

FDA's Draft Guidance on Submission of Warning Plans for Cigars Exposes Shortcomings in Cigar Warnings Required by Final Rule

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FDA's Draft Guidance for Industry on Submission of Warning Plans for Cigars exposes shortcomings in the health warning statements for cigars required under section 1143.5 of the final "deeming rule" issued May 10, 2016. These health warning statements do not satisfy the public health standard mandated by section 906(d) of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The public health standard is the core of the Tobacco Control Act, and requires every regulation issued by FDA to be "appropriate for the protection of the public health," taking into account the risks and benefits to both users and nonusers of the tobacco product. The rule's required warning statements for cigars fail to meet that rigorous standard because of problems with the required content, format, and implementation.

The Content of the Cigar Health Warning Statements Fails to Protect the Public Health Because it Does Not Adequately Warn Users and Non-Users About the Dangers of Cigar Use

The text of the required health warning statements for cigars fails to adequately communicate the health consequences of using cigars, becoming addicted to cigars, or being exposed to the secondhand smoke of cigars, and therefore does not effectively protect users or nonusers, which is in violation of the public health standard.

Available scientific evidence suggests that alternative wordings for all of the health warning statements would make them more impactful and therefore better protect the public health. In particular, the required warning statement for addiction, "WARNING: This product contains nicotine. Nicotine is an addictive chemical," misses the mark for at least four reasons: (1) it fails to communicate how easily addiction occurs, especially among youth and young adults; (2) it fails to address the fact that addiction is a disease and a complicated process; (3) adolescents and young adults in particular have a difficult time understanding what addiction means, including lacking the understanding that addiction means that it will be difficult to quit and not recognizing how quickly and how little they need to smoke to become addicted;^{1, 2} and (4) it fails to communicate in a way that is known to be effective with youth and young adults. Indeed, FDA itself conducted extensive research for its "The Real Cost" campaign on how to communicate the concept of addiction; however, this knowledge is not reflected in the required warning statement. We described in detail the importance of appropriately communicating the risk of addiction in a comment we previously submitted in the Proposed Deeming Rule docket, incorporated by reference.³

Evidence shows that both youth and adults have difficulty quitting smoking. The

2007 Youth Risk Behavior Survey, for example, found that while 60.9% of high school daily smokers have tried to quit, only 12.2% were successful.⁴ In adult populations, 70% of current smokers reported wanting to quit, 44% attempted to quit, and between 4-7% were successful.⁵

The process of addiction can happen well before the onset of daily smoking.^{6,7} Despite clear evidence that adolescents and adults become addicted to nicotine,⁸ and do so well before regular daily tobacco use,⁹ both adults and children show confusion over the term addiction, and both adolescents and adults display skepticism about whether becoming addicted will and can happen.^{1,2}

Sixty percent of adult smokers and close to half of adolescent smokers believe that they can smoke for a few years and then quit,¹⁰ though actual quit rates are much lower.

Qualitative research shows that adolescents display optimism regarding their ability to quit smoking as well as skepticism over the seriousness of nicotine addiction.^{1,2,11} Qualitative studies also show that while youth and young adults are aware of the risk of nicotine addiction, they display a great deal of uncertainty over what nicotine addiction actually entails. In particular, adolescents do not realize that "addiction" means it is very difficult to quit using these products,¹² and that many of the "pleasures" of tobacco use, such as relaxation, are simply the results of self-medication (with nicotine) to treat the symptoms of acute nicotine withdrawal.^{1,2,13}

These findings about adolescents' and adults' misperceptions about nicotine are particularly important for warning messages on all tobacco products, including cigars. If individuals think they can start using these products and quit whenever they wish, then warnings regarding the long- and even short-term health consequences become moot as individuals will think they can choose to quit smoking before ever having to deal with these health effects.¹

Given the evidence that adults and adolescents do not understand addiction, it is vitally important to provide comprehensive, detailed messages on nicotine addiction.

The FDA's additional health warning message (WARNING: This product contains nicotine. Nicotine is an addictive chemical) does not address any of these nuanced concerns regarding individuals' understanding of addiction.

Specifically, the FDA's proposed warning fails to recognize youth and young adults' lack of understanding and skepticism of addiction. Instead, messages need to provide more detailed examples and definitions of addiction in order to be effective.

Extensive research shows that youth and young adults do not just underestimate the risk of addiction. Adolescent smokers perceive significantly less risk of many health consequences, including long-term consequences such as heart attack and lung cancer, as well as short-term consequences such as having trouble breathing.^{1,14} Further, adolescents without smoking experience who hold low perceptions of cigarette risk and

high perceptions of cigarette-related benefits are significantly more likely to initiate smoking than adolescent non-smokers who perceive greater risks and fewer benefits.^{15, 16}

Warnings that are comprehensive and engage the reader emotionally are significantly more effective at transmitting information than warning labels that present the information alone.¹⁷

The FDA should have utilized its own research when finalizing the warning labels and tie warnings to its research-based "The Real Cost" educational campaign. Results from the FDA's qualitative research used to design the Real Cost campaign (a copy of which was provided to SA Glantz in response to a FOIA request¹⁸) shows that many youth and young adults smoke in emotionally charged situations, such as when they are stressed, mad, or frustrated, and that teens respond the best to campaigns that focus on concepts such as "Why Let a Cigarette Tell You What to Do" and "Cigarettes are not the Answer." Additionally, the FDA's own work indicates that effective portrayals of nicotine addiction should be straightforward, but also portray addiction as a sinister and unwanted presence in one's life.¹⁸

The messages that the FDA created from these findings for the Real Cost Campaign effectively communicate important information by being visually stimulating and graphic; for example, images of a young man pulling out his own tooth or a young woman peeling at her skin as payment for a cigarette (FOIA material). The Real Cost Campaign's goal is to create messages that highlight consequences that youth and young adults are concerned about, such as cosmetic health effects and loss of control due to addiction.¹⁹ Other research confirms the importance of focusing on social consequences of tobacco, not just long-term health effects¹⁴⁻¹⁶

Warnings should speak to the lack of control associated with addiction. This understanding should be reflected in the FDA's warning labels on tobacco products.

For these reasons we suggest the following warning messages regarding addiction for all tobacco products, including cigars:

- 85% of smokers wish they had never started smoking. Nicotine is highly addictive.
- 70% of smokers want to stop smoking. Nicotine is highly addictive.
- The process of nicotine addiction starts well before you are smoking every day. Nicotine is highly addictive.
- Tobacco can be harder to quit than heroin or cocaine. Nicotine is highly addictive.
- Most smokers smoke for years longer than they want. Nicotine is highly addictive.
- Nicotine is highly addictive. It will take many attempts to quit before you will be successful
- 75% of teens who smoke are still smoking five years later. Nicotine is highly addictive.
- Addiction is the disease. Smoking is the symptom. Nicotine is highly addictive.

While not ideal, the FDA's reproductive health warning statement for cigars

(WARNING: Cigar use while pregnant can harm you and your baby.) is better than the optional Federal Trade Commission (FTC) consent decree warning statement (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight), and cigar manufacturers (especially those who were not signatories to the consent order) should not have been given the option to choose a less effective option.

We described in detail the importance of including a warning about the reproductive risk of cigars to users and non-users in a comment we previously submitted to the Proposed Deeming Rule docket, which is incorporated by reference.²⁰

As compared to the newly mandated warning, the FTC warning is too wordy, too complicated, and less impactful. Moreover, because they were introduced more than 15 years ago, they are stale and more likely to be ignored.

FDA should insist that cigars bear the new, fresh reproductive health warning statement to avoid message fatigue.

A major concern with warning labels is message fatigue; studies show that health warnings have their greatest impact shortly after implementation and decline in effectiveness over time.¹⁷ The FDA should regularly update and refresh warning labels for maximum educational impact.

All of the six required cigar health warnings would be strengthened if the word “WARNING” (or “SURGEON GENERAL WARNING”) were removed from the messages.

While the word “Warning” (or “Surgeon General Warning”) can function as a signal word, it can also function as a “stop” word in which the individual reads the word “warning,” but nothing after it. It also takes up space, which is limited, thereby requiring the remaining information in the warning statement to be printed in smaller type.²¹

The Format of the Cigar Health Warning Statements Fails to Protect the Public Health Because the Warnings are Too Small and Not Salient

A strong body of scientific evidence demonstrates that to be effective, health warning statements must be prominent. Studies show that youth and adults are more likely to notice and recall larger health warning statements, and larger messages have a greater impact.²² Several international bodies and other countries required larger health warning statements. For example, the FCTC suggests that warnings should cover 50% or more of a pack’s principal surface.²³ A number of countries, including Canada, have taken the initiative to create packages with warning messages that are at least 50% of the packaging.²⁴ The April 2014 revision of the European Union’s Tobacco Products Directive requires that the general warning and information message for tobacco products for smoking cover 50% of the surfaces on which they are printed.²⁵

Despite the clear evidence that to be effective, health warning statements should

cover at least 50% of the two principal display panels, the cigar warning statements required by FDA are only required to cover 30% of the two principal display panels.

Additionally, scientific evidence *and the tobacco companies' own research* shows that to seize and keep reader/user attention, the text color of warning label statements should sharply contrast with the background.²⁶ While the FDA rule requires warnings to appear in either black text on a white background or white text on a black background, the scientific evidence shows that black text on a white background grabs consumers' attention much more quickly than white text on a black background, and black text on a yellow background is even more impactful.²⁶ ***FDA's required health warning labels on cigars should be black text on yellow, not black on white, and certainly not white on black.***

Even the FTC consent order's cigar health warnings are better than the FDA's, because they are required to be black on white, and can not be white on black.

The required font size (12-point font) is woefully too small to ensure that the health warning statement will grab and keep a consumer's attention. Once again, the approach taken by the FTC for cigar warnings would be better, requiring progressively larger font size and warnings for packages as they get progressively bigger,

Cigars Sold Individually Should be Required to Display Health Warning Statements

Under the new rule, cigars that are sold individually (without any packaging) are exempt from the health warning statement requirements that adhere to cigars sold in boxes or packages. Instead of warnings on the cigars themselves, retailers must post an 8-1/2 x 11 inch sign with all six warnings within three inches of the cash register. ***Not requiring warnings on the cigars themselves in many cases would fail to protect the actual users of the cigars; since cigars are often bought as gifts, the recipient would never see the health warnings. Also, youth and young adults may find individual cigars stashed in drawers at home, and never get the opportunity to see the health warning statement.***

Moreover, adolescents are more likely to obtain tobacco products including cigars from their peers than purchasing these for themselves, thus reducing the chance that they will ever see the warning message (Myers, Delucchi & Halpern-Felsher, in preparation). Additionally, this rule means there would be no warning labels (and no physical signs) for individual cigars that are sold online. Because of the recognized negative health consequences, the Tobacco Control Act prohibits sales of cigarettes in packages containing less than 20 cigarettes. ***To uphold the essential public health standard, FDA should similarly not allow cigars to be sold individually; at minimum, if the FDA allows cigars to be sold separately, than the FDA should require individual cigars to be packaged with a warning label printed on each individual package.***

In any case, the required format (17-point font size on a sign that is 8.5 x 11 inches) for the alternative sign to be placed near the cash register when individual cigars do not display their own health warning statements is too small to be noticed or effective.

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