, if anything, in this report bears on your opinion about the comparative mutagenicity of the tar from low tar cigarettes.

A: The authors make clear that they were confirming prior experiments. The very last paragraph in the document, on the second page, says: "The take home lesson from this experiment is that dilution of a cigarette appears to increase the activity of the WSC (more

dramatically for some cigarettes than for others)." So this document directly supports my statements that dilution – in a certain range – increases the mutagenicity of tar.

Q: Based on your first-hand knowledge and your review of internal documents, has Philip Morris changed its design of "Light" cigarettes in response to its studies and knowledge concerning mutagenicity?

A: No, Philip Morris has not. Despite the consistent test results demonstrating increased specific mutagenicity resulting from increased filter dilution, Philip Morris continued to utilize this design parameter as the primary design difference between its low tar cigarettes and its "regular" cigarettes.

Q: Are you aware of any evidence that Philip Morris has tested other design parameters to reduce the greater per milligram mutagenicity of the tar of the "light" versions of their full flavor brands?

A: To my knowledge, Philip Morris has not performed side-by-side biological tests to determine more appropriate design parameters. Philip Morris's own internal documents and testing results demonstrate that the low tar cigarettes – including but not limited to Marlboro Lights – have higher specific mutagenicity as measured by the Ames TA98 and TA100 tester strains than "regular" cigarettes. These test results include not only comparisons between what Philip Morris refers to as "low tar reference" cigarettes and "regular" reference cigarettes, but also testing that conclusively establishes a connection between filter ventilation/dilution and increased specific mutagenicity. Virtually every Ames assay test ever conducted by Philip Morris resulted in data that showed the mainstream smoke condensate from a low tar cigarette is higher in specific mutagenicity than the mainstream smoke condensate from a regular cigarette of otherwise comparable design?

Q: Dr. Farone, you have been shown U.S. Ex. 20,399. Please describe it for the Court.

A: U.S. Ex. 20,399 is a January 28, 1994 report from a scientist at INBIFO to Cathy Ellis, then a Director of Research at Philip Morris in Richmond, Virginia.

Q: What is this letter about?

A: The INBIFO scientist states that increased cigarette filtration, porosity, and ventilation, which were the primary methods used by Philip Morris to reduce the FTC method tar and nicotine yields, would result in an increase in the degree to which cigarette smoke was toxic to living cells, the irritation it caused to smokers, and the likelihood of the smoke to generate mutations such as tumors and/or cancer. Specifically, the document says: "Increased filtration will result in a relative enrichment of gas phase constituents, leading to increased cytotoxicity and irritancy . . . . Increased porosity and ventilation will . . . increase the specific mutagenicity." This document supports what I just said to you – that Philip Morris tests demonstrate that increased ventilation leads to an increased specific mutagenicity for mainstream smoke condensate.

Q: Dr. Farone, from your review of documents from tobacco companies other than Philip Morris, do you have an opinion about whether they also recognized that "light" versions of full flavor cigarettes have higher mutagenicity on a per milligram of tar basis?

A: Yes.

Q: What is your conclusion?

A: It is my conclusion that at least RJR and Lorillard also recognized this characteristic of light cigarettes.

Q: Can you identify and describe the bases for your conclusion.

A: Yes. First, U.S. Ex. 20,863, is a May 9, 1983 report compiling all of RJR's past Ames

testing work. The third item on page 2, Bates ending in 3579, states that a May 1980 memo showed that "There is a trend for low 'tar' cigarettes to show higher revertant numbers per mg 'tar'." U.S. Ex. 20,863 actually attaches the May 15, 1980 memo it referred to. That study tested the cigarette smoke condensate (CSC) of 24 domestic cigarette brands, and one of the conclusions was that "Some of the low-tar brand cigarettes exhibit higher mutagenicity per unit weight of tar."

Second, U.S. Ex. 56,344, a December 18, 1989 Lorillard memorandum, Bates number 87067762, titled "Project B-451, 'Urea,'" obtained a related finding. The document states that "Experiments were conducted investigating air dilution changes, ranging from 0-75%. It was determined that air dilutions exceeding 25% yielded increases in benz[a]pyrene." So this document is showing that increasing dilution increases the levels of benz[a]pyrene, a known carcinogen. Since all carcinogens are mutagens, this finding would also mean that the tar in these experiments would be more mutagenic.

Q: To your knowledge, has any of the tobacco Defendants disclosed to smokers the results of its studies that reveal that its "Light" cigarettes test more mutagenic than their full flavor counterparts?

A: No. Philip Morris never reported these mutagenicity results to the public health community such that the public could understand the relationships for Marlboro Lights compared to Marlboro Reds and never performed the required additional testing that should have resulted from these test results.

Q: Dr. Farone, in light of your experience and training, do you have an opinion about whether "light" cigarettes as designed are likely to be any less hazardous than their full flavor counterparts?

A: Yes. My opinion is that such "light" cigarettes – because they generally permit easy compensation and employ levels of dilution that increase the mutagenicity of the tar – are not any less hazardous than their full flavor versions.

Q: In your experience, did Philip Morris's understanding of compensation influence its cigarette design choices?

A: Yes.

Q: In what way?

A: We had to decide whether and how much compensation a cigarette should allow to occur. A simple way to prevent compensation is to make lower delivery cigarettes with a tighter filter so that they have a high resistence to draw.

We knew how to make cigarettes with filters that essentially prevented compensation or made it very obvious to the smoker that they were compensating – by making them suck on the cigarette much harder. Also, a cigarette with ventilation holes in the filter can deliver more air to the smoker, and thus can be a good way to reduce the delivery of toxins. But if you add more holes, you may in fact create smoke that's more toxic because it burns differently, as I described earlier. So, the issue is to add enough holes to the cigarette and design the cigarette to prevent nicotine compensation, so that the smoker does not at the same time increase the delivery of tar by sucking harder. We knew that you needed to add a lot of holes to reduce smokers' ability to compensate. However, Philip Morris intentionally avoided including those features in some of their major lights and lower tar cigarettes, to ensure that smokers could compensate.

Q: What is the implication of avoiding those design features to defeat compensation?

A: To me, the decision to keep such a low resistance to draw in light cigarettes – cigarettes that are essentially identical to their full flavor counterparts – indicates that they were designed to

give comparable nicotine deliveries to their regular counterparts. For example, Marlboro Lights and Marlboro have the same nicotine-to-tar ratio, and Marlboro Lights has a low resistance to draw, making it easy to get a tar yield comparable to a Marlboro Red with little effort.

Q: Could Philip Morris have made cigarettes that in fact delivered tar and nicotine to smokers in amounts that matched their FTC ratings?

A: Yes. In most cases one could do this for low delivery cigarettes, especially the very low delivery cigarettes, by making filters with a high resistance to draw.

Q: Why didn't Philip Morris do that, in your view?

A: Well, if you change the cigarette to the point where smokers couldn't extract the dosage of nicotine needed to satisfy their addiction, in some cases they might get used to the lower level out of frustration, in some cases they would smoke more cigarettes. If you produce a cigarette that reduces the nicotine so low that it became very difficult to compensate, all the evidence says they will not buy it. That cigarette is not going to be a market success.

Q: Are there design features that could potentially provide enough nicotine?

A: Yes. There are several potential ways to do it – increasing the nicotine-to-tar ratio dramatically or augmenting the filter with nicotine, and at the same time adding smoothing agents such as glycerine.

Q: What evidence supports your view that Defendants have decided not to reduce tars further?

A: Some of that evidence is the graph of sales-weighted tar and nicotine values in Figure 5.1 in Monograph 13 (U.S. Ex. 58,700), and the data and approach taken by Philip Morris toward the Cambridge cigarette in the 1980s. One of my publications concerned the Cambridge data.

Q: Taking the Monograph 13 graph first, how does the graph of sales-weighted tar and

nicotine average in Monograph 13 support your opinion?

A: It shows that the sales-weighted average tar and nicotine numbers are essentially unchanged since about 1980.

Q: Is it technically difficult to lower the tar and nicotine levels below the sales-weighted tar average and maintain consumer acceptability?

A: No. For example, in 1975, Philip Morris had data that Merit, which was around 7-8 milligrams of tar by the FTC method when it was introduced, was equal in acceptability to 75% of smokers of Marlboro Reds.

Q: Did Philip Morris employees use their knowledge of puff compensation in designing cigarettes with the FTC test machine in mind?

A: Yes. In the case of Cambridge, we used the new laser perforation technology to impede compensation and to get the FTC tar delivery all the way down to zero to three milligrams for the three original Cambridge styles.

In the case of Marlboro Lights, that cigarette was designed – before I got to Philip Morris – such that it could score one level on the FTC machine while simultaneously delivering the needed dose of nicotine for the smoker.

Q: Dr. Farone, you just mentioned Phillip Morris's Cambridge brand of cigarette. I want to ask you some questions about this brand. When was the Cambridge cigarette first manufactured and sold in the United States?

A: 1980.

Q: Were you involved in the creation of the Cambridge cigarettes at Philip Morris?

A: Yes.

Q: What year was that?

A: The background work started in 1978 based on the new laser perforation technology but the bulk of the work on Cambridge specifically was done in 1979 under code name "Trinity."

Q: How would you describe the first Cambridge cigarettes?

A: There were three original different cigarette models – hence the "Trinity" name. One of the three was intended to be the lowest cigarette in tar and nicotine of any product on the market. At that time, there were two competing products on the market: Carlton, which was manufactured by American Tobacco; and NOW, which was manufactured by R.J. Reynolds. One of the Trinity cigarettes was to be lower in tar and nicotine than all the cigarettes already on the market. The lowest one was supposed to be as close to 0.00 as we could get it. The other two in the Trinity group were slightly higher in tar and nicotine: one was 1-2 two milligrams of tar, 0.1-0.2 milligrams of nicotine; the third was 3-4 milligrams of tar, 0.3 to 0.4 milligrams of nicotine.

Q: You have been provided U.S. Ex. 20,015 for review. Please describe this document.

A: These are the typed minutes from the October 15, 1979 meeting discussing the Trinity project. As the minutes show, I attended this meeting. In the middle of the page, it states that "Physical specifications for Trinity cigarettes have been established." It then lists the three products I just described.

Q: Focusing on the left-most version, the "83s Box," what are the tar and nicotine specifications?

A: It says 0.0 for tar, 0.03 for nicotine.

Q: How, if the tar rating is 0.0, could the nicotine level be listed as 0.03 mg?

A: Since the tar measurement is what is left on the pad after the nicotine and water is

subtracted from the total particulate matter, if there is no tar left, there can still have been nicotine that was subtracted from the measuring pad. This was Philip Morris's own internal measurement.

Q: In the course of your involvement in the Trinity project, did you ever have any personal involvement or participation in discussions about Philip Morris's long-range plans for the Cambridge brand?

A: Yes.

Q: When did these discussions take place?

A: In 1979, at Richmond monthly meetings. I was part of the project because the laser perforation, which I had helped develop, was required to achieve the high dilution levels and low tar delivery of this product.

Q: And what was the long-range plan for this cigarette?

A: The long-range plan was to introduce the product as a low tar product and then eventually to increase the tar of the product.

Q: Why did Philip Morris plan to do that?

A: Well, it was anticipated that the product would not sell very well at that low tar and eventually they would increase the tar, and having sold it as a low tar product people still would think of it as a low tar product. In my view, and from my experience, the lowest yielding version of many brands, including the original Cambridge, but also B&W's Carlton, RJR's NOW, etc., were created to give the brands a lowest tar image, while the sales are in the higher tar and nicotine versions of those brands. Those lowest yield versions of the brand are very hard to find in stores.

As a matter of fact, Philip Morris never even bothered to consumer test the 0.0 mg

version against the similar variant of Carlton and this is a major piece of evidence that they had no plans to keep it on the market. My observation from my years at Philip Morris, including my work with the Subjective Evaluation Facility, was that Philip Morris always consumer tested any product that they intended to keep on the market.

Q: Dr. Farone, you have been provided U.S. Ex. 35,306 for review. Please describe this document.

A: It is a September 20, 1979 memo from Leo Meyer titled "Project Trinity" to a number of people, including Dr. Seligman. It identifies the three different original versions of Cambridge.

Q: Which of the three models is described in the first numbered paragraph?

A: The 0.0 mg. version.

Q: What does the memorandum say just under that paragraph?

A: "Consumer testing is not required for this model."

Q: Were there any other cigarettes that you knew Philip Morris did not bother to run consumer testing?

A: Yes. There was also a very low delivery version of Benson & Hedges that was marketed without consumer testing at that time if I recall correctly and it also was to be able to say that the delivery was very low in one version of the product.

Q: Have you created a chart that depicts FTC tar deliveries for Philip Morris's Cambridge cigarette?

A: Yes, I have.

Q: Would you explain the chart, a demonstrative which is labeled U.S. Ex. 17,349, for the Court?

A: Yes, this is a chart that shows the FTC tar deliveries of the various Cambridge products

over a period of time spanning from approximately 1981 to 1998. I'll refer to it as the Cambridge Chart.

Q: Where do the numbers on this chart come from?

A: Some of these numbers come from the Federal Trade Commission reports, although some years the Federal Trade Commission did not publish the reports. Thus, I used the numbers that were listed in the Philip Morris Cigarette Information Reports that were the type that would be submitted to the Federal Trade Commission. I also want to point out the numbers at the bottom with quotes were from a period of time when there was a tremendous number of cigarette brands, so the Federal Trade Commission got behind in publishing. You see three entries at the lower left-hand corner that are 1999/another year. That means that the report came out in 1999, but they reference the products for '96, '97 and 98.

Q: Could you describe what the Cambridge Chart depicts?

A: Yes. What I have attempted to do here is to categorize the tar delivery of the Cambridge products over the years. The product on the far left is the one that I mentioned as the lowest tar product – 0.0 on that scale – was a Box 85 millimeter product. That means the cigarettes were 85 mm in length, which is the standard length for a cigarette. It was introduced in 1980, but reported in 1981, since the FTC reports tend to be about a year behind by the time the rating is submitted. Philip Morris advertised the 0.0 tar, by their measurement, as being the lower tar product on the market. The next one I talked about varies from 0.0 to 2.2 in November of 1985. And then there is a Regular 100 product which is 2.9 going up to 6.0 in 1985, and then this drops back down to 4.8 in 1988.

Q: Why do the numbers for the first two stop after the November 1985 listing?

A: They were taken off the market.

Q: After these first three products, what were the next versions of the Cambridge brand introduced?

A: In 1986, Philip Morris introduced two versions of Cambridge Lights – "Lights 100" and "Lights King."

Q: What were their tar deliveries?

A: The Lights 100 was 11.3 mg of tar, and the Lights King was 12.0 mg of tar.

Q: In 1986, what was the FTC tar delivery of the Cambridge Regular 100, listed in the middle column?

A: It was 4.9 mg.

Q: Simultaneously Philip Morris was marketing Cambridge Lights that delivered 11 to 12 mg, and Regular Cambridge that was 4.9 mg?

A: According to the records, yes.

Q: Then what was the next packing of Cambridge introduced?

A: In 1987, Philip Morris introduced the Full Flavor King version, at 16.1 mg.

Q: Was there also a "Regular 100" still on the market at that time?

A: Yes, the Regular 100 was 4.8 mg FTC tar.

Q: Then what was the next type of Cambridge put on the market?

A: In 1989, a year after the "Regular 100" at 4.8 mg was taken off the market, Philip Morris introduced the "Ultra Lights 100" at 5.0 mg FTC tar.

Q: So Philip Morris began marketing an Ultra Light version of Cambridge that had even more tar than the "Regular" version it had removed from the market a year earlier?

A. Yes.

Q: Dr. Farone, you have been shown U.S. Exhibit 61,261. Please describe it.

A: This is a 1986 memo to the "Entire Sales Force" from Larry Glennie. The subject of this memo is "Cambridge Lights National Introduction." The first sentence of the second paragraph states that Philip Morris was using the consumers' "established familiarity" with the Cambridge name to market the cigarette brand.

Q: Dr. Farone, in light of your foregoing testimony, do you have an opinion as to whether Philip Morris in fact carried out the plans for the Cambridge brand that had been discussed in 1979?

A: Yes.

Q: What is your opinion?

A: That Philip Morris did exactly what they planned to do from the outset – associate the brand with a "lowest tar" image, then gradually increase the tar and nicotine yields over time.

Q: So, how would you describe Philip Morris's intention with respect to the Cambridge brand?

A: The plan all along was to deceive the public into thinking that the Cambridge Light cigarette was a low tar cigarette, when in fact it was not. One can quibble that these deliveries are still low in an absolute sense but the trend to increasing tar deliveries in the product is very clear and there is no advertising that says that such increases are being made.

Q: Dr. Farone, is it your conclusion that other tobacco companies who are Defendants in this case have also long been aware of nicotine-driven compensation?

A: Yes.

Q: Can you please identify some of the evidence on which you rely for this conclusion?

A: Yes. For example, U.S. Ex. 22,012, the July 1976 Lorillard document I mentioned earlier, also states that "Indications are that the smoker adjusts his smoking habits to satisfy the

desire for nicotine either by frequent or large puffs on the cigarette, or smoking a large number of cigarettes."

Another Lorillard document, U.S. Ex. 34,210, is a December 10, 1976 report reviewing the scientific literature concerning the compensation phenomenon. The abstract states: "It seems that, within limits, smokers can and do control their nicotine intake from smoke by varying their smoking techniques." In the introduction part of this report, it says, "Smokers were known to smoke more when offered low nicotine cigarettes. . . . It would seem desirable to have a low tar cigarette with a nicotine content between the threshold and optimum doses level." Clearly, these statements indicate an understanding of smoker compensation to achieve the needed nicotine level, and an interest in exploiting this knowledge.

These are just two examples from one company. I have reviewed many documents from the other Defendant tobacco companies that reach similar conclusions.

Q: Is it also your opinion that other Defendants were aware that cigarette design features could limit or preclude smokers from compensating to obtain their needed nicotine levels?

A: Yes.

Q: What is the basis for that opinion?

A: As I stated earlier, one of the things we did when I was at Philip Morris was track the patent activity of the other tobacco companies. And while I was there I saw a patent that had issued from RJR about a special filter that claimed to efficiently remove particulate matter from the smoke at comparatively low resistance to draw. During the course of this case, I reviewed research reports from Reynolds discussing this "multijet" filter. And those documents also report that smoke retention in the lung decreased significantly when this filter was used, and that the

filter was successful at removing larger particles from the smoke.

VII. Opinion No. 4 – Agreement Not to Compete on Health Issues

Q: Dr. Farone, I'd now like to turn to another area of your testimony, relating to Defendants' approach to biological research. Please briefly restate for the Court your opinion about this area of Defendants' research strategy.

A: It is my testimony that Defendants had an agreement not to compete against each other in the marketing of cigarettes by claiming that their products were potentially any safer than other cigarettes. Related to that agreement was an agreement not to perform certain biological research on commercially marketed cigarettes in their domestic facilities.

Q: What types of biological research were covered by that agreement?

A: Testing involving cigarettes or products of cigarettes smoke, like tar, that used intact animals. This includes mouse skin painting, long term inhalation studies, short term acute toxicity studies, long term cancer studies, and so forth.

Q: You have been shown U.S. Ex. 22,893. What is this document?

A: It is a November 2, 1959 memo from R.J. Reynolds' scientist Alan Rodgman. It is on my reliance list.

Q: On the first page, Dr. Rodgman states that "Medical experience has shown that man responds to various chemical substances in the same manner as experimental animals." Does that comport with your view as to the special scientific significance of animal research?

A: Yes. The reason you choose a particular animal is because you have reason to believe it will react, in the biochemical sense, in approximately the same way as a human.

Q: So what would be the potential implication of animal research that yielded evidence

that animals' health were adversely affected by cigarette smoke or cigarette tar?

A: The implication would be that the same substance – cigarette smoke or tar – would likely have an adverse effect in humans. That is why you do animal research.

Q: Was this agreement referred to by any particular name?

A: It was referred to internally as the Gentleman's Agreement.

Q: What is your basis for the knowledge of the Gentleman's Agreement?

A: When I was at Philip Morris, I was told by my colleagues and superiors, including Dr. Seligman, Wally McDowell, Helmut Wakeham, Dr. Osdene, Paul Eichorn, Dr. Hausermann, Bob Carpenter, Ray Fagan and Jim Charles, about the agreement among the tobacco companies not to compete on health issues. I'm sure I discussed it with others, but these were some of the key people in ensuring that we lived up to the deal in R&D instead of just talking about it.

Q: Were you told the purpose or reason for the agreement?

A: I was told it was to protect the industry from lawsuits. It supported their basic position that no cigarettes were scientifically proven to cause any disease. If they had competed on health issues, and told the public that this brand is safer or potentially delivers less carcinogens than other brands, it would have implicitly acknowledged that the other brands – the ones with higher delivery of carcinogens or more potent carcinogens – were less safe.

Q: Are there any other bases for your testimony about the agreement's existence?

A: I have also seen documents that support this agreement.

Q: During your time at Philip Morris did you see any documents that actually referred to this Gentleman's Agreement?

A: Yes.

Q: You have been shown U.S. Ex. 21,617 to review. Have you seen this document

before?

A: Yes. I saw this when I was at Philip Morris.

Q: What is the document?

A: It is a November 15, 1968 draft of a memorandum by Helmut Wakeham to senior management, entitled "Need for Biological Research by Philip Morris Research and Development."

Q: Is there a reference in this document that bears on your testimony about the Gentleman's Agreement?

A: On the fourth page, Bates number ending in 7058, Wakeham wrote:

> We have reason to believe that in spite of gentlemans [sic] agreement from the tobacco industry in previous years that at least some of the major companies have been increasing biological studies within their own facilities.

Q: Have you seen other documents in which Wakeham discussed the potential value of an in-house biological research program at Philip Morris?

A: Yes, some of those documents are on my reliance set. One such exhibit is U.S. Ex. 35,216.

Q: Did Philip Morris listen to Dr. Wakeham and establish a biological research program at Philip Morris's Richmond facilities to evaluate the health effects of the cigarettes it marketed commercially?

A: No. They did establish <u>in vitro</u> (cell level) facilities, and animal facilities for studying nicotine analogs, but no animal safety studies laboratories.

Q: How do you know that Philip Morris did not conduct in-house intact animal

research in Richmond facilities?

A: Through the time when I was there, through 1984, there was no in-house biological safety research using intact animals being done in Philip Morris's Richmond labs.

Q: Have you subsequent to your time at Philip Morris seen other documents that confirm the existence of this agreement?

A: Yes.

Q: What is another example of such a document?

A: There is a 1983 memo by RJR's Alan Rodgman and Frank Colby that refers to the Gentleman's Agreement.

Q: You have been shown U.S. Ex. 21,737 for review. Have you seen this document before?

A: Yes, this is the RJR memo that refers to the Gentleman's Agreement that I just referred to.

Q: What is the passage in this document about the Gentleman's Agreement?

A: On the page with Bates number ending in 3504, the memo states that

> Throughout the domestic industry, two "gentleman's agreements" were operative in the early days:
>
> > [a]ny company discovering an innovation permitting the fabrication of an essentially 'safe' cigarette would share the discovery with others in the industry; and
> >
> > No domestic company would use intact animals in-house in biomedical research.

Q: Does that document accurately capture the scope of the Gentleman's Agreement as it was described to you at Philip Morris?

A: Yes. I was told by my colleagues and superiors that there was an agreement with other tobacco manufacturers that none would conduct biological research internally on as-sold commercial products, none would conduct in-house research using animals, and that Philip Morris's animal biological research on the health effects of cigarettes would be conducted by an overseas entity called the Institute for Biological Research ("INBIFO") in Cologne, Germany.

Q: You have been shown U.S. Ex. 58,608. What is this document?

A: It is a 1972 internal American Tobacco Company memorandum. It is on my reliance set.

Q: Please identify what, if any, passage supports your opinion about the agreement not to conduct in-house biological research.

A: The document is a directive that states: "Let me repeat. Biological and medical experimentation is outside the scope of the Department of Development and Research of the American Tobacco Company." He also reports – though denies any involvement of his company – that in congressional testimony Ernst Wynder had implied that he had been told personally by researcher directors at American tobacco companies that "were it not for their supervising executives, significant changes could be made in smoking products to make them 'safer.'"

Q: Have you prepared a list of documents that further supports your testimony as to the existence of an agreement to restrict the performance of certain biological testing in the domestic research facilities of the Defendants?

A: Yes.

Q: Did that agreement not to compete on health claims impact the Philip Morris Research and Development department?

A: Yes.

Q: How?

A: All of our research was done for "defensive" reasons. By that I mean, that Philip Morris was preparing for a time when they were forced – by the government or by competitors in the marketplace – to make meaningful changes to their products. So when items were found that could potentially provide a reduced risk or reduced harm product they were not tested biologically and compared against the current products directly for everyone to know about the results. These techniques were put "on the shelf" until they might become needed, unless they could lead to an immediate profit. It also meant that we spent more time on developing technologies that were unrelated to supporting health-related marketing claims.

Q: What is an example of such work unrelated to supporting health-related marketing claims?

A: We developed a system for perforating cigarette filters to use in ventilating cigarettes by using lasers instead of mechanical hole punchers. It was implemented and saved Philip Morris millions of dollars. Now I believe that, because it allowed you to make cigarettes with very high ventilation levels to significantly dilute the smoke, it had a potential to contribute to reducing smoke deliveries, and the toxicity of smoke, but it was not used that way, except in the rare example like the original Cambridge.

Q: Please review U.S. Ex. 20,092. Have you seen this document before?

A: Yes.

Q: What is this document?

A: It is a Helmut Wakeham presentation to the Philip Morris Board of Directors in October 1964.

Q: Is there anything in this document that supports your opinion that Philip Morris's approach to less hazardous cigarette development was "defensive," as you put it?

A: Yes. The last page of the document states:

> [T]he Research and Development Department is working to establish a strong technological base with both defensive and offensive capabilities in the smoking and health situation. Our philosophy is not to start a war, but if war comes, we aim to fight well and to win.

Q: Does this accurately reflect Philip Morris's approach to research and development that you experienced during your 8 years there?

A: Yes. When I first got there, I did not think so, based on what I was told when I was hired. However, over time it became increasingly clear to me while I was there that Philip Morris was not fully committed to actually putting into the commercial marketplace the cigarette technologies that my directorate developed which had demonstrated potential to reduce the delivery of known harmful constituents in smoke.

There was a term used in two different ways at Philip Morris and it was a favorite term of Cliff Goldsmith, who was a senior executive with PM while I was there. He used the term "paralysis by analysis" to cover cases where one keeps analyzing situations and drawing no conclusions to delay making a decision. When he used the term with regard to marketing projects that he wanted to move forward it was deemed a bad thing, but when it came to smoking and health issues it was a good thing because by doing the same projects and tests over and over and not coming to any definite conclusion.

Q: Have you seen any documents about Philip Morris's approach to research since you

left in 1984?

A: Yes, I have reviewed Philip Morris's official R&D Plans, as well as other documents produced from the R&D department that discuss the research being done.

Q: What do these documents tell you about whether that approach to new technology development continued after you left?

A: Philip Morris continues to study the same projects over and over. They repeat the same research areas with similar promising findings, but I have not seen documents in which they reach conclusions that result in implementation. For example, near-total reduction of nitrosamines has been possible since 1987 but they still study minor reductions. Fermentation to reduce nitrates and other compounds was studied while I was there and is still studied.

At least three times Philip Morris has engaged in research for genetic modification of tobacco. It is known that one can genetically modify tobacco to have very little nicotine, to have lower amounts of nitrogen compounds, to pick up less unwanted material, to deposit less heavy metals, and so forth, but none of these programs go to completion. A genetic modification program I that started while at Philip Morris was stopped, and it was restarted twice.

Q: Dr. Farone, is there anything unusual or improper in science about taking a new look at past technologies to see whether they can be improved beyond past knowledge?

A: Certainly not. Every scientist is trained to review and understand past work as a basis for the new.

Q: So please explain why you draw the conclusion you do about Philip Morris's approach to research.

A: In my view Philip Morris is unusual in that it has developed and patented many new things relative to risk reduction, has hired some excellent scientists and conducted so much

research to know all about the products without ever making any progress in reducing the fatalities caused by their cigarettes.

Q: Did this agreement you were told about impact how Philip Morris and the other Defendants marketed cigarettes?

A: Yes.

Q: How?

A: It became apparent to me over time while I was there that PM was not interested in doing anything to improve their marketed products, safety-wise, unless forced to do so for some reason such as by law or by competitive pressure from other companies. The agreement among the companies removed any competitive pressure to develop a product that could legitimately be marketed as potentially safer.

Q: Did the industry's approach to novel product development differ from your experience, for example, at Lever Bros.?

A: Yes, dramatically.

Q: In what way?

A: At Lever Brothers, in addition to consumer acceptability, a major priority in product design and development was consumer safety. So we looked at products' safety when used as intended, but also when used in unintended ways, or in conditions of exaggerated use. That did not happen at Philip Morris. Preserving consumer acceptability was a much higher priority than consumer safety.

Q: You stated earlier that all such animal safety testing would be done at INBIFO in Germany. What is INBIFO's relationship to Philip Morris?

A: Philip Morris owns INBIFO.

Q: Do you know when Philip Morris bought INBIFO?

A: In the early 1970s.

Q: When you were Director of Applied Research at Philip Morris from 1977-1984, did you know that Philip Morris owned INBIFO?

A: No.

Q: Do you know whether INBIFO performed such animal biological tests for Philip Morris?

A: Yes, I know they did.

Q: How do you know this?

A: From personal knowledge. It wasn't hidden inside Philip Morris. It was well known that INBIFO did biological testing for Philip Morris.

Q: You say that part of the agreement involved not testing as-sold commercial products. Can you please explain that further?

A: I mean that the agreement was not to conduct whole animal testing on the brands of cigarettes that you actually can buy in a store, like Marlboro or Marlboro Lights or Virginia Slims.

Q: So what were the cigarettes that Philip Morris conducted biological tests on at INBIFO?

A: They tested cigarettes that were specially made for research purposes only. These came in two different categories. First, there were cigarettes called "reference cigarettes," which were a batch of cigarettes made at one time by the University of Kentucky in the early 1970s. There were a few different types of reference cigarettes that were predominantly used. One was called the 1R4F, which was made to approximate a 10 mg. FTC tar yield cigarette; another was the

1R5F, which was made to approximate a 5 mg FTC tar yield cigarette.

Q: Was Philip Morris the only company to use these reference cigarettes?

A: No. Anybody could buy them, and they were used by other cigarette companies for testing, too.

Q: How do these cigarettes differ from brands sold commercially?

A: They lack a lot of the ingredients and flavorants that commercially sold brands have.

Q: Why does that matter?

A: As I said earlier when discussing my experience at Lever Bros., I consider biological research to be the responsible approach to this product and essential to development of a cigarette that demonstrated lower levels of toxicity on well-accepted toxicological tests. You have to test the version of the product you actually sell, in order to find out whether, when all the ingredients are present at the same time, anything unexpected happens. Sometimes the exact combination of ingredients causes problems or poses dangers that you don't see unless you test the product as you sell it. You lose that perspective if you only test special lab cigarettes made just for research.

For example, commercial cigarettes have much higher levels of free-base nicotine than reference cigarettes and even though the reference cigarettes may contain many of the same toxic chemicals, the extent to which they are going to be used is critical in calculating exposure levels.

Q: But Dr. Farone, if, as you testified earlier, Philip Morris had to tweak the formula for its cigarettes regularly, to take account of variations in the tobacco crops, what scientific value would there be in testing, Marlboros, for example, if the formula is going to change frequently?

A: First of all, Philip Morris never conducted meaningful biological or toxicological tests ever on Marlboros or any marketed cigarettes until recently. So in my view the fact that a

product may change does not justify never testing any version of the as-sold product.

Further, in other industries, consumer products like shampoos, cleansing bars and even detergents, are tested whenever the formulation is changed. Kraft Foods, owned by Philip Morris Companies, now Altria, recently tested and withdrew corn products from the market that might have contained genetically modified corn.

Q: So do reference cigarettes serve any purpose?

A: Yes. They serve an important and valuable scientific purpose. As the name suggests, they act as a predictable point of reference to use in research that allows you to compare differences among different types of cigarettes by seeing how those different types perform compared to the reference cigarette.

Q: So why isn't that sufficient?

A: Because if you never conduct the biological tests on the as-marketed products, you can't obtain the information that could tell the consumer that Marlboro Lights are potentially less hazardous than Marlboros, or Merits are potentially less harmful than Virginia Slims. In fact, it is my view that Philip Morris did not perform such biological testing on its brands because it did not want to generate any data showing that some brands were likely less harmful than others. Their public view was that no cigarettes were harmful, and if such information got out – let alone communicated to consumers – it would undercut that public view.

Q: What was the other category of research cigarettes that Philip Morris used in testing?

A: I mentioned earlier that Philip Morris had – and I believe still has – a small manufacturing facility, known as the semi-works, that can make small batches of cigarettes specially for research. So for example, if scientists want to see how a particular design feature

might affect the tar yield, they can ask semi-works to make some prototypes that have the design feature, and some that don't have that feature, so they can evaluate the effect of the design.

This facility also makes cigarettes for consumer testing. The semi-works can make a Marlboro as it is currently sold and make another version with a new design feature or a blend change. The Marlboros may be identical in every respect to the cigarettes that are already being sold, except that they do not have the Marlboro name printed on them, so that the tests are "blind" – that is, the consumer testers do not know it is a Marlboro. While I was there cigarettes were coded so that one identified the cigarettes by the codes. You can see evidence of this in all the internal reports where codes are given and then the cigarettes are identified. These coded cigarettes were used in the testing at INBIFO and I was told by Dr. Osdene that these same cigarettes were being tested.

Q: Was there someone at Philip Morris in Richmond who was responsible for coordinating the research at INBIFO?

A: Yes. Dr. Osdene.

Q: Do you know what his title was?

A: While it changed over time, at one point it was Director of Biochemical and Extramural Research. Basically, he was in charge of smoking and health research conducted internally and externally.

Q: What do you mean by "internally" and "externally"?

A: By "internal," I mean the <u>in vitro</u> work at R&D, and the program at FTR and INBIFO, although I did not know INBIFO was "internal" at the time. By "external," I mean work done at the Council for Tobacco Research and any other work paid for by PM in other labs and special projects.

Q: Did the fact that certain animal biological testing was done only at INBIFO affect the work of the Applied Research directorate when you were the Director?

A: Yes.

Q: How?

A: Because it meant that when we wanted to test a new cigarette technology in animal tests, we couldn't do it directly. We did plenty of chemical analyses, but animal biological tests were very important to help us figure out whether the technologies had promise, and how further development, if any, should proceed. But if we wanted animal tests done we had to have test cigarettes made up in the semi-works, and give them to Osdene to send to INBIFO. Then only he would get the results directly.

Q: Did Osdene communicate to you the results of the smoking and health research being conducted externally, including at INBIFO?

A: Sometimes. If the animal testing related to any specific problems in specific brands – for example if the testing showed dilution at the level of Marlboro Lights yielded tar that was more toxic than the tar of Marlboros full flavor – that result would have been censored. I was not given documents I could keep. Occasionally in his office he would show me a piece of paper with results on them, but he kept the paper himself. Other times I received information orally. I was told by Dr. Osdene that some of the controls used in the testing of modifications were exact replicas of commercial products although they were not identified as such.

Q: Why were you not given access to the results of such tests?

A: The policy was that only a limited number of people would see testing on any product that came close to being a branded product because the data itself was an admission of liability and this type of data was to be kept out of PM files.

Q: Who told you of this policy and its basis?

A: Several people, including Dr. Seligman, Dr. Hausermann, Dr. Osdene, Dr. Charles, Mr. Carpenter, Mr. Newman, and Mr. Holtzman.

Q: Can you explain further the document and information control procedures that were used at Philip Morris at that time for research documents related to smoking and health?

A: The procedures depended on the level of document for two kinds of projects. Projects that were normally confidential but not top secret were maintained in the library, and there was a distribution list that they went to. And when you were finished with that document, you had to return it. There were other documents that required permission of a particular person, in most cases it was Dr. Osdene, to have access to them. Those documents were to be returned immediately. Those were documents related to smoking and health that had to do with things that were being done that weren't generally available to the scientists below manager level.

Q: Were you, as a Director, denied access to any information?

A: Yes.

Q: As the scientist responsible for applied research at Philip Morris, as a scientist hired to design and develop potentially less hazardous cigarettes, and based on your experience at Lever Bros. prior to Philip Morris, what did you think of this approach to biological research?

A: It was strange but as explained to me, it was being done under advice of counsel. The position was that since there was no legal obligation to do such testing and the results could only be used against the company, it would be done in secret. This would give us the information we needed without creating the paper trail.

Q: Do you know how Dr. Osdene maintained the documents he kept for himself?

A: Yes, he kept them in a personal safe in his house.

Q: How do you know this?

A: He showed me. We were friendly. We were both stamp collectors, and he acted as a sponsor for both Bob Seligman, our mutual boss, and I to join the Bull and Bear Club in Richmond, so that we could have informal evening meetings over dinner. Although our positions were widely divergent on these issues of how to make progress with the company, and we argued our separate points of view to our superiors and with each other, we tried to maintain a very cordial but not personal relationship with each other.

Q: Did he ever write memos or notes to you while you were both at Philip Morris?

A: Yes, frequently. We would write back and forth about scientific matters, commenting on research conducted at Philip Morris, at another company, or from independent health researchers.

Q: Looking at U.S. Ex. 34,424, is this a document that you have seen before?

A: Yes, many times.

Q: Do you recognize the handwriting?

A: Yes.

Q: Whose handwriting is it?

A: Dr. Osdene's.

Q: What does the document say?

A: It says:

"(1) Ship all documents to Cologne by Tom

(2) Keep in Cologne.

(3) OK to phone & telex (these will be destroyed).

(4) Please make available file cabinet. Jim will put into shape by end of August or beginning Sept.

(5) We will monitor in person every 2-3 months.

(6) If important letters have to be sent please send to home – I will act on them and destroy.

(7) Advise Rylander – when writing re INBIFO

(8) Can UH, RR + TSO meet in July in Cologne to discuss.

Q: Who is "Rylander"?

A: Ragnar Rylander is a German professor who worked closely with Osdene and acted as an intermediary between Philip Morris USA and INBIFO.

Q: Is the reference to "advise Rylander" consistent with your recollection of how documents and information were distributed where INBIFO and Osdene were involved?

A: Yes. As I said, Rylander was part of Osdene's inner circle of people coordinating Philip Morris's research related to smoking and health.

Q: Is RR in point (8) another reference to Rylander?

A: I believe so.

Q: And TSO?

A: Those are Osdene's initials, and how he usually referred to himself in memos and notes.

Q: Are the references in items (2), (3), and (6) – keeping documents in Cologne, and destroying "important" documents sent to Osdene – consistent with your recollection of Dr. Osdene's approach to document management at Philip Morris?

A: Yes.

Q: Was this just a personal thing Osdene thought of and implemented on his own?

A: No, not at all. The communications and distribution policy relating to information between Philip Morris and INBIFO was official policy.

Q: How do you know?

A: I was told by Drs. Osdene, Seligman, and Hausermann about the general policy of restricting all such work to "offshore" consistent with the legal policy on limitations of liability and I knew the names of the people involved. I did not know the exact relationship between the people when I was at Philip Morris, because I was not privy to these communications – or the results of INBIFO's smoking and health work. However, I later became aware of more evidence of Philip Morris's efforts to keep its relationship with INBIFO a secret.

Q: You have been shown for review U.S. Ex. 20,295. Have you seen this document before?

A: Yes, it is a 1977 letter from Robert Seligman, who was at the time my boss as the Vice President of Research & Development in Richmond, and Max Hausermann, who was then at Philip Morris's Swiss facility and took Seligman's place as VP for R&D in Richmond for the last 3-4 years I was at Philip Morris.

Q: The letter says,

> **We have gone to great pains to eliminate any written contact with INBIFO and I would like to maintain that structure. . . . Therefore, I am advising Jerry Osmalov to continue sending samples to Neuchatel for transshipment to INBIFO. If this procedure is unacceptable to you, perhaps we should consider a "dummy" mailing address in Koln for the receipt of samples. The written analytical data will still have to be routed through FTR if we are to avoid direct contact with**

INBIFO and Philip Morris U.S.A. . . . I would suggest you retrieve the March 24 letter Helmut Gaisch sent to Jerry, including all copies. My copy is returned herewith.

How is this document, along with Dr. Osdene's handwritten note (U.S. Ex. 34,424), significant to your opinions?

A: They support my opinion about Philip Morris not wanting to have results of animal research in its domestic facilities – particularly research conducted at a Philip Morris-owned lab – lest that information get out and undercut Philip Morris' public position that cigarettes were not a health threat.

Q: Who is Helmut Gaisch?

A: He was a high-ranking scientist and Director of Research at Philip Morris's Swiss facility, known as FTR, for many years.

Q: Did you know him personally?

A: Yes. His position was comparable to Osdene's and mine combined. We had mutual projects between his department and mine and when he visited the U.S., we would meet together.

Q: Returning to Philip Morris's domestic research facilities, when you were at Philip Morris, were other scientists within R&D aware of this policy restricting any acknowledgment that Philip Morris was performing some animal safety-related research on cigarette smoke or cigarette smoke products?

A: No. In fact, that was a recurring topic at Philip Morris, because company scientists wanted to publish research they felt was substantial and important, but the lawyers and executives were very careful about what could get published. In general, we were allowed to publish papers about the chemistry of tobacco smoke, and testing or manufacturing procedures,

but could not present research that could suggest smoking was biologically harmful.

Q: Why did Philip Morris not want the outside world to know it was supporting animal research?

A: Because the lawyers and executives believed that it would constitute an admission that there was something in cigarettes that was harmful. That is what I was told by many persons including both of my superiors, Dr. Seligman and Dr. Hausermann, while I was there.

Q: Did this restriction limit Philip Morris's communications with the independent scientific community about the properties of its products?

A: Yes.

Q: To your knowledge, how did this restriction compare with restrictions that may exist in other industries?

A: Philip Morris's policy went far beyond that of other companies that I've been involved in, where the restrictions are mainly for intellectual property reasons.

Q: Were you personally involved in any instances that reflected the awareness of this policy among the scientists?

A: Yes. In the early 1980s, Victor DeNoble was doing some rat research related to nicotine's effects, and wanted to present the results at a scientific meeting.

Q: But I thought you said that PM did not do any intact animal research while you were there?

A: Yes. However, Philip Morris considered DeNoble's work to fall outside the Gentleman's Agreement because this was related to nicotine, not the health effects of inhaling cigarette smoke. But it still raised concern among the scientists, because it was basically counter to PM policy.

Q: You have been given U.S. Ex. 87,562 for your review. This is a January 26, 1981

memorandum from Paul Eichorn requesting permission of Robert Seligman, to circulate for internal review a report of DeNoble's study that involved administering nicotine to rats. Have you seen this document before?

A: Yes.

Q: Did you know Paul Eichorn?

A: Very well. He ran the manuscript review board.

Q: How did the manuscript review process work?

A: Paul would send the manuscript around to the internal reviewers and to the Directors and higher in the R&D Department, and we would read and return comments to Paul.

Q: The first page of the document states: "Before the Manuscript Review Board starts its review we would like to know if the subject matter (nicotine and physiological response – study in our facilities) would be allowed for release." Based on the letterhead and signature, do you agree that this note was written by Paul Eichorn?

A: Yes.

Q: The same page contains another handwritten note, dated February 2, 1981: "I plan to pass this by Alex Holtzman before going back to the M.S. board." Do you recognize the handwriting and initials?

A: I do. They are Dr. Seligman's.

Q: Please remind the Court who Alexander Holtzman is.

A: He was Philip Morris Inc.'s counsel in New York.

Q: Do U.S. Ex. 87,563, U.S. Ex. 87,564, and U.S. Ex. 87,565, which I have shown you, look like the types of comments the manuscript review board would typically provide back?

A: Yes.

Q: Will you please explain these responses?

A: Yes. U.S. Ex. 87,563 actually includes my handwriting. The first comment, "Are we willing to publish results of studies performed inhouse on intact animals?" was from WFG, who was Walt Gannon. The second, "Good question" was from RT, Robert Thomson, another Director. The third says "Since word of this work and similar stuff does appear to find its way outside the company anyway publication may be preferable to suspicions." That was from me. I was arguing for greater disclosure. The last comment "Need to get legal OK out of N.Y." does not have a writer, but I believe the handwriting to be that of Leo Meyer, who was Director of Product Development.

The second document has a similar comment, "Do we want it known that we do animal studies?" That was from CHO, Cynthia H. O'Donohue, who at that time worked in R&D.

The third document says, "Longest abstract I've seen. I'm still doubtful on publishing rat projects." That was from BK, Bernie Kosakowski who worked for another Director, Dick Thomson.

Q: So do these comments accurately reflect PM's philosophy towards animal research and letting the outside world know about PM's animal research?

A: Yes.

Q: During your time there, do you know if there is other nicotine-related rat research conducted by Dr. DeNoble that he sought to publish that Philip Morris actually prohibited from being published?

A: Yes.

Q: What did that work relate to?

A: Dr. DeNoble's work showing rat self-administration of nicotine, and research that showed that other chemicals could interact with and reinforce the effects of nicotine.

Q: During your entire time at Philip Morris, did Philip Morris continue to support the nicotine-related rat research being conducted by Dr. DeNoble?

A: No.

Q: How do you know that?

A: I was there and present for the meeting where we, as Directors, were told that the project was shut down. The project was shut down in April of 1984.

Q: Were you told why the project was being shut down?

A: Yes.

Q: What was the reason given?

A: We were told that the work showed proof of addictive effects which was negative to the company position and that any research that was contrary to the company position in the areas of smoking and health and addiction would be shut down, as explained by Fred Newman, Assistant General Counsel.

VIII. <u>Opinion #5 – Defendants' Failure to Develop, Meaningfully Test, and Commercialize Feasible Cigarette Technologies</u>

Q: Dr. Farone, in your view did the agreement not to compete on health issues in cigarettes or the agreement not to perform biological research in-house on commercially sold brands influence the research of Defendants in other ways?

A: Yes.

Q: Will you please explain that answer further?

A: Yes. It is my opinion that Defendants' research and development activities demonstrate

substantial understanding of which chemicals in cigarette smoke were overwhelmingly likely to contribute to causing the harms of smoking. Defendants in fact knew of and have developed technologies that reduced or eliminated harmful agents from smoke that were technically and commercially feasible, but did not meaningfully test them, incorporate them into marketed products, or compare cigarettes with these features to commercially sold brands. It is my opinion that Defendants did not want to generate comparative scientific data that could show some cigarettes likely to be less harmful than others. As part of this strategy, Defendants adopted a strategy of endlessly studying and restudying scientific issues and problems, inevitably concluding that products with real potential safety advantages were not consumer acceptable or that there was insufficient data to support implementing changes with potential safety advantages. It is my opinion that the absence of potentially less hazardous products from the market is the result of choices by Defendants, not technological limitations.

Q: Again, what are the bases for this opinion?

A: The same bases as for my other opinions – my scientific education, training and experience, including at Lever Bros. and Philip Morris, and my review of the published literature, including patents, and other documents created by the tobacco companies.

Q: What do you mean by "meaningful," when you refer to testing, incorporating, and comparing potentially innovative cigarette technologies?

A: To exploit these technologies in a meaningful fashion means to use them to the extent necessary to accomplish the objective that Defendants themselves identify in many research plans I have reviewed – to reduce the harms caused by smoking. I believe that accomplishing that objective may require informing and educating consumers about how to smoke the products, and alerting them to potential taste differences.

Q: To your knowledge from your time at Philip Morris, did Philip Morris examine issues of consumer taste preferences or acceptability?

A: Yes.

Q: What is the basis for your knowledge?

A: I was personally involved in discussions related to such information, and as a Director I reviewed the research done on these issues at Philip Morris.

Q: Did that research concerning consumer taste preferences or acceptability address whether consumer preferences can shift over time?

A: Yes.

Q: What did Philip Morris understand about whether consumer taste preferences shift over time?

A: The companies themselves recognized as the FTC yield decreased over time, and with light cigarettes, that consumers gradually adjust to the taste over time, especially if the changes are introduced gradually. U.S. Ex. 26,072 is an example of this, where Dr. Dunn in April 1975 discussed research showing that smokers adjusted to the decrease in Marlboro's FTC tar and nicotine deliveries over time – and generally did not even notice the differences.

Q: What are some technologies that you conclude Defendants have failed to meaningfully pursue and exploit?

A: Three broad areas are filtration technology, including charcoal filters and filters that prevent compensation; reduction in known harmful constituents, especially TSNAs; and modification or elimination of combustion, to reduce the harmful compounds created when things burn.

Q: Have you created a demonstrative exhibit, U.S. Ex. 17,350, to assist your testimony

on this issue?

A: Yes.

Q: Dr. Farone, to frame this part of your testimony, please define what you mean when you use the term "potentially less hazardous cigarette" or "less hazardous cigarette."

A: I use the term to mean a product that, on a battery of established toxicological tests, shows a reduction in the deliveries of the known toxic chemicals that is so significant that you would have a reason to expect that epidemiological studies would show a significant reduction in the incidence of morbidity and mortality.

Q: We will discuss each of these broad areas in turn. Dr. Farone, at the outset, is it your testimony that any of these technologies, if implemented, would definitely result in a less hazardous cigarette?

A: Again, I can't say that because there are so many design parameters that any one of the technologies I might identify could potentially be offset by other changes to the cigarette. However, to put it most simply, to me as a chemist, and from my understanding of biochemistry, this is ultimately about exposure to chemicals, and the understanding of the dose-response relationship.

Q: Looking at filtration technology, which you mentioned first, what is your opinion about Defendants' approach to charcoal filters?

A: It is my opinion that Defendants – including Philip Morris, R.J. Reynolds, and Brown & Williamson – have failed to meaningfully pursue, test, and exploit the capabilities of a charcoal or activated carbon filter. They are currently studying them once again and using them in some of the recent reduced risk cigarettes they are trying to develop. The advantages of charcoal filters in the reductions of toxicity have been known for years. While charcoal is not a panacea, it does

work. During the 1960s, Philip Morris and RJR did some testing that showed the potential health-related comparative advantages of cigarettes with charcoal filters.

Q: As an initial matter, what are charcoal or activated carbon filters?

A: They are filters to which some form of charcoal or carbon – I use the terms interchangeably – has been added.

Q: How is the charcoal added to the filter?

A: The charcoal can be added in different ways. One way it has been done is to essentially sprinkle carbon particles to the standard cellulose acetate filter. Another way is to have a "plug" of carbon sandwiched in a space between two pieces of regular filter. This is known as a "plug-space-plug," or PSP, design.

Q: Did you see reports on, or participate in research involving, plug-space-plug filter designs when you were at PM?

A: Yes. PSP was the main way to implement any selective filtration idea and we used them to test a wide variety of materials in the Physical Research Division. PSP was used on some of PM's early brands and in cigarettes made for Liggett for overseas delivery. I spent several days studying the filter making machines that could accommodate PSP designs as a means of understanding how we could use those machines in a major brand.

Q: Your referred to the "capabilities" of a charcoal filter. What are those capabilities?

A: Charcoal or activated carbon is an effective absorber. What that means is that certain types of particles and chemicals either in the particles or in the gas phase, as they pass by, will stick onto charcoal. Charcoal molecules have a big surface area, so it has the capacity to adsorb a lot of particles and a lot of chemicals in those particles.

Charcoal is capable of removing certain components of smoke known to be carcinogenic

or otherwise related to disease. Work of the 1960s showed that charcoal can reduce many of the irritants that are associated with emphysema. Various animal models, including cat mucous studies, were used by numerous tobacco companies for a period to study this reduction in probable risk associated with emphysema.

Q: To your knowledge, did the companies continue doing this intact animal testing on branded products in-house beyond the mid-1960s?

A: No.

Q: Why did they stop?

A: That is a good question. I was told why at Philip Morris: such testing was inconsistent with the Gentleman's Agreement I described before.

Q: What do charcoal's capabilities mean in the context of a cigarette?

A: It means that in cigarettes, charcoal can very effectively remove certain things from cigarette smoke as the smoke passes through the filter – in particular, the constituents of smoke that are delivered in the gas or vapor phase of smoke: for example, the aldehydes and 1-3 butadiene.

Q: Are there factors that affect whether and how well a charcoal filter could potentially remove these gas-phase constituents?

A: Yes, many things. How much carbon is used, the type of carbon that is used, how it is incorporated into the filter, the particle size of the smoke constituents, what else is in the cigarettes, all will affect charcoal's ability to scrub the gas phase of cigarette smoke. Also, charcoal gradually loses its effectiveness over time as it is exposed to air, so its effectiveness is also affected by how long the carbon has been sitting around.

Of course, the main point is to have enough carbon to show the proven maximum

reduction in aldehydes, hydrogen cyanide, etc., for the design. Merely sprinkling a bit of charcoal in the filter is not sufficient. One needs to see the reductions in smoke chemistry as a function of quantity to see if it really is an effective charcoal filter.

Q: How long have the tobacco companies known about charcoal filters?

A: Since at least 1959. Documents from throughout the industry show that the companies were well aware of charcoal's properties.

Q: You have been shown U.S. Ex. 22,986, a document dated February 18, 1964, and titled "Smoking and Health Significance of the Report of the Surgeon General's Committee to Philip Morris Incorporated." Have you seen this document before?

A: Yes. I saw it when I was at Philip Morris.

Q: On page 4, Bates number 5618, Wakeham stated that "[t]he [Surgeon General's] report gives inadequate recognition to the selective adsorption of certain gas phase components from smoke which affect pulmonary cleansing mechanisms (viz., mucus flow, cilia activity). The statement that carbon filters previously employed do not have specific power to scrub the gas phase ignores pioneer work at American Tobacco reported in Tobacco Science, Vol. 3, pp. 52-56, 1959." What does this document tell you?

A: It says that Philip Morris knew of the ability of carbon filters to remove gas phase constituents from cigarette smoke by 1964, and that American tobacco was already publishing on this subject 5 years earlier, in 1959.

Q: Have you seen other Philip Morris documents that discuss the capabilities of charcoal filters?

A: Yes. U.S. Ex. 20,092, a presentation to the Philip Morris Board of Directors from 1964 by Dr. Wakeham, discusses Philip Morris's development of a charcoal-filtered cigarette,

Saratoga, that it considered "physiologically superior."

Another document on my reliance list, U.S. Ex. 20,070, is a document prepared by Helmut Gaisch and sent to Dr. Osdene in 1983. On the page with Bates number ending in 6354, Dr. Gaisch recounts research from 1969 that found that carbon "effectively . . . filters . . . the biologically active components of smoke."

Q: Have any of the tobacco companies ever used charcoal filters in fully marketed brands?

A: Yes, most of them have had at least one model of cigarette with a filter that has some charcoal in it at one time or another.

Q: So are these less hazardous cigarettes, in your opinion?

A: It is not so simple. With all other design parameters being equal, they could potentially be less hazardous if they had enough charcoal, but I don't know exactly how much less hazardous, and more importantly, neither do the companies. If you use a high Burley blend and an inadequate charcoal filter it could be worse than a cigarette made from Maryland tobacco without a carbon filter. The problem is that with 57 design parameters, it is difficult to give yes or no answers. That is a main problem, in my opinion.

Q: What in your view would be necessary to determine whether a particular cigarette could be potentially less hazardous?

A: There are established toxicological tests that can give you a pretty good idea about the biochemistry. There is no single established standard battery of tests, but each of the tobacco companies is aware of the types of tests that should be done. Epidemiological studies should also be done. Dr. Wakeham recognized this in U.S. Ex. 22,986, where he stated that "a prospective survey of filter v. non-filter smokers is appropriate" to see whether filters offered a

true health-related advantage.

In the case of charcoal filters, even when the companies sold cigarettes with charcoal filters, they didn't conduct the necessary research to confirm whether the charcoal-filter cigarettes, as they were actually making them, offered any exposure reduction or potential health advantage.

The main point is that in the early animal testing, they showed that certain of these products had the potential of being safer. This testing was based on chemical analysis of smoke which showed significant reductions of certain toxic chemicals. Further, even if they did conclude that a charcoal cigarette was potentially less harmful, it is my opinion that Defendants' agreement among themselves to avoid competing on health issues prevented them from reporting on or pursuing features with real potential to offer relative harm reductions.

Thus, while all of Defendants have offered a cigarette that has charcoal in it, they have provided a consumer no way of knowing whether the cigarettes achieves a meaningful reduction on harmful chemicals. Even the companies don't know. If the use of charcoal is not meaningful, it is simply a marketing device for the health conscious.

Q: Looking back at U.S. Ex. 20,092, Dr. Wakeham's 1964 presentation for the Operations Department to the Philip Morris Board of Directors, is there anything in this document that supports your opinion about the agreement not to compete?

A: Starting on the first page, Wakeham told the Board that

> Two years ago, in anticipation of a health crisis to be precipitated by the Smoking and Health Report of the Surgeon General's Committee, we undertook to develop a physiologically superior product

And then, on the next page:

. . . . With [mucus flow and respiratory tests] as criteria we did put together a charcoal filter product with performance superior to anything in the marketplace. That product was Saratoga. Physiologically it was an outstanding cigarette. Unfortunately then after much discussion we decided not to tell the physiological story which might have appealed to the health conscious segment of the market. The product as test marketed didn't have good 'taste' and consequently was unacceptable to the public ignorant of its physiological superiority.

Q: The passage from U.S. Ex. 20,092 you highlighted refers to "'taste.'" Does adding carbon or charcoal to the filter affect the taste?

A: Yes. However, I am also aware of documents showing that Philip Morris made and consumer tested cigarettes where smokers generally couldn't tell the difference between the cigarettes with and without carbon.

Q: You have been shown U.S. Ex. 21,934 and 21,933 for review. Have you seen these documents before?

A: Yes.

Q: What are they?

A: U.S. Ex. 21,934 is a November 5, 1997 document by or to Peter Lipowicz, and it is titled "Selective Filtration." U.S. Ex. 21,933 is an undated document about product design and development.

Q: What company are these documents from?

A: They are both Philip Morris documents. On U.S. Ex. 21,934, I recognize some of the names listed as Philip Morris employees. U.S. Ex. 21,933 refers to the semiworks, the Philip

Morris facility that makes prototype cigarettes for research, and also to Tomorrow, a Philip Morris project that I know concerned ignition propensity, as indicated in this document.

Q: What in this document, if anything, do you consider significant to your opinion about charcoal, and why?

A: The documents state that an objective of the first project listed, concerning "activated carbon" – that is another name for charcoal – is to "Develop model of carbon adsorption." U.S. Ex. 21,933, on the first page, lists as one of the filter-related projects "Effects of carbon filters on gas phase deliveries." These documents show me that in the late 1990s, Philip Morris continued to study basic scientific problems that Philip Morris studied, and knew the answer to, even before I arrived at Philip Morris. But none of this has yet lead to marketed products with charcoal filters that Philip Morris tested and showed actually reduced the delivery of gas phase constituents. This is another example of paralysis by analysis – the continued study of the same items without putting the technology into practical use in the main brands in a manner that would be highly likely to make a difference.

Q: Dr. Farone, are you familiar with any of the products that Defendants have test-marketed or have disclosed as in development that they discuss as potentially reduced delivery cigarettes?

A: Yes.

Q: Which products are you familiar with?

A: I have seen documents or received information that related to these products, including RJR's Premier and Eclipse, Philip Morris's Accord, and B&W's Advance. I have also seen information related to Philip Morris's SCoR project, which to my knowledge has not yet resulted in any products being sold.

Q: Focusing first on Advance and SCoR, do you know how they achieve their purported reduction in delivery of harmful substances?

A: I do not know the precise specifications of these products, but I do know the general technologies and how they are intended to work as reflected in the documents I have seen. It is my understanding that these both use charcoal filters, but that is not necessarily the sole reason why they achieve the reductions. They also use ventilation and blend changes. In other words it goes back to the 57 parameters that can vary smoke. There is nothing in these cigarettes that represents a new technical breakthrough that was not available in 1980, as far as I have seen.

Q: You also mentioned filters that prevent a smoker from compensating, as another technological approach Defendants have failed to pursue. What do you mean by that?

A: I am talking about things like RJR's multijet filter, which I described earlier. In addition, a scientist at Philip Morris while I was there conceived of a non-inhalable cigarette.

Q: Please take a look at U.S. Ex. 35,775, and describe the document's significance for the Court.

A: This a memo I wrote in 1981 to Leo Meyer, who was Director of Product Development. In the bottom part of the first page, it mentions the idea of a non-inhalable cigarette that was championed by Dave Lowitz, another scientist. That document mentions that raising the pH would "achieve nicotine transfer in the mouth" to give addicted smokers greater nicotine impact without the need to inhale.

Q: Dr. Farone, were you involved in any other filter-related work to reduce the delivery of harmful gases delivered in smoke?

A: Yes.

Q: Please describe that work.

A: My Directorate developed a special filter attachment that could reduce the levels of carbon monoxide and oxides of nitrogen in smoke. As we developed it, it could have been sold along with a pack of cigarettes, and would have been effective for about a pack's worth.

Q: Looking at U.S. Ex. 89,064, do you recognize the handwriting on this document?

A: Yes, it is my handwriting, it is a document I wrote to Max Hausermann, titled "7-Year Applied Research Review." My name is also printed on the cover memo sheet.

Q: What, if anything, in this document shows your work in this area?

A: On page 4, Bates number ending in 8202, the first listed item under "Minor Accomplishment" states: "Completed the long standing CO reduction by filter catalyst using the CO/alumina catalyst. We were able to show a cigarette holder product that could be used for 10-20 cigarettes."

Q: Was this product ever developed and commercialized?

A: No.

Q: A second area of potentially less hazardous cigarette development you identified was approaches to reduce TSNAs. What are these approaches?

A: There are several, including blend selection, curing practices, denitrification processes, and supercritical fluid extraction.

Q: How can blend selection lower TSNAs?

A: A first approach to lowering TSNAs would be to select types of tobacco that are naturally lower in TSNAs. This could be done by natural selection, by changing conditions in tissue culture to cause greater genetic modifications and by direct genetic modification. Just as Defendants control nicotine levels through blend selection, they could control TSNA levels, too.

Q: What is your basis for saying that genetic modifications to the tobacco could reduce

TSNAs?

A: My statement is based on the fact that there are genetic strains known to have virtually no nicotine, and since nicotine is needed for the formation of NNK, if you could select the low-nicotine strains, you could reduce NNK levels. At the time I left Philip Morris I had sponsored a program with a company called Crop Genetics International with the intent of making the necessary genetic modifications and reintroducing those tobaccos into commerce.

Q: What happened to the program?

A: I don't know, but I have been unable to find any reports or documents on that program from after I left Philip Morris.

Q: I have provided you U.S. Ex. 22,216 for review. What is this document?

A: It is an April 1, 1985 document by Philip Morris scientists Sue Tafur and Ed Lambert to Ted Sanders, and copied to other scientists including Jim Charles, Robert Ferguson, Robin Kinser, and William Morgan. They were reporting on their experiment "to determine if it is possible to deliver adequate nicotine to MS [mainstream] smoke while reducing mainstream TSNA by using an experimental filler blended from a high alkaloid tobacco with low alkaloid and oriental tobaccos. This work was designed to provide a preliminary indication of the feasibility of the concept."

Q: Why is this document significant to your opinions?

A: They concluded that "[t]he data presented here indicate that the approach to delivering adequate nicotine to MS while reducing TSNA can be met by judicious blending of tobaccos." It is important because we had the technology to perform the selection and we had technology to change the curing and to change the amount of nitrates that would further reduce TSNAs.

Q: Dr. Farone, you also mentioned curing practices. Can you explain that further,

please?

A: Yes. We knew the importance of curing and its chemical effects on tobacco when I was at Philip Morris.

Q: Looking again at U.S. Ex. 89,064, your handwritten 7-year summary, what if anything does this document say about curing?

A: As it says on the first page, the Applied Research directorate had established "the importance of curing as the single biggest change in tobacco chemistry (other than variety/genetics)."

Q: So did Philip Morris develop any curing methods that potentially reduce the delivery of TSNAs?

A: Yes. In the early 1980s, Philip Morris patented a special way of curing Bright tobacco that made it an effective substitute for Burley, which is naturally higher in TSNAs. This method substantially lowered the oxides of nitrogen, which are responsible for TSNA formation. Right above the quotation I just read in U.S. Ex. 89,064 about the importance of curing to tobacco chemistry, there is a reference to our successful demonstration of this air-cured Bright tobacco. It is also in U.S. Ex. 35,775, the 1981 memo I wrote to Leo Meyer.

Q: You have been shown U.S. Ex. 88,040 for review. Have you seen this document before?

A: Yes, this is the patent from Dan Teng concerning air-cured Bright tobacco that I just referred to.

Q: What part of this patent is significant to your opinion?

A: The patent states:

> This novel tobacco, when formulated as a smoking article, such as a

cigarette, and smoked, presents the aroma and taste of a blended tobacco smoking article and may be substituted in whole or in part for burley tobacco in blended tobaccos while substantially maintaining the subjective qualities of the burley tobacco and yet, as compared to the burley tobacco-containing blends, provides a reduced NO content in the smoke.

This shows that Philip Morris had a way of replacing burley tobacco with a tobacco that was lower in TSNAs but had the same "subjective qualities" – in other words, it tasted the same to smokers.

Q: Did Philip Morris ever sell cigarettes that had air-cured bright tobacco in them?

A: Yes. At some point, I believe in the early 1980s, Philip Morris bought about $3 million of it, and put it into cigarettes that they sold. As far as I know, there was no problem or consumer complaint with the cigarettes, but Philip Morris did not continue to use air-cured bright.

Q: How do you know this?

A: I was the Director responsible for the program. I worked with Mr. Witcher Dudley, Vice President in the Leaf Department to arrange for purchase, stemming and storage of this tobacco. We then had cigarettes made and tested in various consumer tests.

Q: Have any companies actually used curing practices that reduce TSNA levels?

A: To my knowledge, Philip Morris may have. I know that because I am aware of litigation involving the patent for a method of curing Bright tobacco invented by a small tobacco company called Star Scientific. The method differs from how cigarettes have traditionally been cured, and results in a reduction in the TSNA levels of Bright tobacco. I am also aware that commercial cigarettes have been made and sold using this technology.

Q: Can you briefly describe the method and its effect?

A: Yes. Instead of curing the Bright tobacco using direct propane burners, the curing is done by an indirect heating method that does not expose the tobacco directly to the propane heater gases. It turns out that combustion of natural and hydrocarbon gases creates a lot of oxides of nitrogen, many of which ended up in the tobacco.

Q: Does using this tobacco lower the TSNA deliveries to the smoker?

A: It may, depending upon what other types of tobacco are in the cigarettes and what the total blend is, what additives and flavorants are used, and other design parameters. Burley tobacco is naturally higher in TSNA content, so how much burley is in the blend will influence how much of a total reduction occurs.

Q: Did Philip Morris develop any other ways to reduce TSNAs?

A: Yes. While I was there, scientists developed at least three different methods for removing the nitrates from reconstituted tobacco leaf – known as RL – which significantly reduced the TSNA levels in smoke from cigarettes containing RL denitrified by these processes. Philip Morris concluded that each of them were economically and commercially feasible. At least two of these processes which were microbial in nature, can be used directly on the tobacco, not just on the RL.

Q: Did Philip Morris already have a method in place for denitrifying RL?

A: Yes, they were removing about 90% through a process called crystallization but we knew that PM's nitrate levels were still the highest, and we needed to reduce the other 10% just to make our levels comparable to the competition. The use of these processes in RL was only to be a first step. The goal was to use the process on Burley tobacco in general because this was the real problem. The use of the air cured Bright as a replacement for Burley was another solution to

the same problem.

Q: Dr. Farone, can you please identify the documents that support your testimony concerning Philip Morris's development of denitrification methods?

A: Yes. These documents include: U.S. Ex. 20,351; U.S. Ex. 20,355; U.S. Ex. 20,493; U.S. Ex. 21,568; U.S. Ex. 22,192; U.S. Ex. 22,219; U.S. Ex. 23,057; and U.S. Ex. 37,394.

Q: Have you reviewed each these documents before?

A: Yes. They are all on my reliance list. In addition, I am personally aware of these events. In the 7-year Applied Research Review to Max Hausermann, numbers 4 and 5 on the list of Major Accomplishments refer to the denitrification processes we developed.

Q: To your knowledge, were any of these technologies permanently incorporated into marketed products?

A: No.

Q: Why not?

A: The claimed reason I have heard is that one of the technologies gave a "fecal odor" in one of its incarnations. However, that was only a less expensive version of a different process that tested better; and second, that problem was overcome, as indicated in U.S. Ex. 22,219.

Q: Dr. Farone, I have provided U.S. Ex. 45,774 for your review. Have you seen this document before?

A: Yes, it is one of the documents I considered in this case. It is a March 8, 2000 document by Philip Morris scientist Jane Lewis titled "Status Update."

Q: Please direct your attention, about two-thirds down the page, to the reference to "active bacterial denitrification" and the final sentence in that paragraph, which reads: "The goal is to make recommendations about appropriate interventions or modifications in

the RL process potentially to eliminate or reduce nitrosation events." First, what is nitrosation?

A: Nitrosation is the reaction of nitrates, nitrites or oxides of nitrogen to produce nitroso compounds such as the nitrosamines. The nitrosation of nicotine leads to NNK, nicotine nitrosamine ketone.

Q: Please explain to the Court the significance of this document.

A: It shows that they completely understand the possibilities for the microbial technology. The work in the European subsidiary FTR also proved the same points.

Q: Dr. Farone, you also mentioned supercritical fluid extraction as a way to reduce TSNAs. How does that technology work?

A: Philip Morris developed and used supercritical fluid extraction to remove the nicotine from cigarettes. The same process removes a large percentage of the TSNAs from the tobacco as well. This is a program I initiated while at Philip Morris and was just getting to the pilot stage when I left in 1984. The documents show that by 1987, they knew it would remove TSNAs from all tobacco products.

Q: I have provided U.S. Ex. 37,158 for review. What is this document?

A: It is a Philip Morris document title "Reduction of Tobacco-Specific Nitrosamines."

Q: Please direct your attention to the page titled, "Successful Means of MS TSNA Reduction," ending in Bates number 3526. What are the three methods listed there?

A: The first is "blend component modification." That is what I talked about before, choosing low TSNA tobaccos, substituting things air-cured Bright instead of Burley. The second is "addition of antioxidants to filler." I didn't mention that, but one can also reduce these chemical reactions by adding chemicals that interfere with the nitrosation. These fall in the class

known as anti-oxidants. And the third is "supercritical fluid extraction of filler," which is the process I just described.

Q: If you now turn to the Bates number ending in 3570, titled "Supercritical Fluid Extraction," what are the results reported on that page?

A: The result is "virtually all filler TSNA removed."

Q: Does that mean that no TSNAs would be delivered to the smoker?

A: No. To the extent that nitrate still remains or there were a lot of protein or amino acids there would still be some nitrosamines produced but the level would be very low, even perhaps, for example, below the recommended exposure levels for NNK recently published by the State of California.

Q: Dr. Farone, please turn your attention back to Bates number ending in 3508, titled "PM Research Results, Sidestream TSNA." The last line reads "ETS NNK levels increase with time." From a chemistry perspective, what does that mean chemically?

A: Chemical reactions continue in smoke even after it leaves the cigarette. They occur in secondhand smoke and continue to occur for hours after the cigarette is extinguished so the exposure to these carcinogenic TSNAs increase over time even when the smoker is not smoking.

Q: I have provided you with U.S. Ex. 37,155. What is this document?

A: It is a 1985 research report on Project Tasso, which the document says was initiated to study the levels of nitrosamines in sidestream smoke.

Q: Where was the research conducted?

A: At Neuchatel, Switzerland, at a division of Philip Morris known as FTR.

Q: The second two sentences of the abstract state: "First experiments confirmed an increase in the NNK concentrations up to four hours after smoking. The important role of

nicotine in NNK formation was proved." Can you please interpret what that means?

A: I already discussed above that some of the NNK comes from what is in tobacco due to curing. However a lot more is formed by the reaction of oxides of nitrogen with nicotine. This result shows that the NNK is formed by the reaction of nicotine and oxides of nitrogen. Therefore, just removing NNK from the tobacco is not adequate to remove it from smoke. You also have to remove the oxides of nitrogen from the smoke and the nitrates from tobacco that form them. This was the entire basis of the Philip Morris denitrification processes. If you have nitrites or nitrates in tobacco that produce nitric oxides in smoke, they will react with the nicotine, and NNK will form even if you remove it all from the tobacco.

Q: You have been shown U.S. Ex. 37,424 for review. What is this document?

A: It is a 1986 report from Project Tasso.

Q: On the second page, the document states that "The NNK formation rate and concentration 3.5 h. after smoking is directly related to the filler nitrate content." Can you please interpret for the Court what that passage is saying?

A: Yes. The chemical reactions that result in the formation of NNK, a tobacco-specific nitrosamine, continue in the air as long as there are adequate concentrations of nicotine and oxides of nitrogen. This occurs in secondhand smoke.

Q: I have provided you U.S. Ex. 37,427, a 1985 report written by a C. Blake at Philip Morris. Please explain the significance of this document to the Court.

A: This is a document about a Project POLDI, another Philip Morris project to measure the levels of toxic compounds in sidestream smoke. It confirms, on the second page, that "Concentration of NNK rose sharply until 4 hours after smoking run" and that other TSNA levels rose as well. This is more confirmation of Philip Morris's awareness, in 1985, that undesirable

sidestream smoke reactions effects continued for hours after the sidestream smoke entered the air.

Q: Are you aware of any subsequent research that disproved the results obtained in these POLDI and TASSO series of experiments?

A: There is no work I am aware of that disproves the chemistry. However, Philip Morris has pointed out that the experiments were done in unventilated rooms such as small offices and that the effect in large ventilated areas would be less. This is not a refutation of the concept. It simply means that the issue is how many people will be exposed to what level of carcinogen, and not over the fact that they will be exposed and that the chemicals are toxic.

Q: Dr. Farone, you testified that combustion and pyrolysis are responsible for the creation of many of the harmful compounds in smoke. Have any of the Defendants explored ways to affect these processes?

A: Yes. If you can alter or avoid combustion, you have the potential to prevent the formation, and thus the delivery of many of the harmful compounds in smoke.

Q: In your view, have Defendants developed feasible technologies in this area that they have failed to pursue to commercialization?

A: Yes. The first practical device was patented in about 1964 based on research done for BATCo at Battelle. It had the project name of Ariel. Various embodiments have been pursued since then and have been shown to be commercially feasible.

Q: Can you please briefly describe Ariel's design?

A: Ariel was basically a ceramic tube placed in the middle of a conventional cigarette to run the complete length of the rod. The tube was connected to the filter or a mouthpiece, but that filter or mouthpiece is isolated from the tobacco that surrounded the ceramic rod. Nicotine or

nicotine plus flavor was placed inside the tube so that when the tobacco burned the nicotine and flavor were released when the hot zone reached that portion of the ceramic tube. The ceramic could be made to break or crumble when the hot zone passes along the tube. Thus it had the look and feel of a cigarette but the only chemicals delivered in the mainstream were the ones placed in the tube.

Q: Please review U.S. Ex. 20,425. What is this document?

A: It is an "Idea Disclosure for an Indirect Cigarette" from Philip Morris scientist Scott Osborne in 1972.

Q: Please explain what you interpret the author to mean by an "indirect cigarette."

A: Osborne was describing a product which could use indirect heat to generate and deliver to the smoker an aerosol. Indirect heat means that the tobacco wouldn't undergo the combustion or pyrolysis that creates many of the harmful compounds in smoke. As Osborne proposed, "[t]he particulate phase of the aerosol is generated from pure substances and its composition is under full control; hence, it is capable of being made not only not unhealthful, but positively healthful."

Q: Do you know what BATCo concluded about whether Ariel was technologically and commercially feasible?

A: Based on the documents, BATCo's scientists concluded it was feasible.

Q: What do you rely on for that conclusion?

A: The Ariel documents, including patents which were granted, and therefore show that BATCo believed its design to be novel and to work. While this does not guarantee the economic success of the invention, and economics are a key to successful commercialization, it does indicate that the inventor believed that the technology would work. Also, other documents show that BATCo scientists, after smoking prototypes and obtaining sufficient quantities of nicotine

out of the cigarette, made statements that they agreed it was feasible. They even provided a fairly short timeline for introducing products.

Q: What are some of the documents that support your testimony on this point?

A: These documents include U.S. Ex. 20,581, 21,547, and 22,023, and 34,924.

Q: Did BATCo ever commercialize a product based on the Ariel technology?

A: Not to my knowledge, although I have seen references to it long after they stopped working on it.

Q: Dr. Farone, have any of the Defendant tobacco companies developed and marketed tobacco products that do not undergo combustion, but rather heat the tobacco?

A: Yes. RJR developed and test-marketed Premier in the late 1980s, then ended the test market and put Eclipse in test markets in the mid-1990s. Philip Morris developed Accord, and began selling it in test market in the later 1990s.

Q: What is your view of these products as potentially less hazardous cigarettes?

A: It depends what they are compared to. It is my view that the companies' approach to these products is intended to avoid doing anything to implicate their other products. Looking at Accord, for example, Philip Morris has not given people in the test market any health-related reason to smoke them. In scientific presentations, Philip Morris claims it tested Accord's smoke deliveries against about 55 experimental cigarettes, of which 50 were labeled as "conventional." Not Philip Morris brands or other cigarettes on the market, just test prototypes. So even if smokers were directly informed of this, how are consumers supposed to figure out whether Accord could be less hazardous than the brand they are smoking? They can't. So there is no basis of comparison, and therefore no threat, to the conventional cigarettes out there already, like Marlboros.

IX. Opinion #6 – Recent Product Development and Research Activities

Q: Dr. Farone, I want to turn now to the last of the six basic opinions you articulated at the outset of your testimony. Are you familiar with some of Defendants' most recent product development and research activities?

A: Yes. Some of the testimony I've just given is relevant to this issue.

Q: On what is your knowledge based?

A: I have reviewed several Defendants' recent R&D plans produced in this case, as well as other recent scientific documents produced in this case. I have also tried to keep abreast of Defendants' presentations and publications related to new cigarettes and research. In addition, I have served as a witness in other cases where I have been shown research and product development documents created recently by Defendants.

Q: What do you mean by "recently"?

A: Within the last decade.

Q: Most generally, what is your opinion about Defendants recent research and product development activities?

A: They are essentially unchanged from the past. They are all looking once again at old technologies to make supposedly new products for "harm reduction" or "reduced risk" that actually have higher deliveries for some of these chemicals than products that have been made and marketed for years.

Q: You have been shown U.S. Ex. 61,312 for review. What is this document?

A: It is a March 1999 presentation made to CORESTA, the conference of tobacco scientists, by Cathy Ellis of Philip Morris about smoke, pH, ammonia, and nicotine.

Q: Who is Cathy Ellis?

A: At the time I was at Philip Morris she was a recent addition to the scientific staff and I was aware of her reports. She was identified by Dr. Osdene in our succession planning as being a unique scientist based on her scientific views. I believe when this was presented she was Vice President for R&D.

Q: Have you seen this presentation before?

A: Yes.

Q: How does it bear on your opinions about Philip Morris's recent scientific conduct?

A: This supports the ideas of what I consider to be a misleading use of science. It is very carefully worded to make you think it answers a question that it does not answer. It tries to make the case that ammonia has nothing to do with nicotine delivery but the data, which one can validate, show that the test cigarettes used were not completely explained. For example, measuring extractable ammonia does not tell you anything about the materials in the cigarettes that can decompose to make ammonia. Further, it is always possible to design test cigarettes to have low smoke pH even when ammonia is added. I have shown that the regular cigarettes used in the same paper, in fact, show an increase in nicotine with ammonia.

Another important point is that the Ellis paper ignores another effect that ammonia compounds have – increasing the percentage of free nicotine, which has been aptly demonstrated by Dr. Pankow. Lorillard did a similar study in 2000 that is in my reliance set that is even more obvious in showing the ammonia effects in cigarettes, where they claim there is no such effect.

Q: What else informs your views about Defendants' more recent scientific and product development efforts?

A: I have reviewed some of Defendants' more recent R&D plans and documents relating to recent research projects. A lot of what I see is them studying and re-researching the same types

of things that Philip Morris scientists had studied extensively and reached valid conclusions about before I arrived at Philip Morris in 1976, and that Philip Morris scientists studied and made progress on during the years I was there.

Q: What else supports your conclusions about Defendants' recent conduct?

A: I also look to Defendants' recent statements about and approach to the scientific testing of their "new" products, like Accord, B&W's Advance, and Eclipse, which have basically just been made available in small test markets, as opposed to how they have approached testing of the conventional products that they actually sell all over the place.

Q: Thank you, Dr. Farone.