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September 30, 2015

Stephen Ostroff, M.D.

Commissioner

Food and Drug Administration

ATTN: Division of Dockets Management (HFA-305)

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852

RE: Docket No. FDA-2015-N-1514; RIN 0910-AH2. Advanced Notice of Proposed Rulemaking: Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-liquid(s), and Other Tobacco Products

Dear Dr. Ostroff:

Truth Initiative, formerly known as Legacy, appreciates the opportunity to comment on the critically important proposals to require child-resistant packaging and the placement of nicotine exposure warnings on electronic nicotine delivery systems (ENDS) and other packaging containing the nicotine liquid used in those products. The liquid nicotine associated with ENDS presents an extremely serious health risk to children, which must be addressed promptly and effectively. We urge the Food and Drug Administration (FDA) to move forward to issue such requirements as soon as possible after the deeming regulation has been finalized. To that end, we further urge FDA to finalize the deeming regulation immediately.

Truth Initiative also signed on to comments led by the Tobacco Control Legal Consortium (TCLC); we incorporate those comments by reference here. Further, we wholeheartedly agree with our public health colleagues who submitted separate comments led by the American Academy of Pediatrics (AAP) regarding the need for and implementation of standards for child-resistant packaging. As such, we fully support and incorporate by reference Sections II (FDA has clear authority under the Tobacco Control Act to regulate tobacco products to prevent child poisoning) and III (FDA must take urgent action to reduce the risk of child poisoning related to tobacco products) of that comment.



We believe that the information contained in that comment regarding FDA's authority to adopt child-proof packaging is valuable and that FDA should adopt those recommendations.

These additional comments focus on FDA's questions related to nicotine warnings on ENDS. We offer two additional recommendations:

1. A Nicotine-Exposure Warning Is Essential to Protect Children, But Should Not Overstate the Risks to Adult Smokers, Thereby Unnecessarily Deterring Them from Using E-cigarettes or Other Regulated Forms of Non-Combustible or Medicinal Nicotine Instead of Combustible Tobacco

Truth Initiative is second to none in our support of the need to protect children from the proven and substantial dangers of exposure to liquid nicotine. Therefore, FDA must require a nicotine exposure warning. Further, we have a long tradition of supporting smokers in quitting, and support the concept of harm minimization. That is, we believe that combustible tobacco smoking is so detrimental to health, that for those smokers who cannot or will not quit we recommend switching completely to less harmful products such as ENDS. The long-term health effects of e-cigarettes are as yet unknown, but while they are not completely safe, all indications are that they are orders of magnitude less harmful than smoking combustible tobacco.

Therefore, we caution FDA against making nicotine exposure warnings so dire that adult smokers are not even willing to try switching, and maintain combustible smoking because they fear that nicotine delivered in non-combustible tobacco products such as ENDS, or medicinally via nicotine replacement therapies (NRT) is as unhealthy or as dangerous as combustible tobacco use.

A number of studies on the use of NRT have shown that there are widespread misperceptions on the safety of nicotine.¹⁻⁷ At least one study has shown that these misperceptions about safety have caused smokers to not use NRT.⁷ Several researchers have suggested that labeling, inserts and advertising materials should be modified to help correct these misperceptions.^{1,7-9} Recent research in the UK points to increased harm perceptions of e-cigarettes compared to cigarettes between 2014 and 2015.¹⁰

2. "Keep Out of Reach of Children" is the Appropriate Warning for ENDS

This leaves FDA with the task of balancing the important concerns of protecting children by conveying the very real dangers of nicotine exposure, but at the same time not discouraging smokers from trying less harmful nicotine products. We



believe the appropriate approach is to adopt the “Keep Out of Reach of Children” warning currently used on many widely available consumer products, such as household chemicals and pharmaceuticals that also pose dangers to children. This well-known and straightforward warning appropriately educates parents that the product is dangerous to their children and encourages them to make sure their children do not have access to the product.

The “Keep Out of Reach of Children” warning should appear on all nicotine-containing ENDS products, including cartridges and liquid nicotine, as soon as possible. Further, FDA should research additional nicotine exposure warnings that strike an appropriate balance between conveying the poisoning risks of nicotine, particularly for children, but that are not likely to deter combustible tobacco users from trying ENDS as a means to quit using combustible tobacco.

Conclusion

We urge FDA to require child-resistant packaging for ENDS and e-liquids as an issue of utmost priority in protecting public health. Children must not be exposed to nicotine, and child-resistant packaging is an important step in preventing accidental ingestion, or absorption through the skin or eyes of liquid nicotine. For the same reason, we also urge FDA to include a “Keep Out of Reach of Children” warning on ENDS and liquid nicotine products. Any additional nicotine warnings that FDA should consider should not perpetuate misperceptions about the safety of nicotine in ENDS compared to combustible tobacco products, or discourage smokers from trying ENDS as a means to quit combustible tobacco products. We note that these comments only refer to nicotine warnings; other health impact-related warnings should be developed by FDA to appropriately communicate the risks of tobacco product use.

We look forward to working with you further on this and other issues to protect public health. Please do not hesitate to contact Stacey Gagosian in our Government Affairs Department, should you have questions at sgagosian@truthinitiative.org or 202-454-5774.

Sincerely,

M. David Dobbins
COO



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