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LORILLARD STATEMENT ON CIPOLLONE TRIAL DOCUMENTS

A number of internal, tobacco company documents were used in the Cipollone trial. These documents were part of a vast quantity of documents obtained by plaintiff attorneys during the discovery process for that case. When viewed in their entirety, and not in a distorted, piecemeal fashion, the documents show that the tobacco companies have been both responsive and responsible in addressing research findings about smoking and health.

In any large corporation, dozens of memoranda expressing divergent points of view are written every day. Some of the Cipollone trial documents reflect the different views and opinions of individual employees; many do not reflect corporate policy. These documents must also be viewed in the context of their times, a period that involved a great diversity of medical and scientific opinion on smoking and health issues. This diversity of opinion exists today, as the Cipollone trial clearly demonstrates.

Taken in their entirety, the documents show that, faced with research that showed a statistical association between smoking and chronic diseases, the industry:

- o Has funded independent scientific and medical research in an effort to determine the basic causes of cancer and tobacco's relationship, if any, to the disease.

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- o Has communicated the results of that and other research, whether they cast a favorable or unfavorable light on tobacco, to the scientific community, the public and the government.

- o Has worked to redesign its products to reduce those elements of tobacco smoke that some researchers conducting animal tests have asserted might be harmful.

The documents contain no evidence whatsoever that the companies suppressed any information or that they conspired among themselves to confuse the public about smoking and health. On the contrary, the documents show an industry that, faced with health allegations, explored them with research and acted responsibly to modify their products, which they have every legal right to provide, even though the scientific evidence was inconclusive about what, if anything, was causing a problem.

The Industry and Health Research

The principal health issue facing cigarette companies in the 1940s stemmed from complaints by smokers that smoking was irritating their throats and nasal passages. The companies responded to this concern by adding humectants (ingredients that add moisture) to their cigarettes and then conducting tests that demonstrated the improved cigarettes were less irritating to the throat and nasal passages.

The situation confronting the tobacco industry began to change in the early 1950s with the publication of the first substantial epidemiological studies indicating a statistical association between cigarette smoking and lung cancer. Those studies, like all epidemiological evidence, did not prove that cigarette smoking caused lung cancer; they indicated only a statistical association warranting further research.

The industry reacted to these studies by engaging in a research effort to assess the health criticisms of smoking, to determine the basic causes of cancer and to learn what, if anything, might be carcinogenic in cigarette smoke.

While several companies launched research efforts on their own, in 1954 a number of companies also established and funded the independent Tobacco Industry Research Committee, subsequently renamed the Council For Tobacco Research (CTR). The principal purpose of the CTR was, and still is, to provide funding for experiments by independent, outside scientists on smoking and health issues, including the concerns expressed over lung cancer.

These independent, outside scientists develop their own proposals and submit requests for funding to the Scientific Advisory Board (SAB) of CTR. The SAB is composed of eminent scientists from various fields of expertise, prominent universities and research organizations. The Board also is entirely independent of the tobacco companies. The SAB independently evaluates the research proposals and funds those it believes have merit. No project has ever been turned down because of interference from a tobacco company. Moreover, no project considered worthwhile by the SAB has been rejected for lack of funding.

CTR grantees are free to publish their research results in scientific journals. Between 1954 and 1986, the CTR's independent Scientific Advisory Board awarded 969 grants to 522 scientists who reported their research results in more than 3,000 scientific papers. These papers were published in such prestigious journals as the Journal of the National Cancer Institute and the New England Journal of Medicine, and some have even been cited by critics of tobacco and in various Surgeon General's reports.

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Industry members have also contributed more than \$25 million to a number of research facilities for other independent research into smoking and health. These research facilities include the Educational Research Fund of the American Medical Association (for cancer, heart disease and respiratory problems), which published the results as a 1978 book entitled "Tobacco and Health;" Washington University in St. Louis (for cancer immunology) and Harvard University (for respiratory diseases).

Skin Painting and Whole Smoke Tests

In 1953, Dr. Ernst Wynder published the results of experiments that involved painting smoke condensate on the backs of a specially bred strain of mice. The condensate was derived by collecting smoke from hundreds of cigarettes, solidifying it at extremely low temperatures, and then mixing it with solvents such as acetone. This technique resulted in skin cancer on the backs of some mice.

Animal studies, which use mice specially bred to be extremely sensitive to any possible carcinogenic activity, have shown such common items as sugar and the lactic acid produced in human bodies to be carcinogenic. Thus, no responsible scientist can use mouse skin painting tests of this nature by themselves to predict human cancer. In fact, in the 1950s, when the original studies were reported, large numbers of qualified scientists did not believe the studies showed that smoking causes cancer in humans.

The tobacco companies conducted their own mouse skin painting studies to see if Dr. Wynder's experiments could be replicated and to better understand the technique and the scientific work being done by industry critics. Despite the questionable usefulness of the technique, mouse skin painting was also used as a bioassay for other condensates because it was and still is the only bioassay available.

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In the mouse skin painting studies, the doses of smoke condensate applied to the mouse's back are massively greater than the amount of particulate matter that a smoker would encounter in a normal smoking situation. Given these circumstances, the tobacco companies have sponsored animal studies by independent scientists that more closely resemble the human smoking condition, experiments in which the animals inhale fresh, whole smoke. To this day, these studies have failed to find experimentally produced lung cancer in any of the thousands of laboratory animals subjected to fresh whole smoke.

Product Modifications

Even though mouse skin painting experiments do not in any way prove or disprove that cigarette smoking causes cancer, the tobacco companies have taken responsible steps that address the concerns of their customers. In responding to consumer demand throughout the last three decades, tobacco companies have undertaken efforts to change their products so as to reduce those smoke elements which critics have contended might be responsible for various health problems. These efforts have yielded many changes, including the following:

- o Improved filters to reduce the amount of "tar" inhaled by a smoker. In 1955, an average cigarette delivered 37 milligrams of "tar" compared to 12 milligrams of "tar" today. Indeed, there are ultra-low "tar" brands that deliver as little as one or two milligrams of "tar" per cigarette, a 95 percent reduction from the 1955 level.
- o Developed filters designed to eliminate or reduce to the most minute quantities certain allegedly harmful constituents such as phenols.

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- o Designed methods for diluting cigarette smoke with fresh air in order to reduce "tar" delivery still further. First used in the late 1950s, this process has developed from mere pin pricks in filter material to the present technology in which lasers make microscopic holes throughout the entire cigarette paper to allow more complete dilution.

Can there be a "safer" cigarette? The federal government engaged in a decade-long search for a "less hazardous" cigarette beginning in 1968 through the Tobacco Working Group (TWG) which was under the auspices of the National Cancer Institute. However, after a decade of work, the TWG was disbanded. In 1981, the work of the TWG was reviewed by the Surgeon General who issued his own report concluding "that the search for less hazardous cigarettes has not yielded a product which can be considered 'safe'." This 1981 conclusion covered Liggett's palladium-nitrate process which was publicly disclosed with great fanfare four years before the Surgeon General's Report.

The Need to Communicate

From the early 1950s onward, the industry has faced criticism at different times from the Surgeon General, Congressional Committees, the Federal Trade Commission, the Federal Communications Commission and other administrative agencies. The industry has also been the subject of a highly vocal series of attacks by public health groups and others. Under these circumstances, it is only natural that the industry, like any other, supports its industry association, the Tobacco Institute, and employs public relations specialists to present its side of the story and to inform the public about research results relating to tobacco and health.

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The Product Liability Catch-22

The funding of scientific research into cancer causation and the development and introduction of product modifications continue to this day. And, as in the past, hardly anything could be more publicized, better known or more discussed than issues concerning smoking and health. Today, however, smoking and health has become highly politicized, and the tobacco companies find themselves in a Catch-22 situation: had the companies done nothing to respond to the test results published by certain scientists, even though the companies and other independent researchers believed those results might not apply to people, they undoubtedly would have been attacked for being irresponsible. Yet, because they in fact responded with research and product modifications, they are now attacked on the grounds that the research and development effort constitutes an admission that all of the tests relied upon by critics were valid and that cigarettes constitute a health hazard.

This "damned if you do, damned if you don't" view flies in the face of fact and a historical record that clearly shows the industry, as a whole and as independent companies, has acted in a responsible manner in responding to the smoking and health concerns of the public. They have, in fact, helped those discussions proceed. They have not withheld information but have added to the information available to the public, the medical community and policy makers. And they have acted responsibly to try to reduce the presence of certain smoke elements which have been implicated in animal tests, even though they know there is only limited evidence to suggest that those elements represent health dangers to smokers.

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