



July 18, 2017

Commissioner Scott Gottlieb, M.D.  
c/o Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses”; Further Delayed Effective Date; Request for Comments; Extension of Comment Period

**Docket No. FDA-2015-N-2002**

Dear Dr. Gottlieb:

The Tobacco Control Legal Consortium is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the FDA’s final rule, “Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ‘Intended Uses’; Further Delayed Effective Date; Request for Comments; Extension of Comment Period.” The Tobacco Control Legal Consortium, a program of the Public Health Law Center, is a national network of nonprofit legal centers providing technical assistance to public officials, health professionals and advocates concerning legal and policy issues related to tobacco and public health.<sup>1</sup>

Since its establishment, the Consortium has worked with state and local public health entities and their partners as they implement innovative tobacco control policies that are now mainstays throughout the country. With the Family Smoking Prevention and Tobacco Control Act of 2009, state and local tobacco control stakeholders recognized the massive potential to reverse the death and disease caused by tobacco—the only consumer product that, when used as intended, kills up

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<sup>1</sup> The Tobacco Control Legal Consortium is a program of the Public Health Law Center, at Mitchell Hamline School of Law in St. Paul, Minnesota. The Consortium’s affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Public Health Policy, at University of Maryland Francis King Carey School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Public Health and Tobacco Policy Center, both at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at Center for Social Gerontology, Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.

to half of its users worldwide.<sup>2</sup> In the U.S., that amounts to more than 480,000 deaths each year.<sup>3</sup> Since 2009, state and local tobacco control stakeholders have sought to understand the scope and impact of the FDA's tobacco product authority—both to lend a strong public health voice in the federal regulatory process and to inform their own tobacco control policy goals. The Consortium helps to facilitate that understanding and engage the public health community when opportunities arise to participate in the FDA's regulatory process.

On January 9, 2017, the FDA issued its final rule clarifying when products made or derived from tobacco would be regulated as drugs, devices, or combination products (Final Rule). This was an important first step towards achieving one of the Center for Tobacco Products' key strategic priorities: establishing an integrated, FDA-wide regulatory policy on nicotine-containing products that is public health based.<sup>4</sup> The Final Rule will provide clarity not only to the regulated industry but also to a diverse set of tobacco control stakeholders working to complement and build on the FDA's efforts to reduce tobacco-related death and disease. The Final Rule will also serve as the basis for future regulatory actions to significantly reduce consumer confusion about the variety of products on the market made or derived from tobacco, especially those intended for recreational use, that make claims related to quitting smoking and treatment of nicotine addiction.

The delay of the effective date of the Final Rule to March 19, 2018, was published in the Federal Register on March 20, 2017 (Final Rule Extension). The notice included a request for comments on specific issues raised in a petition for reconsideration and stay of the Final Rule (Petition) regarding amendments to the intended use regulations for drugs and devices at 21 CFR 201.128 and 801.4. The Final Rule Extension also sought comments about any aspect of the Final Rule, including issues related to "intended uses" generally and whether the delay in the effective date should be modified or revoked.

**The delay in the effective date of the Final Rule allows the harms of tobacco to continue to negatively impact the public's health.**

The Final Rule Extension represents over six years of delay on the simple jurisdictional boundaries between Centers at the FDA regarding regulation of

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<sup>2</sup> WORLD HEALTH ORG. TECHNICAL REP. SERIES, THE SCIENTIFIC BASIS OF TOBACCO PRODUCT REG. 3 (World Health Org. Press 2007), [http://www.who.int/tobacco/global\\_interaction/tobreg/who\\_tsr.pdf](http://www.who.int/tobacco/global_interaction/tobreg/who_tsr.pdf).

<sup>3</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL, ch. 12 p. 659 (2014), <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>.

<sup>4</sup> *Center for Tobacco Products' Key Strategic Priorities*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/TobaccoProducts/AboutCTP/ucm404197.htm> (last updated Aug. 8, 2016).

products made or derived from tobacco. As indicated in the Final Rule, the FDA issued a letter to stakeholders in 2011 shortly after the *Sottera Inc. v. U.S. Food and Drug Administration*<sup>5</sup> decision on e-cigarettes. That letter stated that the agency was considering whether to issue a guidance or regulation on therapeutic claims related to products made or derived from tobacco,<sup>6</sup> and the Final Rule was the result of the FDA's deliberations on the issues raised by *Sottera*.

Prolonging consumer confusion about intended uses of marketed products made or derived from tobacco only results in further detriments to the public's health. Without regulations and enforcement of the laws and regulations, the FDA and other tobacco control stakeholders are left to fight a lop-sided battle where industry profits and not public health reign. Clarity also benefits the regulated industry as they determine how best to comply with applicable laws and regulations.

Every year tobacco regulations are delayed represent at least another 480,000 lives lost or adversely impacted by tobacco. We share the view you expressed in your first remarks to FDA staff where you indicated the agency needs to "redouble efforts to help more smokers become tobacco-free" and "at all times ... protect kids from the dangers of tobacco use."<sup>7</sup> To achieve these goals, there should be no further delay in implementing the Final Rule. The sooner the effective date, the better as fewer lives will have to endure the harmful consequences of tobacco use and exposure.

**A comprehensive view of claims and evidence to establish intended use for products made or derived from tobacco is appropriate.**

The Tobacco Control Legal Consortium supports the FDA's consideration of the full context of claims for products made or derived from tobacco in making jurisdictional determinations.<sup>8</sup> The FDA observed in its Final Rule that (1) product marketing, including text and images, can lead to consumer confusion about a

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<sup>5</sup> 627 F.3d 891 (D.C. Cir. 2010).

<sup>6</sup> Lawrence R. Deyton & Janet Woodcock, *Stakeholder Letter: Regulation of E-Cigarettes and Other Tobacco Products*, U.S. FOOD & DRUG ADMIN. (Apr. 25, 2011), <https://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm>.

<sup>7</sup> Scott Gottlieb, Comm'r, U.S. Food & Drug Admin., Dr. Gottlieb's First Remarks to FDA Staff (May 15, 2017), <https://www.fda.gov/NewsEvents/Speeches/ucm558566.htm>

<sup>8</sup> Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses", 82 Fed. Reg. 2193, 2205 (to be codified at 21 C.F.R. pts. 201, 801, 1100) [hereinafter Made or Derived from Tobacco Jurisdictional Regulation].

product's intended use;<sup>9</sup> (2) tobacco products are advertised in a variety of media that can include conflicting information about intended uses;<sup>10</sup> and (3) both youth and adults already perceive certain products made or derived from tobacco to be intended for purposes that are not FDA approved or authorized.<sup>11</sup> These points are even more alarming in light of the fact that several major tobacco product manufacturers have been found liable for violations of the Racketeer Influenced and Corrupt Organizations Act by fraudulently concealing health risks and marketing their products to children.<sup>12</sup>

Given these concerns, the FDA's ability to have a comprehensive view of all relevant sources of evidence is warranted. As the FDA also noted in the Final Rule, "neither the opinions of the scientific and medical communities nor public opinion considered alone should dictate when a product made or derived from tobacco is regulated as a medical product or MRTP [modified risk tobacco product]."<sup>13</sup> In our view, this approach is enough to balance regulated industry and individual user concerns that their products will effectively be taken off the market without any ability to counter an intended use determination.

**The FDA should aggressively enforce existing laws and continue to pursue an integrated, FDA-wide nicotine regulatory policy that prioritizes public health.**

Because the jurisdictional lines already exist between drugs, devices, combination products, and tobacco products, the FDA is not creating new lines or imposing new obligations on product manufacturers.<sup>14</sup> The Final Rule simply clarifies the circumstances for the FDA, the regulated industry, and other stakeholders to know which regulatory framework to apply to particular products. The Final Rule also outlines the already existing consumer confusion about the various intended uses of

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<sup>9</sup> Made or Derived from Tobacco Jurisdictional Regulation, 82 Fed. Reg. at 2204; see Christine D. Czoli et al., *How Do Consumers Perceive Differences in Risk Across Nicotine Products? A Review of Relative Risk Perceptions Across Smokeless Tobacco, E-Cigarettes, Nicotine Replacement Therapy and Combustible Cigarettes*, 26 TOBACCO CONTROL e41 (2017).

<sup>10</sup> Made or Derived from Tobacco Jurisdictional Regulation, 82 Fed. Reg. at 2212; see Ganna Kostygina et al., *New Product Marketing Blurs the Line Between Nicotine Replacement Therapy and Smokeless Tobacco Products*, 106 AM. J. PUB. HEALTH 1219 (2016); Jennifer L. Pearson et al., *Misperceptions of Harm Among Natural American Spirit Smokers: Results from Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study (2013-2014)*, 26 TOBACCO CONTROL e61 (2017).

<sup>11</sup> Made or Derived from Tobacco Jurisdictional Regulation, 82 Fed. Reg. at 2212-13; see Czoli et al., *supra* note 9; Kostygina et al., *supra* note 10.

<sup>12</sup> TOBACCO CONTROL LEGAL CONSORTIUM, *THE VERDICT IS IN: FINDINGS FROM UNITED STATES V. PHILLIP MORRIS* (2006), <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-is-in.pdf>.

<sup>13</sup> Made or Derived from Tobacco Jurisdictional Regulation, 82 Fed. Reg. at 2199.

<sup>14</sup> *Id.* at 2214.

the wide variety of products made or derived from tobacco and how it is likely to increase without clear regulatory guidance and enforcement.<sup>15</sup>

Ensuring that products made or derived from tobacco and intended for human consumption are either safe and effective or reduce the public health threat posed by tobacco are Congressional mandates that express societal values about the standards medical and tobacco products should meet. While the FDA's tobacco product authority is relatively new, it has similarities to its medical product authorities that the agency will certainly learn from as it continues to establish its tobacco product regulation legacy. Because tobacco products are so fundamentally different from medical products, though, and the missions and incentives are not as aligned between the FDA and tobacco industry as they are with medical product manufacturers, the agency's administration and enforcement of seemingly similar authority for these different types of products should necessarily look different.<sup>16</sup>

The FDA has a long history of protecting consumers and the public's health, and even in its relatively short history with tobacco products, the agency has witnessed and experienced an industry whose only incentive is to maximize the sales of its product. Bold and creative enforcement of existing laws is necessary for the FDA to maintain its primary mandate to protect public health.<sup>17</sup> Aggressive FDA enforcement of both the jurisdictional boundaries between regulatory product frameworks for products made or derived from tobacco and MRTP claims would ensure that the agency's goals are met. Clear communication of those enforcement activities to the public would also amplify state and local tobacco control efforts, maximizing limited public health resources. State and local public health professionals could focus on determining how to best meet their public health goals rather than attempting to counter industry talking points about the relative harm of various products.

The FDA has powerful regulatory tools at its disposal to accelerate the decline of harmful tobacco product use and exposure, and the Final Rule is a solid foundation for the agency to set policy and incentives that will meet that goal. Encouraging timely innovation of medical products that will ultimately eliminate the harms of tobacco while also facilitating the development of truly reduced harm or risk products is achievable now that the FDA has regulatory authority over tobacco.

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<sup>15</sup> *Id.* at 2196.

<sup>16</sup> Desmond Jenson et al., *FDA's Misplaced Priorities: Premarket Review Under the Family Smoking Prevention and Tobacco Control Act*, 25 *TOBACCO CONTROL* 246, 247 (2016).

<sup>17</sup> Gottlieb, *supra* note 7.

We appreciate the opportunity to comment and hope the FDA does not delay the effective date of the Final Rule, which merely codifies existing FDA jurisdictional lines to facilitate more effective regulation of these products across FDA centers. The Final Rule reflects the agency's diligent work over the years to use its regulatory authority to reduce the death and disease caused by tobacco, and implementing it fulfills our shared goal of advancing the FDA's special mission and realizing opportunities from science.<sup>18</sup>

Respectfully,



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<sup>18</sup> *Id.*