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September 23, 2009

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

Re: FDA-2009-N-0294

Dear Sir/Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to provide comments on the implementation of the Family Smoking Prevention and Tobacco Control Act.

Since 1924, the American Heart Association has dedicated itself to building healthier lives free of 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, our efforts have contributed to a 30.7% reduction in deaths from coronary heart disease and a 29.2% reduction from stroke – an early achievement of our goal. While we've made significant progress, we continue to work toward needed reductions in the risk factors that lead to heart disease and stroke as well as eliminating disparities in care.

Reducing tobacco use and eliminating exposure to secondhand smoke are two important strategies for reducing the incidence and risk of cardiovascular disease and stroke. Smoking is a major cause of cardiovascular disease. Of the approximately 440,000 Americans who die from smoking each year, 150,000 people or about 35% of these deaths are from cardiovascular disease. Smokers are two to four times more likely to develop coronary heart disease than non-smokers, and two to three times more likely to die from it. Smokers are also at increased risk for heart attack, stroke, and peripheral vascular disease. Unfortunately, non-smokers who are exposed to secondhand smoke face similar risks. Secondhand smoke increases the risk of heart disease by 25 to 30% and results in an estimated 46,000 deaths from heart disease each year due to secondhand smoke exposure.

AHA is therefore very pleased that the Food and Drug Administration (FDA) has been given the authority to regulate the manufacture, marketing, and distribution of tobacco products. FDA regulation of the tobacco industry will have a dramatic effect on public health, saving countless lives and reducing future health care costs. AHA would like to work with the Agency as you implement your new authority. The Association can serve as a resource to the FDA and provide scientific expertise as you develop regulations to implement the new law, and we would be happy to support your efforts to implement the Act.

AHA offers the following comments on the specific topic areas included in the *Federal Register* notice.

Federal, State, and Local Government Collaboration

Because smoking is a major public health concern, a number of federal, state, and local agencies have a longstanding interest in tobacco control. Collaboration with these agencies will be essential. AHA encourages the FDA to work closely with other federal agencies that have responsibility for tobacco control efforts such as the Centers for Disease Control and Prevention (CDC), the Interagency Committee on Smoking and Health (ICSH), the Federal Trade Commission (FTC), and the National Institutes of Health (NIH), among others.

In addition to collaborating with federal agencies, the FDA should work closely with state and local agencies to implement its new authority, particularly on issues related to the promotion and advertising of tobacco products, the prevention of tobacco use by minors, and enforcement. To ensure that state and local officials are aware of the Agency's actions and have an opportunity to provide input, the FDA should maintain a regular dialogue with state and local agencies. The July 8th conference call between FDA, CDC, and state and local health officials may provide an appropriate model for future discussions between the groups.

AHA also suggests that the Agency clearly define its role in tobacco regulation. Because so many federal, state, and local agencies play a role in tobacco control, there is the potential for confusion. For example, state and local agencies may question if their role and responsibilities will change due to the FDA's new authority to regulate tobacco.

New Product Submission and Approval

The Act requires tobacco manufacturers to submit all new tobacco products to the FDA for premarket review. When evaluating the application, the law instructs the FDA to take a number of factors into consideration including whether permitting the product to be marketed would be appropriate for the protection of public health, the increased or decreased likelihood that existing users of tobacco products will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using them. AHA understands these provisions to mean that a new tobacco product should not be approved if it would increase the number of people addicted to tobacco or if the new product would be more harmful than other tobacco products already on the market. AHA requests that the FDA place a significant emphasis on these factors when conducting premarket reviews.

We also recommend that the FDA pay special attention to new smokeless tobacco products such as “orbs” and “strips” and any associated health claims by their manufacturers. Manufacturers may claim that such products protect the public health because they do not produce secondhand smoke and do not require the user to inhale smoke into their lungs, implying that the user would have a reduced risk of lung cancer or respiratory disease. While any “improvements” in tobacco products should be considered, the FDA’s evaluation of a tobacco product cannot focus on the product’s impact on one disease state or condition. The Agency’s evaluation must consider all of the disease states affected by tobacco as well as the overall burden of disease, including the product’s effect on cardiovascular disease, instead of focusing on one specific condition.

AHA is currently developing a paper that examines the impact of smokeless tobacco on cardiovascular diseases. We would be pleased to provide the FDA with a copy of the paper when it is published in 2010.

Product Ingredient Disclosure

The new law requires tobacco manufacturers to provide the FDA with a list of ingredients for each of its products. The disclosure must include all product constituents and smoke constituents, a description of the nicotine content and delivery, and all documents related to the health, toxicological, behavioral or physiological effects of the products.

AHA strongly supports the product disclosure requirement; we support comprehensive disclosure of all tobacco constituents. And we appreciate the Agency’s recent action to quickly implement this requirement.

To ensure that this information is of maximum utility, we urge the Agency to make this information publicly available, and to educate the public about the health risks associated with specific ingredients. Tobacco companies have had to report this information to the Department of Health and Human Services since 1986 and Texas and Missouri also have disclosure laws; however, this information was not provided on a brand by brand basis and was not made public. Unfortunately, without public disclosure, this information is of little use. The FDA should reverse this trend and make ingredient information available to the public. Public disclosure of the ingredients will allow consumers to make informed choices regarding use of tobacco products.

Prevention

AHA appreciates the emphasis the FDA is placing on prevention as part of its implementation of the Act; reducing the incidence and prevalence of tobacco use will save countless lives. Because tobacco prevention is a new area for the Agency, we reiterate our recommendation that the FDA work with other federal agencies already focused on this issue. Coordination with the CDC’s Office on Smoking and Health will be especially critical.

We also recommend that the FDA collaborate with other agencies that have a direct link to target populations such as minors. Studies have shown that approximately 80% of all smokers began

as teens.¹ And each day more than 3,500 children try a cigarette for the first time; 1,100 of whom will become new, regular daily smokers.² The FDA should explore working with the Department of Education (DOE), which has a direct link to school-age children, to combat tobacco use among minors. In addition to collaborating on educational campaigns to discourage tobacco use, the FDA should also partner with the DOE and CDC to combat use of non-traditional tobacco products in schools. New products such as orbs and strips do not look like tobacco, are difficult to recognize as such, and are easier to conceal. Therefore, tobacco use among students may increase as orbs and strips are easier to use while avoiding detection. School administrators, teachers, and parents should be taught how to recognize these products and the risks associated with them.

The Agency must also strictly enforce all youth access and marketing restrictions. And, as previously stated, the FDA should publicly disclose product ingredient lists. Educating the public about the types of ingredients a tobacco product contains may discourage non-smokers from starting and may encourage smokers to quit.

Tobacco Use by Specific Groups

AHA is pleased that the FDA is examining the use of tobacco by specific population groups including minors, women, and racial and ethnic minorities. As discussed above, we are concerned by the number of minors who begin smoking each year and we urge the Agency to place a special focus on advertising and marketing geared toward children and to consider how new products such as tobacco orbs and strips may increase tobacco use by this population.

We are also concerned by current advertising and marketing campaigns that appear to target women and girls. In the past two years, tobacco manufacturers have launched an aggressive campaign that depicts smoking as feminine and fashionable in an attempt to hook young girls on smoking at an early age. Colorful packages, “purse packs”, “super slim” cigarettes, and promotional giveaways of cell phone jewelry, cosmetics, purses, and wristbands are all intended to appeal to a young female audience.³ Strict enforcement of the Act’s provisions intended to curtail these tactics, such as the ban on free giveaways of non-tobacco items, the ban on packages containing less than 20 cigarettes, the ban on flavored cigarettes, and the advertising restrictions in publications with significant teen readerships will be crucial to decreasing the prevalence of tobacco use among these populations.

Another area of significant concern for the Association is the apparent targeting of consumers in economically depressed communities. AHA requests that the FDA examine tobacco manufacturer advertising and marketing tactics in economically depressed communities and compare those tactics to those utilized in non-economically depressed communities, especially as they relate to the marketing of new products.

¹ Surgeon General. Preventing Tobacco Use Among Young People, 1994.

² Substance Abuse and Mental Health Services Administration. Office of Applied Studies (2008). Results from the 2007 National Survey on Drug Use and Health: National Findings. Rockville, MD.

³ American Heart Association, American Cancer Society Action Network, American Lung Association, Robert Wood Johnson Foundation, and Campaign for Tobacco-Free Kids. Deadly in Pink. February 18, 2009.

We are also concerned by the dangers of tobacco products flavored with menthol, and urge the Agency to commence its study on the use of menthol in cigarettes and its impact on public health as soon as possible. Menthol allows smokers to inhale more deeply and speeds the absorption of nicotine, which unfortunately increases health risks, makes the product easier to smoke, and increases the product's addictive properties. Menthol cigarettes are a critical issue for tobacco control, particularly in the African-American population where their use is significantly higher.

Given the known health risks, we urge the FDA to consider banning menthol in tobacco products, or, at a minimum, limiting the amount of menthol a tobacco product can contain. We recommend that the Agency look at the available science, and consider the public health impact – including the effect that such a ban would have on the millions of addicted users – before acting.

Some of these issues may be addressed at the upcoming “Second Conference on Menthol Cigarettes” which is advertised as examining a broad range of scientific questions associated with the toxicity, pharmacology, epidemiology, prevention and marketing of these products.⁴ Members of the Agency's staff or its Tobacco Products Scientific Advisory Committee may find the conference and its content useful as the Committee begins to develop its report on this issue.

Tobacco Addiction

AHA recommends that the Agency take a two-prong approach when addressing tobacco addiction. First, the FDA should conduct research and confirm the nicotine levels in tobacco products. Confirmation of the nicotine level in new products is especially important as it is our understanding that some manufacturers are increasing the amount of nicotine in their new products.

Second, the FDA should task the Tobacco Products Scientific Advisory Committee with evaluating whether a limit on the nicotine content of tobacco products should be established. The Committee should, for instance, examine whether a high nicotine level results in people smoking fewer cigarettes because they receive a larger dose of nicotine per cigarette; or whether a lower nicotine limit would result in people smoking a greater number of cigarettes and inhaling more deeply in order to obtain a high amount of nicotine. Any limit on nicotine must be science-based and should be designed to decrease tobacco addiction, and ultimately, tobacco use.

Smoking Cessation

As with prevention, AHA recommends that the FDA collaborate with the CDC's Office on Smoking and Health to promote smoking cessation.

We also request that the Agency closely examine any product claiming to facilitate smoking cessation. We are concerned that smokeless tobacco products and e-cigarettes may be marketed as smoking cessation tools. The FDA should require manufacturers of these products to provide

⁴ Second Conference on Menthol Cigarettes. Convened by the American Legacy Foundation in collaboration with the University of Maryland College Park and the Tobacco Related Disease Research Program at the University of California. October 19-20, 2009. Washington, DC.

scientific evidence supporting their use as an effective cessation product. We ask that the Agency also examine the available evidence indicating whether such products can be a pathway to addiction or can sustain an existing addiction to tobacco products, and that manufacturers be required to disclose such information in their possession to the Agency.

In addition, manufacturers should be prohibited from marketing a tobacco product as a cessation tool claiming that it reduces health risk if it only impacts one disease state. Using an earlier example, a smokeless tobacco manufacturer may claim that its product reduces the risk of lung cancer or respiratory disease and attempt to market the product as a healthier alternative or a smoking cessation tool. However, if the product does not reduce the overall burden of disease, the product is not a cessation tool as it is not producing healthier lives.

AHA's upcoming paper on the impact of smokeless tobacco on cardiovascular disease addresses the potential role of smokeless tobacco for cardiovascular risk reduction, and we will provide this paper to FDA when it is published in 2010.

Data Collection

AHA requests that any data collected by the Agency be made available to the research community. Industry-provided research submitted to the FDA should also be made accessible to the public in an organized fashion.

Products with Reduced Harm/Risk Claims

The Act requires tobacco manufacturers to get explicit FDA approval before marketing a product that makes a reduced harm or reduced risk claim. Manufacturers will be required to provide scientific evidence in support of the claim in order to obtain FDA approval. AHA strongly supports this requirement.

Claims made by tobacco manufacturers should be held to the same standard as any other FDA-regulated product. Drug and device manufacturers are required to submit substantial scientific evidence in order to obtain FDA approval, and food manufacturers are required to meet evidence standards before making a health claim. We see no reason why tobacco manufacturers should be exempt from this same type of requirement.

In fact, tobacco manufacturers' long history of intentionally misleading consumers about the safety of their products supports arguments that tobacco products should be held to an even higher standard. As the FDA is aware, tobacco manufacturers were found guilty of violating civil racketeering laws in 2006 and that judgment was upheld in May of this year. According to the original court's finding:

... [the tobacco industry] survives, and profits, from 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. Defendants have known these facts for at least 50 years or more. Despite that knowledge, they have consistently, repeatedly, and with enormous

skill and sophistication, denied these facts to the public, to the Government, and to the public health community...⁵

It is clear that the tobacco industry cannot be trusted to self-regulate or self-substantiate any type of reduced harm or reduced risk claim. The independent scientific scrutiny by the FDA of any proposed claim is crucial to ensure that consumers are not misled by this type of deceptive marketing practice again. We reiterate our strong support for this requirement.

In addition to the reduced harm/risk requirement, the law also bans the use of descriptive terms such as “light”, “low”, or “mild”. AHA strongly supports this ban. Terms such as “light”, “low”, and “mild” falsely convey that these products are less harmful or contain fewer harmful constituents. Tobacco manufacturers use these terms to communicate that one product is healthier or causes fewer health problems than another. Unfortunately, this lessens the motivation for smokers to quit. Smokers may instead switch from a “regular” tobacco product to a “light” or “low” product rather than quit smoking altogether.

But banning the use of these terms, as over 40 countries have already done, provides tobacco manufacturers with one less way to mislead consumers about the health risks associated with their products.

However, as past experience has taught us, tobacco manufacturers have a history of circumventing restrictions. Tobacco manufacturers may attempt, as they’ve done in other countries that have instituted a ban, to use other methods to convey the same type of message. For instance, companies may color code their packages or use numbers or symbols to indicate that a product is “low”, “light”, or “mild” without using the actual terms on the package or in advertising. AHA recommends that the Agency watch for these attempts to sidestep the ban and prohibit them whenever possible.

On a related note, AHA is aware that several tobacco manufacturers recently filed a suit challenging both the requirement that they scientifically justify any reduced risk claims and the ban on descriptive terms, as well as the graphic warning label requirements and several of the marketing and advertising restrictions. According to the suit, these provisions are in violation of the First Amendment’s Freedom of Speech. We hope the FDA and the Administration will strongly defend itself against the suit, and will move forward with plans to implement these provisions of the Act as mandated.

Enforcement

Enforcement is an important component of the new law and AHA encourages the FDA, in conjunction with its state and local partners, to enforce the law aggressively. While the FDA will hold primary responsibility for monitoring and enforcing compliance with the new tobacco requirements, states will also play a vital role. We encourage states to monitor compliance with outdoor and point-of-sale advertising restrictions, vending machine restrictions, and sales

⁵ U.S. District Judge Gladys Kessler. U.S. District Court for the District of Columbia. *United States of American v. Philip Morris USA, Inc.* Civil Action No. 99-2496 (GK). August 17, 2006.

restrictions to underage buyers, and encourage the FDA to provide guidance to states on how to notify them of violations of the law. We also recommend that states consider strengthening laws related to underage possession and use of tobacco products. Although minors are prohibited from purchasing cigarettes, there is no age restriction on the possession and use of tobacco products. AHA would like to see these laws changed.

AHA also suggests that the FDA institute some method of self-reporting that would allow members of the public to report violations either by telephone or on online.

Research and Testing

AHA encourages the FDA to work with other federal agencies such as the NIH to conduct research in the following areas.

First, the FDA should examine tobacco product ingredients. This research should focus on why a specific ingredient is added to a tobacco product, what the ingredient's purpose is, and what the ingredient's health impact is, especially when it is burned versus when it is in a non-combustible product. The Agency should examine products on an individual basis as well as compare product ingredients across brands. This information will be useful as the Agency develops its list of harmful or potentially harmful constituents and considers establishing product standards.

Second, the FDA should research the use of menthol in tobacco products. We'd like to see the Agency examine the role on menthol in the manufacturing process, its effect on tobacco addiction, and its impact on health, particularly on cardiovascular disease.

Third, the Agency should examine if there are changes that could be made to the manufacturing process, such as the non-use of specific ingredients, which would result in reduced health risks, including reduced cardiovascular risks.

Fourth, we recommend that FDA examine methods that could result in an improved success rate for smoking cessation therapies. For example, the Agency could research whether the use of genetic testing could personalize smoking cessation strategies by identifying those therapies with the greatest likelihood of success for each individual.

Advertising and Marketing of Tobacco Products

AHA is pleased that the Act contains strong advertising and marketing restrictions. The law requires the reinstatement of the Agency's 1996 rule restricting tobacco marketing and sales to minors and provides the FDA with authority to further limit marketing when necessary to protect public health. This authority will allow the Agency to restrict advertising and marketing tactics that target minors, provide inaccurate information, or misrepresent health risks. We are hopeful that these restrictions will lead to a reduction in the number of underage smokers, as well as reduce the overall incidence and prevalence of tobacco use.

We are, however, concerned that the tobacco industry may attempt to circumvent the advertising and marketing restrictions. Tobacco manufacturers may develop new marketing tactics that are not specifically prohibited by the Act or the FDA, but have the same end results. Therefore, we

urge the FDA to closely monitor new advertising and marketing techniques. State and local officials should be able to assist the Agency in these efforts.

We also repeat our request that the FDA defend the advertising and marketing restrictions contained in the Act. According to the suit filed by the tobacco industry, the “Act’s provisions cut off nearly every currently available avenue of tobacco advertising and marketing... and run afoul of [their] right to free speech”.⁶ AHA disagrees with the industry’s claims. Tobacco manufacturers may still advertise and market their products within the limitations established by the Act; limitations that were carefully crafted not to violate the First Amendment Freedom of Speech.

Label Statements and Warnings

AHA strongly supports the new label statement and warning requirements. Although tobacco products have contained warning statements for over 40 years, the current statements have limited effectiveness. The current warning statements are 25 years old and limited in number. Unfortunately, consumers have become desensitized to the warnings and many may no longer even notice the statements on the tobacco package.

Label statements and warnings have great potential to be important sources of information. They can encourage consumers to quit smoking and inform them of the extent of the health risks. Therefore, we are pleased that the Act mandates the use of nine new label statements that warn consumers of the *specific* health risks that tobacco products impose. The new statements should help consumers understand that tobacco use is not just an unhealthy habit, but an activity that causes very serious and significant health effects.

We also are pleased that the Act includes a requirement for large color graphics depicting the negative health consequences of smoking to accompany the label statements. Colorful, graphic warnings have been found to be a marked improvement over plain text warnings. For example, after the Canadian government implemented new graphic warnings in 2002, 90% of smokers noticed the new warnings, 43% were more concerned about the health effects of smoking, 44% felt an increased motivation to quit smoking, and 21% resisted the temptation to smoke on one or more occasion.⁷ As the Agency implements this requirement, we suggest that the FDA look to the warning labels in Canada as a successful example. The Canadian warnings are colorful, use pictures, and include a clear and easily understandable message.

We look forward to seeing these requirements implemented and encourage the FDA to issue implementing regulations as soon as possible. We also encourage the Agency to establish a process to periodically review and revamp the label statements and warnings to ensure that they remain fresh, effective and strong.

⁶ Commonwealth Brands, Inc; Conwood Company, LLC; Discount Tobacco City and Lottery; Lorillard Tobacco Company; National Tobacco Company LP; and R. J. Reynolds Tobacco Company v. United States of America; U.S. Food and Drug Administration; Margaret Hamburg, Commissioner of the FDA; and Kathleen Sebelius, Secretary of the U.S. Department of Health & Human Services. U.S. District Court for the Western District of Kentucky: Bowling Green Division. September 2009.

⁷ World Health Organization. The Tobacco Atlas. Dr. Judith MacKay and Dr. Michael Eriksen. 2002. Pg. 78.

In addition, AHA recommends that the Agency consider expanding the label statement and warning requirement to include information on smoking cessation resources. The FDA should require manufacturers to include referrals to government-run smoking cessation resources such as 1-800-quit-now and www.smokefree.gov on tobacco product packages and advertising. By including these resources along with the required label statements and warnings, tobacco users would not only be told how bad tobacco use is, but also how to quit.

Tobacco Product Standards

The new law allows the FDA to establish product standards for tobacco products if appropriate for the protection of public health, and bans the use of flavors, herbs, and spices that are characterizing flavors in the product or the product's smoke. AHA supports these provisions and we are particularly excited by the ban on flavored cigarettes; flavored cigarettes appear to have only one purpose – to attract underage smokers.

In order to ensure that the ban on flavored cigarettes is effective, AHA recommends that the Agency develop a stringent definition of “characterizing flavor”. As AHA has previously expressed in a joint communication with the American Cancer Society Cancer Action Network, American Lung Association, and Campaign for Tobacco-Free Kids, we support a definition that includes the following components:

A cigarette shall be deemed to have a characterizing flavor if the cigarette or any component (including but not limited to the tobacco, paper or filter) or its smoke imparts a distinguishable taste or aroma other than tobacco or menthol either prior to consumption or during consumption.

A product will be deemed to have a characterizing flavor if it or any component part thereof is advertised or marketed as having or producing a flavor, taste, or aroma other than tobacco or menthol.

The definition must be clear and explain what qualifies as a flavored product. The definition should also be accompanied by guidance directed to tobacco manufacturers, retailers, and enforcement personnel that explains what is and what is not allowed. Retailers and enforcement personnel may need assistance determining what products violate the characterizing flavor ban.

We also encourage the FDA to monitor the tobacco industry's response to the ban and to be leery of any attempts to evade the flavoring ban. We are concerned that tobacco manufacturers may recharacterize their flavored cigarettes as other products that they claim are not subject to the ban such as “little cigars”. The Agency should make clear that any flavored tobacco product, no matter the type and no matter how marketed, is prohibited.

Sale and Distribution of Tobacco Products

As previously discussed under ‘enforcement’, AHA recommends that the FDA work with states to monitor compliance with sales restrictions to underage buyers and to encourage states to adopt laws prohibiting not just the sale of tobacco product to minors, but also their use and possession.

We also look forward to the development of regulations that address sales that are conducted through means other than a direct, face-to-face exchange between retailer and consumer. The regulations should be designed to erect additional barriers to prevent minors from purchasing tobacco products over the Internet, as well as purchases by tax evaders using the Internet to avoid paying state taxes on tobacco products.

Manufacturing Restrictions and Facilities Control

AHA recommends that the FDA conduct regular inspections of tobacco product manufacturing facilities. The Agency should assign inspectors to domestic as well as foreign manufacturing facilities that export tobacco products to the United States. Internationally-produced products should be periodically tested to make sure they comply with U.S. law.

This requirement would bring tobacco products into line with other products regulated by the Agency. The FDA periodically inspects the manufacturing facilities for drugs, devices, food, and cosmetics, and we believe tobacco products should be held to the same standard.

Other

AHA requests that the FDA consider the issue of secondhand smoke when exercising its new regulatory authority. We understand that the Agency believes secondhand smoke may be beyond its purview,⁸ but we believe this is an incorrect interpretation of the law. The Act provides the FDA with the authority to require changes in current and future tobacco products to protect public health. This authority includes the ability to require a reduction or elimination of harmful ingredients, additives, and constituents, including smoke constituents.

We believe this authority extends to any harmful constituent – including secondhand smoke. As mentioned above, approximately 46,000 non-smokers die from coronary heart disease each year due to secondhand smoke. And even brief exposure to secondhand smoke can cause blood platelets to become more adhesive, damage the lining of the blood vessels, and decrease coronary flow velocity, which elevates the risk of heart attack. Since we are not aware of any language in the law that restricts the effects of the harmful constituents to the individual user of the tobacco product, it appears that the Agency has the authority to address the issue of secondhand smoke.

Conclusion

In closing, we reiterate our appreciation for the opportunity to contribute to the public dialogue on FDA regulation of tobacco. Tobacco use has a devastating effect on public health and we are pleased that the Agency has been given the authority to stop harmful tobacco manufacturer practices that appeal to children, mislead consumers, and lead to over 440,000 deaths – many from cardiovascular disease – each year.

We look forward to working with you on this issue and we stand prepared to support the Agency's efforts to decrease the incidence and prevalence of tobacco use.

⁸ Transcript. FDA/CDC conference call with state and local health officials. July 8, 2009.

American Heart Association
September 23, 2009

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If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Regulatory Affairs Manager, at 202-785-7908 or susan.k.bishop@heart.org.

Sincerely,

A handwritten signature in black ink that reads "Nancy A. Brown". The signature is written in a cursive style with a long horizontal flourish at the end.

Nancy A. Brown
Chief Executive Officer
American Heart Association