Dr. Scott Gottlieb  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  


June 15, 2018  

Dear Commissioner Gottlieb:  

The Food and Drug Administration (FDA) has issued an advanced notice of proposed rulemaking to “obtain information for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes.”¹  

The Heartland Institute understands the FDA is considering reducing nicotine levels in combustible cigarettes by 98 percent. Heartland urges FDA to reconsider such a significant reduction. There is very little research on the effects of nicotine at this time, and there is also limited evidence showing that reducing nicotine levels would generate the outcomes the agency aims to achieve. For instance, users of cigarettes may choose to smoke greater quantities to offset the reduction, or they may turn to the black market. Many people looking to quit using combustible cigarettes are already, in large numbers, turning to tobacco harm reduction products, including nicotine replacement therapy, smokeless tobacco and snus, electronic cigarettes and vaping devices, and heat-not-burn products.  

Heartland urges FDA to investigate nicotine further, as well as the role of tobacco harm reduction products, prior to imposing a nicotine reduction in combustible cigarettes.  

More Research on the Potential Harms of Nicotine Is Necessary  

There is a significant lack of scientific evidence related to the health implications of using nicotine apart from combustible cigarettes. More problematic, many erroneously believe that it is the nicotine in cigarettes that causes harm to human health.²  

As early as the 1940s, some in the health community began to claim it is the nicotine in combustible cigarettes that make those products addictive, although they acknowledged it might not be the ingredient causing the most harm.³ In 1976, Michael Russell declared that “people smoke for nicotine, but die from the tar.”⁴  

Existing evidence “indicates that nicotine itself, while not completely benign, carries substantially lower risks than smoking.”⁵ This consensus is shared by the U.S. surgeon
general and the U.K. Royal College of Physicians, who agree that “nicotine, while addictive, is not the primary cause of smoking-related diseases.”

Regarding cancer risks associated with nicotine consumption, “authoritative reviews of carcinogens in tobacco and tobacco smoke have not listed nicotine among the carcinogens.” Evidence from the Lung Health Study concluded that the use of nicotine replacement therapy (NRT) products was “not significant predictors of cancer in the models for gastrointestinal cancer or all cancers.” According to the U.S. surgeon general, “nicotine does not act as a complete carcinogen on its own.”

Data from human epidemiology studies have led researchers to come to similar conclusions. The Royal College of Physicians noted that risks associated with long-term use of NRT products do not lead to “an increase in cancer risk or tumour growth in humans.” These conclusions were reached examining both long-term users of NRT products and snus.

Smoking has been determined to be one of the leading causes of cardiovascular diseases, but this association does not seem to be caused by nicotine. Examining cardiovascular and endocrine effects of nicotine, researchers found that high doses of nicotine “caused no short-term effects on the cardiovascular system.” In the five-year Lung Health Study, researchers examined more than 3,000 participants that had used nicotine polacrilex gum, finding it “to be safe and unrelated to any cardiovascular illnesses or other serious side effects.”

The Swedish experience with snus, a smokeless tobacco product that is banned in all countries of the European Union except Sweden, provides valuable insight into the harms associated with nicotine used apart from combustible cigarettes. Snus circulates nicotine through users’ bodies in a manner that is consistent with what occurs when people use combustible cigarettes. If nicotine were to cause cancer, “one would expect snus use to be associated with increased risk of lung cancer and many other cancers.” However, the evidence indicates that this is not the case. Swedish men have the highest rate of smokeless tobacco use in Europe and the lowest smoking rate. Men in Sweden “also have the lowest rates of lung cancer and other smoking-related diseases in Europe.”

Researchers have determined that consumption of “snus is unassociated with cancer of the oropharynx, esophagus, stomach, pancreas, lung or other sites, or with heart disease.” It estimated that risks of developing cancer from the use of snus are “no more than 1% of smoking.”

FDA should also be aware that some studies suggest that nicotine in cigarettes might not be the chemical most responsible for some people’s addiction to tobacco. Researchers in a 2016 study in Tobacco Control examined the role of pyrazines in cigarettes to understand the role of additives in tobacco addiction. They concluded that these additives might play a larger role by making “it easier for non-smokers to initiate smoking, more difficult for current smokers to quit … and may [mask] the risks of both active and passive smoking.”

Before reducing nicotine levels, FDA and policymakers should find better evidence to understand the effects of nicotine when consumed apart from combustible cigarette smoke.

**Reducing Levels by 98 Percent Would Be Implausible, Impractical, and Could Have Far-Reaching Implications**
Cigarette manufacturers explored the possibility of creating low-nicotine cigarettes as early as the “1950’s through the late 1960’s.” In the 1980s, tobacco manufacturers considered low-nicotine tobacco further but found dissatisfaction among consumers. Initial market research conducted by tobacco companies determined smokers “did not want to smoke cigarettes with a minimum of nicotine over time.”

With growing research on the health effects of certain elements of tobacco smoke, including tar and nicotine, tobacco manufacturers began to develop an “alkaloid reduced tobacco program.” Philip Morris “invested $300 million … on the ART project” and reduced nicotine content by 95-98 percent. In 1989, Philip Morris introduced Next, a reduced nicotine cigarette, to a limited market and found “disappointing sales (less than 0.2 market share) and was withdrawn by the end of 1989.” Tobacco manufacturers have also genetically modified tobacco to produce lower nicotine levels.

A recent analysis found a low-nicotine cigarette plan would come with “unintended consequences.” Rather than move smokers away from combustible cigarette use, users of lower-nicotine cigarettes will “instinctively get more [nicotine] by inhaling more deeply or covering air holes with their fingers.”

Nicotine reductions could also create an incentive for a black market in which tobacco users seek out illegal tobacco products with sufficient nicotine levels. Due to draconian taxes on tobacco products, users are already utilizing black market cigarettes to avoid taxes. New York, with the highest tax rate in the country, leads the nation in cigarette smuggling, “with an estimated 56.8 percent of cigarettes consumed in the state deriving from smuggled sources in 2015.”

Policy Solutions

It is of great importance FDA understands the emergence of tobacco harm reduction products, including smokeless tobacco and electronic cigarettes, vaping devices, and heat-not-burn products. These innovations have been proven to be effective in delivering nicotine without the harmful components of cigarette smoke. Recently, FDA deemed e-cigarettes as tobacco products. There is a significant risk that should FDA impose reduced nicotine levels in combustible cigarettes, it will likely apply the same levels to all tobacco harm reduction products in the future as well. Such a standard would dramatically threaten tobacco harm reduction efforts.

Rather than limiting the nicotine levels in combustible cigarettes, FDA should allow the free market to continue providing safer nicotine delivery products. A 98 percent reduction of nicotine levels would further demonize the use of nicotine, even though there is not enough sufficient evidence to conclude that nicotine is the most dangerous component of tobacco cigarettes. Should nicotine levels be reduced to 2 percent, a black market will undoubtedly develop. Additionally, should FDA reduce nicotine levels allowed in combustible cigarettes, it could threaten tobacco harm reduction products and additional innovations by applying the same reduced levels to these products in the future.

For these important reasons, FDA should not move forward with a reduction of nicotine levels.
Sincerely,

[Signature]

Lindsey Stroud
State Government Relations Manager
The Heartland Institute


7 Raymond Niaura, supra note 6.


9 Raymond Niaura, supra note 6.


11 Raymond Niaura, supra note 6.


15 Raymond Niaura, supra note 6.


17 Peter N. Lee, supra note 12.


21 Ibid.

22 Ibid.

23 Ibid.

24 Ibid.


27 Ibid.