

# **FDA Should Not Extend the Compliance Period for Marketing Applications and Other Submissions**

Docket No. FDA-2014-N-0189

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There is no rational justification for FDA's proposal to extend the compliance period for submitting a marketing application under either the substantial equivalence (SE) pathway or the premarket tobacco application (PMTA) pathway to 24 months following the effective date of a final rule under the current rule making. The FDA should shorten the compliance periods to no more than 6 months.

## **Premarket authorization and the substantial equivalence loophole**

The Tobacco Control Act requires manufacturers to submit a premarket application and obtain a marketing authorization order before introducing a new tobacco product into interstate commerce. (Section 910) However, a premarket application and marketing authorization order is not required if the manufacturer submits a "substantial equivalence" report under section 905(j) and obtains an order under section 910(a)(2). Under this scenario, a new tobacco product may enter the market if it is "substantially equivalent" to a "predicate product," i.e., a product that was commercially marketed in the United States as of February 15, 2007. In addition to determining that the new product is substantially equivalent, FDA must also determine that the new tobacco product is in compliance with the requirements of the Tobacco Control Act and "does not raise different questions of public health" under section 910(a)(3)(A)(ii).

The substantial equivalence pathway has created a huge loophole, allowing tobacco companies to continue selling products for which premarket approval has not yet been granted so long as SE applications were submitted and the new products were placed on the market before March 11, 2011. To date, five years after enactment of the TCA, more than 3,500 conventional tobacco products remain on the market awaiting an FDA determination that they are NOT substantially equivalent and thus FDA orders them to be removed from the market.<sup>1</sup> We have previously described the problems associated with allowing products to be placed on the market while waiting for FDA to consider the SE application<sup>2</sup>, as well as problems with FDA's statistical analysis of industry SE claims<sup>3</sup>.

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<sup>1</sup> FDA website, Total number of product submissions received or filed in the month, <http://www.accessdata.fda.gov/FDA/track/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all>, accessed on June 15, 2014.

<sup>2</sup> <http://tobacco.ucsf.edu/fda-removes-first-4-tobacco-products-market-3513-go>

<sup>3</sup> <http://tobacco.ucsf.edu/comment-regarding-power-and-effect-size-when-fda-evaluates-industry-claims-substantial-equivalence>

**Highly addictive new tobacco products with toxic or unknown health impacts would remain on the market indefinitely while awaiting FDA’s action under its proposed extension of compliance periods**

In the case of e-cigarette products and other currently unregulated new products, FDA’s proposal would allow these thousands of products to remain on the market for at least another 24 months after a final rule is enacted, so long as the manufacturers submit SE or PMTA applications by that date, and then indefinitely after that unless and until FDA makes a determination that the products are not substantially equivalent or do not otherwise obtain premarket approval. Realistically, this means that most of these highly addictive products, with health effects that are either known to be toxic or are as yet unknown, will remain on the market for at least three years from now, and more likely for close to ten years, if FDA’s previous record is a guide.

Since the proposed rule would permit companies to wait two years after the final rule’s effective date to apply, companies will likely wait until the last possible minute to submit applications and in so doing allow the products to remain on the market for the longest possible time. Companies evidently used this strategy when the TCA was first enacted, as the FDA’s SE website demonstrates that companies submitted 3,552 SE applications in March 2011<sup>4</sup>. If the companies use this obvious tactic for newly deemed tobacco products, FDA will become inundated all at once with thousands of new applications, on top of the thousands already pending, making FDA’s task even more difficult and resulting in thousands of new products remaining on the market pending FDA’s determination.

**Prior to marketing their products, manufacturers must demonstrate that their products are appropriate for the protection of the public health**

FDA correctly notes in the proposed rule that the SE pathway may not be available to many newer products because there were no predicate products on the market as of February 15, 2007, the statutorily mandated reference date. However, this does not create a justification for extending compliance periods, whether or not as a practical matter newly deemed products could use the SE pathway.

In enacting the Tobacco Control Act, Congress made extensive legislative findings regarding the lethal and addictive nature of tobacco products, including that tobacco use by youth is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults (section 2(1)); that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects (section 2(2)); that nicotine is an addictive drug (section 2(3)); and that tobacco use is the foremost preventable cause of premature death in the U.S. (section 2(13)). All of these findings are continually confirmed by scientific evidence, much of which was recently amassed in the 2014 Surgeon General’s Report<sup>5</sup>. Of particular relevance, Congress also found that it is “essential that

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<sup>4</sup> FDA website, Total number of product submissions received or filed in the month, <http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all>, accessed on June 15, 2014.

<sup>5</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, GA: 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.

*manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will 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>6</sup> and that that the FDA has the scientific expertise to evaluate whether products contain harmful substances and to evaluate claims about the safety of products in connection with its mandate to promote health and reduce the risk of harm<sup>7</sup>.*

There is no “safe and effective” tobacco product, so the standard used for approval of drugs cannot be applied to tobacco products. Instead, the Tobacco Control Act reflects Congress’s intent to impose a public health standard for tobacco products that *places the burden on tobacco manufacturers to demonstrate that their products are appropriate for the protection of the public health.*

In other words, there is no underlying assumption that tobacco products are “innocent until proven guilty”; rather, *premarket* approval by FDA is necessary to ensure that new products will not harm the public, but instead will “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.” The substantial equivalence pathway already provides a huge loophole that enables many tobacco manufacturers to effectively evade this important mandate.

If it happens that e-cigarette manufacturers and other new product manufacturers cannot take advantage of this unfortunate loophole that already does not adequately protect the public health, the law already provides the alternative PMTA pathway, which is preferable from a public health standpoint. Tobacco product manufacturers, including e-cigarette companies, have been anticipating FDA’s proposed deeming rule for years, and already have had more than enough time to gather data supporting health and safety claims for their products. They certainly do not need an additional 24 months beyond the date of the final rule to submit such evidence, and such a delay will cause harm. In a previous comment submitted to FDA under this rulemaking, the authors calculated that by shortening the compliance period from two years to six months, the FDA could reduce the number of youth who will try e-cigarettes from 186,243 to 48,873 and reduce the number of youth who would become current e-cigarette users and therefore be more likely to become addicted to nicotine from 54,777 to 13,492.<sup>8</sup>

**Because of the tobacco companies’ history of manipulating nicotine delivery to create and sustain addiction, FDA must not delay analysis of nicotine delivery mechanisms, including non-combustible products**

In his June 11, 2014 remarks at the American Legacy Foundation, the Director of FDA’s Center for Tobacco Products urged the public to recognize that “it’s not the nicotine that kills half of all long-term smokers, it’s the delivery mechanism.”<sup>9</sup> However, the FDA must also

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<sup>6</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, Section 2(36) (June 22, 2009)

<sup>7</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, Section 2(44) (June 22, 2009)

<sup>8</sup> Dutra, L and Glantz, S, *The Proposed Two Year Phase in for Requiring Premarket Approval of Newly Deemed Tobacco Products is Too Long; 6 Months Would be More Appropriate*, Docket No. FDA-2014-N-0189, tracking number 1jy-8cis-skj5 (June 6, 2014)

<sup>9</sup> Clarke T. FDA aims to develop e-cigarette standards; nicotine policy. Reuters. June 11, 2014. Accessed June 15, 2015 at <http://www.trust.org/item/20140611224252-ieqd0>

remember, as Congress did when enacting the Tobacco Control Act, that in August 2006 a United States district court judge found that the major tobacco companies “designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine- related research. *USA v. Philip Morris, USA, Inc., et al.* (Civil Action No. 99–2496 (GK), August 17, 2006).”<sup>10</sup> All those companies have since entered the e-cigarette market while also still selling cigarettes and other combustible tobacco products.

These companies’ past racketeering activities provide ample reason for concern that they may be designing or manipulating e-cigarettes to similarly “precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction.” Indeed, the “delivery mechanism” itself could be designed in a way to maximize these companies’ profits by controlling nicotine delivery levels to increase the likelihood that non-users will become users of nicotine, to decrease the likelihood that current users will stop using nicotine, and that e-cigarette and new product users will become dual users of both combustible and non-combustible products.

FDA needs to analyze products *before* they are introduced into the market, not after they have been marketed for at least three or more years, to prevent products from entering the market that may be deliberately designed to attract and hook more youth and adults, including current users and non-users, to combustible as well as non-combustible products.

**Compliance dates for premarket applications and ingredients submissions for all tobacco products should be no longer than 6 months after date of final rule**

There are significant disadvantages and no benefits for the public health of a compliance period as long as 24 months, let alone longer than that. We propose an alternative compliance date of 6 months following the effective date of a final rule. FDA should not provide for different compliance dates for different kinds of tobacco products.

The very purpose of premarket applications and ingredients submission requirements is to provide FDA with sufficient information upon which to make determinations about whether products are appropriate for the public health. This need is greater, not lesser, for new products about which FDA has little information. It would be premature, irresponsible, and a dereliction of its mandate to protect the public health to assume that any tobacco products, especially newly emerging technologies, are less likely to cause non-users to initiate tobacco use or more likely to cause current users to stop using tobacco products.

If it turns out to be true, for example, that electronic cigarettes are helpful for cessation, manufacturers should be eager to provide scientific evidence to FDA supporting these claims. There would be every reason to submit this information as soon as possible, rather than to delay submission by several years.

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<sup>10</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, Section 2(49) (June 22, 2009)

**Compliance dates should be uniform for all products, and there should be no distinction for products with unsupported claims that they are marketed only to adults or are less harmful**

It is important also to recognize that while the Tobacco Control Act is especially concerned with the devastating impact of tobacco products on youth, its provisions apply to the population as a whole, including adults as well as youth. Therefore, there is no legal or rational justification for making different compliance dates for new products for whose marketing is claimed to be limited to existing adult users. If products are toxic for adults, FDA is mandated to protect adults from those products.

Additionally, for many years tobacco manufacturers have hidden behind claims that their marketing is only directed to adults, but these claims have been proven to be bogus.<sup>11</sup> Similarly, it would be ridiculous for FDA to accede to industry claims that sexy ads for e-cigarettes in magazines such as *Sports Illustrated* are “limited to adults.”<sup>12 13</sup> Moreover, ads that are supposedly *intended* for adults in fact reach youth, and those “adult messages” tend to make those products even more attractive to youth.<sup>14 15 16</sup> We previously submitted a comment under this rulemaking that discusses in detail the enormous negative health consequences of industry marketing efforts targeted at youth, and we incorporate by reference that comment and all of the references therein.<sup>17</sup>

FDA also requests comment on what FDA should consider to help expedite the application review for products that have fewer or substantially lower levels of toxicants that are seeking PMTA marketing authorization. Again, FDA is putting the cart before the horse by even suggesting that some products might be permitted a fast track to authorization because they *claim* to have fewer toxicants. How could FDA possibly know that any particular product has fewer or substantially lower levels of toxicants before applications and supporting documents are first submitted and reviewed by FDA? FDA should not consider extending or staggering compliance dates because it does not have sufficient information upon which to assume that some products are less toxic or addictive than others.

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<sup>11</sup> *USA v. Philip Morris, USA, Inc., et al.* (Civil Action No. 99–2496 (GK), August 17, 2006)

<sup>12</sup> Alpert, H.R., et al. (2008). After the Master Settlement Agreement: Targeting and exposure of youth to magazine tobacco advertising. *Health Affairs*, 27 (6): w503-w512

<sup>13</sup> Hamilton, W.L., et al. (2002). Cigarette advertising in magazines: the tobacco industry response to the Master Settlement Agreement and to public pressure. *Tobacco Control*, 11(Suppl. II): ii54-ii58

<sup>14</sup> Glantz SA. Preventing tobacco use—the youth access trap [editorial]. *Am J Public Health* 1996;86:156–8.

<sup>15</sup> Wakefield, M., Terry-McElrath, Y., et al., Effect of Televised, Tobacco Company–Funded Smoking Prevention Advertising on Youth Smoking-Related Beliefs, Intentions, and Behavior. *American Journal of Public Health* 96:12, 2154-2160 (2006)

<sup>16</sup> Landman, A., Ling, P., and Glantz, S. Tobacco Industry Youth Smoking Prevention Programs: Protecting the Industry and Hurting Tobacco Control. *American Journal of Public Health*: June 2002, Vol. 92, No. 6, pp. 917-930

<sup>17</sup> LM Dutra, RA Grana, L Lempert, JK Cataldo, SA Glantz, BL Halpern-Felsher, PM Ling, L Popova, M Walsh, *FDA Should Restrict E-cigarette Marketing to Protect Youth as Part of the Currently Proposed Regulation*, Docket No. FDA-2014-N-0189, tracking number 1jy-8cl6-lmao (June 10, 2014).

To adequately protect the public health, FDA should require the fastest possible submission of information about the ingredients, toxicants, addictiveness, and appeal of all new tobacco products.