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NATIONAL HEADQUARTERS

Charles D. Connor
President &
Chief Executive Officer

1301 Pennsylvania Ave., NW
Suite 800
Washington, DC 20004-1725
Phone: (202) 785-3355
Fax: (202) 452-1805

14 Wall St.
Suite 8C
New York, NY 10005-2113
Phone: (212) 315-8700
Fax: (212) 608-3219

www.LungUSA.org

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2012-D-0071

To Whom It May Concern:

The American Lung Association has submitted comprehensive comments about the Food and Drug Administration's (FDA) Draft Guidance for Industry on Modified Risk Tobacco Product Applications (MRTP) in conjunction with other public health partners. These comments are submitted as a supplement to those comments, and represent the views of the American Lung Association.

Because of the tobacco industry's long and disgraceful history of targeting children, youth, adolescents, specific racial groups, women, as well as other adults to become addicted and sustain that addiction to tobacco products and to create "replacement smokers" for the smokers who died from their addiction, the American Lung Association wishes to emphasize the importance of requiring MRTP applications to include data that specifically discusses the impact of MRTPs on these and other populations at high risk for tobacco use. The Institute of Medicine found in its report on the Scientific Standards for Studies on Modified Risk Tobacco Products (IOM Report) that in order to have "regulatory usefulness," MRTP studies must be generalizable to "specific populations, including populations at high risk for tobacco use. ***Failure to include relevant populations in studies will result in incomplete evidence on the effect of an MRTP on the public's health and, therefore, will be inadequate to support regulatory decisions about the marketing of MRTPs***." (IOM Report, Finding 6, p. 16. Emphasis added.) The IOM recommended that the FDA require studies to include populations of special relevance, including (but not limited to):

1. Users of tobacco products, including users who are and are not interested in quitting;
2. Nonusers of tobacco products;
3. Former smokers;
4. Beginning smokers;
5. Adolescents; and
6. Populations at a high risk for tobacco use, including, but not limited to, those low in socioeconomic status and educational attainment, and certain ethnic minorities. (IOM Report, Recommendation 6, pp. 16-17.)

Section 911(l)(2) of the Family Smoking Prevention and Tobacco Control Act requires that any regulations or guidance issued on MRTPs shall be developed in consultation with the Institute of Medicine, and the Lung Association urges FDA to heed the IOM's very clear directive.

Indeed, the recent *Report of the Surgeon General on Preventing Tobacco Use Among Youth and Young Adults* finds that tobacco companies spend more than a million dollars an hour in this country alone to market their products, and concludes that tobacco product advertising and promotions are effective, and still entice young people and other targeted populations to start using tobacco products, to continue smoking, or to switch to other more appealing products. Additionally, the Surgeon General's Report concludes that through the use of advertising and promotional activities, packaging, and product design, the tobacco industry encourages the myth that smoking makes you thin, and has especially targeted this false message to young girls.[1]

The tobacco industry has targeted its advertising promotions to women (e.g., Virginia Slims "you've come a long way, baby" campaign); to African Americans (e.g., Kool menthol cigarettes); to Native Americans (e.g., American Spirit cigarettes) and to the LGBT community ((e.g., RJ Reynolds' Project SCUM ["subculture urban marketing"] plan to market their Red Kamel brand to gay men in San Francisco and other "alternative lifestyle" areas). These campaigns have been so successful that 33% of American Indian/Alaska Natives and 19.1percent of African Americans report that they currently smoke every day or some days (as compared to 17.4% Whites), and LGBT adults and youth are twice as likely to smoke as the national average.[2] These deliberate and cynical marketing programs result in severe and deadly health consequences for these communities.

Moreover, internal tobacco industry documents and marketing practices reveal that tobacco manufacturers have modified product design and marketing to enhance product appeal to novice users, including adolescents and young adults. Much as they did for cigarettes, manufacturers of smokeless tobacco altered the pH levels of their products to lower free-nicotine delivery in "starter products" that were widely distributed as free samples and were advertised as less harsh. Once the new user had adapted to low dose products, they were encouraged through marketing to progress to higher free-nicotine brands.[3]

In addition to using misleading brand descriptors and words such as "light" and mild", the industry also designed cigarettes with higher levels of filter ventilation which not only produced deceptively low tar and nicotine numbers under machine testing, but also produced "lighter tasting" smoke, which reinforced the misleading descriptor on the packages.[4] Many health-concerned smokers reported switching to these brands as an alternative to quitting, and studies show that these

descriptors likely also promoted the initiation of smoking among youth. The Surgeon General's report cites a study showing that an estimated 50 percent of students aged 13-15 believed that "light" cigarettes contain less tar than regular cigarettes; 40 percent believed that "light" cigarettes were less harmful; and 30 percent believed that "light" cigarettes are easier to quit than regular cigarettes. Taken together, the combined effect of the industry's use of misleading brand descriptors, lower emission numbers, and "lighter" tasting smoke have undermined perceptions of health risk among smokers.[5]

Additionally, at least three recent studies that examined consumers' perceptions of color descriptors show that consumers perceive the color descriptors (such as Marlboro's use of "gold" and "silver" to replace "light" and "ultralight") in the same way as the "light" and "mild" descriptors they replaced. The Surgeon General's report cited one study showing that more than 75 percent of US adults surveyed indicated that a brand labeled as "silver" would have lower levels of tar and less health risk than a "full flavor" brand.[6] Tobacco industry documents themselves reveal that "lower delivery products tend to be featured in blue packs. Indeed, as one moves down the delivery sector, then the closer to white a pack tends to become. This is because white is generally held to convey a clean healthy association." The American Lung Association and our partners have previously urged FDA to address the issue of descriptors, including this set of comments filed in September of 2009.

In addition to the evidence demonstrating that lower-nicotine tobacco products may be a gateway to higher-nicotine products, tobacco use is also strongly associated with the use of other substances such as alcohol, cocaine, and marijuana and is considered a "gateway drug". For example, among high school male cigarette smokers, about 84 percent also drink alcohol, 53 percent smoke marijuana, 29 percent use smokeless tobacco, 8 percent use cocaine, and 5% use inhalants.[7]

For these reasons, it is essential that FDA require MRTP applications to include detailed pre- and post-market studies that specifically address the impact of the tobacco manufacturer's implicit or explicit claims about its MRTP products – *as actually used* – on populations at high risk for tobacco use, including low socioeconomic status and educational attainment, targeted racial and ethnic minorities including African Americans and Native Americans, and other targeted populations including the LGBT community and women and young women. In particular, FDA must demand studies verified by independent third parties that consider whether the advertising, labeling, package design, formulation of the tobacco product, and other promotional activities or use of words ***or color or images*** have the effect of causing nonsmokers to begin smoking; are specifically targeted to beginning smokers, adolescents, or young people; are targeted to particular vulnerable populations; or may serve or have served as a gateway to other tobacco products or other dangerous substances such as alcohol or marijuana.

Finally, the Lung Association reiterates our strong support for the Institute of Medicine's recommendation that all tobacco-industry submitted research be designed, conducted by, overseen, and/or verified by independent third parties that have been approved by the FDA in advance of the research. (Recommendation 10, IOM Report, p. 18.) As the IOM correctly found:

> It has been established in public records and *as a matter of law* that the tobacco industry has engaged in illegal and improper practices, including the destruction and manipulation of

> scientific data. As a result, the tobacco industry is profoundly isolated from the mainstream scientific community. Many major universities have policies against acceptance of tobacco funding, and many high-impact scientific and medical journals will not accept tobacco industry-supported manuscripts. The consequence of this isolation is a lack of the expertise and the resources necessary to produce high-quality science across the range of disciplines to support an application to market an MRTP.
> (Finding 10, IOM Report, p. 18)

Because of its long and notorious history of deception and lying, which is painstakingly documented by the United States District Court in *U.S. v. Philip Morris*,[8] any report or study produced by the tobacco industry is on its face suspect. Therefore, we urge FDA to require MRTP applicants to use independent third parties to design and conduct their pre- and post-market research studies, and these independent third parties must be pre-approved by the FDA.

It is clear that in order for FDA to carry out its Congressionally mandated duty to protect public health by regulating the marketing, packaging, and labeling of tobacco products, it must insist that tobacco manufacturers provide independently-verified data on the impact of its products, especially those that might be misleadingly characterized as "modified risk", on those communities most vulnerable to the industry's campaigns. Anything short of this could be lethal for hundreds of thousands of Americans.

Sincerely,

Charles D. Connor
President and Chief Executive Officer

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[1] Surgeon General's Report at pp. 30-79 and references cited therein and at pp. 112-128.
[2] Centers for Disease Control and Prevention, Behavioral Risk Factor Surveillance System Survey Data (BRFSS), 2010, unpublished data as reported by the Kaiser Family Foundation, available at http://www.statehealthfacts.org/comparetable.jsp?ind=82&cat=2&print=1; *Tobacco Use Among Sexual Minorities in the USA, 1987 to May 2007: A Systematic Review.* Lee, JG, Griffin, GK, and Melvin, CL. 2009, Tobacco Control, Vol. 18, pp. 275-282; *Smoking Out A Deadly Threat: Tobacco Use in the LGBT Community.* American Lung Association, 2010. Available at http://www.lung.org/assets/documents/publications/lung-disease-data/lgbt-report.pdf.
[3] Surgeon General's Report at pp. 530-541 and references cited therein and at pp. 603-627.
[4] Surgeon General's Report at p. 531 and references cited therein.
[5] Ibid.
[6] Surgeon General's Report at p. 532 and references cited therein.
[7] Surgeon General's Report at pp. 193-194.
[8] *U.S. v. Philip Morris, USA, Inc.*, 449 F.Supp.2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F. 3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S.Ct. 3501 (2010).