



FDA REGULATION OF TOBACCO IS A WOMEN'S HEALTH ISSUE

There is no greater action we can take to improve the health of women in America than to reduce tobacco use and its deadly effects. To accomplish this, it is critical that the U.S. Food and Drug Administration (FDA) have the authority to regulate tobacco in order to restrict deceptive marketing practices and marketing aimed at girls and women, to limit kids' access to tobacco, and to require that tobacco products are manufactured in ways that produce the least harm to those who become addicted to them.

While tobacco use is the leading preventable cause of death for both women and men, killing over 400,000 Americans every year, it has especially deleterious effects on women's health. In addition, girls and women have long been, and continue to be, specifically targeted by tobacco companies.

THE DEADLY FACTS

- More than 178,000 American women die from smoking-related diseases every year.¹
- About 80-90 percent of all lung cancer deaths among U.S. women smokers are attributable to smoking.² The risk of developing lung cancer is about thirteen times higher in female smokers than lifelong non-smokers.³
- Lung cancer death rates among women increased by more than 600% between 1950 and 2003. In 1987, lung cancer passed breast cancer as leading cause of cancer death among women.⁴
- Cardiovascular disease is the number one killer of women, taking the lives of over 460,000 women each year. A study of women <44 years of age found that there was a strong dose-relationship for myocardial infarction (MI), with a risk of 2.5 for those smoking 1 to 5 cigarettes per day, rising to 74.6 for those smoking more than 40 cigarettes per day, compared with nonsmokers.⁵
- While smoking is strongly linked to heart disease and many cancers in both men and women, it is also linked to cervical cancer and osteoporosis in women.⁶
- Smoking by women and exposure to environmental tobacco smoke significantly increases the risk of health problems to women and children, including: spontaneous abortions, fetal brain damage, low birth weight, SIDS, and mental retardation.⁷
- Currently, nearly one out of every five adult American women smoke (18.0%)⁸ and more than one out of every four high school girls is a current tobacco user (25.1%).⁹

IMPACT OF FDA REGULATION OF TOBACCO PRODUCTS ON WOMEN

Effective FDA regulation of tobacco will improve the health of all Americans, particularly women and girls. Specifically, effective FDA regulation will restrict deceptive and misleading advertising aimed at girls and women, stop tobacco companies from misleading women about so-called reduced risk products (e.g., “light” cigarettes), and help prevent illegal sales of tobacco products to girls.

Tobacco Companies Target Women and Girls

For decades, tobacco companies have successfully targeted women and girls with their products, appealing to their sense of fashion and independence.

- Cigarette companies first began targeting women in the 1920s to recruit female smokers, equating smoking with freedom and emancipation.¹⁰
- Historical data from the National Center for Health Statistics show an abrupt increase in smoking initiation among girls around 1967 – the same time advertisements for brands specifically targeted at women entered the market.¹¹
- Six years after the introduction of Virginia Slims and other brands aimed at the female market, the rate of smoking initiation of 12-year-old girls had increased by 110%. Increases among teenage girls of other ages were also substantial.¹²
- Tobacco companies have targeted young women by offering product tie-ins, such as Philip Morris’ “V Catalog” which features a variety of clothing, jewelry and household items targeted at young women and available through catalogues with Virginia Slims proof of purchase coupons. The tobacco companies have also published women’s magazines, such as “Captivate” by Brown and Williamson which features articles about fashion styles and trends as well as coupons and ads for their Capri brand cigarettes.
- Marketing cigarettes as “slims” or “thins” plays into social pressures on young women to control their weight, manage stress and appear grown-up. One study found that girls who had dieted up to once per week had twice the odds of becoming smokers, and girls who dieted more often had four times the odds of becoming smokers.¹³

While the tobacco companies claim they changed their marketing practices after the Master Settlement Agreement (MSA) with the states in 1998, empirical evidence reveals that they did not – they have instead continued to aggressively target girls and young women, among others, with their advertising (see Campaign’s website for specific examples, www.tobaccofreekids.org/reports/women). In March 2007, R.J. Reynolds launched Camel No. 9, a cigarette clearly aimed at girls and young women. Camel No. 9 has sleek packaging, flowery ads and the slogan “light and luscious.” News reports have estimated that RJR is spending between \$25 and \$50 million to launch its new product. Full-page ads are running in women’s magazines that have high youth readership such as Glamour, Cosmopolitan, Marie Claire, InStyle and Vogue. Point-of-sale marketing is expected to be heavy and is already saturating stores and bodegas in New York City.

- A study conducted by the Massachusetts Department of Health found that cigarette advertising in magazines with high youth readership actually increased by 33% after

the November, 1998 Master Settlement Agreement, in which the tobacco companies agreed not to market to kids.

- A separate study by the University of Illinois-Chicago revealed that cigarette companies increased advertising and promotions in and around retail outlets like convenience stores, where many kids hang out, after tobacco billboards were banned by the Master Settlement Agreement.¹⁴
- Finally, the Federal Trade Commission reported that in 2005 the cigarette companies spent more than \$13.1 billion (or \$35.9 million every day) marketing and promoting their products.¹⁵ This is a 95 percent increase since the tobacco companies agreed to curtail some aspects of their marketing as part of the November 1998 legal settlement with the states.

Effective FDA authority over tobacco would bring about real change in how tobacco products are marketed to women, girls, and others by allowing the agency to restrict tobacco companies from marketing their products to children and to prevent deceptive marketing that negatively impacts women's health.

Tobacco Company Claims About Reduced Risk Products Harm Women and Girls

In November 2001, the National Cancer Institute (NCI) released Monograph 13, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*. In this study, the NCI's main conclusion was that, "Epidemiological and other scientific evidence, including patterns of mortality from smoking-caused diseases, does not indicate a benefit to public health from changes in cigarette design and manufacturing over the last fifty years."¹⁶ Put differently, light and low tar cigarettes are no safer than full strength brands yet the tobacco companies marketed and sold them as safer products, particularly to individuals interested in quitting.

In fact, this public health fraud that tobacco companies have perpetrated on American smokers through the marketing of "light" and "low tar" cigarettes has affected women disproportionately. Rather than reducing harm to women, these products have discouraged quitting, with a negative impact on women's health. This women's health disaster will continue if tobacco companies are allowed to produce and market the new generation of so-called "reduced risk" products, such as RJR's Eclipse, Vector's Omni, and Brown & Williamson's Advance, the way they have in the past.

The fact that women are more likely to switch to so-called low tar brands for health reasons, combined with the lack of evidence of any positive health benefits from these products, make FDA regulation of tobacco products particularly important for women.

- Women (63%) are much more likely than men (46%) to report smoking light or ultra-light cigarettes.¹⁷
- Women smokers of light and ultralight cigarettes are also more likely (48% vs. 39%) than men who smoke those brands to say they switched to a low tar brand "just to reduce your health risk." Smokers who switch brands are twice as likely as non-switchers to believe their brand is less hazardous than others. This may explain why some studies have shown that respondents who switched to low tar cigarettes are less likely to have quit than those who have never switched.¹⁸ A 2006 study

published by the *American Journal of Public Health* 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.¹⁹

- There is no evidence that a smoker who chooses low tar and nicotine brands reduces the risk of myocardial infarction, chronic obstructive pulmonary disease or lung cancer.^{20 21} In fact, a number of studies have linked low-tar cigarettes and smokers' compensation (especially their drawing smoke from low-tar cigarettes more deeply into lungs) to increases among smokers of adenocarcinoma, a previously rare type of lung cancer that afflicts the tiniest airways of the lung.²²
- Tobacco companies continue to claim that some of their new products may reduce harm to smokers. Vector advertises Omni cigarettes with the slogan "Reduced Carcinogens, Premium Taste." Advance is marketed with the slogan "All of the taste . . . less of the toxins." RJR claims "Eclipse may present smokers with less risk of certain smoking-related diseases, compared to other cigarettes." In stark contrast, the Institute of Medicine concluded that none of the so-called "reduced risk" products now on the market have been proven to be less hazardous and may in fact increase the incidence of tobacco-related disease by deterring current smokers from quitting or encouraging new smokers to start.²³

Effective FDA regulation will ensure that tobacco companies are not allowed to make misleading claims about their products that entice girls and women to continue smoking. It will also make certain that any real advances in cigarette technology are used to reduce the overall harm of tobacco to the public health rather than as a marketing device for tobacco companies to continue to hook new smokers and maintain current ones.

EFFECTIVE FDA REGULATION OF TOBACCO PRODUCTS FOR ALL AMERICANS – MEN AND WOMEN, BOYS AND GIRLS

- The Food and Drug Administration (FDA) is the agency best equipped (in terms of expertise and experience) to regulate tobacco products. At a minimum, FDA must be provided with the authority to:
 - Restrict tobacco industry marketing, particularly marketing that appeals to kids.
 - Ensure that tobacco products are not sold illegally to children.
 - Require independent scientific testing of products and health claims.
 - Prohibit unsubstantiated health claims or claims that discourage people from quitting or encourage them to start using tobacco. As the tobacco industry prepares to market the next generation of allegedly "reduced risk" products, the FDA should have the authority to stop a repetition of the "lights" public health disaster that has disproportionately affected women.
 - Regulate the tobacco industry in the same way that it regulates other manufacturers of consumable products, including requiring disclosure of ingredients and additives and the reduction or elimination of harmful components when technologically possible.
- FDA would monitor the tobacco industry in the same manner it oversees every other food, drug or device manufactured in the United States.

- FDA regulation of tobacco products would allow Americans, for the first time ever, to make truly informed decisions about the use of tobacco products by requiring companies to disclose information on safety claims as well as the harm caused by any naturally occurring constituents or ingredients added to tobacco products.
- FDA regulation of tobacco products will help to counteract the marketing efforts of tobacco companies to American men and women of all ages, and it will help to begin to reverse the deadly toll that tobacco has taken on younger and older generations of Americans.

¹ U.S. Centers for Disease Control and Prevention, "Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses – United States, 1997-2001," *Morbidity and Mortality Weekly Report (MMWR)* 53 SS-2 <http://www.cdc.gov/mmwr/PDF/wk/mm5425.pdf>, July 1, 2005.

² U.S. Department of Health and Human Services. *Women and Smoking: A Report of the Surgeon General*. Atlanta: US Department of Health and Human Services, Public Health Service, Centers for Disease Control, Office on Smoking and Health, 2001. http://www.cdc.gov/tobacco/sgr/sgr_forwomen/index.htm

³ U.S. Department of Health and Human Services. *The Health Consequences of Smoking: A Report of the Surgeon General*, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office on Smoking and Health, 2004. http://www.cdc.gov/tobacco/sgr/sgr_2004/index.htm

⁴ Department of Health and Human Services. *Women and Smoking: A Report of the Surgeon General, 2001*. See also, American Cancer Society. *Cancer Facts and Figures 2006*. Atlanta: American Cancer Society, 2006. <http://www.cancer.org/downloads/STT/CAFF2006PWSecured.pdf>

⁵ American Heart Association. *Heart Disease and Stroke Statistics – 2007 Update*. Dallas, Texas, 2006. <http://www.heart.org/downloadable/heart/1140534985281Statsupdate06book.pdf>

⁶ Husten, C.G., et al., "Trends and Effects of Cigarette Smoking among Girls and Women in the United States, 1965-1993" *Journal of the American Medical Women's Association (JAMWA)*, 1996, Vol. 51, No. 1&2. See also, *The Health Consequences of Smoking: A Report of the Surgeon General, 2004*.

⁷ On spontaneous abortions, see, e.g., Chatenoud, L., et al., "Paternal and Maternal Smoking Habits Before Conception and During the First Trimester: Relation to Spontaneous Abortions," *Annals of Epidemiology* 8 (8): 520-26 (November 1998); Windham, G.C., et al., "Parental Cigarette Smoking and the Risk of Spontaneous Abortion," *American Journal of Epidemiology* 135(12): 1394-403 (June 15, 1992); Kline, J., et al., "Smoking: A Risk Factor for Spontaneous Abortions," *New England Journal of Medicine* 291(15): 793-96 (October 1977).

On early delivery, low birthweight babies, and growth problems after birth, see e.g., Wiborg, K., et al., "Smoking During Pregnancy and Pre-term Birth," *British Journal of Obstetrics and Gynaecology* 103(8): 800-05 (August 1996); Dejin-Karissou, E., et al., "Does Passive Smoking in Early Pregnancy Increase the Risk of Small-for-Gestational-Age Infants?," *American Journal of Public Health* 88(1): 1523-27 (October 1998); Martin, T.R. & M.B. Bracken, "Association of Low Birth Weight with Passive Smoke Exposure in Pregnancy," *American Journal of Epidemiology* 124(4): 633-42 (October 1986); Jones, G., et al., "Maternal Smoking During Pregnancy, Growth, and Bone Mass in Prepubertal Children," *Journal of Bone and Mineral Research* 14(1): 146-51 (January 1999); Eskenazi, B. & J.J. Bergmann, "Passive and Active Maternal Smoking During Pregnancy as Measured by Serum Cotinine, and Postnatal Smoke Exposure. I. Effects on Physical Growth at 5 Years," *American Journal of Epidemiology* 142(9 Supplement): S10-18 (November 1995); Elwood, P.C., et al., "Growth of Children from 0-5 Years: With Special Reference to Mother's Smoking in Pregnancy," *Annals of Human Biology* 14(6): 543-57 (Nov. – Dec. 1987).

On SIDS, see, e.g., Cooke, R.W., "Smoking, Intra-Uterine Growth Retardation and Sudden Infant Death Syndrome," *International Journal of Epidemiology* 27(2): 238-41 (April 1998).

On impaired intellectual development, see e.g., Frydman, M., "The Smoking Addiction of Pregnant Women and the Consequences on the Offspring's Intellectual Development," *Journal of Environmental Pathology, Toxicology and Oncology* 15(2-4): 169-72 (1996); Olds, D.L., et al., "Intellectual Impairment in Children of Women Who Smoke During Pregnancy," *Pediatrics* 93(2): 221-27 (February 1994) [correction published in 93 (6, Pt 1): 973 (June 1994)].

⁸ U.S. Centers for Disease Control and Prevention (CDC), "Cigarette Use Among Adults – United States, 2006," *Morbidity and Mortality Weekly Report (MMWR)* Vol. 56 No. 44, November 9, 2007. <http://www.cdc.gov/mmwr/PDF/wk/mm5644.pdf>

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- ⁹ U.S. Centers for Disease Control and Prevention (CDC), "Youth Risk Behavior Surveillance – United States, 2005," *Morbidity and Mortality Weekly Report (MMWR)* 55(SS-5): 1145-1148, June 9, 2006. <http://www.cdc.gov/mmwr/PDF/ss/ss5505.pdf>
- ¹⁰ Ernster, Virginia, "Mixed Messages for Women" *New York State Journal of Medicine*, July 1985.
- ¹¹ Pierce J.P., Lee L., Gilpin E.A., "Smoking initiation by adolescent girls, 1944 through 1988: An association with targeted advertising," *JAMA*, 1994, Vol. 271, No. 8.
- ¹² *Ibid.*
- ¹³ Austin, S, Gortmaker, S. "Dieting and Smoking Initiation in Early Adolescent Girls and Boys: A Prospective Study," *American Journal of Public Health* 2001;91:446-450.
- ¹⁴ Wakefield, Melanie, et al., "Changes at the point of purchase for tobacco following the 1999 tobacco billboard advertising ban." University of Illinois at Chicago. Research Paper Series, No. 4 July 2000.
- ¹⁵ U.S. Federal Trade Commission (FTC), *Cigarette Report for 2004 and 2005*, 2007 [data for top five manufacturers only] <http://www.ftc.gov/reports/tobacco/2007cigarette2004-2005.pdf>
- ¹⁶ National Cancer Institute. Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02-5074, October, 2001. <http://cancercontrol.cancer.gov/tcrb/monographs/13/>.
- ¹⁷ Pillitteri, J.L., et al., "Smokers beliefs about light and ultralight cigarettes," 2001; *Tobacco Control* 10(Suppl):i17-i23 (and underlying data supplied by the authors).
- ¹⁸ Giovino, G. et al., "Attitudes, Knowledge, and Beliefs About Low-yield Cigarettes Among Adolescents and Adults," in *The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes; Report of the NCI Expert Committee*. National Institutes of Health. National Cancer Institute. Smoking and Tobacco Control Monograph 7.
- ¹⁹ 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.
- ²⁰ Djordjevic, M.V., et al., "Nicotine Regulates Smoking Patterns," *Preventive Medicine* 1997 Jul-Aug;26(4):435-40.
- ²¹ Farrow DC and J Samet. Identification of the high risk smoker. *Clinics in Chest Medicine* 1991;12(4): 659-68.
- ²² See, e.g., Stellman, S.D., et al., "Risk of Squamous Cell Carcinoma and Adenocarcinoma of the Lung in Relation to Lifetime Filter Cigarette Smoking," 1997 August; *Cancer* 80(3): 382-88. Russo, A., et al., "Changes in Lung Cancer Histological Types in Varese Cancer Registry," *European Journal of Cancer* 1997 September; 33(10): 1643-47. Osann, K.E., "Epidemiology of Lung Cancer," *Current Opinions in Pulmonary Medicine* 1998 July; 4(4): 198-204. Wynder, E.L. & J.E. Muscat, "The Changing Epidemiology of Smoking and Lung Cancer Histology," *Environmental Health Perspectives* 1995 November; 103(Supplement 8): 143-48. See, also, BBC News, "Low Tar Cigarettes Linked to Cancer Upsurge," <http://news.bbc.co.uk> (November 18, 1999).
- ²³ "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction," National Academy Press, February 22, 2001.