AMERICAN LUNG ASSOCIATION.

Harold P. Wimmer
National President and
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February 15, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: FDA-2017-N-6529

Dear Commissioner Gottlieb:

The American Lung Association appreciates the opportunity to submit comments on the Food and Drug Administration's (FDA) Approach to Evaluating Nicotine Replacement Therapies (CAG-00450N).

The Lung Association works on behalf of the 33 million Americans living with lung diseases including lung cancer and COPD – which are primarily caused by tobacco use and exposure to secondhand smoke. Tobacco use remains the leading preventable cause of death and disease in the United States, killing 480,000 Americans each year. Another 16 million Americans live with tobacco-caused death and disease. The total estimated cost attributable to cigarette smoking is over $332 billion annually. This includes over $175 billion in direct medical expenses in 2013, and productivity losses from premature death of over $150 billion among current and former smokers and over $5.6 billion from secondhand smoke exposure among nonsmokers.

The Lung Association has been helping people quit smoking for over 35 years through our Freedom from Smoking® program, which is ranked as one of the most effective programs in the country. Over the course of a typical year, the Lung Association convenes a thousand of our in-person eight session Freedom From Smoking group clinic.

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Smokers Want To Quit but Need Help

Approximately 70 percent of smokers – say they want to quit but this is an incredibly powerful addiction.[1] As FDA and its Nicotine Steering Committee moves forward with its efforts, the Lung Association urges you to prioritize the almost 26 million American smokers who want to quit as its top tier focus.

The Lung Association does not accept the idea that a certain percentage of tobacco users can't quit. One of our core beliefs is that **every smoker can quit** using all tobacco products.

The Lung Association also believes that a significant portion of the remaining 30 percent of smokers who say they don't want to quit would still like to do so – but they're feeling defeated and worry they will fail at quitting. And of course – there is a good likelihood they will fail along the way before ultimately being successful: it takes an average of 8 or more quit attempts for most smokers to end their addiction for good, which is why the FDA's new "Every Try Counts" campaign is so powerful and important.

To protect the public health, the FDA cannot look to or prioritize products or treatments that have not been found to be safe or effective in helping smokers end their addiction. And switching to another tobacco product is not quitting.

Science-Based Cessation Attempts

In fall of 2015 the US Preventive Services Task Force[2] (USPSTF) updated the cessation interventions recommendation, reiterating that all three types of counseling and all seven FDA-approved medications are effective in helping tobacco users quit and that there is not sufficient evidence to recommend e-cigarettes as a cessation device.

The "Treating Tobacco Use and Dependence: 2008 Update[3]" and the 2015 USPSTF statement confirmed what works to help smokers quit, which the American Lung Association refers to as a "comprehensive cessation benefit."

Because of the USPSTF designation of an "A" grade, virtually all private health insurance plans and Medicaid expansion plans beginning after October 1, 2016 must comply with the updated rating – although this must be enforced by HHS if it is to work. It is not enough for there to be treatments for smokers to use in helping them quit – smokers must also be able to access them.

Where FDA Can Intervene

The American Lung Association sometimes hears "I tried the gum but it didn't work." There is not a one-size-fits-all solution to quitting smoking, and different treatments and combinations of treatments work for different people; however, the Lung Association believes that in many cases, smokers aren't using the medication correctly. Here are the three most common mistakes the Lung Association sees:

1. **Smokers aren't using the NRT correctly**. For example, with nicotine gum, smokers are supposed to chew until there's a tingling and then "park it" between their cheek and gum until the tingling fades. And then chew it again until it tingles. That's how the nicotine is supposed to be absorbed, through the buccal mucosa. If nicotine gum is chewed like a regular piece of gum, the user doesn't receive the intended dose of nicotine. Nicotine that is swallowed ends up getting destroyed by the liver and not absorbed. If a smoker is using the 24-hour patch, it needs to remain on for the full 24 hours – not taken on and off throughout the day as some users do.

2. **Smokers aren't using enough of that specific NRT.** To save money or perhaps because they don't like taking medication in general, some smokers effectively skimp on the amount of NRT they are using. Rather than chewing at least 9 pieces of nicotine gum per day as recommended, they only chew 4 or 5 pieces. Or perhaps unknowingly, a highly addicted person uses the 2-mg gum when they should be using the 4-mg gum.

3. **Smokers aren't using the NRT long enough**. Instead of using NRT for 10-12 weeks as recommended, many smokers use the product for far less time. The Lung Association often hears of people using NRT for 2-4 weeks, because that's what they received when they called 1-800-QUIT NOW or because that's all their insurance plan will cover. This is unacceptable if smokers are to be successful in their quit attempt.

In an April 3, 2017 MMWR article "Quit Methods Used by US Adult Cigarette Smokers, 2014-2016[4], researchers quantified the ten most *common* quit methods used by adult smokers. The study found three-quarters of current adult smokers used multiple quit methods during their most recent quit attempt. The most common quit method was giving up all cigarettes at once (65.3%), the second was reducing the number of cigarettes smoked (62.0%), the third was to turn to e-cigarettes (35.3%) – another tobacco product.

Only one-quarter – 25.4 percent – turned to the FDA-approved patch or gum, which is the fourth most cited option. FDA must ask why only a fourth of the almost 26 million Americans who want to quit smoking use treatments that FDA has found to be safe and effective – while a third are turning to another tobacco product with its own toxins and carcinogens?

The Lung Association believes this is a result of an uneven playing field. Most smokers are desperate to quit – and they're willing to try anything. And from the very early days, the e-cigarette industry has been willing to tell these desperate smokers that their products will help them quit – with almost no response or intervention from the Center for Drug Evaluation and Research (CDER).

If an e-cigarette manufacturer really believes its product can help smokers quit – the manufacturers have been and are still free to go through the same rigorous clinical trials that the 7 current FDA-approved cessation treatments completed. But manufacturers must be required to demonstrate both safety and efficacy. **FDA must hold these companies accountable and use the**

same standard of evidence for e-cigarettes as it did for the patch, gum, lozenge and other quit smoking products. It cannot and should not allow a class of tobacco products to avoid compliance with the law. It is no wonder that smokers are so confused and turn to products that have been almost free to claim anything they want, when the makers of these proven treatments are carefully limited in what they are allowed to say.

CDER must use its existing authority to crack down on the unproven therapeutic claims that e-cigarette manufacturers have made in the beginning and are still making today.

Egregious Claims from the E-Cigarette Industry

Here is one of the very first claims the American Lung Association saw when the e-cigarette market first was gaining prominence in 2010. This is a poorly Babel Fish-translated press release – this was one of many from all but certainly fictional press agent named "Harry Heiti." It reads, "The doctors recommend for traditional cigarette smokers the electronic cigarette or the e-cig product.[5]"

It's rather reminiscent of the old "four out of five doctors prefer Camel" campaign from the 40s and 50s.[6]

The Heiti press release then goes on to say "Most especially for pregnant smokers the doctor recommended it for them." (Please see Appendix A)

Therapeutic Claims Are Being Made Without a Response from FDA

N-E Where Electronic Cigarettes came out with this flagrant therapeutic claim in 2013[7]. While most manufacturers are not this flagrant anymore, unproven therapeutic claims are still abound. (Please see Appendix B)

In July of 2016, Klein et al published a study "Online E-Cigarette Marketing Claims: A Systematic Content and Legal Analysis."[8] It concluded, "In this marketplace where the majority of smokers are interested in quitting, it is essential for the FDA to ensure that consumers are not misled into choosing products based on misleading or inaccurate health-related claims. In this way, enforcement by the FDA can lead to the promotion of public health and the protection of vulnerable consumers."

The Lung Association can understand there was some confusion during these days of Harry Heiti before the *Sottera* case was resolved, but since that time in 2010, the Lung Association believes there is no excuse for the inaction on cracking down on these unproven therapeutic claims since the letter to stakeholders issued jointly by CDER and the Center for Tobacco Products (CTP) in April of 2011[9].

Additional Steps FDA Can Take

In addition to cracking down on the unproven therapeutic claims from both e-cigarette manufacturers and retailers, FDA can also take a number of additional steps:

1. One prevalent myth that the Lung Association often hears and still must counsel smokers against believing is the notion that if a smoker is wearing a nicotine patch, slips up and smokes a cigarette, he or she is likely to suffer a heart attack that very day. This fear keeps many people from using nicotine replacement therapy, one of the best tools available to help them break their tobacco addiction.

   While the over-the-counter (OTC) nicotine replacement therapy (NRT) warning labels were changed in 2013[10], much of the language is still ambiguous. In addition, smokers may still remember the original warning language that read "Do Not Use if you continue to smoke…"

   Smokefree.gov has a page on "Busting NRT Myths" but HHS must be proactive with its public education – much more so than a webpage if it is to end the misconceptions that have become so engrained.

2. As mentioned above, the Lung Association believes smokers often are not using NRT correctly. This starts to address the second question posed by FDA f. FDA *can* help smokers use the current OTC treatments more effectively by working to develop clearer and consistent labels and public education messaging for both prescribers and patients.

   The low socio-economic status population makes up a large proportion of smokers in the U.S. today. This group faces multiple challenges including that they are less likely to have a regular healthcare provider, less likely to have the time and relationship with a real healthcare provider to have a meaningful conversation about using NRT and they may not be able to get the information they need to fully succeed with these evidence-based treatments. This should be one of the first populations that FDA considers when working with manufacturers in developing the labeling and any warning labels of NRT.

3. How can labeling be made more accessible and put in plain language? Why are the current directions less understandable and straight-forward than the warnings? Do smokers realize NRT has been found to be safe and effective – and that any side effects are wholly less dangerous than smoking? FDA can and must take steps to answer these questions and convey this information to the public.

4. FDA must make the size and therefore the price of NRT packages more accessible to those with limited financial means. Smokers should be able to buy a package of over-the counter NRT at the same place and for around the same price as a pack of cigarettes. For someone with limited income, it's a lot easier to pay $6.00 for a pack of cigarettes than $56.00 for a box of nicotine gum.

5. There are myriad of opportunities for additional FDA research – specifically regarding the populations that continue to smoke at elevated rates. What cessation interventions work for the behavioral health population without reducing efficacy of common psychiatric drugs or

causing more severe side effects? There is evidence that the behavioral health population needs NRT longer – but much more research is needed into this population. Instead of making a behavioral health diagnosis an exclusion criteria for study participation, it should be the focus of many more research studies in this area.

OTC NRT products can and should be studied for use in combination. Would smokers benefit by using the patch for a steady state of nicotine throughout the day and use the nasal spray to help overcome cravings as they occur? While that may be practice for many cessation providers already, there still must be published evidence to back up the promising anecdotal stories.

FDA Must Take Action to Help Youth Smokers Quit

Tobacco is a pediatric disease in that over 90 percent of smokers start before the age of 18 and the earlier someone quits smoking, the better their health outcomes are. The American Lung Association strongly encourages FDA to use their authorities under the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act to require and incentivize the study of NRT in youth so that labeling changes can be made to these treatments and once evidence has been gathered, cessation treatments are made accessible to young smokers trying to quit. The Lung Association also urges FDA to include in its evaluation criteria that any new NRT products must not have the unintended consequence of attracting new tobacco product users in the youth population.

Closing

The American Lung Association is pleased to see FDA engage in these critical questions about the nation's leading cause of preventable death and looks forward to contributing in any way we can about ways to help smokers quit. There is much we can do to make evidence-based tobacco cessation treatments more available to those seeking to quit. At the same time, we must be careful not to repeat the mistakes of the past or give false hope to tobacco users who want and need to break their addiction. So-called "light" and "low-tar" cigarettes seemed at one point to be a less harmful choice but still caused millions of tobacco-related deaths. We must not allow e-cigarettes to be the next "light" cigarette.

Sincerely,

Harold P. Wimmer
National President and CEO

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[1] Babb S, Malarcher A, Schauer G, Asman K, Jamal A. Quitting Smoking Among Adults — United States, 2000–2015. MMWR Morb Mortal Wkly Rep 2017;65:1457–1464. DOI: http://dx.doi.org/10.15585/mmwr.mm6552a1

[2] Final Update Summary: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions. U.S. Preventive Services Task Force. September 2015. https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1

[3] Treating Tobacco Use and Dependence. Agency for Healthcare Research and Quality. April 2013. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/update/index.html

[4] Caraballo RS, Shafer PR, Patel D, Davis KC, McAfee TA. Quit Methods Used by US Adult Cigarette Smokers, 2014–2016. Prev Chronic Dis 2017;14:160600. DOI: http://dx.doi.org/10.5888/pcd14.160600

[5] Press release: http://www.officialwire.com/main.php?action=posted_news&rid=54235&catid=1076. Date accessed 1/12/2010

[6] Four out of five physicians prefer Camels. Adweek. September 2007. http://www.adweek.com/creativity/four-out-five-physicians-prefer-camels-16855/

[7] Premium Vapor Products. NEwhere, www.newhere.com/index.php

[8] Klein, E. G., Berman, M., Hemmerich, N., Carlson, C., Htut, S., & Slater, M. Online E-cigarette Marketing Claims: A Systematic Content and Legal Analysis. Tobacco Regulatory Science, 2016; 2(3), 252–262. http://doi.org/10.18001/TRS.2.3.5

[9] Food and Drug Administration Letter to Stakeholders: Regulation of E-Cigarettes and Other Tobacco Products. https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm. Date accessed: 4/15/2014

[10] Modifications To Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use; A Notice by the Food and Drug Administration, 78 Fed. Reg. 19718 (April 2, 2013). https://www.federalregister.gov/documents/2013/04/02/2013-07528/modifications-to-labeling-of-nicotine-replacement-therapy-products-for-over-the-counter-human-use

Appendix A

Is Electronic Cigarette Meant For Women Too? Find out if E-cig does not affect women in any way

Published on January 12, 2010

by Harry Heiti

(OfficialWire)

LOS ANGELES, CA

www.electroniccigarette123.com

Cigarette smoking kills an estimated 178,000 women in the United States annually. The three directing smoking–related causes of death in women are lung cancer (45,000), heart disease (40,000), and chronic lung disease (42,000). Women who smoke have an increased risk for other cancers, including cancers of the oral cavity, pharynx, larynx (voice box), esophagus, pancreas, kidney, bladder, and uterine cervix.[2] Women who smoke double their risk for developing coronary heart disease and increase by more than tenfold their likelihood of dying from chronic obstructive pulmonary disease.

The doctors recommend for traditional cigarette smokers the electronic cigarette or the e-cig product. Most especially for pregnant smokers the doctor recommended it for them. Our electronic cigarettes have the same look and feel as traditional cigarettes, but are completely free of tar, carcinogens and other toxins. Since the cigarettes are non-flammable and do not contain tobacco, you have the freedom of smoking virtually everywhere!

The cigarettes are rechargeable and use advanced micro-electronic technology to deliver nicotine to the user. The nicotine cartridges come in a variety of concentrations making it easy for you to slowly breakdown your intake. The draw from a cigarette is almost identical to traditional smoking. The 'smoke' which is produced is actually vapor and therefore a friendlier alternative to your environment.

"Traditional" smoking has proven to be a hazard to the health, often leading to lung- and cardiovascular diseases amongst heavy smokers. A single tobacco cigarette contains over 4000 chemical substances which are inhaled by the smoker.

New Smoke e cigarettes give smokers their nicotine dose, but don't pass on other harmful substances to you or your environment. Our products are your ideal alternative to traditional cigarettes!

Guaranteed 30-day program on how to quit smoking. Order now to have a chance to get **BONUS ITEMS**!

Visit www.electroniccigarette123.com or call 1-888-288-4847.

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Appendix B