

Benjamin E. Chu, M.D., M.P.H., M.A.C.P., Chair
President, Southern California Region
Kaiser Foundation Health Plan and Hospitals
Pasadena, CA

Susan Curry, Ph.D., Vice-Chair
Dean, College of Public Health
Distinguished Professor, Health Management and Policy
University of Iowa
Iowa City, IA

Lawrence G. Wasden, Treasurer
Attorney General of Idaho
Boise, ID

Donald K. Boswell
President & CEO
Western New York Public Broadcasting Association
Buffalo, NY

Jonathan E. Fielding, M.D., M.P.H.
Director Health Officer, Los Angeles County Department
of Public Health
Professor of Health Services and Pediatrics,
Schools of Public Health and Medicine,
University of California, Los Angeles
Los Angeles, CA

Tom Miller
Attorney General of Iowa
Des Moines, IA

Charles K. Scott
Wyoming State Senator
Casper, WY

Leticia Van de Putte
Texas State Senator
San Antonio, TX

Cass Wheeler
Chief Executive Officer Emeritus
American Heart Association
Dallas, TX

Bethlehem Berni (Youth Board Liaison)
Temple University
Philadelphia, PA

Cheryl G. Heaton, Dr. P.H., Ex-Officio
President & CEO
American Legacy Foundation

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VIA electronic mail: oira_submission@omb.eop.gov

ATTN: FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

**RE: Docket No. FDA-2009-N-0406 - Tobacco Product
Establishment Registration and Submission of Certain Health
Information**

OMB control number: O910-NEW

The American Legacy Foundation (“Legacy”) is pleased to comment on the importance of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) provisions regarding the submission of tobacco product health information, including ingredient listing and health related documents. First, Legacy would like to applaud the Food & Drug Administration (FDA) for moving expeditiously to ensure the collection of tobacco product health information, pursuant to new Section 904 of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by FSPTCA. The FDA has invited comment on whether the proposed collection of such information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility. Legacy writes to assure the FDA and the Office of Information and Regulatory Affairs (OIRA) that the information the FDA proposes to collect—and indeed is required to collect pursuant to FSPTCA—will have great practical utility for improving the public health of our nation.

Legacy is dedicated to building a world where young people reject tobacco and anyone can quit. Located in Washington, D.C., Legacy develops programs that address the health effects of tobacco use, including **truth®**, an award-winning youth smoking prevention campaign, and **EX®**, an innovative tobacco cessation program. Legacy also conducts research exploring the causes, consequences and approaches to reducing tobacco use and operates a nationally-renowned program of

outreach to priority populations who disproportionately bear the toll of tobacco. Legacy was created as a result of the 1998 Master Settlement Agreement (MSA) between the states and the tobacco industry. Pursuant to the terms of the MSA, Legacy cannot lobby, and therefore took no position on FSPTCA as it made its way through the legislative process.

As noted in the FDA's request for comments, new Section 904 requires tobacco manufacturers to submit a list of ingredients included in their tobacco products as well as all post-FSPTCA documents that relate to the health effects of these products. This information is of vital importance to the FDA's performance of its new regulatory responsibility over tobacco products and will also help educate the American people about the health effects of smoking. As such, this information must be disclosed to the FDA and also belongs in the public domain.

Today, the only information tobacco companies are required to disclose about the ingredients in their products is a composite list of cigarette ingredients required to be submitted annually to the Secretary of Health and Human Services pursuant to the Federal Cigarette Labeling and Advertising Act of 1966, 15 U.S.C. §§ 1331-1340. Given that this information is required by statute *not* to "identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients," 15 U.S.C. § 1335a(a), and is only made publicly available if the Secretary determines it appropriate to include in a report to Congress, *see id.* at § 1335a(b)(1)-(2), it is of limited utility to the scientific and public health community's efforts to fully understand the health effects of tobacco. It is also of no utility to consumers who seek information about ingredients in specific tobacco brands and subbrands. Accordingly, Section 904's requirement that the industry disclose all ingredients by brand and by quantity in each brand and subbrand will have great practical utility, not only in providing important and reliable information to the consumer, but also in advancing our understanding of how specific cigarette ingredients contribute to the adverse health effects of tobacco use. Such information will consequently aid in the development of more targeted and effective prevention and treatment programs.

It is also vitally important that the tobacco industry be required to disclose its internal documents regarding the health effects of its products. For more than a half century, the tobacco industry knew the devastating health effects of tobacco use but concealed this knowledge from the American people. As a federal district court judge found in 2006, the major tobacco companies were "selling a highly addictive product which causes diseases that lead to a staggering number of deaths per year, an immeasurable amount of human suffering and economic loss, and a profound burden on our national health care system . . . [yet] consistently, repeatedly and with enormous skill and sophistication, denied these facts to the public, the Government, and to the public health community." *United States v. Philip Morris*, 449 F. Supp. 2d 1, 28 (D.D.C. 2006) *aff'd*, 566 F.3d 1095 (D.C.Cir. 2009). Most recently, the industry advertised low-tar cigarettes as a healthy alternative to traditional cigarettes and also denied the deadly effects of second-hand smoke, even while their internal documents revealed that low-tar cigarettes can be just as harmful as regular cigarettes and that second-hand smoke cause serious adverse health effects. *Id.* at 854-867. Only by requiring the public disclosure of

all internal documents regarding the health effects of tobacco products can we prevent this type of deadly fraud from being reenacted on the American people. While one of the Master Settlement Agreement's most important achievements was to require the public disclosure of decades of internal tobacco industry documents, the industry's disclosure obligations under the MSA will soon come to an end. Accordingly, the Section 904 health information requirements will also be of tremendous practical utility to both the FDA and the American public at large.

Legacy plans to submit additional comments regarding FSPTCA in response to the FDA's request for comments, but wanted to highlight these important issues given the expedited processing of this proposed collection of information requested by the FDA. If you have any questions or need further information, please contact Stephenie Foster, Legacy's Senior Vice President of Government Affairs at either 202-454-5559 or sfoster@americanlegacy.org.