



December 30, 2015

Dr. Stephen Ostroff, M.D.  
Acting Commissioner  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2014-N-2002, RIN 0910-AH19, Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses”**

Dear Acting Commissioner Ostroff:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to provide comments on the proposed clarification of when products made or derived from tobacco are regulated as drugs, devices, or combination products. ACS CAN is the nonprofit, nonpartisan advocacy affiliate organization of the American Cancer Society dedicated to eliminating cancer as a major health problem by supporting legislative, regulatory, and policy efforts that will make cancer a top national priority.

ACS CAN encourages the Food and Drug Administration (FDA) to take into account the collective authorities of its different centers to work collaboratively towards the goal of decreasing the number of people who use and are harmed by tobacco. The top priority of the FDA should be to develop products that enable tobacco users to quit entirely and eventually terminate their dependence on nicotine. Our comments highlight several areas related to industry product applications and claims made in order to avoid unintended public health consequences that warrant particularly critical review by the FDA. ACS CAN supports the FDA’s proposal that a product made or derived from tobacco and intended for human consumption be regulated as a drug device, or combination product if the product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. We believe this “intended use” standard should be interpreted broadly to encompass any claims related to health or the pharmacologic effects of nicotine. However, we have strong concerns about the portion of the rule that would essentially grandfather “customarily marketed” claims that were commonly used in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

While not the main focus of this proposed rule, central to FDA’s ability to decrease death and disease from tobacco use is its full authority over all tobacco products. The absence of a final rule deeming all tobacco products under its authority has led to an unregulated market of new product development and promotion that undercut the interests of public health. . Authority over the full continuum of all new tobacco products is required if the FDA is to achieve its stated strategic priority to establish an integrated, agency-wide policy on tobacco and nicotine-containing products.

## **Introduction**

Use of tobacco is responsible for more than 480,000 premature deaths each year and is the number one preventable cause of death in the United States.<sup>1</sup> Tobacco use increases the risk of at least 14 types of cancer and is responsible for 87 percent of lung cancer deaths and 30 percent of all cancer deaths.<sup>2</sup> The American Cancer Society has documented the lethal consequences of smoking and its detrimental effects on almost every organ of the body, and ACS CAN has advocated for comprehensive public policies to effectively reduce tobacco use and exposure to secondhand smoke in this country. In fact, the reductions in overall U.S. cancer mortality over the past few years can be partially attributed to our work in tobacco control to prevent youth from initiating tobacco use and by helping current users quit.

This progress is in spite of the tobacco industry's long history of altering product design and using marketing strategies to quell concern about the health risks of its products and addict new, young smokers as replacement users for those who have quit or died prematurely from using tobacco. In 1999, the U.S. Government brought a major lawsuit against the tobacco industry alleging the industry was violating the Racketeer Influenced and Corrupt Organizations Act ("RICO"). In this lawsuit, the industry was proven to have engaged in a lengthy, unlawful conspiracy to deceive the American public about the health effects of smoking and environmental tobacco smoke, the addictiveness of nicotine, the health benefits from low tar, "light" cigarettes, and to have manipulated the design and composition of cigarettes in order to cause and sustain nicotine addiction. The verdict was upheld by the DC Circuit Court of Appeals, and the US Supreme Court declined to overturn it.<sup>3</sup>

In the 2006 decision in *U.S.A. v. Philip Morris*, Judge Gladys Kessler found that "Defendants have marketed and sold their lethal products with zeal, with deception, with a single minded focus on their financial success, and without regard for the human tragedy or social costs that success exacted."<sup>4</sup> This litigation represents an important landmark in public understanding of the predatory marketing of tobacco products, and underscores the difficulty of having a legal standard premised on language used by the US Supreme Court six years prior. As explained more fully below, codifying the standard in the proposed rule for tobacco products "as customarily marketed" into regulations is likely to result in more confusion for consumers, as well as creating practical issues of determining what qualifies under the standard.

## **Background on FDA Regulation of Tobacco Products**

In order to appropriately respond to this proposed rule, it is important to understand the history of FDA's authority over tobacco products. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) defines drug, device, and combination product as medical products based on their intended use and requires premarket approval as safe and effective for those intended uses.

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<sup>1</sup> U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

<sup>2</sup> American Cancer Society. Cancer Prevention & Early Detection Facts & Figures 2015-2016. Atlanta: American Cancer Society; 2015. Available at <http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2015/index>

<sup>3</sup> *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in part & vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009) (*per curiam*), *cert. denied*, 130 S. Ct. 3501, 177 L. Ed. 2d 1090 (2010).

<sup>4</sup> *Id.*, at 28.

*The term “drug” means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).<sup>5</sup>*

*The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-*

- (1) Recognized in the official National Formulary, or United States Pharmacopoeia, or any supplement to them,*
- (2) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatments, or prevention of disease, in man or other animals, or*
- (3) Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purpose.<sup>6</sup>*

The FDA has extensive authority over premarket approval of new drugs, devices, and combination products through the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH). A manufacturer, through an application process, must establish that a new drug, device, or combination product is safe and effective for users and that the proposed labeling of the product reflects the intended use. The FDA has approved several applications by manufacturers of products made or derived from tobacco whose intended use includes the cure or treatment of nicotine addiction and symptoms like nicotine craving that result from tobacco cessation. In addition to approving applications, the FDA has the enforcement authority to remove products from the market when manufacturers market products for unapproved intended uses.

In 1996, the FDA issued the first regulation restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. The agency’s position was that cigarettes and smokeless tobacco products were devices to deliver the drug nicotine – which has significant pharmacological effects – and therefore these combination products were under the FDA’s jurisdiction. The regulation was immediately challenged in court by the tobacco industry. Ultimately the Supreme Court, in *FDA v. Brown & Williamson Tobacco Corp.*, ruled that the FDA did not have jurisdiction over tobacco products “as customarily marketed,” and the regulation was not implemented.<sup>7</sup> Notably, the Supreme Court did not define the term “as customarily marketed,” nor is the term in current statute. It is, however, a major component of the current proposed rule.

In June of 2009, almost ten years after the Supreme Court’s opinion, Congress passed and the President signed into law the Family Smoking Prevention and Tobacco Control Act (TCA), which finally granted the

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<sup>5</sup> 21 U.S.C. § 321(g)(1).

<sup>6</sup> *Id.* at § 321(h).

<sup>7</sup> *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 156 (2000).

FDA the authority to regulate tobacco products. Specifically, the agency now has authority to regulate the manufacture, marketing, sale, and distribution of tobacco products. The TCA provides important public health protections, such as prohibiting unsubstantiated health claims and requiring FDA review of any modified risk claims, and prohibiting the marketing directed at youth. In addition, the TCA gives the FDA the authority to require product standards. ACS CAN is committed to ensuring the TCA is fully implemented and enforced for the best protection of public health.

The TCA established a statutory definition of a tobacco product:

- (1) *The term “tobacco product” means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).*
- (2) *The term “tobacco product” does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 353(g) of this title.*
- (3) *The products described in paragraph (2) shall be subject to subchapter V of this chapter.*
- (4) *A tobacco product shall not be marketed in combination with any other article or product regulated under this chapter (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).<sup>8</sup>*

The definition clearly states that those tobacco products regulated as drug, device, or combination products are not subject to the regulations that otherwise apply to tobacco products. Importantly, the TCA recognizes that no tobacco product can ever be determined to be “safe” when used as intended. The law established a new Center for Tobacco Products (CTP) at FDA, as well as a new public health standard to govern the regulation of tobacco products. The public health standard requires the CTP to regulate tobacco products in a manner that is appropriate for the protection of public health and requires the Center to consider “(1) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (2) the increased or decreased likelihood that those who do not use tobacco products will start using such products,” particularly youth, non-users and former users. An important distinction is that the CTP can issue marketing orders for new tobacco products using the new standard whereas CDER can approve a new drug using the safe and effective standard. Finally, the law prohibits a tobacco product manufacturer from explicitly or implicitly stating that their product has been approved by the FDA.

At the same time Congress was considering the TCA, the FDA seized and denied entry into the U.S. several shipments of electronic cigarettes, declaring these products were unapproved drug-device combination products. In the case of *Sottera Inc. v. FDA*, the importer and distributor sued the agency, claiming it had inappropriately categorized e-cigarettes. The Court of Appeals for the DC Circuit Court determined, based on the decision in *FDA v. Brown & Williamson Tobacco Corp.*, that “customarily marketed tobacco products” are to be regulated as “tobacco products” and tobacco products “marketed for therapeutic purposes” are to be regulated as drugs or devices.<sup>9</sup> As a result, electronic cigarettes are permitted to be sold and marketed in the U.S. as long as they do not make therapeutic claims.

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<sup>8</sup> 21 U.S.C. § 321 (rr)(1)-(4).

<sup>9</sup> *Sottera, Inc. v. Food and Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010).

## **ACS CAN Comments on Proposed Rule**

In the proposed rule, the FDA clarifies when a product made or derived from tobacco will be regulated as a drug, device, or combination product as opposed to a tobacco product. The purpose of the clarification is to assist manufacturers intending to market a product made or derived from tobacco as to what application they will need to submit for premarket review and to reduce consumer confusion about whether a particular product is being regulated as a drug, device, or combination product. The rule proposes that “a product made or derived from tobacco and intended for human consumption would be regulated as a *drug device, or combination product* in two circumstances: (1) If the product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or (2) if the product is intended to affect the structure or any function of the body in any way that is different from effects of nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.”

### **The Role of CDER, CDRH, and CTP**

In the April 2013 *Section 918 Report to Congress: Innovative Products and Treatments to Achieve Abstinence from Tobacco Use, Reductions in Consumption of Tobacco, and Reductions in the Harm Associated with Continued Use*, the FDA indicated it was developing “a comprehensive strategy that incorporates the work of CDER and CDRH on medical products and CTP on tobacco products” in order to achieve the public health goal of decreasing the number of people who use and are harmed by tobacco.<sup>10</sup> Key to this strategy will be the approval of new products at CDER and CDRH and the issuing of marketing orders for new products and modified risk claims at CTP, as well as implementation of the other provisions of the TCA designed to protect the public health. ACS CAN encourages FDA to continue to pursue a strategy that can coordinate an information exchange across the centers in order to facilitate appropriate regulatory action to achieve this goal.

#### *CDER Authority*

The FDA’s authority over new products should prioritize those products that enable users to quit tobacco entirely and end their dependence on nicotine. As indicated in the report, there are opportunities for manufacturers of products made or derived from tobacco to receive approval as a drug or device including accelerated approval and fast track processes, new indications, and a new definition of “breakthrough therapies.” Many of these options were not available when FDA approved the existing nicotine replacement therapies and offer new, potentially expedited ways to get FDA-approved drugs to tobacco users. FDA states that it remains open to considering these pathways for new drugs or devices to aid in tobacco cessation, as well as new claims made by existing drugs and devices, and ACS CAN encourages the FDA to prioritize assisting manufacturers interested in these pathways.

#### *CTP Authority*

Section 911 of the TCA was established to address marketing claims and, in particular, so-called “harm reduction” claims a tobacco manufacturer intends to make about its product. This portion of the law is

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<sup>10</sup> U.S. Department of Health and Human Services. Section 918 Report to Congress: Innovative Products and Treatments to Achieve Abstinence from Tobacco Use, Reductions in Consumption of Tobacco, and Reductions in the Harm Associated with Continued Use. April 2013. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM348930.pdf>.

meant to ensure that the tobacco industry does not again mislead consumers about the “reduced harm” of products. Under the TCA, manufacturers need strong evidence to prove modified risk claims, including that the product actually and significantly reduces overall harm and benefits the population as a whole. The standard set by law states:

*(g)Marketing.—*

*(1) Modified risk products.—Except as provided in paragraph (2), the Secretary shall, with respect to an application submitted under this section, issue an order that a modified risk product may be commercially marketed only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—*

*(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and*

*(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.<sup>11</sup>*

The three key components of this standard are (1) the determination is based on how the product is actually used by consumers, not just intended; (2) there needs to be a proven significant reduction in harm to individual tobacco users; and (3) there must be an overall benefit to the population as a whole. The FDA will have to consider not just whether one product is less harmful than a comparison product, but also the impact of the marketing of a modified risk product on discouraging tobacco users to quit and encouraging initiation by non-tobacco users (which includes former tobacco users). Furthermore, the burden of proof for a proposed modified risk claim is on the manufacturer and post-market surveillance is required for any modified risk claim that receives a marketing order.

While this rule is primarily focused on the development of new products and the issuance of modified risk marketing orders, ACS CAN believes there are critically important provisions of the TCA that CTP can and should implement now to protect the public health. These include graphic warning labels on cigarettes, requiring product standards such as addressing menthol in all tobacco products and flavors in tobacco products other than cigarettes, and requiring and enforcing restrictions on the sales and marketing of tobacco products to youth, including online.

#### *Collaboration*

As stated previously, the product requirements and standards to which products will be assessed are different when reviewed by CDER and CDRH or CTP. Therefore it is imperative the FDA be vigilant in ensuring that any new product or marketing claim will achieve the public health goal of decreasing tobacco use and the harm from tobacco use. Specifically, the same products should not be permitted to be approved as a cessation aid by CDER or CDRH and permitted to be marketed for “recreational” use under CTP. We believe FDA should also give careful consideration to not only whether individual products, but also product categories, should be permitted to be approved as aids for smoking cessation and marketed as a tobacco product by considering whether consumers will be able to distinguish FDA-approved medical products from tobacco products. ACS CAN addresses several concerns about specific categories of claims in the next section.

In addition, the FDA should discourage the development, sales, and marketing of products promoted for dual use, such as in places where smoking is prohibited. The promotion of dual use provides no public health benefit and may cause additional risk in extending the duration of smoking, which is an important

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<sup>11</sup> 21 U.S.C. § 911(g).

risk factor for lung cancer. The FDA should use the full strength of its enforcement authority to remove from the market claims that explicitly or implicitly have not been proven, whether as a drug or a modified risk claim.

At the same time, regardless of which FDA Center asserts jurisdiction over a product, FDA should not purposefully or unintentionally create disincentives for manufacturers to develop products that can help reduce death and disease from tobacco use while at the same time maintain its rigorous scientific standards. The action of one center will impact the actions of the others and therefore it is critical that all are working collaboratively to exercise their respective responsibilities to reduce the number of people who use and are harmed by tobacco.

### **Claims Related to Nicotine**

Claims related to nicotine pose an especially difficult area of regulation, and may result in significant consumer confusion if the regulation is enacted as proposed. The FDA has approved several products made or derived from tobacco – such as nicotine gum or patches – as drug or device products which make claims associated with the cure or treatment of nicotine addiction and its symptoms. These claims refer to nicotine craving as a result of tobacco cessation. We agree that products making such claims should continue to be regulated as drug or device products.

In the structure/function prong claims discussion, the proposed rule states that the FDA will *not* consider “claims suggesting that a tobacco product provides an alternative way of obtaining the effects of nicotine” as claims that would require the product to be regulated as a drug or device. These claims could include references to a tobacco user getting a “nicotine fix.” We are concerned that this approach could create consumer confusion as these kinds of claims may not be distinguishable from drug or device claims related to symptoms of nicotine addiction. In addition, the language could be perceived as making modified risk claims. Thus, we believe any claims related to health or the pharmacological effects of nicotine should be regulated under the intended use standard.

In addition, the proposed rule acknowledges that “claims related to satisfaction, pleasure, enjoyment, and refreshment have been recognized as euphemisms for the delivery of a pharmacologically active dose of nicotine.” Consumer perception of relative harm is a major driver of consumer behavior and one that the tobacco industry manipulates effectively through its marketing. The tobacco industry’s aggressive marketing of cigarette filters and “low-tar” cigarettes – despite no proven reduced risk from these product designs – is one example of implied health claims. Claims related to the delivery of nicotine and other unsubstantiated health claims could be reviewed by CDER, CDRH, or CTP depending on the manufacturers’ intended use of the product. We strongly encourage the FDA to carefully monitor and incorporate thorough analysis of consumer perception when making determinations on potential modified risk or drug, device, or combination product claims and ensure there is an ongoing and open exchange of information between the centers to address such claims comprehensively.

As stated previously, a product regulated as a drug or device must meet the safe and effective standard. The TCA created a new public health standard for premarket review of new products and modified risk claims. Adding to the complexity, the TCA “grandfathered” many tobacco products that don’t require premarket review although FDA could still establish product standards for those products. This means that there will be tobacco products and drug products containing nicotine on the market that have varied risks and benefits and that are subject to completely different product regulations. This is likely

to create consumer confusion about the risks and benefits of different products. Therefore, there must be critical oversight and regulation of what claims these products can make.

ACS CAN believes it is important for consumers to know when a product has been approved as safe and effective, and when it has not. The average consumer will be unlikely to distinguish the regulatory framework governing a specific item, so product claims and marketing are crucial vehicles for communicating safety to consumers. Extending the intended use doctrine to claims regarding pharmacological effects would allow the FDA to regulate these items more consistently.

### **“As Customarily Marketed” and Intended Use**

ACS CAN supports the agency’s ability to examine the “intended use” of the product to determine if it will be regulated as a drug, device or combination product. The FDA should have the ability to look at the broad range of claims made, whether in labeling, promotion, or advertising. Also, the agency must be able to examine direct and circumstantial evidence in marketing in order to determine whether therapeutic claims have been made by or on behalf of manufacturers.

In contrast, we do not support use of the “customarily marketed” standard in the regulation. Because these terms are not defined by either the US Supreme Court or the DC Circuit, the proposed language would codify uncertainty into regulation. Such uncertainty engenders questions of proof. For example, if a manufacturer made a specific marketing claim twice in 1999, would that qualify as “customary”? Or would it require a claim to be made over a dozen times over the course of a decade? Not only does the standard lack specific boundaries, it would entail extensive literature review of documents that are by definition over 15 years old. The practical implications of conducting such a review would be onerous.

Our priority is that the FDA act within its authority to ensure that any product claims or marketing are truthful and not misleading to consumers about the actual or relative benefit or harm of a product. The FDA should use the strongest base of scientific evidence available when evaluating claims made by the tobacco industry and use its full enforcement authority to remove products from the market that have made unapproved claims. We know the tobacco industry’s long history of bypassing or simply violating regulations in order to market and sell its products. It is important for tobacco users to be able to distinguish between products that have been FDA-approved as safe and effective for their intended use from tobacco products that have not met that product standard.

Additionally, we strongly encourage the FDA to use its enforcement authority for intended use to review the types of claims made by and on behalf of tobacco manufacturers through all types of media. In particular, we believe the sheer volume and consistency of claims made online and in social media about electronic cigarettes warrants an investigation to determine if these claims (1) convey to consumers that these products are intended uses for drugs, devices, or combination products or pose less risk than other products, and (2) are made by or on behalf of a manufacturer(s).<sup>12</sup>

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<sup>12</sup> The American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative sent a letter on October 14, 2015 to Janet Woodcock, Director of CDER regarding disease claims made by manufacturers of electronic cigarettes without the FDA’s approval.

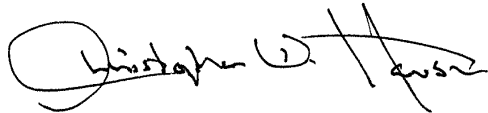


## Conclusion

Decades of experience have shown that the tobacco industry's marketing tactics are hard to predict, have been found in court to be purposefully deceptive, and are based on maximizing profit, not public health. It is incumbent on the FDA to vigilantly apply all of its regulatory and enforcement authority to protect consumers and help prevent consumer confusion. ACS CAN appreciates the opportunity to submit comments on this proposed rule and is ready to assist the FDA in using such authority assertively and aggressively to truly end the enormous toll tobacco takes on our nation.

If you have any questions please feel free to contact either Gregg Haifley at [Gregg.Haifley@cancer.org](mailto:Gregg.Haifley@cancer.org) or Katie McMahan at [Katie.McMahon@cancer.org](mailto:Katie.McMahon@cancer.org). Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Christopher W. Hansen". The signature is written in a cursive style with a large initial "C" and a long horizontal stroke extending to the right.

Christopher W. Hansen  
President  
American Cancer Society Cancer Action Network