

FDA's Proposed Warning Statements Are Weak and Ineffective both in Form and Content and Should Be Replaced with Effective Messages

Docket No. FDA-2014-N-0189

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June 10, 2014

The FDA needs to make evidence-based changes to the current proposed required warning statements both in form and content by doing the following:

- 1) Remove the word WARNING from the messages.
- 2) Increase the suggested size of warning messages from 30% to at least 50%.
- 3) Change the warning message color from black and white to bright yellow background with black text or, in instances where the package is yellow, bright orange with black text and include a black border around the text.
- 4) Provide more and more specific e-cigarette warning messages.
- 5) Do not allow manufacturers who certify that their product does not contain nicotine to be exempt from addiction warning labels.
- 6) Require individually wrapped cigars to carry warning labels on the cigars themselves rather than just requiring point of sale warning messages.
- 7) Require the 5th FTC warning regarding the effects of smoking on reproductive health on cigars.

1. The FDA proposes the following warning regarding nicotine addiction. "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."

While the word "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 in smaller type. **The word WARNING should be removed from the warning labels.**

2. The FDA proposes, “That the health warning statements comprise 30% of the area of the two principle display panels to help ensure that consumers notice and process the critical information conveyed in the required warning statements.”

While this increase from current warning label size would be an improvement over current warning label sizes, it does not go nearly far enough. Numerous studies show that youth and adults are more likely to recall larger warning messages and rate larger messages as having a greater impact.(1)

The FCTC also suggests that warnings should cover 50% or more of a pack’s principal surface.(2) Additionally a number of countries, including Canada, have taken the initiative to create packages with warning messages that are at least 50% of the packaging.(3) 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.(4)

The FDA should increase the warning statement size from 30% of the two principal display panels to at least 50%.

There is also concern that tobacco companies may take the opportunity to create cases or product coverings that strategically cover the warning labels. **For this reason the FDA should require the placement of warning labels on the pack to be rotated at regular intervals.**

3. The FDA proposes that “the warnings appear in black text on a white background or white text on a black background will improve the legibility and noticeability of the warnings.”

This color scheme is not as effective as warning labels with the color scheme of a bright yellow background with black text. Additionally studies show that a black border directs individuals’ eyes to text, so including such a border would also improve the warning messages.(5)

The tobacco companies' research on colors provides wide-ranging information that is useful for designing new health warning labels that would adequately attract and hold consumers’ attention.

In his “Promotion and Policy for a Pandemic Product: Notes of the History of Cigarette Advertising,” Richard Pollay described how Louis Cheskin used ocular measurements and eye movement tests when comparing Marlboro’s ads to competitors’ ads to analyze which of the ad’s elements better attract consumers’ attention. Of particular relevance to current debates about health warning labels, Pollay noted that “this type of research is highly relevant to the questions of warning size, placement and required ‘conspicuousness.’”(6)

Warnings should be black on yellow, not black on white.

The cigarette companies' research found that yellow seizes attention, is the most noticeable, is the fastest color the eye perceives, and *universally signals warning or danger.* (7, 8)

According to color authority Carlton Wagner, yellow is the “fastest” color for your eye to see, because the electrical-chemical process of vision works faster for yellow than for any other color. (7)

In addition to yellow being the most noticeable color, for most products yellow has negative connotations. Yellow shapes and elements that are superimposed on packages, rather than part of the basic underlying package design, and known as “violators” (9). Wagner advises package designers to “take a lesson from nature, and use [yellow color] as an indicator to call quick attention to something.” (7) Yellow “is found in nature (and used by humans) in combination with black to notify or warn you that you should notice something for your own good: stinging bees are yellow and black; so are many road signs.” (7) Taken together, this research clearly shows that yellow would be a much better choice for health warning labels than black and white.

The FDA-required warning labels should have a color scheme of bright yellow background with black text. Warning labels should have a black border and tobacco companies should be prohibited from changing their packaging so that it fits with the new bright yellow and black warning messages as studies show that warning messages that that are visually distinct from the packaging of a product are more noticeable. (10)

When the packaging is yellow (or close to yellow) the FDA should require that the background be a contrasting color, in particular orange. (Orange is also a warning color commonly used on highway signs.)

The FDA should refresh the warnings 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.(5)**The FDA should regularly update and refresh warning labels for maximum educational impact.**

4. **The FDA should expand its suggested warning labels for e-cigarettes.** E-cigarette usage, especially among adolescents, has increased dramatically in a very short amount of time.(11, 12) Youth are being bombarded with advertising for e-cigarettes with one study showing a 256% increase in youth exposure to televised e-cigarette ads between 2011 and 2013.(13)

E-cigarettes are, without approval by the FDA, promoted as a quit aid(14), yet there the overall pattern in population-based studies is that that e-cigarettes inhibit individuals quit smoking traditional cigarettes. (15)

E-cigarettes are viewed by many as having only “harmless water vapor,” yet studies show that the vapor emitted from these products includes toxic chemicals (15, 16). Along with these toxic chemicals the nicotine liquid is a known poison, and phone calls to poison control due to nicotine poisoning or nicotine exposure to the skin have increased dramatically since these products have emerged on the market. (17)

The marketing of fruit and candy flavored e-cigarettes means that these products are likely to be particularly enticing for young people. (18)

Thus there is a need for more robust and varied warning labels for these products in particular.

We suggest the following warning statements for e-cigarettes:

- This product can cause and maintain nicotine addiction
- This product irritates your lungs
- This product pollutes the air others' breathe
- The product has not been proven to help quit smoking
- E-cigarettes have been known to explode
- Nicotine is a poison: Do not drink the liquid in this product
- Nicotine is a poison: Do not let the liquid touch your skin
- To prevent poisoning keep this product away from babies and children

5. The FDA proposes “a self-certification option for manufacturers who certify that their product does not contain nicotine (and that they have data to support that assertion)” allowing for the product to be exempt from the addiction warning label. Such a product would be required to bear the statement, “This product is derived from tobacco.”

There should be no such exemption. Numerous studies show that there is a great deal of variation between the stated amount of nicotine in these products and the actual amount, with studies showing instances of e-cigarette products being labeled as zero nicotine and actually containing nicotine. (19, 20)

6. The FDA also proposes “For cigars sold individually that are not packaged, FDA is proposing that the cigar warnings all be included on a sign located at the point of sale at each cash register in any retail establishment where such cigars are sold.”

Not requiring warnings on the cigars would greatly diminish the effectiveness of such warnings, not to mention the fact that there are potentially many instances where such items are bought as a gift, in which case the recipient would not see these warnings.

Additionally, in instances where cigars are sold online, there would be no physical sign and thus no warning labels (or signs) at all for individually sold cigars on-line. Therefore, we suggest that cigars should either not be allowed to be sold individually or that individual cigars should be required to be packaged (with a warning label printed on the package).

7. According to the proposed rule “the FDA is not proposing the fifth FTC warning (Tobacco use Increases the Risk of Fertility, Stillbirth, and Low Birth Weight) because although cigarette smoke causes these health effects (and cigar smoke is similar to cigarette smoke), the Agency is not aware of studies specifically linking cigars to these reproductive effects.

The FDA should include this fifth FTC warning as a warning for cigars. The FDA acknowledges that cigar smoke is similar to cigarettes smoke, so, based on materials the FDA itself included in the proposed rule, it is illogical to exclude this warning.

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