SECRETARY

September 11, 2008

Federal Trade Commission Office of the Secretary Room H-135 (Annex L) 600 Pennsylvania Avenue, NW Washington, DC 20580

RE: Cigarette Test Method: FTC Matter No. P944509

Dear Chairman Kovacic:

We, the undersigned organizations, are writing to express our support for the Federal Trade Commission's (FTC) proposal (Cigarette Test Method, [P944509]) to rescind its guidance that permits tobacco companies to make factual statements about the tar and nicotine yields of cigarettes based on the Cambridge Filter Method, commonly called the FTC Test Method. The FTC's action is necessary in light of the overwhelming scientific evidence that machine-based measures of tar and nicotine based on the Cambridge Filter Method do not provide meaningful information about how much tar and nicotine are actually received by the smoker or about the relative health risks of different cigarettes. The National Cancer Institute (NCI), the U.S. Surgeon General and other credible scientific bodies agree that there is in fact no meaningful difference in a smoker's exposure to tar, nicotine and carbon monoxide based on whether they smoke "light", "low-tar" or regular cigarettes. 1,2,3

Numerous studies, including a 2001 landmark report by the NCI, have found that while changes in cigarette design reduced the amount of tar and nicotine measured by smoking machines using the Cambridge Filter Method, there is no evidence that these design changes have reduced disease either for smokers as a group or for the whole population. As a result, the reality is that people who smoke cigarettes that score low on the Cambridge Filter Method are not exposed to lower amounts of dangerous toxins and have not reduced their risk of developing lung cancer, emphysema, heart disease and other smoking-caused diseases. This is because the machine test does not take into account the way actual smokers adjust their smoking behavior, for example, by taking more or deeper puffs or blocking ventilation holes, to maintain nicotine levels.

In 2004, the *U.S. Surgeon General's Report on the Health Consequences of Smoking* concluded, "[a]Ithough characteristics of cigarettes have changed during the last 50 years and yields of tar and nicotine have declined substantially, as assessed by the Federal Trade Commission's test protocol, the risk of lung cancer in smokers has not declined." A more recent study that reviewed epidemiological data collected during the American Cancer Society's Cancer Prevention Study II concluded, "[t]here was no difference in risk among men who smoked brands rated as very low tar or low tar compared to those who smoked medium tar brands."

Within the last year, the World Health Organization Study Group on Tobacco Product Regulation (TobReg) and the International Agency for Research on Cancer (IARC) concluded:

The most common measurements used historically for cigarettes have been machine measured tar, nicotine and carbon monoxide (TNCO) yields per cigarette based on the FTC/ISO testing regimen. There is a current scientific consensus that these per cigarette yields do not provide valid estimates of human exposure or of relative human exposure when smoking different brands of cigarettes.⁸

Communication of these measures to smokers creates harm by misleading smokers into believing that differences in exposures and risk are likely to occur by switching to cigarette brands with different machine-measured yields. The public health and scientific communities have been deeply concerned about this issue for two decades. While it is clear that the FTC Test Method does not produce accurate information about smokers' level of exposure to tar and nicotine, it is also clear that the tobacco industry has misused and exploited the test results to encourage more people to begin smoking and to discourage smokers from quitting. Numerous public health authorities, including the NCI in its 2001 report, have found that cigarette manufacturers for decades have deceptively marketed "light" and "low-tar" cigarettes as reducing health risks despite knowing from their own research that this was not the case. The manufacturers' ability to claim that nicotine and tar ratings are based on an FTC-approved testing method has been a vital part of this "low-tar" lie.

The impact of allowing tobacco companies to market in this way has been disastrous for individual smokers and for public health. As a result of this deceptive marketing, it appears that more people are smoking than would be the case if these products were not on the market. 11 Rather than quit smoking, millions of smokers have switched to "light" and "low-tar" cigarettes under the false impression such a change would protect their health. A survey in the American Journal of Preventive Medicine found that many smokers choose "light" or "ultra light" cigarettes to reduce smoking risks. 12 In one study, 44 percent of smokers indicated that they had switched to a "low-tar" or "low nicotine" cigarette just to reduce their health risk. 13 Half of the smokers of "light" cigarettes and nearly three-fourths of "ultra light" smokers said that they smoke these cigarettes to reduce the tar and nicotine they get from smoking. According to another survey, smokers believed that, on average, "light" cigarettes presented a 25 percent reduction in risk and "ultra lights" presented a 33 percent reduction risk compared to regular cigarettes. 14,15 Unfortunately, as a result of switching rather than quitting, smokers of "low-tar" cigarettes have been exposed to the same amount of dangerous toxins and have not reduced their risk of developing lung cancer, emphysema, heart disease and other smoking-caused diseases.

In addition, according to several scientific studies, the people who smoke – or switch to – "light" and "low-tar" brands are the ones most interested in quitting, and who might have quit if they had not been lured into believing that "light" and "low-tar" cigarettes represented lesser health risks to them. ¹⁶ According to a study published in the *American Journal of Preventive Medicine*, 30 percent of "light" smokers and nearly half of "ultra light" smokers indicated one of the reasons they chose to smoke those brands is that they considered it to be a step toward quitting completely. ¹⁷ An earlier survey found that 38 percent of smokers who had switched brands switched to "low-tar" and "low nicotine" cigarettes as a quitting strategy. ¹⁸

Data do not indicate that switching to reduced tar cigarettes increases the likelihood that a smoker will successfully quit. ¹⁹ In fact, the evidence suggests that just the opposite occurs. "Low-tar" cigarettes appear to undermine the motivation to quit smoking among those smokers most interested in quitting. An *American Journal of Public Health* study found that smokers who say they smoke "light" cigarettes to reduce health risks are significantly less likely to quit smoking than people who smoke regular cigarettes. The study found that smokers who switched to "light" cigarettes to reduce health risks were about 50 percent less likely to quit smoking than those who smoked non-"light" cigarettes. ²⁰ A study in *Nicotine and Tobacco Research* found that smokers with the greatest desire to quit were more likely than other smokers to switch to lower tar brands but no more likely to attempt or succeed at smoking cessation. ²¹

The evidence is clear that the marketing of "light" and "low-tar" cigarettes as delivering less tar and reducing smokers' health risks has impacted the behavior of millions of consumers. After decades of deceptive marketing, the *FTC Cigarette Report for 2004 and 2005* reported that over 84 percent of all cigarettes sold in the U.S. have tar yields of 15 mg. or less on the FTC Test Method.²²

The evidence is also strong that the tobacco industry has long known that the FTC Test Method does not provide meaningful information to consumers, but has kept their knowledge secret even as they marketed products that score low on the FTC Test Method in ways that misled consumers. Numerous internal documents demonstrate that Philip Morris knew that the FTC machine measurements did not accurately reflect the actual amount of the tar and nicotine ingested by human smokers or even the relative amount of tar and nicotine ingested by smokers of different cigarettes. In an August 11, 1967 Philip Morris USA document Helmut Wakeham, then Director of Research and Development at Philip Morris USA, informed Paul D. Smith, then Vice President and General Counsel of Philip Morris USA, that human smokers increased their smoke intake when switching from non-filter to filter cigarettes, and as a result they would receive the same amount of tar and nicotine from filter cigarettes as from non-filter cigarettes:

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 by taking a larger puff so that he still gets about the same amount of equivalent undiluted smoke. . . . 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 (emphasis in original).

Subsequently, Philip Morris's scientist, Dr. Jerry Whidby, testified that:

Product Opinion Laboratories was a facility established by Philip Morris to evaluate smokers' reaction to the cigarette brands Philip Morris was selling, as well as to Philip Morris prototype cigarettes, and that he was not aware of any instance, at any time between when Dr. Wakeham wrote this document in 1967 and when [Dr. Whidby] left the company in 1998, in which Philip Morris informed the American public directly of Wakeham's conclusions that the FTC tar and nicotine yields are apparently 'erroneous and misleading,' and dilution filter cigarettes generated lower FTC yields than non-dilution cigarettes, but delivered about the same amount of smoke to smokers. (internal quotations omitted).²⁶

Similarly, a 1969 Philip Morris report of a study of filter smokers' intake patterns stated that the FTC Test Method has "no practical value for predicting smoke intake." 27

James Morgan, a future C.E.O. of Philip Morris U.S.A. who served as Brand Manager of Marlboro from 1969 to 1972 and was Director of Brand Management at Philip Morris at the time of Marlboro Lights' introduction, has admitted that the "light" descriptor as invented by Philip Morris was intended to convey a health message. He has testified that "Philip Morris made a calculated decision to use the phrase 'lowered tar and nicotine,' even though its own marketing research indicated that consumers interpreted that phrase as meaning that the cigarettes not only contained comparatively less tar and nicotine, but also that they were a healthier option." ²⁸

A Philip Morris document, dated September 17, 1975 from Barbro Goodman to Leo Meyer, then Philip Morris Director of Research, demonstrates that, specifically, Philip

Morris was aware that "smokers got as much tar and nicotine from Marlboro Lights as from full-flavor Marlboros." Philip Morris knew that "Marlboro Lights cigarettes were not smoked like regular Marlboros." Their testing demonstrated that there were:

differences in the size and frequency of the puffs, with larger volumes taken on Marlboro Lights by both regular Marlboro Smokers and Marlboro Lights smokers...The panelists smoked the cigarettes according to physical properties; i.e., the dilution and the lower RTD of Marlboro Lights [subconsciously] caused the smokers to take larger puffs on that cigarette than on Marlboro 85's. The larger puffs, in turn, increased the delivery of Marlboro lights proportionally. In effect, the Marlboro 85 smokers in this study did not achieve any reduction in smoke intake by smoking a cigarette (Marlboro Lights) normally considered lower in delivery.

An interoffice memorandum on Philip Morris USA letterhead on March 7, 1974 between Raymond Fagan to Helmut Wakeham, Philip Morris Principal Scientist, entitled "Moral issue on FTC Tar" stated:

Some concern has been expressed concerning the moral obligation of Philip Morris (and perhaps the tobacco industry) to reveal to the FTC the fact that some cigarette smokers may be getting more tar than the FTC rating of that cigarette. You mentioned in your presentation at the Center on Tuesday, March 5, that such concern was voiced in N.Y. at your talk there. And it was expressed again by some individuals who heard you in Richmond. I believe that there need be no such concern, at least from a position of morality.³¹

Another Philip Morris document, dated just six days before, stated under the heading "SUMMARY": "People do not smoke like the machine [referring to the FTC Test Method] ... generally people smoke in such a way that they get much more than predicted by machine. This is especially true for dilution cigarets [sic]." After acknowledging that human smokers get much more tar than indicated by the FTC testing methodology, the document stated in the "CONCLUSION" section: "The FTC standardized test should be retained: 1) It gives low numbers." 33

Philip Morris's internal documents reveal that by 1978, "Philip Morris had substantial evidence that the 'filter dilution which Philip Morris used to reduce FTC tar and nicotine yields was somehow acting to increase' the [biological] 'activity' of the whole smoke condensate ("WSC") collected from its cigarettes," actually indicating that these "light" cigarettes were potentially more hazardous than regular cigarettes.

Additional Philip Morris research conducted in 1979 yielded the same result. A May 11, 1982, Philip Morris document from INBIFO (Philip Morris's secretive overseas research facility) indicated that Philip Morris learned from its testing of low tar reference laboratory cigarettes (cigarettes used for research purposes and not actually sold in stores) that these cigarettes registered higher in standard biological tests than regular-delivery reference cigarettes— *i.e.*, were "more active"— and thus were potentially more carcinogenic: "Low tar reference cigarette . . . [m]ay be slightly more active than [the regular delivery reference cigarette] as a complete carcinogen." ³⁵

Similarly, a January 28, 1994 report from INBIFO to Philip Morris in Richmond, Virginia stated that increased cigarette filtration, porosity and ventilation (primary methods used by Philip Morris to reduce the FTC Test Method tar and nicotine yields in its cigarettes) would result in an increase in the degree to which cigarette smoke was toxic to living cells ("cytotoxicity"), the irritation it caused to smokers, and the likelihood of the smoke to generate mutations, such as tumors and/or cancer ("mutagenicity").³⁶

Additional evidence that Philip Morris knew of increased mutagenicity comes from Clifton Lilly, Senior Vice President of Technology at Philip Morris. He confirmed that data from tests run at Philip Morris's INBIFO facility showed that the Ames test for mutagenicity [designed to measure the degree to which a substance causes mutations, such as tumors and/or cancer] from Marlboro Lights produces significantly higher results than the tar from Marlboro "Reds" products. 37

In the interest of public health, we strongly urge the FTC to prohibit tobacco companies from using terms such as "per FTC method" or any statements that states or implies FTC endorsement or approval of the Cambridge Filter Method or other machine-based test methods. We believe that this action will help to eliminate consumers' misperceptions about these products and will be an important step towards addressing this public health tragedy. This action by the FTC will also help our public health organizations to be more effective in our efforts to prevent children from starting to smoke and to help all smokers to quit. Also enclosed for your review is a brief filed in the case of *Altria v. Good* on June 18, 2008. Thank you for your attention to our concerns and for the opportunity to respond to this Federal Register Notice.

Sincerely,

Matthew L. Myers, President Campaign for Tobacco-Free Kids

Organizations

American Academy of Child and Adolescent Psychiatry

American Academy of Otolaryngology-Head and Neck Surgery

American Association for Respiratory Care

American Dental Association

American Dental Hygienists' Association

American Heart Association

American Legacy Foundation

American Lung Association

American Public Health Association

American Society of Addiction Medicine

American Thoracic Society

Asian & Pacific Islander American Health Forum

General Board of Church and Society of the United Methodist Church

Indiana Latino Institute

Lung Cancer Alliance

National Consumers League

Oncology Nursing Society

Society for Public Health Education

Trust for America's Health

¹ Risks Associated with Smoking Cigarettes with Low Machine-Yields of Tar and Nicotine; Report of the NCI Expert Committee. National Institutes of Health. National Cancer Institute. Smoking and Tobacco Control Monograph 13, 2001.

² Djordjevic, M.V., et al., "Nicotine Regulates Smoking Patterns," Preventive Medicine 1997 Jul-Aug;26(4):435-40.

³ Farrow DC and J Samet. Identification of the high risk smoker. Clinics in Chest Medicine 1991;12(4): 659-68.

⁴ Risks Associated with Smoking Cigarettes with Low Machine-Yields of Tar and Nicotine; Report of the NCI Expert Committee. National Institutes of Health. National Cancer Institute. Smoking and Tobacco Control Monograph 13, 2001.

⁵ Risks Associated with Smoking Cigarettes with Low Machine-Yields of Tar and Nicotine; Report of the NCI Expert Committee. National Institutes of Health. National Cancer Institute. Smoking and Tobacco Control Monograph 13, 2001.

⁶ U.S. Department of Health and Human Services (HHS), The Health Consequences of Smoking. A Report of the Surgeon General, 2004, at 324.

⁷ Harris, Thun, et al., Cigarette Tar Yields In Relation to Mortality from Lung Cancer in the Cancer Prevention Study II Prospective Cohort, 1982-8, British Medical Journal. 328:72, 2004.

⁸ Institute of Medicine, Clearing the Smoke, Assessing the Science Base for Tobacco Harm Reduction, National Academy of Sciences, 2001. See also, Risks Associated with Smoking Cigarettes with Low Machine-Yields of Tar and Nicotine; Report of the NCI Expert Committee. National Institutes of Health. National Cancer Institute. Smoking and Tobacco Control Monograph 13, 2001; SACTob Conclusions on Health Claims Derived from ISO/FTC Method to Measure Cigarette Yield. Scientific Advisory Committee on Tobacco Product Regulation (2003); U.S. Department of Health and Human Services (HHS), The Health Consequences of Smoking. A Report of the Surgeon General, 2004.

⁹ Burns, et al., "Mandated Lowering of toxicants in cigarette smoke: a description of the World health Organization Tob Reg proprosal", 17 Tobacco Control 132 (2008).

¹⁰ Risks Associated with Smoking Cigarettes with Low Machine-Yields of Tar and Nicotine; Report of the NCI Expert Committee. National Institutes of Health. National Cancer Institute. Smoking and Tobacco Control Monograph 13, 2001.

¹¹ Warner, KE, Slade J. "Low tar. High toll." American Journal of Public Health 1992; 82 17-18. See also, Diane Canova, et al., "Changing the future of tobacco marketing by understanding the mistakes of the past: lessons from Lights," Tobacco Control 2001; 10 (Suppl I): i43-i44.

¹² Kozlowski, L.T., et al., "Smokers' Misperceptions of Light and Ultra-Light Cigarettes May Keep Them Smoking," American Journal of Preventive Medicine 15(1): 9-16 (July 1998).

¹³ National Center for Health Statistics. National Health Interview Survey Cancer Control Supplement. Public use data tape, 1987, in The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes; Report

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- 15 Shiffman S, et al, "Smokers beliefs about light and ultralight cigarettes," Tobacco Control 2001; 10 (Suppl I): i17-i23.
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- ²⁰ Tindle, HA et al., "Cessation Among Smokers of 'Light Cigarettes': Results from the 2000 National Health Interview Survey," American Journal of Public Health, August 2006 Vol. 96 No 8.
- ²¹ Andrew Hyland, et al., "Switching to lower tar cigarettes does not increase or decrease the likelihood of future quit attempts or cessation," Nicotine and Tobacco Research, Volume 5, Issue 5, 2003.
- ²² U.S. Federal Trade Commission (FTC), Cigarette Report for 2004 and 2005, 2007,

http://www.ftc.gov/reports/tobacco/2007cigarette2004-2005.pdf.

- ²³ The discussion of the internal tobacco industry documents that follows tracks the discussion of these issues in the brief submitted on behalf of many public health groups in Altria Group, Inc., et al v. Good, No.07-562 in the Supreme Court of the United States (June 2008).
- ²⁴ See, e.g., U.S. v. Philip Morris USA, Inc., 449 F. Supp.2d 1, 461 (D.D.C. 2006).
- 25 ld. at page 462 (emphasis in original).
- 26 Philip Morris, 449 F. Supp.2d at page 462.
- ²⁷ A. H. Laurene, et al., Philip Morris Smoking Behavior Study Labelled SEX-1, Document No. 504208317-8360 at 8319 (March 17, 1971), available at http://tobaccodocuments.org/bliley_rir/504208317-8360.html
- 28 Philip Morris, 449 F. Supp.2d at page 513-514.
- 29 id. at 465.
- 30 Philip Morris, 449 F. Supp.2d at page 465.
- 31 Raymond Fagan letter to H. Wakeham, "Moral Issue on FTC Tar," (March 7, 1974).
- 32 Some Unexpected Observations on Tar and Nicotine and Smoker Behavior, (March 1, 1974).
- 33 Philip Morris, 449 F. Supp.2d at page 465.
- 34 Philip Morris, 449 F. Supp.2d at page at 457.
- 35 ld.
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- ³⁷ See, e.g., Philip Morris, 449 F. Supp.2d at page at 457-458.

in the Supreme Court of the United States

Altria Group, Inc. and Phillip Morris USA, Inc., Petitioners,

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STEPHANIE GOOD, LORI A. SPEILMAN, AND ALLAIN L. THIBODEAU,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF AMERICAN MEDICAL ASSOCIATION, AMERICAN CANCER SOCIETY, INC., CAMPAIGN FOR TOBACCO-FREE KIDS, AMERICAN HEART ASSOCIATION, AMERICAN LUNG ASSOCIATION, AMERICAN PUBLIC HEALTH ASSOCIATION, AMERICAN LEGACY FOUNDATION, AMERICAN COLLEGE OF CHEST PHYSICIANS, ONCOLOGY NURSING SOCIETY, AND AMERICAN ACADEMY OF PEDIATRICS AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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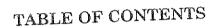


TABLE OF CONTENTSi		
TABLE OF AUTHORITIES iii		
INTERESTS OF AMICI CURIAE1		
SUMMARY OF ARGUMENT2		
ARGUMENT5		
I. Philip Morris Engaged in a Long-term Pattern of Conduct Designed to Mislead Its Consumers		
A. The Antecedents to the "Lights" Fraud Through the 1950s5		
B. The 1960s: The Prelude to the "Lights" Fraud—The "Tar Wars" and the Cambridge Test8		
C. The 1970s: The "Lights" Cigarette Fraud Is Initiated14		
D. The FTC and Philip Morris in the "Lights" Era20		
E. The Federal Cigarette Labeling Act Was Never Designed to Permit the "Lights" Fraud		
II. The Tragic Results of the "Lights" Fraud24		
A. Philip Morris Was Able to Retain and Even Expand Its Consumer		

Base Through the Marketing of Marlboro Lights24 Philip Morris' Deception of the В. Public Health Community......26 Marlboro Lights Are No Less C. Harmful, and May Be More Harmful, Than Regular Marlboros That Philip Morris Was Able To D. Retain Smokers Who Might Have Quit and Attract Vast Numbers of New Smokers Through the Sale of "Lights" Has Led to Dire Health Consequences......31 The Economic Costs Related to E. Smoking......33 There Is Now a Worldwide Consensus III. That the "Light" Cigarette Descriptor Has Deceived Consumers and Has Led to an Increase in Tobacco-Related Economic and Public Health Costs......34

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iv	·
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INTERESTS OF AMICI CURIAE

Amici Curiae are non-profit public health organizations, health professionals, and medical societies that for decades have confronted the devastating health and economic consequences of tobacco use. Hence, Amici are especially qualified to assist this court in comprehending the gravity of Philip Morris' actions in deceptively producing and branding its so-called "Light" and "Lowered Tar and Nicotine" cigarettes, Marlboro Lights and Cambridge Lights. 1

Amici,2 the American Medical Association, American Cancer Society, Inc., Campaign for Tobacco-Free Kids, American Heart Association, American Lung Association, American Public Association. American Legacy Health Foundation, American College of Chest Physicians, Oncology Nursing Society, and American Academy of Pediatrics, share a common interest of ensuring that the tobacco industry is effectively restrained from continuing the type of misconduct that is at issue in this action. Amici seek to educate the American public regarding the widelyheld misconception that smoking "light" or "lowered tar and nicotine" cigarettes is a safer alternative to smoking regular cigarettes. To this day, through their marketing and branding practices, Philip Morris and

¹ Pursuant to Rule 37.6, Amici Curiae state that no counsel for a party authored any part of this brief, and no person or entity, other than the Amici Curiae, its members, and its counsel made a monetary contribution to the preparation or submission of this brief. Counsel of record for both parties have consented to the filing of this brief.

 $^{^{2}\,}$ See Appendix "A" for Statements of Interest of Amici Curiae.

other companies continue to perpetuate this misconception in order to maintain and expand their consumer base.

Amici collectively address this Court in order to place the court of appeal's decision in its broader context, emphasizing that this is a case about fraud and deception and not about a failure to adequately warn. The consequences of the fraud and deception committed by Philip Morris are both broad and profound, and far beyond the regulatory purview of either the Federal Trade Commission or existing federal legislation. Philip Morris has not only committed a fraud upon the consumers of its "Lights" products, but the consequences of that fraud for the physical and economic health of the citizens of Maine and other states have been devastating, and will reverberate for decades to come. Amici urge this Court to be mindful of these real-world consequences of Philip Morris' fraud, and to understand that actions, such as the one brought by Petitioners here, are needed to redress the long-term damage caused by Philip Morris over the past four decades.

SUMMARY OF ARGUMENT

Philip Morris' "light" cigarettes were marketed in a way that led consumers to believe that they were safer than regular cigarettes. This deception was part of a carefully orchestrated and controlled plan initiated by Philip Morris and the other tobacco companies who followed Philip Morris' lead. That plan was designed to (and did) enable Philip Morris, along with the rest of the tobacco industry, to maintain and even increase its cigarette sales—and profits—by offering cigarettes marketed to provide "health reassurance" when compared with "regular" tobacco products. Philip

Morris developed and marketed Marlboro Lights cigarettes to create an "illusion" of a less dangerous cigarette when compared to regular Marlboro "Reds" even though there was no basis for the representation. At no time have Marlboro Lights or Cambridge Lights offered any actual reduction in risk when compared with their regular counterparts.

As the National Cancer Institute's Monograph 133 documents, consumers believed and acted upon Philip Morris' message: "advertising for [light] products led consumers to perceive . . . low-tar delivery products as safer alternatives to regular cigarettes." J.A.830a. At the same time, cigarette industry documents now demonstrate Philip Morris knew the opposite to be true. From the initiation of "lights" as a cigarette "the device. cigarette marketing manufacturers recognized the inherent deception of advertising that offered cigarettes as 'Lights." J.A.897a-898a.

Philip Morris first marketed Marlboro Lights cigarettes in 1971, at the time inventing the word "lights" as a descriptor for its cigarettes. Since their inception, Philip Morris has of its own volition deliberately marketed Marlboro Lights, and later Cambridge Lights, as either "lights" or "lowered tar and nicotine" in a manner never mandated by the FTC or subject to its control, authorization, or regulation. While formally alleging in its briefing to this court that these descriptors were only based upon the "Cambridge Filter Method" ("Cambridge Method"), for thirty years

³ National Cancer Institute, Smoking and Tobacco Control Monograph 13: Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine 199 (2001) ("Monograph 13") (excerpts included at J.A.713a-898a; full report found at Court of Appeals App. 423-673 (hereinafter "C.A. App.")).

Philip Morris has never publicly articulated that alleged basis for naming specific brands "lights" nor did it ever include any FTC tar or nicotine numbers on any of its packaging, cartons, or package labels for Marlboro Lights and Cambridge Lights. At no point did the FTC require or authorize the use of the term "lights" with regard to any category of cigarettes, nor did the FTC establish standards that required or established a "lights" category. Nothing in the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (Apr. 1, 1970), as originally enacted or as subsequently amended, mandates or authorizes the use of such a term or countenances Philip Morris' deception.

The toll on the people of Maine and the American public generally of Philip Morris' consumer fraud has been tremendous. Marlboro Lights are now the number one selling cigarette brand in America. Yet, the National Cancer Institute and others have found that their rapid rise in popularity, as well as that of other "light" and "low tar" cigarettes, has not been met with any concomitant reduction in risk or disease. Moreover, tests of the smoke from Marlboro Lights have shown its condensate to be more mutagenic⁴ than Marlboro "Reds." As a result, Philip Morris' own documents indicate that Marlboro Lights and other "light" cigarettes may have contributed to an increased risk of disease over regular cigarettes. It is for these reasons that a consensus of the American public health community, along with governments worldwide, has called for the end of the use of descriptors, such as "lights," on cigarette labeling.

ARGUMENT

I. Philip Morris Engaged in a Long-term Pattern of Conduct Designed to Mislead Its Consumers

A review of the history of the development and marketing of cigarettes with such descriptors as "lights" or "lowered tar and nicotine," including Marlboro Lights and Cambridge Lights, leads to the conclusion that this is a case about fraud and deception. The FTC has never regulated, much less required, any descriptor used by Philip Morris on its packaging. At all times, Philip Morris has chosen to use these descriptors in a way that deceived its consumers and potential consumers.

A. The Antecedents to the "Lights" Fraud Through the 1950s

In the 1940s and 1950s, scientific researchers began to publish studies that identified a causal relationship between cigarette smoking and various diseases, including lung cancer. As sales started to decline, the cigarette industry quickly recognized the adverse impact that this growing body of public health information had on the industry's economic viability. First, industry executives knew that if the American public understood that smoking caused cancer and other diseases, fewer people would start to smoke and more would quit. Second, those who did smoke (or had smoked) posed a potential threat of civil liability for the industry. Finally, the cigarette industry feared the prospect of stringent government regulations.

On December 15, 1953, tobacco executives held a meeting at the Plaza Hotel in New York City. The presidents of the five major U.S. cigarette

⁴ Mutagenicity refers to the biologic activity that accompanies certain carcinogens.

manufacturers at that time-Philip Morris, R.J. Reynolds, Brown & Williamson, Lorillard, and American met with representatives of the public relations firm Hill & Knowlton. At the meeting, the attendees agreed that the studies linking cigarettes and disease, as well as the public's resulting concerns, were "worthy of drastic action." United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 37 (D.D.C. 2006). As a result of this New York meeting, these companies issued what they called a "Frank Statement to Cigarette Smokers." The "statement" was published in 448 newspapers and aimed at approximately 43 million Americans. In particular, Philip Morris and the other tobacco companies represented the following to the American public: (1) "We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business"; (2) "[T]here is no proof that cigarette smoking is one of the causes [of lung cancer]"; (3) "We always have and always will cooperate closely with those whose task it is to safeguard the public health"; and (4) "We believe the products we make are not injurious to health." Philip Morris, 449 F. Supp. 2d at 40. Every one of these statements was false.

The "Frank Statement" also promised that the Defendants would conduct independent research into tobacco use and health. *Id.* Defendants purported to conduct this research through a newly formed, industry-funded entity known as the Tobacco Industry Research Committee ("TIRC"), later renamed the Council for Tobacco Research ("CTR"). Under the cover of conducting research, TIRC/CTR served as a sophisticated public relations mechanism that enabled Philip Morris and the other tobacco companies to deny

and obscure the harms of smoking. See, e.g., id. at 40-62.⁵

Thus, instead of researching and publicly acknowledging the harmful effects of tar and nicotine, the industry launched a coordinated public relations campaign that misrepresented the state of the scientific evidence demonstrating the link between its products and serious disease. Philip Morris helped organize and set in motion this essential strategy of generating "controversy" about the scientific findings linking smoking to disease, and then adhered to this approach, without wavering, for the next half-century. Philip Morris executives further conspired with the other tobacco company executives through a "gentlemen's agreement" to ensure that the companies would not compete on the basis of health claims. In particular, they agreed: (1) to prohibit the development or marketing of a "safer" cigarette; and (2) not to perform biological research on the link between smoking and disease. Philip Morris, 449 F. Supp. 2d at 37-39. At the same time, they implemented a strategy to falsely reassure, and thereby deceive, the American public that there was still doubt regarding the evidence linking smoking and disease—that it was an "open question," id. at 38-even though their own studies since the early 1950s demonstrated that smoking posed tremendous risks to human health. Id. at 164-68.

⁵ Philip Morris executive Robert Seligman wrote the following historical account: "Bill Shinn [Shook, Hardy & Bacon attorney] described the history, particularly in relation to the CTR. CTR began as an organization called Tobacco Industry Research Council (TIRC). It was set up as an industry 'shield' in 1954." R.B. Seligman, Letter to CTR File, Subject: Meeting in New York—November 15, 1978, Document No. 1003718428-8432 at 8429 (1978), available at http://tobaccodocuments.org/landman/1003718428-8432.html.

B. The 1960s: The Prelude to the "Lights" Fraud—The "Tar Wars" and the "Cambridge Method"

The 1964 Surgeon General's Report established to everyone other than public representatives of the tobacco industry that smoking caused lung cancer, at least in males. At the same time, the Report increased public awareness of the health risks associated with smoking. However, instead of acknowledging the science in the Report, Philip Morris responded to the Report by trying to assuage health concerns while continuing to make sure that their products delivered sufficient amounts of nicotine when smoked by consumers. Monograph 13, J.A.843a.

Philip Morris and the other tobacco companies aggressively marketed their cigarettes as having less tar than competitors, resulting in what was referred to as the "tar derby" or "tar wars." In the mid-1960s, the FTC ended the "tar derby" by prohibiting tar and nicotine claims in advertising. J.A.836a. The FTC then issued a policy statement indicating that a factual statement of the tar and nicotine content based upon the "Cambridge Method" would not be treated as a violation of Section 5 of the FTC Act so long as there were no express or implied representations in advertisements that the represented level of tar or nicotine reduced or eliminated health hazards. *Philip Morris*, 449 F. Supp. 2d at 435-36.

This action resulted from the FTC's efforts, beginning in the 1950s, to conduct tests on smoke condensate, using a smoke-measuring machine method developed by the American Tobacco Company. Monograph 13, C.A. App. 602. This method "utilizes a smoking machine that takes a 35 milliliter puff of two

seconds' duration on a cigarette every 60 seconds until the cigarette is smoked to a specified butt length. The tar and nicotine collected by the machine is then weighed and measured." Federal Trade Commission v. Brown & Williamson Tobacco Corp., 778 F.2d 25, 37 (D.C. Cir., 1985). The measurement is done by analyzing the residue left on pads in order to total the purported tar and nicotine yields of that particular cigarette brand. This method has also become generally known as "the FTC method" or "the Cambridge Filter System."

Numerous internal documents demonstrate that Philip Morris knew that the "Cambridge Method" measurements did not accurately reflect the actual amount of tar and nicotine ingested by human smokers or even the relative amount of tar and nicotine ingested by smokers of different cigarettes. See, e.g., Philip Morris, 449 F. Supp. 2d at 461. In an August 11, 1967, document, Helmut Wakeham, then Philip Morris Director of Research and Development, informed Paul Smith, then Philip Morris Vice President and General Counsel, that human smokers increased their smoke intake when switching from non-filter to filter cigarettes, and as a result they would receive the same amount of tar and nicotine from filter cigarettes as from non-filter cigarettes:

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 by taking a larger puff so that he still gets about the same amount of equivalent undiluted smoke. . . . 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 It has probably misleading. always been so for diluted smoke cigarettes, whether dilution is obtained by porous paper or holes in the filter.

Philip Morris, 449 F. Supp. 2d at 462 (emphasis in original).

Subsequently, Philip Morris's scientist, Dr. Jerry Whidby, has testified as summarized below:

Product Opinion Laboratories was a facility established by Philip smokers' Morris to evaluate reaction to the cigarette brands Philip Morris was selling, as well as to Philip Morris' prototype cigarettes, and that he was not aware of any instance, at any time between when Dr. Wakeham wrote this document in 1967 and when

IDr. Whidbyl left the company in 1998, in which Philip Morris informed the American public directly of Wakeham's conclusions that the FTC tar and nicotine yields are apparently 'erroneous and misleading,' and dilution filter cigarettes generated lower FTC vields than non-dilution cigarettes, but delivered about the same amount of smoke to smokers.

Id. (internal quotations omitted). Similarly, a 1969 Philip Morris report of a study of filter smokers' intake patterns stated that the FTC Method has "no practical value for predicting smoke intake."6

In September 1968, representatives from the major tobacco companies attended a meeting in Hilton Head, South Carolina. The minutes from this meeting show that all of the companies attending agreed to market "health-image" (health reassurance) cigarettes and "health-oriented (minimal biological activity) cigarette[s] to be kept on the market for those consumers choosing it."7 At no time did the tobacco industry disclose to the FTC the results of its private research or the existence of its secret industry agreements, nor is there any evidence that the FTC

⁶ A. H. Laurene, et al., Philip Morris Smoking Behavior Study Labelled SEX-1, Document No. 504208317-8360 at 8319 (Mar. 17, 1971), http://tobaccodocuments.org/bliley_rjr/504208317-8360.html.

Stanton Glantz, et. al., The Cigarette Papers 129 Berkeley: Univ. of California Press (1998), available at http://www.escholarship.org/editions/view?docld=ft8489p25j&chu nk.id = d0e3989&toc.id = d0e3989&brand = eschol.

was aware of the results of this research or these agreements.

In response to the "tar wars," the FTC proposed to require tobacco manufacturers to disclose the tar and nicotine yields as determined by the "Cambridge Method". 35 Fed. Reg. 12,671 (1970). With knowledge of the deficiencies of the test results and their ability to manufacture products that scored low on the test but actually delivered tar and nicotine levels to consumers that bore no relationship to the test results, the five major tobacco companies, including Philip Morris, as well as three minor producers, entered into a private, voluntary agreement ("Voluntary Agreement") among themselves to disclose Cambridge Method test data in cigarette advertisements but not on cigarette packs. Philip Morris, 449 F. Supp. 2d at 435. By entering into this Voluntary Agreement, the companies avoided formal regulation of their cigarette advertising, and circumscribed the role of the FTC. Id.8

The Voluntary Agreement among the cigarette companies prompted the FTC to end its formal rule-making proceedings and any further investigation into the merits of the Cambridge Method test. *Philip Morris*, 449 F. Supp. 2d at 435; 36 Fed. Reg. 784 (1971). Because the FTC was not a party to the Voluntary Agreement, it never established the Voluntary Agreement, it never established the agreement's terms as a "Trade Regulation Rule" pursuant to 15 U.S.C. § 57a. As such, the agency has never had the authority to enforce it. *See FTC*, 778 F.2d at 37.

Thus, at the time Philip Morris voluntarily entered into the agreement with the FTC, it was well aware: (1) that smokers of dilution-based "low-tar" cigarettes did not actually receive less tar and nicotine; (2) that the test results did not provide meaningful information about the relative amount of tar and nicotine actually delivered to consumers by different tobacco products; and (3) that, therefore, the FTC measurements did not provide any useful information to consumers looking to reduce their tar and nicotine intake out of health concerns. The industry was also aware that one reason the FTC measurements were useless was because their cigarettes were being manufactured in such a way as to enable smokers to alter how they smoked by subconsciously "titrating" or "compensating" for the lower delivery of nicotine from

> While each company will fully adhere to the voluntary program submitted, it does not by doing so admit that the failure affirmatively to disclose in its advertising any "tar" and nicotine test results . . . constitutes a violation of law.

⁸ In its cover letter, Philip Morris, through The Tobacco Institute, Inc., made clear that the Voluntary Agreement was indeed voluntary and that Philip Morris did not acknowledge the authority of the FTC to institute regulations:

In submitting the program embodied in the enclosed letter on behalf of these companies, [CTR has] been directed to state further on behalf of each of them that it is not to be considered an admission that the Federal Trade Commission is authorized to promulgate a trade regulation rule, or that this voluntary program may be included for any purpose in any public hearing held on the Federal Trade Commission's proposal of August 8, 1970, or any like proposal.

Letter from Horace R. Kornegay, President & Executive Director, The Tobacco Institute, Inc., to FTC (Oct. 23, 1970), C.A. App. 675-76.

dilution-based low-tar cigarettes in order to achieve the consumers' required nicotine load. See Philip Morris, 449 F. Supp. 2d at 435-44.

C. The 1970s: The "Lights" Cigarette Fraud Is Initiated

Instead of developing and marketing a truly safer cigarette, in 1971, shortly after entering into the Voluntary Agreement, Philip Morris introduced Marlboro Lights cigarettes nationwide as "light," while including the phrase "lowered tar and nicotine" on all of its packaging. As acknowledged by Philip Morris' own internal documents, in labeling, designing, and marketing these cigarettes, Philip Morris intended that consumers would purchase "light" cigarettes perceiving them to have a health benefit when compared with regular Marlboro cigarettes. representation to consumers was never associated with tar and nicotine testing, as Philip Morris never included tar and nicotine figures on the packages of Marlboro Lights cigarettes while representing on all of its packaging that these cigarettes were "light" and delivered "lowered tar and nicotine."9

James Morgan, a future C.E.O. of Philip Morris USA, who was Director of Brand Management at Philip Morris at the time of Marlboro Lights' introduction, has admitted that the Marlboro Lights descriptors were invented and intended by Philip Morris to convey a health message. He has testified that:

Philip Morris made a calculated decision to use the phrase "lowered tar and nicotine," even though its own marketing research indicated that consumers interpreted that phrase as meaning that the cigarettes not only contained comparatively less tar and nicotine, but also that they were a healthier option.

Philip Morris, 449 F. Supp. 2d. at 513-14.

His admission is consistent with contemporaneous internal Philip Morris documents. For example, a May 1976 study prepared for Philip Morris by The Roper Organization, Inc., entitled "A Study of Smokers' Habits and Attitudes with Special Emphasis on Low Tar Cigarettes," stated:

⁹ Philip Morris has admitted that it never included tar and nicotine figures on its "light" cigarette packages, such as Marlboro Lights. See Aspinall v. Philip Morris, Companies, Inc., No. 98-6002, 2006 WL 2971490 at *8 (Mass. Sup. Ct. Aug. 9, 2006). In Petitioners' Br., at 9, n.5, Philip Morris explains this by stating that: "The FTC has not extended this requirement to cigarette packages because, under 15 U.S.C. § 1334(a), only Congress has the authority to require a statement relating to smoking and health... on any cigarette package." Yet, Philip Morris ignores the fact that in 1971 it alone made the decision to describe Marlboro Lights as "lights" with "lowered tar and nicotine" included on all packaging. (In 2003, Philip Morris removed the term "lowered tar and nicotine" from Marlboro Lights immediately after the trial of Price v. Philip Morris, Inc., 219 Ill. 2d 182, 848

N.E.2d 1 (2005).) Moreover, Philip Morris has never been restricted from placing tar and nicotine numbers on its packaging. In 2005, on various ultra-low tar products, such as those yielding 3 mg. tar or less, cigarette manufacturers have generally chosen to include tar and/or nicotine numbers on over 90% of these packs. Yet, at the 4-7 mg. tar level, only 1.2% of the packs contained a similar disclosure. FTC Cigarette Report For 2004 and 2005 Table 8A (2007), available at http://www.ftc.gov/reports/tobacco/2007cigarette2004-2005.pdf ("FTC Cigarette Report").

[T]his study shows that the smoking public is convinced that to the extent any brands are better for health, it is the low tar brands that are. . . Low tar brand smokers cite as the most liked characteristic of their brand . . . as compared with smokers of flavor filters, they say it is "better for your health" and cite its "more effective filter. . . . " Brands Thought Better For Health - The low tar brands have cornered opinion that to the extent any brands are better for your health, they are.

Id. at 524-25.

At the same time, in order to deal with regulators and representatives of the public health community, Philip Morris designed its cigarettes to take advantage of the discrepancy between the Cambridge Method test and actual smoker intake. It intentionally designed its "lights" cigarettes to score low on the Cambridge Method, while enabling them to deliver more tar and nicotine to normal smokers based on the manner in which they were smoked. *Id.* at 462-63. Philip Morris was assisted in this effort by the development of its proprietary alternative testing machine, the human smoke simulator, that it used internally to test actual smoker nicotine and tar yield deliveries. *Id.* at 464.

A Philip Morris document, dated September 17, 1975, from Barbro Goodman to Leo Meyer, the Philip Morris Director of Research, reflects the depth of Philip Morris's knowledge. *Id.* at 465. Specifically, Philip Morris was aware that "smokers got as much tar and nicotine from Marlboro Lights as from full-flavor Marlboros." C.A. App. 412-14. Philip Morris knew that "Marlboro Lights cigarettes were not smoked like regular Marlboros." *Id.* Its testing demonstrated that there were:

[D]ifferences in the size and frequency of the puffs, with larger volumes taken on Marlboro Lights by both regular Marlboro Smokers and Marlboro Lights smokers. . . . the The panelists smoked cigarettes according to physical properties; i.e., the dilution and the lower RTD of Marlboro Lights caused [subconsciously] smokers to take larger puffs on that cigarette than on Marlboro 85's. The larger puffs, in turn, increased the delivery of Marlboro lights proportionally. In effect, the Marlboro 85 smokers in this study did not achieve any reduction in smoke intake by smoking a (Marlboro Lights) cigarette normally considered lower in $delivery.^{10}$

¹⁰ As Dr. David M. Burns, an author of the 1981 Surgeon General's Report, has explained:

[[]T]here are three things that are powerfully significant in this document: (1) It very clearly demonstrates that, in contrast to what we believed six years later when we wrote the 1981 Surgeon

Id.

Philip Morris did not, however, let moral qualms deter it from representing its "light" cigarettes as safer. As stated in a 1974 Philip Morris interoffice memorandum:

Some concern has been expressed concerning the moral obligation of Philip Morris (and perhaps the tobacco industry) to reveal to the FTC the fact that some cigarette smokers may be getting more tar

General's Report, smokers who smoked brands of cigarettes on the market in 1975 were not getting different yields when they smoked those products. We [in the public health community] believed they were. (2) [T]his is dated 1975, six years prior to the time the [1981] Surgeon General's Report reached its conclusion. And we did not have access to this information or comparable information. (3) [T]his study was done on a machine that mimicked actual smoking behaviors, that actually matched the behavior of the individual when the machine smoked the cigarette. In 1981, one recommendations that we made . . . was that this type of machine should be developed so that we could develop a better understanding of the relationship between delivery of tar and nicotine of these cigarettes when they were actually smoked. So ... six years prior to the time we were reviewing that evidence for the Surgeon General, this information was available to Philip Morris.

Philip Morris, 449 F. Supp. 2d. at 466 (internal quotation marks omitted).

than the FTC rating of that cigarette. You mentioned in your presentation at the Center on Tuesday, March 5, that such concern was voiced in N.Y. at your talk there.... I believe that there need be no such concern, at least from a position of morality. 11

Another Philip Morris document, dated just six days before, stated under the heading "SUMMARY":

People do not smoke like the machine [referring to the Cambridge Method]... Generally people smoke in such a way that they get much more than predicted by machine. This is especially true for dilution cigarets [sic]. 12

After acknowledging that human smokers get much more tar than indicated by the Cambridge ("FTC Test") Method, the document stated in the "CONCLUSION" section: "The FTC standardized test should be retained: 1) It gives low numbers." J.A.930a.

Thus, based on information available to Philip Morris, but not the FTC, Philip Morris consciously exploited the use of the Cambridge Method in the 1970's to deceive government regulators and public health leaders. Specifically, it marketed its "light"

Memorandum from Raymond Fagan to Helmut Wakeham, Philip Morris Principal Scientist, "Moral Issue on FTC Tar" (Mar. 7, 1974), J.A.931a.

¹² Some Unexpected Observations on Tar and Nicotine and Smoker Behavior (Mar. 1, 1974), J.A.929a.

cigarettes as healthier than Marlboro Reds, all the while knowing that Marlboro Lights' design readily enabled smokers to receive as much tar and nicotine from Marlboro Lights as from Marlboro Reds.

D. The FTC and Philip Morris in the "Lights" Era

Since the invention of the term "lights" by Philip Morris and its introduction in 1971, the FTC has taken no regulatory action regarding "light" cigarette advertising; nor has it taken any regulatory action based on the Cambridge Method. In fact, rather than promulgate a trade regulation rule enshrining the Cambridge Method, the FTC ceased conducting its own testing of "light" cigarettes in 1987, closing its laboratory. 62 Fed. Reg. at 48,158. This absence of action cannot be viewed as approval. The record is clear that the FTC has never required, authorized, approved, or regulated Philip Morris' use of the "lights" or "lowered tar and nicotine" descriptors.

In 1997, the FTC solicited public comment on whether it should regulate descriptors such as "light." 62 Fed. Reg. at 48,163 (J.A.291a-292a). The FTC stated in its request that "[t]here are no official definitions" for terms such as "low tar," "light," or "ultra light," but explained that "they appear to be used by the industry to reflect ranges of FTC tar ratings." J.A.292a (emphasis added). After soliciting comments, the FTC ultimately took no regulatory action.

In 1999, the United States brought suit in federal district court under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968, against Philip Morris and tobacco-related entities, several of whom were signatories to the 1971 Voluntary Agreement. With respect to Philip Morris, the United States alleged, in part, that it had engaged in a decades-long unlawful conspiracy to deceive the American public about the health benefits derived from smoking "light" cigarettes, *Philip Morris*, 449 F. Supp. 2d. at 1, an action dramatically inconsistent with Philip Morris' assertion that the United States had regulated, controlled, and authorized its use of the term "light." Petr.'s Br. at 21.

Indeed, as the Government's RICO suit proceeded, in 2002 Philip Morris itself acknowledged that the FTC had never regulated the use of the term "lights" when it petitioned the FTC to promulgate a trade rule which would require tobacco companies to define and regulate the use of descriptors such as "light". Petition for Rulemaking Preliminary Statement 1, 32-35 (FTC filed Sept. 18, 2002) J.A.1043a-1044a, 1083a-1085a. That petition was never acted upon by the FTC.

Immediately before the trial of *Price v. Philip Morris*, *Inc.*, Philip Morris further demonstrated that it has always had the power to add to or to alter its packaging of Marlboro Lights products without prior authorization from the FTC:

In 2002 and 2003, PM USA periodically placed an onsert on its medium, mild, light and ultra light packaging. The onserts contained information . . . that there is no

¹³ The Tobacco Institute Testing Lab, an organization funded by major tobacco companies, took over the role of conducting the Cambridge Method tests after that. J.A.271a.

such thing as a safe cigarette, that low-tar cigarettes have not been proven to be less hazardous than other cigarettes and are not a substitute for quitting, that the amount of tar and nicotine that a smoker obtains from a cigarette depends on how the individual smokes the cigarette and that smokers may intake more tar and nicotine than is measured by the standard government test method.¹⁴

In sum, the FTC has neither compelled nor authorized Philip Morris to market or label its cigarettes as "lights" or "lowered tar and nicotine." Philip Morris has voluntarily marketed its cigarettes as "lights," because this marketing has proven highly profitable. The history of the development and marketing of cigarettes labeled as "lights" or "lowered tar and nicotine" leads to the conclusion that in its marketing of its cigarettes, Philip Morris at all times acted on its own.

E. The Federal Cigarette Labeling Act Was Never Designed to Permit the "Lights" Fraud

The federal government never intended to authorize Philip Morris to commit fraud, and the Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (July 27, 1965), was never

intended to immunize the tobacco industry when it did commit such fraud. Nor did this Court do so in Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992). The court below was correct in its analysis:

held that plurality The misrepresentation "fraudulent claims that do arise with respect to advertising and promotion (most notably claims based on allegedly false statements of material fact made in advertisements) are not pre-empted by [§ 1334(b)]. Such claims are predicated not on a duty "based on smoking and health" but general rather on a more duty not obligation—the deceive." Id. at 528-29, 112 S.Ct. 2608. The plurality saw this result as consistent with the text. structure, and purpose of the FCLAA. Id. at 529, 112 S.Ct. 2608. First, the FCLAA "offered no sign that [Congress] wished to manufacturers from insulate longstanding rules governing fraud"-in fact, the Act "explicitly reserved the FTC's authority to identify and punish deceptive advertising practices. . . ." Id. Second, reading § 1334(b) to exclude fraud claims would not frustrate the FCLAA's stated goal of protecting commerce from nonuniform, and "diverse. confusing cigarette labeling and regulations with advertising

¹⁴ Missouri Proxy Statement, *DEF 14A SEC Filing*, filed by Altria Group Inc., at 40 (Mar. 15, 2004), available at http://sec.edgar-online.com/2004/03/15/0001193125-04-042244/Section18.asp.

respect to any relationship between smoking and health," 15 U.S.C. § 1331(2), because "state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity." 505 U.S. at 529, 112 S.Ct. 2608.

Good v. Altria Group, Inc., 501 F.3d 29, 35-36 (1st Cir. 2007).

II. The Tragic Results of the "Lights" Fraud

A. Philip Morris Was Able to Retain and Even Expand Its Consumer Base Through the Marketing of Marlboro Lights

Philip Morris' marketing campaign for "lights," based as it was on the premise that there would be market-wide recognition that "light" equated to "health" and that health concerns would move the market for these products, has proven devastatingly effective. As stated in the Brief of Amicus Curiae Chamber of Commerce of the United States of America in Support of Petitioners at 9-10: "Properly designed product labels can rapidly and efficiently convey information critical to consumer purchasing decisions while, at the same time, allowing producers to identify the characteristics that set their products apart from those of competitors." By the same token, labels that misrepresent products, like the label "lights," can just as "rapidly and efficiently" convey false information to consumers.

As described by Monograph 13, J.A.893a, "[s]everal tactics were employed by the tobacco industry that misled consumers to perceive filtered and

low-tar delivery products as safe or safer and as a viable alternative to quitting." The fact that many smokers chose these products as an alternative to quitting—a change that would produce real reductions in disease risks—makes this deception an urgent public health issue. J.A.719a-720a.

The proposition that "light" cigarettes, including Marlboro Lights cigarettes, are somehow a less risky alternative to regular cigarettes has been fostered by enormous expenditures on advertising by Philip Morris and other tobacco manufacturers. These expenditures have been a significant part of the record \$15.15 billion advertising expenditures for all cigarettes, including "lights," in 2003, and later \$13.11 billion in 2005. FTC Cigarette Report at 3. It is estimated that \$66.8 million is currently spent each year on advertising in Maine alone. 15

The resulting tragedy is that millions of smokers did switch to supposedly lower tar "light" products, falsely believing they were safer, including many who would otherwise have quit altogether. Monograph 13, J.A.730a-732a. These people took what they were led to believe was a rational step to reduce their health risk from smoking because of how these products were marketed. The misleading marketing worked all too well. The devastating reality of Philip Morris' consumer fraud is that the market share of cigarettes sold with a tar yield of 15 mg. or less has increased from a mere 2% in 1967 to nearly 85% of the 351.6 billion cigarettes sold in 2005. See FTC Cigarette Report at Table 4A. Meanwhile, Marlboro, the most

Tobacco in Maine, http://www.tobaccofreekids.org/reports/settlements/toll.php?StateID=ME (hereinafter "Toll of Tobacco").

heavily advertised brand, constitutes almost 55% of the youth market, as well as about 35% of smokers over age $25.^{16}$

As to Maine, 1,900 of Maine's children (under 18 years old) become new daily smokers each year, with Maine's children buying or smoking approximately 2.3 million packs of cigarettes each year. Approximately 16.2% of Maine's high school students smoke (11,600 children), while the percentage of adults in Maine who smoke is slightly higher at 20.2% (210,000 adults). Toll of Tobacco.

B. Philip Morris' Deception of the Public Health Community

The prevailing view within the public health and scientific communities in the 1960s through the early 1990s was that the Cambridge test data provided useful information to smokers who sought to compare tar and nicotine yields of cigarettes. Petitioners correctly cite the fact that Amicus Curiae the American Cancer Society at one time suggested that consumers be provided with tar and nicotine information, because it believed that lower numbers would equate with a comparatively less harmful cigarette. Petr.'s Br. at 5.

Thus, Amici do not dispute the fact that based on the scientific evidence available to them at the time, the public health community along with public health authorities believed that cigarettes yielding less tar on the "Cambridge Method" tests would likely produce less cancer as well. See Monograph 13, J.A.722a.

However, these views changed beginning in the 1990s, in significant part as a result of the availability for review of a large number of internal industry documents, such as research reports, which were brought to light only by litigation against the tobacco companies. See, e.g., id. at i-ii, 10; J.A.717a, 736a-737a.

These documents made it clear that as early as the 1970s, if not earlier, Philip Morris internally recognized, based upon its sophisticated understanding of cigarette design and smoker compensation, that "light" cigarettes as manufactured by Philip Morris and then being marketed offered no clear health benefit. Philip Morris, 449 F. Supp. 2d. at 431 et seq. They further revealed that Philip Morris had chosen to keep this information secret from the government and the public health community while continuing to sell Marlboro Lights as "light" and "lowered tar and nicotine" and, at the same time, defend the "Cambridge Method" to the public health community as a useful means of measuring tar and nicotine yields. As Dr. Burns, one of the principal authors of the 1981 United States Surgeon General's Report, stated: "Had that information [from internal documents] been available to us, we would not have then offered the recommendation to the population of the United States that it would be a good idea to shift to these products." Philip Morris, 449 F. Supp. 2d at 445.

By hiding its own investigations into the comparative health risks of "light" and "low tar" cigarettes, Philip Morris took advantage of the government's and public health community's lack of accurate information to help perpetuate its fraud and deception on consumers. Philip Morris was aware that the government and public health community had long

Facts, Maine Department of Health and Human Services, Maine Center for Disease Control and Prevention, http://www.tobaccofreemaine.org/facts.html (herinafter "PTFM").

struggled to respond effectively to the devastating health consequences of cigarette smoking and to give smokers meaningful information. Despite knowing that the government and public health community were basing their conclusions on erroneous information, tobacco industry "[d]ocuments charged [their own] subordinates to 'root out' adverse information that would generate negative implications and to produce information that would encourage consumers to continue to smoke." Blue Cross and Blue Shield of New Jersey v. Philip Morris, Inc., 178 F. Supp. 2d 198, 224 (E.D. N.J. 2001) overruled on other grounds, Empire Healthchoice, Inc. v. Philip Morris USA, Inc., 393 F. 3d 312 (2d Cir. 2004).

C. Marlboro Lights Are No Less Harmful, and May Be More Harmful, Than Regular Marlboros

Philip Morris' documents further reveal that in the process of creating cigarettes which would register lower tar and nicotine numbers on the "Cambridge Method," Philip Morris was creating cigarettes that may well have increased the threat to smokers' health over their regular counterparts. Indeed, Philip Morris' own research has shown that the dilution design of "light" cigarettes not only has succeeded in gaming the FTC smoking machine, but also delivers more toxins to the smoker, delivers the harmful cigarette particulate matter to more sensitive areas of the smokers' body, and increases the mutagenicity of the smoke constituents received by the smoker. 17

¹⁷ See, e.g., former Philip Morris scientist Dr. Farone's testimony, *Philip Morris*, 449 F. Supp. 2d at 456-57:

Internal Philip Morris documents reveal that by 1978, "Philip Morris had substantial evidence that the 'filter dilution which Philip Morris used to reduce FTC tar and nicotine yields was somehow acting to increase' the [biological] 'activity' of the whole smoke condensate ('WSC') collected from its cigarettes," *Philip Morris*, 449 F. Supp. 2d at 457, actually indicating that these "light" cigarettes were potentially more hazardous than regular cigarettes. Additional Philip Morris research conducted in 1979 yielded the same result.

This was confirmed by research conducted by Philip Morris at its secretive overseas research facility INBIFO. A May 11, 1982, Philip Morris document indicates that Philip Morris learned from its testing of low tar reference laboratory cigarettes (cigarettes used for research purposes and not actually sold in stores) that these cigarettes registered higher in standard biological tests than regular-delivery reference cigarettes and thus were potentially more carcinogenic: "Low tar reference cigarette . . . [m]ay be slightly more

[I]n the case of Marlboro Lights, the Philip Morris test data that 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 Light-increased Marlboro ventilation-resulted in a potentially more dangerous product.

active than [the regular delivery reference cigarette] as a complete carcinogen." Id. at 457. A January 28, 1994, report stated that the primary methods used by Philip Morris to reduce tar and nicotine on the Cambridge Method—increased cigarette filtration, porosity, and ventilation—would enhance both the degree to which cigarette smoke was toxic to living cells as well as its ability to generate mutations, such as tumors and/or cancer: "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." Id.

Additional evidence that Philip Morris knew of increased mutagenicity comes from Clifton Lilly, Senior Vice President of Technology at Philip Morris:

[Lilly] confirmed that data from tests run at Philip Morris's INBIFO facility showed that the Ames test for mutagenicity [designed to measure the degree to which a substance causes mutations, such as tumors and/or cancer] from Marlboro Lights produces significantly higher results than the tar from Marlboro full flavor products.

Id. at 457-58.

More recently, a study that reviewed epidemiological data collected during the American Cancer Society's Cancer Prevention Study II concluded that "[t]here was no difference in risk among men who smoked brands rated as very low tar or low tar

compared to those who smoked medium tar brands." 18 Also in 2004, the Surgeon General's Report on Smoking and Health concluded that "[a]lthough characteristics of cigarettes have changed during the last 50 years and yields of tar and nicotine have declined substantially, as assessed by the Federal Trade Commission's test protocol, the risk of lung cancer in smokers has not declined." U.S. Department of Health and Human Services, The Health Consequences of Smoking, 2004, at 324 (hereinafter "Consequences of Smoking").

D. That Philip Morris Was Able To Retain Smokers Who Might Have Quit and Attract Vast Numbers of New Smokers Through the Sale of "Lights" Has Led to Dire Health Consequences

The tragic result of the "lights" fraud is that even as Americans tried to reduce their risk of disease by switching to what they thought were lower tar products, the overall incidence of disease among smokers (the vast majority of whom now smoke "light" and "lower tar" cigarettes) actually went up. Monograph 13, J.A.730a-732a. 19 In the United States, nearly 21 percent of adults (45.3 million people) currently smoke, and cigarette smoking is responsible for about 438,000 deaths per year, or about one in five deaths annually. 20 In Maine, seven people die from

¹⁸ Harris, Thun, et al., Cigarette Tar Yields In Relation to Mortality from Lung Cancer in the Cancer Prevention Study II Prospective Cohort, 1982-8, BRITISH MED. J. 328:72 (2004).

¹⁹ See, e.g., Consequences of Smoking.

²⁰ Centers for Disease Control and Prevention ("CDC"), Smoking & Tobacco Use: Fact Sheet, Adult Cigarette Smoking in

tobacco use every day, with up to one of these being a nonsmoker exposed to secondhand smoke, see PTFM, which translates to about 2,200 of Maine's adults dying from their own smoking each year. See Toll of Tobacco. 29,200 of Maine's kids now under 18 will ultimately die prematurely from smoking, while 110 to 330 of Maine's adult non-smokers will die each year from exposure to secondhand smoke. PTFM; Toll of Tobacco.

Not only has the risk of lung cancer in smokers failed to decline with the introduction of "light" cigarettes, ²¹ but among cancers adenocarcinomas of the lung have substantially increased since the introduction of dilution cigarettes, like Marlboro Lights. Moreover, deaths caused by cigarettes are by no means limited to cancer. Chronic Obstructive Pulmonary Disease ("COPD"), which includes emphysema and chronic bronchitis, is the fourth leading cause of death in the United States—and it is the only one of the top five causes of death that is increasing. Between 80 and 90% of COPD is caused by smoking.

Nor do deaths tell the entire story. For every person who dies of a smoking attributable disease, there are 20 people suffering from smoking-related illnesses. In Maine, more than 21,000 residents suffer from emphysema, and over 46,400 from chronic bronchitis. See American Lung Association, Estimated

Prevalence and Incidence of Lung Disease by Lung Association Territory, Table I at 34 (May 2008).

Secondhand smoke triggers up to 26,000 new cases of asthma in the U.S. each year, and exacerbates asthmatic symptoms in some one million children. Maine has the highest rate of asthma in the nation. *PTFM*. Thus, with Marlboro Lights now the preferred choice of smokers, ²³ it cannot be disputed that Philip Morris' actions, as described herein, have substantially exacerbated the devastating public health consequences of smoking.

E. The Economic Costs Related to Smoking

It is well established that cigarette smoking also has widespread economic consequences. In 2004, in Maine alone, total health care expenditures directly caused by smoking were over \$600 million. ²⁴ Smoking-caused lost productivity costs in Maine in 2004 were nearly \$500 million. Smoking Data Highlights 2006. Hence, the true cost of smoking for the State's health care economy was in excess of \$1 billion—an astonishing \$658 per household. See Toll of Tobacco.

the United States: Current Estimates (updated Nov. 2007), http://www.cdc.gov/tobacco/data_statistics/factsheets/adult_cig_smoking.htm.

²¹ Consequences of Smoking at 61.

²² See CDC, Cigarette Smoking-Attributable Morbidity – U.S., 2000, MMWR Vol. 52(35) (Sept. 5, 2003).

[&]quot;Sales data from 2006 indicate that Marlboro is the most popular brand in the United States, with sales greater than the five leading competitors combined. The market share for Marlboro is 40.5%. National survey data for 2005 revealed that Marlboro is preferred by 48% of cigarette smokers aged 12-17 years, 51% of smokers aged 18-25 years, and 40% of smokers aged 26 years or older." CDC, Fact Sheet: Tobacco Brand Preferences (updated Apr. 2007), http://www.cdc.gov/tobacco/data_statistics/Factsheets/tobacco_brand_pref.htm (internal citations and numbering omitted).

²⁴ Toll of Tobacco. See CDC, Smoking Data Highlights— 2006, http://www.cdc.gov/tobacco/data_statistics/state_data/ data_highlights/2006/2006.htm ("Smoking Data Highlights 2006").

In 2004, each pack of cigarettes sold in Maine cost an estimated \$11.60 in direct medical expenses and lost productivity attributable to smoking. See Smoking Data Highlights 2006. Smoking-attributable Medicaid costs in Maine in 2004 were \$2.29 per pack of cigarettes—a total of \$216 million.²⁵ Id.

III. There Is Now a Worldwide Consensus That the "Lights" Cigarette Descriptor Has Deceived Consumers and Has Led to an Increase in Tobacco-Related Economic and Public Health Costs

The publication in October 2001 of Monograph 13 confirmed the emergence of a public health community consensus that lower machine-measured yields of tar and nicotine in fact did not lower the risk of disease from smoking. Immediately after the release of this publication, *Amicus Curiae* the American Medical Association issued the following statement on behalf of its membership:

In the nearly 40 years since the first U.S. Surgeon General's Report linking cigarette smoking

to lung cancer and other diseases, tobacco companies have rolled out all sorts of marketing gimmicks and deceptive advertising to convince American Smokers that 'light' cigarettes are somehow safer.

It is both absurd and tragic that the tobacco industry continues to manufacture and pitch its deadly wares without any concern for the health of its customers. The tobacco industry has directly caused the deaths of millions of Americans. "Light'...cigarettes falsely raised hopes of many smokers, keeping them from quitting, and enticed non-smokers to start—most of whom did so before the age of 18."26

In August 2006, following more than two years of discovery and a trial at which countless scientists, government officials, and tobacco industry members testified, the federal district court for the District of Columbia held that Philip Morris had falsely marketed and continues to falsely market "light" cigarettes through its use of the descriptor "lights" in violation of RICO:

By using descriptors such as "lights" and "low tar," Defendants

with smoking-attributable medical costs for 2004 nationwide surpassing \$96.75 billion and lost productivity costs caused by smoking surpassing \$97.65 billion, total smoking-caused losses approached \$195 billion. Smoking Data Highlights 2006, Table 4.

The national average medical costs per pack of cigarettes sold in 2004 equaled \$5.31, the productivity costs per pack were \$5.16, and the Medicaid costs per pack were \$1.63. The national average costs in medical care and lost productivity were over \$12 per pack of cigarettes. *Id.* The national average price (including tax) for a pack of cigarettes in 2004 was \$4.79. *Smoking Data Highlights 2006*, Table 3.

²⁶ Press Release, Randolph D. Smoak, Jr., M.D., American Medical Association, *AMA Commends Report Exposing Dangers of Light Cigarettes* (Nov. 27, 2001).

the false knowingly convey impression that cigarettes with those labels are less harmful than other cigarettes. Consumers' false pervasive and belief is so and has been longstanding. promoted by and exploited Defendants for so long, that restraining and preventing Defendants' future fraud requires a ban on any future use of descriptors which convey a health message.

Philip Morris, 449 F. Supp. 2d at 924-25.27

Nor are the District Court and the American public health community alone in this conclusion. Governments around the world have similarly concluded that marketing cigarettes as "lights" has been deceptive and a threat to public and financial health. In 2006, following an investigation by the Canadian Competition Bureau, tobacco manufacturers agreed to discontinue the use of "light" cigarette designations in Canada.²⁸ The European Union, as well as Israel, Brazil, and Australia, have also recently banned such descriptors. The European Union concluded that "certain texts, such as 'low-tar,' 'light,'.

.. may mislead the consumer into the belief that such products are less harmful . . . " 29

In May 2003, the 192 member states of the World Health Organization completed negotiation of the Framework Convention on Tobacco Control, which includes a provision requiring parties to the treaty to enact legislation banning the use of any descriptor that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products, including terms such as "low tar" and "light." To date, 168 countries, including the United States, have signed the treaty, and 154 countries are parties to it.³⁰

In conclusion, there is now a consensus among governments and public health leaders world-wide. No government authorized Philip Morris' "lights" fraud, but now people both in Maine and throughout the rest of the world are living with the consequences of that fraud and deception.

²⁷ The U.S. Court of Appeals for the District of Columbia has stayed the injunction pending an appeal.

²⁸ Canada v. JTI-Macdonald Corp., 2007 SCC 30 at ¶10 (Jun. 28, 2007), available at http://scc.lexum.umontreal.ca/en/2007/2007scc30/2007scc30.html; See Canadian Ministerial Advisory Council on Tobacco Control, Findings of the International Expert Panel on Cigarette Descriptors at 7 (Aug. 27-28, 2001).

²⁹World Health Organization Regional Office for Europe, Regulation of Tobacco Products: An Update on European Developments 1999-2001 at 16-17 (Oct. 2001), http://www.euro.who.int/document/e74524.pdf; See European Union, Council Decision of 2 June 2004 Concerning the Conclusion of the WHO Framework Convention on Tobacco Control (2004/513/EC), in Official Journal of the European Union 15.6.2004 at 213/8-24, available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/1_213/1_21320040615en00080024.pdf.

³⁰World Health Organization, Framework Convention on Tobacco Control (2003), http://www.who.int/tobacco/framework/download/en/index.html.

CONCLUSION

The decision of the court of appeals should be affirmed.

Respectfully submitted,

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APPENDIX

Appendix A

STATEMENTS OF INTEREST

The American Medical Association ("AMA"), an Illinois non-profit corporation founded in 1847, is an association of approximately 240,000 physicians, residents, and medical students. Its members practice in every state, including Maine, and in all fields of medical specialization, and it is the largest medical society in the United States. Its objects are to promote the science and art of medicine and the betterment of public health. The AMA has long had an interest in the regulation of tobacco products and the tobacco industry. As an institution, it has developed expertise in the pharmacology of nicotine, the toxic effects of cigarette smoke, and the societal implications of tobacco usage. For many years, the AMA has been one of the leading anti-smoking organizations in the United States.1

The American Cancer Society, Inc. ("ACS") is the nationwide community-based public health organization dedicated to eliminating cancer as a major health problem through research, advocacy, education, and service. Research conducted and supported by ACS since the 1950s has played a pivotal role in identifying the use of tobacco products as a

The AMA joins this brief on its own behalf and as a representative of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition between the AMA and the medical societies of each state, plus the District of Columbia. It was formed to represent the viewpoint of organized medicine in the courts.

major cause of cancer. With three million volunteers and representation in every state, ACS is the world's largest voluntary health organization, including many victims of tobacco-caused cancer and their family members.

The Campaign for Tobacco-Free Kids is a freestanding, privately-funded, 501(c)(3) non-profit organization that works to reduce tobacco use and exposure to secondhand smoke, particularly among youth. The Campaign focuses on increasing public awareness and on assisting efforts to develop and implement effective public and private policies and programs to prevent and reduce tobacco use and secondhand smoke exposure, thereby reducing the enormous related harms and costs. The Campaign for Tobacco-Free Kids has more than 125 member organizations, including health, civic, corporate, youth, and religious groups. But the Campaign does not accept any public funding, or any funding or support of any kind from the tobacco industry or any affiliated businesses or organizations.

The American Heart Association ("AHA") is the nation's largest voluntary health agency, with over 22.5 million volunteers and supporters. Since 1924, the American Heart Association has dedicated itself to reducing disability and death from cardiovascular disease and stroke—the #1 and #3 leading causes of death in the United States—through research, education, community-based programs, and advocacy. Since 1999 when AHA and ASA committed to achieving a 25% reduction in cardiovascular disease, stroke, and associated risk by 2010, the Association's efforts have contributed to a 25.8% reduction in deaths from coronary heart disease—an early achievement of their goal—and a 24.4% reduction from stroke. While

it has made significant progress, AHA continues to work toward needed reductions in the risk factors that lead to heart disease and stroke, as well as eliminating disparities in care for women and minority populations.

The American Lung Association ("ALA") is one of the nation's oldest voluntary health organizations, with volunteers and affiliates in all 50 states and the District of Columbia. The ALA has nearly 400,000 volunteers. Since cigarette smoking is a major cause of chronic obstructive lung disease and lung cancer, ALA has long been active in research, education, and public policy advocacy on the adverse health effects of tobacco products. ALA has advocated for the regulation of tobacco products for more than two decades.

The American Public Health Association ("APHA") is a national organization devoted to protecting Americans and their communities from preventable serious health threats. Founded in 1872, APHA is the world's oldest and most diverse public health organization. APHA represents a broad array of health providers, educators, environmentalists, policy makers, and health officials at all levels working both within and outside governmental organizations and educational institutions. APHA advocates for national tobacco control measures to protect the public's health from the adverse effects of tobacco products.

The American Legacy Foundation is dedicated to building a world where young people reject tobacco and anyone can quit. The foundation's programs address the health effects of tobacco use, especially among vulnerable populations

disproportionately affected by the toll of tobacco, through grants, technical assistance and training, research and evaluation, partnerships, youth activism, and youth prevention and adult cessation countermarketing and grassroots campaigns. The foundation was created as a result of the November 1998 Master Settlement Agreement ("MSA") between 46 states and the tobacco industry.

The American College of Chest Physicians ("ACCP"), founded in 1935, is an international medical society dedicated to providing postgraduate medical education for physicians, surgeons, and allied health professionals involved in the diagnosis and treatment of chest diseases. ACCP, and the more than sixteen thousand health care professionals it represents, help promote the prevention and treatment of diseases of the chest through leadership, education, research, and communication. ACCP publishes CHEST, a leading scientific journal featuring clinical research in pulmonary, critical care sleep and chest medicine disciplines. ACCP also advocates before government agencies and the courts offering expert opinion on issues impacting cardiopulmonary health. See, e.g., Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) (ACCP amicus brief available at 1991 WL 11003931) or New York v. EPA, 413 F.3d 3, 30 (D.C. Cir. 2005) (discussing the health effects of air pollution emissions, as presented by amici, including ACCP).

Oncology Nursing Society ("ONS"), the largest professional oncology association in the world, is composed of more than 37,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. Because tobacco use is responsible for one in three cancer deaths in the

United States, ONS has long supported the regulation of tobacco products to help reduce and prevent tobacco-related disease, disability, and death. ONS maintains a steadfast commitment to supporting policies, programs, and other efforts that seek to reduce adult and youth tobacco use, promote tobacco cessation, protect nonsmokers against secondhand smoke, and help increase access to tobacco use prevention and cessation services.

The American Academy of Pediatrics, founded in 1930, is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of AAP has grown from the original group of 60 physicians specializing in children's health to 60,000 primary care physicians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 77 years, AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice and has demonstrated a continuing commitment to working with hospitals and clinics, as well as with state and federal governments to protect the well-being of America's children. AAP has engaged in broad and continuous efforts to prevent harm to the health of children and adolescents caused by the use of tobacco products and exposure to second-hand tobacco smoke.