



December 24, 2015

Division of Dockets Management (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

RE: Docket No. FDA-2015-N-2002, Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses”

The undersigned organizations submit these comments in the above-designated docket regarding FDA’s proposed rule that is intended to clarify when products made or derived from tobacco are regulated as drugs, devices, or combination products subject to Section V of the Food, Drug and Cosmetic Act (FD&CA), and thus regulated by the Center for Drug Evaluation and Research (CDER), or, alternatively when such products are subject to the provisions of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA) and subject to regulation by the Center for Tobacco Products (CTP).<sup>1</sup>

The principal recommendation in these comments is that FDA should broaden the focus of its discussion to go beyond a technical legal analysis of the relevant statutes and case law and also include a discussion of how its proposed allocation of jurisdiction may affect the public health. The proposed regulation discusses the legal issues in isolation, focusing only on the statutory language as interpreted in relevant judicial decisions. Restricting the discussion in this manner makes it more difficult for FDA to identify and analyze the public health consequences of its decisions.

Moreover, in accordance with the stated purpose of the proposed regulation to clarify the distinctions FDA is proposing, fully considering the policy implications of these distinctions will help FDA recognize ambiguous issues and resolve them in the manner most likely to benefit the public health. Broadening the focus of the inquiry will also enable FDA to identify actions that both CDER and CTP—and FDA as a unified agency—should take to most effectively minimize the number of people who die from tobacco use.

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<sup>1</sup> 80 Fed. Reg. 57756 (September 15, 2015).

Moreover, a final rule addressing these jurisdictional boundaries should also set forth the principles that FDA will apply in the regulation of products containing nicotine, regardless of which FDA Center asserts jurisdiction. In formulating a final rule, FDA should establish an explicit goal of exercising its authority over all nicotine-containing products in a manner that will a) maximize the number of people who quit using cigarettes, cigars and the other combusted tobacco products, and b) minimize the use of all nicotine-containing products by young people and former smokers.

## **DISCUSSION OF LEGAL ISSUES**

Under the FD&CA, whether or not a product is a drug depends on its intended use. A product is a drug if it is intended (1) for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease (the “disease prong” of the definition), or (2) to affect the structure or any function of the body (the “structure/function prong” of the definition). It has been long recognized that the fact that a product is made or derived from tobacco does not preclude it from being considered a drug under existing case law. Long before FDA first asserted jurisdiction over cigarettes, it was regulating nicotine replacement therapy (NRT) products.

Whether products are categorized as “drugs” or “tobacco products” is significant from both a legal and a public health standpoint. Products classified as drugs may not be marketed in the absence of an FDA order finding them to be “safe and effective” for their intended use. Products subject to the Tobacco Control Act, on the other hand, are subject to a set of regulations, designed specifically for tobacco products, that are “appropriate for the protection of the public health.” Such products are subject to different procedural and substantive standards. Despite these differences, the goal of both CDER and CTP is to act in the best interest of the health of the American public, and FDA’s overall mission is to ensure that its constituent Centers work as effectively as possible toward the achievement of that goal.

FDA’s proposed rule analyzes these distinct regulatory regimes, taking into consideration two important judicial decisions construing the application of the FD&CA to products made or derived from tobacco.

First, in *Brown & Williamson Tobacco Corp. v. FDA*, 529 U.S. 120 (2000), the Supreme Court considered whether FDA could assert jurisdiction over cigarettes as devices for the delivery of a drug (nicotine) because nicotine was intended to affect the structure or function of the body. The Court held that, despite the fact that cigarettes meet the literal terms of the definition, FDA could not exercise jurisdiction over cigarettes as “customarily marketed” under the definition because, the Court concluded, Congress had demonstrated its intention to exclude cigarettes as customarily marketed from the definition. In 2009, Congress responded by enacting the Tobacco Control Act, giving FDA jurisdiction over tobacco products, defining tobacco

products to include products “derived from tobacco,” and subjecting them to jurisdiction under a set of substantive standards established specifically for tobacco products.

Second, FDA sought to assert jurisdiction over electronic cigarettes under the disease prong of its drug/device authority, but the U.S. Court of Appeals for the District of Columbia Circuit held that, because electronic cigarettes contained nicotine “derived from tobacco,” they are tobacco products subject to regulation under the Tobacco Control Act in the absence of a therapeutic claim. *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

FDA is correct that *Brown & Williamson* and *Sottera* left in place the application of the drug and device sections of the FD&CA in situations in which a cigarette or other product made or derived from tobacco is sold with “therapeutic claims.” FDA is also correct that these rulings never defined the phrase “as customarily marketed” or the phrase “claims of therapeutic benefit,” leaving the FDA with some discretion as to what claims fall within each category when the distinction is not crystal clear based on existing precedent.

#### *Disease Prong Claims*

In its proposed rule, FDA correctly concludes that nothing in *Brown & Williamson* or *Sottera* limits its authority to exercise jurisdiction over products made or derived from tobacco as drugs or devices if they fall under the disease prong of the definition. As FDA also concludes, claims that a product reduces nicotine withdrawal symptoms indicate that the product is intended to cure or treat nicotine addiction and bring it within the definition of a drug. FDA also correctly concludes that claims that a product reduces nicotine craving associated with quitting smoking and prevents relapse are properly categorized as therapeutic claims and are subject to FDA’s drug/device jurisdiction.

Moreover, FDA is correct in concluding that “consumers are particularly susceptible to confusion where products made or derived from tobacco. . .make claims related to quitting smoking” and that such claims should be subject to careful scrutiny to prevent consumers from becoming confused. In most cases, FDA concludes, correctly in our view, disclaimers are insufficient to mitigate such confusion.<sup>2</sup>

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<sup>2</sup> In this connection, several of the undersigned organizations recently brought to FDA’s attention the fact that some manufacturers of electronic cigarettes have been making disease claims for their products in the absence of meeting the requirements for the marketing of drugs and devices. Letter of October 14, 2015 from American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative to Janet Woodcock, Director of CDER. In light of FDA’s conclusion that consumers are “particularly susceptible to confusion” regarding precisely such claims, it is important for FDA to take prompt and decisive action to enforce these requirements. FDA should make it a priority – now and in the future - to scrutinize these and other claims currently being made for products now on the market that make explicit and/or implicit cessation claims

### *Structure/Function Prong Claims*

FDA's explanation accompanying the proposed rule concludes that neither *Brown & Williamson* nor *Sottera* prevents FDA from exercising jurisdiction over products made or derived from tobacco as drugs/devices under the structure/function prong if they are marketed in a manner that was not "customary" at the time of the *Brown & Williamson* decision. In *Brown & Williamson*, the Supreme Court majority that invalidated FDA's assertion of jurisdiction nevertheless agreed that nicotine was "intended to affect the structure or . . . function of the body," fell within the literal terms of the definition of "drug," and, because cigarettes deliver nicotine, were a device under the literal terms of the statute. Despite this conclusion, the majority invalidated the FDA rule because it concluded that other Congressional actions demonstrated a legislative intent to preclude classification of cigarettes as drugs/devices, principally for two related reasons. First, the majority found that classification of cigarettes as drugs/devices would require FDA to prohibit the marketing of cigarettes since they could never meet the "safe and effective" standard. 529 U.S. at 135-36. Second, the majority found that other statutes, enacted over the course of several decades, demonstrated that Congress intended to preserve the availability of cigarettes "as customarily marketed." 529 U.S. at 159.

In the current Federal Register notice FDA concludes that it retains the ability to regulate tobacco products under the structure/function prong if claims relate to the effects of nicotine that were NOT commonly and legally made in the marketing of cigarettes and smokeless tobacco products prior to the date of the Supreme Court's decision in *Brown & Williamson*. FDA asserts that tobacco products falling within this category would include those marketed to "maintain healthy lung function," "relieve tension," "support the immune system," or "promote weight loss." We agree. On its face, this category of claims would seem to be a narrow one.

### *Tobacco Product Claims*

FDA also cites a number of claims that it concludes would not lead a product to be categorized as a drug/device under the law. We agree that "claims related to satisfaction, pleasure and enjoyment," would not cause the product to be categorized as a drug/device, nor would the promotion of products with lifestyle claims. The same is true for FDA's categorization of claims such as "smoke-free" for smokeless tobacco products, or "full taste and satisfaction" or "spit free tobacco pleasure."

However, several of FDA's other examples pose more difficult questions. FDA concludes that the claims "satisfying tobacco alternative" or that "a tobacco product will provide the same effects as another tobacco product" are tobacco claims, but each implies that the product provides an alternative to the nicotine in cigarettes. Without explicitly saying so, such claims send a message that these products address a tobacco user's nicotine craving, just as do products FDA concludes fall into the drug/device category. The fact that the claim is implicit

rather than explicit should not make a difference. At the very least this categorization requires closer scrutiny and a further explanation.

It is also unclear whether FDA would categorize a claim that says, “Product X will help you switch from cigarettes to Product X because it delivers nicotine in a way that will satisfy the nicotine craving you receive from a cigarette” as a drug claim or as a tobacco claim. It is unclear how such a claim would differ from the claims FDA concludes are drug claims, except that it doesn’t say that the product will help you end your addiction to nicotine altogether. If that is the distinction FDA is making, FDA should make this distinction explicit and explain both its legal rationale and the public health implications.

It is also unclear whether FDA would categorize the following two claims differently:

“Product X will help you switch from cigarettes to Product X and by doing so you will reduce your risk of disease,” versus

“If you switch from smoking cigarettes to Product X, you will reduce your risk of disease”.

The first statement claims a product will help you quit smoking; the second does not make a claim about effectiveness in helping you to quit smoking, but speaks of a benefit that occurs only if you do quit. While the second on its surface falls into the category of claims FDA says fall under the TCA as modified risk claims, will FDA permit the second claim without also requiring the manufacturer to prove the product is likely to help you switch completely from cigarettes to Product X? The second claim would be harmful to the public health if it were allowed without evidence that a product is reasonably likely to help a cigarette smoker switch completely to Product X. However if FDA requires that a manufacturer must present evidence satisfactory to FDA that Product X is likely to help a smoker switch completely, does that requirement cause the product to be reclassified as a drug?

How FDA handles these examples has public health implications as well as legal implications. The final rule should clarify how FDA would classify such claims. A full examination of the public health implications of jurisdictional decisions may well reveal other significant questions that should be addressed in the course of establishing jurisdictional boundaries.

## **PUBLIC HEALTH IMPLICATIONS OF HOW DIFFERENT PRODUCTS ARE CATEGORIZED**

CTP Director Zeller repeatedly has indicated that establishment of a comprehensive nicotine policy ranks as a major strategic objective of FDA tobacco regulation. The goal of this effort should be to promote the fundamental objectives of regulation: to reduce most effectively the toll of death and disease resulting from the use of tobacco products and to prevent young

people from becoming addicted to a deadly product. The establishment of such a policy requires consideration of the jurisdiction of both CDER and CTP and how both Centers will exercise their respective responsibilities.

The marketplace for products containing nicotine is very different now from that which existed when nicotine was available only in traditional tobacco products or through FDA-approved cessation products. Policies developed under prior market conditions may no longer be adequate to meet current challenges. Under the *Sottera* decision, e-cigarettes are to be treated as tobacco products unless their manufacturers make therapeutic claims and FDA's delay in adopting a final deeming rule has meant that e-cigarettes have been marketed with no regulation at all. As a result, nicotine-based products have become and will remain freely available, a reality that did not exist just six years ago, and are widely marketed for non-therapeutic purposes. E-cigarettes are already a significant presence in the market and, given the law as it now stands, will continue to be marketed in some form even after the deeming rule becomes effective. The realities of the new marketplace for nicotine challenge FDA to implement regulatory policies responsive to current conditions.

In establishing jurisdictional lines between CDER and CTP, FDA should focus not only on the legal definitions of different products, but also on what division of responsibility best promotes the purposes regulation was designed to serve. Accomplishing this objective requires FDA to consider how substantive rules and jurisdictional divisions will affect the conduct of those who manufacture, sell, and use these products. The most effective regulatory policies should create incentives for manufacturers and sellers to develop products that can help reduce death and disease from the use of tobacco products and promote them in ways that don't discourage full cessation and minimize use of any tobacco products by young people.

Current policies do not accomplish this goal. As currently applied, the regulatory structure and policies appear to impose the greatest burdens on the actions that would most promote the public health. Thus, for example, FDA regulation of NRTs has imposed limited indications that have hampered the effectiveness of these products and discouraged manufacturers from developing products more likely to be successful in helping more smokers to quit the use of cigarettes and other harmful products. If products like e-cigarettes have a public health value, it is as a way to substantially increase the number of cigarette smokers who quit using tobacco completely or, for those who can't or won't quit using cigarettes, to provide a means to completely switch to the use of products that deliver nicotine in the safest, most regulated ways. Today, however, manufacturers who wish to design products that are more likely to help smokers achieve either goal, and who want to promote them accurately and consistent with the evidence reviewed by FDA to adult smokers who can't or won't quit, face regulatory hurdles in meeting the standards for marketing drugs or devices that have discouraged innovation. By contrast, manufacturers who design and promote products with no regard to cessation, no regard for appeal to youth, and who market them as lifestyle choices, face virtually no regulatory constraints.

Thus, it would be a truly lost opportunity if FDA failed to take into consideration how best to reduce the number of people who die from tobacco use in making its current decision. To do so, it must go beyond simply deciding which Center should have jurisdiction over which products and must set out how each Center will carry out its responsibilities. The status quo does not serve the interests of the public health.

FDA's objective in establishing a comprehensive nicotine policy, and in allocating jurisdiction between CDER and CTP, should be to create incentives for the development of products that will promote the fundamental goal of the regulatory program: to reduce the toll of death and disease from tobacco products. To achieve this goal, the most desirable outcome and the top priority is to develop products that enable smokers to quit tobacco use entirely and eventually terminate their dependence on nicotine. As noted above, however, to date FDA policies have not created adequate incentives for the development of such products and have hamstrung the kind of innovation and incentives necessary for doing so. Policies that make it too onerous to develop such products have proved counterproductive.

Given that nicotine products are and will be available under current law, for existing smokers who cannot become permanently nicotine-free, completely switching to properly designed and well-regulated alternative nicotine products is likely to be a healthier outcome under the right circumstances than continued smoking, even if the smoker continues to be addicted to nicotine for an indefinite period and even though this outcome for existing smokers is less desirable than total cessation of nicotine. It is certainly a more desirable outcome than what has happened in the marketplace in the absence of FDA regulation of these products.

Thus, a comprehensive regulatory policy should create incentives for the development of properly regulated products that can help smokers who can't or won't quit to switch completely even if they continue their addiction to nicotine. Such products should not be promoted in a manner that would lead non-users to initiate tobacco use, deter current smokers from quitting or encourage former smokers to reinitiate use. Regulation of these products should also recognize the harms of nicotine; it needs to be flexible and subject to change because there is still much that we don't know, both about the health effects of the use of these products long term and their actual potential to help smokers quit on a population-wide basis. Thus, it will be necessary to require manufacturers to carefully monitor how these products are used, by whom, and with what impact and to report this information to FDA on a real-time regular basis.

In providing incentives for the development of nicotine-based products that are effective at helping smokers quit or switch completely, FDA should also crack down on explicit or implicit claims for products that have not been shown to be effective at doing so and take steps to rein in the sale and marketing of nicotine-based products that appeal to youth, discourage quitting, and expand the market place for nicotine addiction. In addition, in order to avoid confusion in the marketplace, the same products should not be allowed to be marketed for cessation and complete switching, as well as for recreational purposes.

Products that are promoted and used to facilitate dual use, such as use in situations where combusted products cannot be used, do not provide a health benefit; nor do products that are ineffective at helping cigarette smokers quit or switch completely or that are promoted and used for recreational purposes or for the promotion of a lifestyle. FDA policy should be to discourage the development, sale and marketing of these products to the extent permitted by the law.

Thus, whether a claim of effectiveness in assisting a smoker to quit smoking cigarettes and thereby reducing his risk of disease, constitutes a therapeutic claim requiring classification of the product as a drug/device or, alternatively, a modified risk claim, has important public health consequences. A principal factor in determining whether CDER or CTP should have jurisdiction over a certain class of products should be the degree to which each Center is best positioned to adopt regulations that result in the greatest reduction in the death and disease caused by tobacco use.

If FDA concludes that CDER should have jurisdiction over such claims, it should examine what CDER can do to foster the development of such products without compromising its scientific review process. CDER should recognize, for example, that fast-track consideration of certain nicotine products, or some other mechanism for expedited treatment, may be appropriate in light of the severity of the tobacco epidemic, the prospect for improvement of the health of individuals who quit smoking completely, and the difficulty that smokers often have in quitting smoking even with the help of currently licensed nicotine replacement therapies. Creation of this pathway to market should be designed to create an appropriate incentive for manufacturers to develop products that can meet these requirements and to market them responsibly.

If FDA concludes that products that make these claims are best handled as an MRTP claim, CTP must establish clearly that no such claim will be allowed unless and until adequate scientific evidence has been presented to FDA that demonstrates that the specific product will in fact be effective at helping cigarette smokers switch completely.

Any comprehensive regulatory policy should both place a high priority on preventing minors from using any nicotine-based product and preventing such products from being used to discourage or delay smokers quitting. Products that contain nicotine are not only addictive, but can have seriously adverse effects on the still-developing adolescent brain. Consequently, a comprehensive regulatory policy should include all the restrictions on marketing of all tobacco products subject to FDA jurisdiction that are included in the FDA's 2010 regulations on cigarettes. In addition, because sales of nicotine-based products to minors on the internet have created a major public health problem, on-line sales should be prohibited. In addition to restrictions on the marketing and sale of e-cigarettes, regulation of the product itself should be designed to minimize youth usage. To accomplish this, a comprehensive regulatory policy should prohibit characterizing flavors in such products.

Regardless of what structure and policy FDA creates with regard to claims for newly deemed products, it is important for FDA to establish strict requirements for the product itself to maximize its public health benefits while minimizing its potential risks. No product should be permitted to be marketed unless the manufacturer can demonstrate that it is free of dangerous toxins and can be manufactured consistently to specifications established by FDA.

In conclusion, we urge FDA, in this rulemaking proceeding, to go beyond the legal issues addressed in its Federal Register notice and to consider also the important policy considerations that should inform any rule clarifying when products made or derived from tobacco should be regulated as drugs, devices, or combination products under the FD&CA.

Respectfully submitted,

Campaign for Tobacco-Free Kids

Tobacco Control Legal Consortium

Truth Initiative