

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

LORILLARD, INC., <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 11-cv-00440 (RJL)
)	
UNITED STATES FOOD AND DRUG)	
ADMINISTRATION, <i>et al.</i> ,)	
)	
Defendants.)	
)	

**MOTION OF PUBLIC CITIZEN, INC., ET AL., FOR LEAVE TO FILE
MEMORANDUM AS AMICI CURIAE IN SUPPORT OF
DEFENDANTS’ MOTION TO DISMISS**

Public Citizen, Inc., and thirteen other organizations¹ interested in issues relating to science and public health policy respectfully request leave to file the accompanying memorandum as amici curiae in support of the defendants’ motion to dismiss the complaint. The grounds for this motion, set forth more fully below, are that the proposed amici curiae have a perspective on and interest in this case that may be helpful to the Court in considering whether the plaintiffs’ complaint states a claim upon which relief can be granted.

The defendants have stated that they consent to the filing of the amici’s memorandum. The plaintiffs have advised counsel for amici curiae that they would consent only on condition that the defendants would agree that the plaintiffs could have 30 days from the filing of this

¹ The organizations joining this motion are: the American Academy of Pediatrics, the American Association for Cancer Research, the American Heart Association, the American Cancer Society, the American Cancer Society Cancer Action Network, the American Lung Association, the American Medical Association, the American Society of Preventive Oncology, the American Thoracic Society, the Association of Schools of Public Health, the Campaign for Tobacco Free Kids, the Center for Science in the Public Interest, and the Oncology Nursing Society.

motion to file a separate memorandum responding to the memorandum of the amici curiae, with a number of pages equal to the number of pages in the amici's memorandum (less any pages devoted solely to describing the amici), and if the proposed order granting leave to file incorporated that condition. The defendants in turn advised that they would not oppose plaintiffs' seeking additional pages for their opposition to the motion to dismiss if, upon review of the amici's memorandum, they considered additional pages necessary; but the defendants would not consent to the plaintiffs' condition that they be allowed to file a separate brief addressing the amici's memorandum. In light of the parties' disagreement on this point, this motion does not have consent of the plaintiffs, and amici curiae request only that the Court grant leave for the filing of their memorandum, with any order relating to the format and timing of the plaintiffs' response to be determined based upon the Court's judgment about what would best serve the Court's convenience and the legitimate interests of the parties.

Amici curiae seek leave to file this brief because the issues in this case affect the functioning and utility not only of the Tobacco Products Scientific Advisory Committee, but of federal advisory committees that address matters of science and public health generally. Amici are organizations that are interested in science-based public health policy, and federal advisory committees play an important role in advising in the development of such policy. Amici fully support the activities of federal advisory committees and the aims of the Federal Advisory Committee Act, including a proper construction of FACA's requirement that advisory committees be fairly balanced. Amici are concerned, however, that the plaintiffs' construction of FACA's "fairly balanced" requirement would impede, rather than advance, FACA's aims. Amici believe that consideration of their arguments (which do not merely repeat those of the

defendants) would help the Court consider whether the complaint's allegations state a claim that FACA has been violated.

More specifically, the proposed amici curiae, and their interests in the subject matter of this case, are as follows:

Public Citizen, Inc., a national consumer-advocacy and government-reform organization founded in 1971, appears on behalf of its approximately 225,000 members and supporters before Congress, administrative agencies, and courts on a wide range of issues. Public Citizen works for enactment and enforcement of laws fostering an open, accountable, and responsive government and protecting consumers, workers, and the public. Through its Health Research Group, Public Citizen advocates the application of scientific and medical research to promote safe drugs, medical devices, consumer products, and workplaces. The Director of Public Citizen's Health Research Group, Dr. Sidney Wolfe, participates directly in the activity of Food & Drug Administration (FDA) advisory committees. Public Citizen has also taken a leading role in litigating issues under FACA, including issues relating to the statute's "fairly balanced" requirement and its requirements of openness and accountability for federal advisory committees.

The American Academy of Pediatrics ("AAP") was founded in 1930 and 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 79 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.

The mission of **the American Association for Cancer Research** is to prevent and cure cancer. Founded in 1907, the AACR is the world's oldest and largest professional organization dedicated to advancing cancer research. The membership includes 33,000 basic, translational and clinical researchers; health care professionals; and cancer survivors and advocates in the United States and more than 90 other countries. The AACR marshals the full spectrum of expertise from the cancer community to accelerate progress in the prevention, diagnosis and treatment of cancer through high-quality scientific and educational programs. It funds innovative, meritorious research grants, research fellowships and career development awards. The AACR Annual Meeting attracts more than 18,000 participants who share the latest discoveries and developments in the field. Special conferences throughout the year present novel data across a wide variety of topics in cancer research, treatment and patient care. Including *Cancer Discovery*, the AACR publishes seven major peer-reviewed journals: *Cancer Research*; *Clinical Cancer Research*; *Molecular Cancer Therapeutics*; *Molecular Cancer Research*; *Cancer Epidemiology, Biomarkers & Prevention*; and *Cancer Prevention Research*. AACR journals represented 20 percent of the market share of total citations in 2009. The AACR also publishes *CR*, a magazine for cancer survivors and their families, patient advocates, physicians and scientists.

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of **the American Cancer Society, Inc. (ACS)**, supports evidence-

based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN works in partnership with ACS to encourage government officials to support effective tobacco control policies, including ensuring the integrity of advice given to agencies such as the FDA. ACS research was instrumental in establishing the original link between tobacco use and cancer, and nationwide ACS's three million volunteers work to fight cancer. Because tobacco use is associated with increased risk for cancer of the cervix, esophagus, kidney and renal pelvis, larynx, lung and bronchus, oral cavity and pharynx, pancreas, stomach, urinary bladder and acute myeloid leukemia, furthering the American Cancer Society and ACS CAN missions depends largely on effective tobacco control.

The American Lung Association (ALA) is the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research. The ALA funds scientific research to improve treatments and find cures for the more than 33 million Americans with chronic lung diseases. The ALA's concerns include asthma, air pollution, lung cancer and chronic obstructive pulmonary disease, as well as the other effects of smoking and secondhand smoke. The ALA is active in promoting public policies on the federal and state level that employ scientific and medical knowledge to advance the fight against lung disease, the number three cause of death in the United States. Ensuring the efficacy of scientific advisory committees that advise relevant federal agencies, including the FDA and EPA, is important to the success of that fight.

The American Heart Association ("AHA") is a voluntary health organization that, since 1924, has helped protect people of all ages and ethnicities from the ravages of heart disease and stroke. AHA is one of the world's premier health organizations, with local chapters in all 50 states, as well as in Washington D.C., and Puerto Rico. The association invests in research,

professional and public education, and advocacy so people across America can live stronger, longer lives. AHA has long been active before Congress and regulatory agencies on tobacco and other health-related matters and has petitioned the FDA on several occasions seeking regulation of cigarette and other tobacco products under the Federal Food, Drug, and Cosmetic Act.

The American Medical Association (AMA) is the largest professional association of physicians, residents, and medical students in the United States. Through state and specialty medical societies and other physician groups, seated in the AMA's House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy making process. The objects of the AMA are to promote the science and art of medicine and the betterment of public health.

The American Thoracic Society (ATS) is an international education and scientific organization founded in 1905 that represents 15,000 health care professionals. ATS works to prevent and cure respiratory disease around the globe through research, education and advocacy. ATS publishes three peer reviewed scientific journals that disseminate groundbreaking research, including studies on the health effects of tobacco product use and addiction.

The American Society of Preventive Oncology (ASPO) is a multi- disciplinary society which, through a variety of professional education activities, is primarily committed to serving as an advocate for cancer prevention and control research. Objectives of the organization are: to stimulate development and communication of information on the causes of human cancer, including environmental exposures, lifestyle, and host susceptibility states; to encourage the development and evaluation of new methods and programs for the prevention and early detection of cancer; to review and monitor programs directed toward reducing cancer incidence, mortality, and morbidity; to assist in professional and public education related to cancer prevention; to

foster and enhance the training of health professionals concerned with preventive oncology; to maintain communication with other societies and groups concerned with oncology; to form advisory groups to provide expertise to appropriate scientific, public health and governmental organizations and agencies, and to private industrial and labor organizations; and to participate in international activities and serve as a worldwide cancer prevention resource.

The Association of Schools of Public Health (ASPH) represents the Council on Education for Public Health-accredited schools of public health. ASPH promotes the efforts of schools of public health to improve the health of every person through education, research, and policy. Based upon the belief that “you’re only as healthy as the world you live in,” ASPH works with stakeholders to develop solutions to the most pressing health concerns and provides access to the ongoing initiatives of the schools of public health.

The Campaign for Tobacco-Free Kids is a non-profit organization that works to raise awareness that cigarette smoking is a public health hazard by advocating public policies to limit the marketing and sales of tobacco to children, and altering the environment in which tobacco use and policy decisions are made.

The Center for Science in the Public Interest (CSPI) is the leading national, non-profit advocacy organization for nutrition and health, food safety, and sound science. Its twin missions are to conduct innovative research and advocacy programs in health and nutrition, and to provide consumers with current, useful information about their health and well-being. CSPI represents the consumers' interests before regulatory, judicial, and legislative bodies on food, alcohol, health, the environment, and other issues. In 2007, the FDA Commissioner awarded CSPI the agency’s highest honor, the Harvey W. Wiley Special Citation. An FDA that considers all

viewpoints—and not just the viewpoints of members of the industries that it regulates—is important to CSPI's missions and goals.

The Oncology Nursing Society (ONS) is a professional organization of over 35,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS seeks to promote excellence in oncology nursing and quality cancer care and to lead the transformation of cancer care. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas. Registered nurses, including staff nurses, advanced practice nurses, case managers, educators, researchers, and consultants, and other healthcare professionals, benefit from membership. The Society offers useful information and opportunities for nurses at all levels, in all practice settings, and in all subspecialties. In addition, the Society plays an active role in advocacy activities at the local, state, national, and international levels.

Amici curiae respectfully request that their motion for leave to file the attached memorandum be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing Motion of Public Citizen, Inc., et al., for Leave to File Memorandum as Amici Curiae in Support of Defendants' Motion to Dismiss, together with the attached Memorandum of Amici Curiae and proposed order, on the following counsel for all parties by e-mail (using their e-mail addresses as indicated in the docket of this case):

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