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Division of Dockets Management, HFA-305  
Food and Drug Administration  
U.S. Department of Health and Human Services  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

RE: Docket Number FDA-2009-N-0294

Dear Colleagues:

On behalf of the North American Quitline Consortium (NAQC), I would like to thank FDA for the opportunity to provide information and share views on the agency's new authority to regulate tobacco products. NAQC strongly supports the FDA's new authority and stands ready to support the agency's regulatory efforts. It is our hope that implementation of the Family Smoking Prevention and Tobacco Control Act will have a significant, positive impact on the health of millions of Americans for years to come.

As you may know, a quitline is a health service that offers telephone support – information, counseling, medication and other support – for people who want to quit using tobacco. Quitlines exist in all 50 states, the District of Columbia, Puerto Rico and Guam as well as all 10 Canadian provinces, Nunavut and the Northwest Territories; and Mexico. NAQC is a non-profit professional organization that aims to maximize the access, use and effectiveness of quitlines; provide leadership and a unified voice to promote quitlines; and offer a forum to link those interested in quitline operations. NAQC is comprised of over 400 quitline professionals at state and provincial health departments, quitline service provider organizations, research institutes and national organizations in the United States and Canada. The Consortium enables professionals from these organizations to learn from each other and to improve quitline services.

NAQC recommends that FDA should:

1. Include 800-QUIT-NOW, a toll-free number that links callers with their state quitlines, and [www.smokefree.gov](http://www.smokefree.gov), a website that contains quitting information, on all label statements and warnings for tobacco products. In addition, NAQC recommends that the number and website should be required on all tobacco product advertising including point-of-sale advertising. Such action will encourage tobacco users to think about quitting and link those who want to quit with effective no-cost services.
2. Take full advantage of FDA's broad authority around dissemination of information to educate consumers about effective cessation options. Such action will make tobacco

users more aware of effective services that exist in their communities and will encourage them to use the services.

3. Decrease the allowable level of nicotine in all tobacco products to a non-addictive level. Such action will give tobacco users the opportunity to make a true choice -- *one not influenced by addiction* -- about using tobacco products.
4. Conduct definitive research on the link between menthol and the higher burden of tobacco-related diseases and lower rate of cessation among menthol users. Such action may help in the battle to prevent youth from using menthol-flavored products as “starter products” and to make it easier for tobacco users, especially African Americans and Hispanics, to quit.

More detail and supporting arguments for each recommendation are provided below, along with background information on quitlines.

### **Overview of Quitlines**

Quitlines are a health service that offers telephone support – information, counseling, medications and other support – for people who want to quit using tobacco. Quitline services generally include telephone counseling along with a range of services such as: mailed materials, referrals to other cessation services, taped messages or web programs, the provision of nicotine replacement therapies (NRTs) and other medications or assistance in obtaining them, and language- or culturally-appropriate services directed toward specific state populations.<sup>1</sup> A snapshot of the services available in each state is shown on the map at [www.NAQuitline.org](http://www.NAQuitline.org).

In 1992, after research demonstrated that telephone-based counseling for tobacco cessation is an effective treatment, the California Department of Health launched the first statewide telephone counseling service to help smokers quit. By mid-1990's, Massachusetts, Arizona and Oregon had launched quitlines. The number of states and provinces in North America offering quitline services for smokers and other tobacco-users increased exponentially in the late 1990's<sup>2</sup>. In the U.S., this increase in quitlines was driven, in large part, by the influx of funds from the states' Master Settlement Agreement with the tobacco industry; in Canada, a six-province pilot study funded by Health Canada helped drive adoption of this new intervention. Today, 50 states, the District of Columbia, Puerto Rico and Guam; and all 10 Canadian provinces, Nunavut and the Northwest Territories; and provide tobacco cessation services to their residents through local quitlines. In Mexico, a national quitline was launched in October 2007.

The impact of quitlines in the U.S. has been extensive and impressive. Data from NAQC's most recent annual survey of quitlines<sup>3</sup> shows that in fiscal year 2008, U.S. quitlines received over 650,000 calls and reached 1 to 2 percent of all U.S. smokers. The median budget for state quitline services increased from \$622,000 in 2005 to \$994,000 in 2008. States invested an average of \$3.33 per adult smoker in quitline services, with a range from \$0.08 to \$24.05. All state quitlines offer proactive counseling services – as recommended by the U.S. Public Health Services clinical guideline on tobacco dependence treatment<sup>4</sup>. In addition, all quitlines reported having counseling services available at least 5 days per week, and at least 8 hours per day. Fifty-one state quitlines provided counseling in Spanish, and 52 quitlines sent specialized

materials to special populations, including pregnant women, smokeless tobacco users, racial/ethnic populations, youth (under 18) and others. In addition to telephone counseling services, 33 quitlines also offered some form of internet-based counseling (up from a total of 6 in 2004). Thirty-seven (70%) provided some type of free NRT or other medications to at least select callers – up from 18 in 2005. Forty-nine state quitlines were integrated into the health care community through fax referral programs, and the same number provided referrals out to other services.

The existing network of state quitlines is connected through a national toll-free portal 1-800-QUIT-NOW, established by the U.S. DHHS in 2004. Any tobacco user in the U.S. can call 1-800-QUIT-NOW to receive help with quitting from his or her state quitline.

**Recommendation One: Include 800-QUIT-NOW, a toll-free number that links callers with their state quitlines, and [www.smokefree.gov](http://www.smokefree.gov), a website that contains quitting information, on all label statements and warnings for tobacco products. In addition, NAQC recommends that the number and website should be required on all tobacco product advertising including point-of-sale advertising.**

The Family Smoking Prevention and Tobacco Control Act (“the Act”) grants FDA authority to require stronger health warnings on tobacco packaging and to regulate advertising of tobacco products. In addition, the purpose of the Act is to curb the significant adverse consequences of tobacco use. NAQC’s first recommendation is within the authority of FDA and would help achieve Congress’ stated purpose for the Act.

According to the literature, warning labels on cigarettes and other tobacco products communicate the risks of smoking and have excellent recall with smokers.<sup>5 6 7</sup> Literature also demonstrates that smokers who perceive greater smoking-related health hazards are more likely to consider quitting and to quit successfully.<sup>8 9</sup> However, NAQC asks FDA to require more than the communication risks and health hazards on the label. We ask FDA to require that actionable information be provided to smokers and other tobacco users on how to receive help with quitting. Such a requirement will advance the use of labels and capitalize on the existing national portal number, 1-800-QUIT-NOW, and the U.S. DHHS website, [www.smokefree.gov](http://www.smokefree.gov). Increased awareness of quitlines will result in a significant public health benefit by encouraging tobacco users to think about quitting and linking those who want to quit with effective no-cost services.<sup>10</sup>

As discussed above, quitlines are effective cessation services as documented in numerous research studies; quitlines are recommended by the U.S. Public Health Services Clinical Guideline on Tobacco Dependence Treatment.<sup>11</sup> Quitlines are available to all tobacco users in the U.S. These services are available at no-cost to consumers in all 50 states, the District of Columbia, Puerto Rico and Guam.

The recommendation is feasible for the tobacco industry. Approximately 20 nations currently require a quitline number on their tobacco package labeling, including Finland (2002), the Netherlands (2002), Denmark (2003), Iceland (2003), Malta (2003), the U.K (2003), France (2003) Sweden (2003) Hungary (2002) Poland (2004), Germany (2006), Belgium (2007), South Africa (1995) Brazil (2002), Singapore (2004), Australia (2006), Switzerland (2006), New Zealand (2008), and Norway (2006)<sup>12</sup>. In addition, Philip Morris included the 1-800-QUIT-NOW number as part of onserts for Marlboro products during U.S. campaigns in 2005 and 2006.

The recommendation is an effective way to encourage tobacco users to quit, thereby curbing the significant adverse consequences of tobacco. In New Zealand, the appearance of the quitline telephone number on cigarette packages yielded more calls to the quitline than TV advertising.<sup>13</sup> In a recent study of seven EU countries, the findings showed an increased call volume to quitlines in the first and second year after the quitline number appeared on the label. In the EU, the quitline telephone number appeared only on every 14<sup>th</sup> cigarette package, but still had a significant impact on calls to the quitline. During the first year, the mean increase in call volumes was 100% (range from 50-232%) and in the second year, the mean increase was 76% (range from -43 to 184%).<sup>14</sup> The EU data were not adequate to predict the increase in call volume in the U.S., but based on recent experience with quitline campaigns and the new federal tobacco tax, we believe placing 1-800-QUIT-NOW on tobacco packages will more than double call volumes in the first year.

Recently, Health Canada began work on the development of the next generation of health warning messages (HWMs) for tobacco packaging. A proposed new component of this labelling renewal is the inclusion of a pan-Canadian toll-free quitline number. Health Canada, the provinces and the territories are currently researching the feasibility of this new component although no final decision has been approved yet. As part of its work, Health Canada conducted focus group testing on the idea of a pan-Canada toll-free quitline number. Smokers viewed the information in a very positive way. Smokers contemplating a quit viewed the information most positively. The focus group research should be publicly available in September 2009.<sup>15</sup>

As FDA considers moving forward with the inclusion of 800-QUIT-NOW on health warning labels for tobacco products, you may also wish to contact Health Canada to learn of its experience and approach to tobacco control regulatory activities. Please contact Cathy Sabiston, Director General, Controlled Substances and Tobacco Control.

This recommendation also is feasible for state quitlines. Although quitlines currently reach only 1-2 percent of smokers in the U.S., the HHS Interagency Committee on Smoking and Health determined that quitlines have the capacity to serve 10-15 percent (about 4 million smokers) each year.<sup>16</sup> The inclusion of the phone number on tobacco packages will help increase the reach of quitlines to smokers who want to quit. To avoid having this become an unfunded mandate for states, NAQC recommends that FDA and the states discuss possible funding solutions. An increase of \$0.03 to \$0.05 in the federal tobacco tax would generate adequate revenues to cover the costs of services and an evaluation of the impact of placing 1-800-QUIT-NOW on tobacco packaging.

This recommendation vis-à-vis point-of-sale advertising also is feasible for States and local governments and may be an area for FDA collaboration with States and local governments. Some jurisdictions, including New York City, are considering such action. In July 2009, the New York City Department of Health and Mental Hygiene Board of Health held a hearing on a proposal to require health warnings and smoking cessation information where tobacco is sold<sup>17</sup>. This type of action may be ripe for cross-jurisdiction collaborations.

### **Recommendation Two: Take full advantage of FDA's broad authority around dissemination of information to educate consumers about effective cessation options.**

The Family Smoking Prevention and Tobacco Act emphasizes the importance of communicating with consumers and disseminating information to them. No information is more important to tobacco users than information about effective cessation options. Research has

documented that better awareness of smoking cessation resources increases utilization.<sup>18</sup> NAQC urges FDA to not only communicate risk and health hazard information but to also communicate actionable information about effective cessation options. Quitlines are one type of effective cessation service. Research also has demonstrated the effectiveness of other services, such as face-to-face counseling by clinicians and community-based counselors as well as pharmacotherapy. Newer approaches, such as web interventions, currently are undergoing effectiveness evaluation. We look forward to adding them to the toolbox of cessation options once their effectiveness has been demonstrated. We recommend that FDA rely on the U.S. Public Health Services Clinical Guideline in determining effective cessation options.<sup>19</sup> We also recommend that FDA disseminates timely and clear information to the public about cessation options that have not been shown to be effective, such as e-cigarettes.

### **Recommendation Three: Decrease the allowable level of nicotine in all tobacco products to a non-addictive level.**

As a law student, I attended a lecture in which tobacco companies were promoted as a great financial investment because “their products can be made for a penny, sold for a dollar and they are addictive.” The influence of nicotine’s addictive nature on the purchasing behavior of consumers was not lost on the lecturer or any of the students. Allowing addictive levels of nicotine in tobacco products effectively undermines consumers’ ability to make a true choice. By reducing the allowable level of nicotine in all tobacco products to a non-addictive level, FDA will give tobacco users the opportunity to make a true choice -- *one not influenced by addiction* -- about using tobacco products.

Several studies have found that people do not fully appreciate the addictive nature of tobacco products.<sup>20 21 22</sup> Research shows that tobacco products are addictive and that most smokers are addicted to cigarettes.<sup>23 24</sup> The addictive nature of tobacco products keeps smokers smoking. Nearly all smokers (95%) regret their decision to ever start smoking.<sup>25</sup> National surveys have shown that although 70% of current smokers want to quit, only 41% have made a quit attempt in the past year.<sup>26</sup> In a New York City survey, two-thirds of smokers indicated that they want to quit, but need help to be successful in staying quit.<sup>27</sup>

Although FDA may not have authority to ban nicotine from tobacco products, the Act grants authority for developing standards for the reduction or elimination of certain constituents. We encourage FDA to explore ways in which the level of nicotine allowed in cigarettes could be decreased, perhaps in a stepwise approach over several years, from highly addictive levels to a standard sub-addictive level. There could be no better outcome in the exercise of the authority granted under the Act than to eliminate the addictive nature of tobacco products.

### **Recommendation Four: Conduct definitive research on the link between menthol and the higher burden of tobacco related diseases and lower rate of cessation among menthol tobacco users.**

Menthol is a controversial flavoring and ingredient in tobacco products. Segments of the tobacco control community were disappointed that menthol was not eliminated from tobacco products under the Family Smoking Prevention and Tobacco Control Act. We know menthol products are targeted at racial and ethnic communities and that menthol users may have lower cessation rates.<sup>28</sup> We hope that conducting definitive research on the link between menthol tobacco products and the higher burden of tobacco related diseases and deaths and lower rates of cessation, especially among African Americans, will be a priority for FDA.

The current literature on menthol raises many questions about its continued use in tobacco products. Studies show that menthol may encourage people to smoke (including youth) who otherwise cannot tolerate the harshness of cigarettes<sup>29</sup>. We encourage FDA to determine whether menthol products are “starter products” for youth, whether they are “replacement products” for those contemplating a quit and whether smokers erroneously believe that menthol products – because they are less harsh – are also less hazardous. Research also shows that menthol products may increase the risk for cancer (through a physiologic or pharmacologic effect)<sup>30</sup> and may make it harder to for smokers to quit<sup>31</sup>. Again, we encourage FDA to address these issues.

During the two year study period specified in the Act, NAQC encourages FDA to conduct the necessary research to put these controversies to rest. At the end of the study period, we hope FDA will have adequate evidence to determine if menthol should be eliminated as a flavoring and ingredient from all tobacco products.

### **Conclusion**

The authorization of FDA to regulate tobacco products heralds an exciting new era for tobacco control and cessation. NAQC is confident that the recommendations included in this letter are consistent with FDA’s authority and if implemented would help achieve the Family Smoking Prevention and Tobacco Control Act’s goals to curb the significant adverse consequences of tobacco use. NAQC and its network of members across the U.S. and Canada stand ready to help FDA in its efforts.

Thank you, again, for the opportunity to provide input and share views on FDA’s new authority to regulate tobacco products. Should you have any questions about NAQC’s comments, please contact me via email at [LBailey@NAQuitline.org](mailto:LBailey@NAQuitline.org) or via telephone at 602-279-2719.

Sincerely,

A handwritten signature in cursive script that reads "Linda A. Bailey".

Linda A. Bailey, JD, MHS  
President and CEO

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