



## FDA'S PROPOSED "DEEMING RULE": KEY ISSUES

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The Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act or TCA), gave the Food and Drug Administration (FDA) immediate regulatory authority over cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco. It also gave FDA authority to extend its jurisdiction over "other tobacco products" by issuing a regulation "deeming" those products subject to the statute. The TCA broadly defines "tobacco product" to include products made from or derived from tobacco, including their components, parts and accessories, except for products already regulated as drugs (i.e., nicotine replacement therapy products).

On April 25, 2014, FDA published a proposed regulation extending its jurisdiction to various "deemed" tobacco products, including electronic cigarettes.<sup>1</sup> If made final, the proposal would subject deemed products to a number of significant regulations that would apply automatically by virtue of a product being "deemed."<sup>2</sup> It also would subject the deemed products to several additional regulations which FDA has discretion to impose, including (1) requirement for a minimum age for sale, (2) health warnings for product packages and advertisements, and (3) limitation of vending machine sales to adult facilities.

### *A Possible "Premium Cigar" Exemption from Regulation*

A significant issue on which FDA is seeking public comments is whether FDA should assert jurisdiction over all cigars or whether it should exempt from regulation what it terms "premium cigars." FDA cites assertions by some that different kinds of cigars "may have the potential for varying effects on public health," particularly if there are differences in youth initiation and frequency of use by youth and young adults. The possibility of a premium cigar regulatory exemption was introduced into the deeming rule after it was sent by FDA for review by the Office of Management and Budget (OMB).

The proposed rule contains two alternative proposals for coverage of cigars and requests public comment on which option FDA should adopt. Under one option, all cigars would be made subject to FDA jurisdiction; under the other option, cigars designated as "premium cigars" would remain unregulated. Such premium cigars would be exempt from any and all regulation by FDA, even from the minimum age requirement and the health warnings proposed by FDA for all other cigars. FDA proposes to define the class of exempt premium cigars according to eight criteria, all of which must be met for a cigar to be exempt. Generally speaking, FDA proposes to exempt handmade cigars, wrapped in tobacco leaf with 100% leaf tobacco binder, with no characterizing flavors, a retail price (after discounts and coupons) of no less than \$10 per cigar (subject to an inflation adjustment) and weighing more than six pounds per 1000 units.

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<sup>1</sup> 79 Fed. Reg. 23142 (April 25, 2014)

<sup>2</sup> FDA describes those "automatic" provisions as the following: (1) enforcement action against products determined to be adulterated and misbranded; (2) required submission of ingredient listing and reporting of harmful and potentially harmful constituents; (3) required registration and product listing for all tobacco products; (4) prohibition of modified risk descriptors and claims unless FDA issues an order permitting their use; (5) prohibition on the distribution of free samples (as with cigarettes); and (6) premarket review requirements for new products. 79 Fed. Reg. at 23143.

It is our view that there is no justification for a "premium cigar" regulatory exemption and that the exemption of any category of tobacco product, including premium cigars, creates a dangerous precedent that could lead to other products being exempted. As FDA's proposed deeming rule itself states, "all cigars are harmful and potentially addictive."<sup>3</sup> FDA writes that "all cigars, regardless of size, produce higher levels of carcinogenic tobacco-specific nitrosamines per gram in mainstream cigar smoke than cigarettes produce in mainstream cigarette smoke."<sup>4</sup> Even cigar smokers who do not inhale have a 7 to 10 times higher overall risk of mouth and throat cancer than persons who have never smoked.<sup>5</sup> FDA notes that "cigar tobacco contains nicotine in concentrations similar to those observed in cigarettes" and that since most cigars contain more tobacco, "many typically contain greater quantities of nicotine than cigarettes."<sup>6</sup> Indeed, "a large cigar may contain as much tobacco as a whole pack of cigarettes." "Nicotine levels in cigar smoke," FDA observes, "can be up to 8 times higher than levels in cigarette smoke . . . ."<sup>7</sup>

Given FDA's own recognition of the inherent hazards and addictiveness of any cigar, the proposed exemption from regulation would not be in the interest of public health. Even if FDA concludes that certain of the requirements applicable to other tobacco products should not be imposed on premium cigars, it can fashion an appropriate set of applicable requirements without completely exempting them from regulation.

### ***Sales and Marketing Restrictions***

The proposed deeming rule would establish a national minimum age (18) for the sale of the newly-deemed tobacco products by retailers, as well as requiring age verification. It also would impose on the deemed products some but not all of the sales and marketing restrictions currently applicable to cigarettes to reduce the availability of the deemed products to young people. For example, it would prohibit the sale of deemed products through vending machines, except in facilities restricted to adults, and it would prohibit the distribution of free samples of the deemed products.

However, FDA is not proposing to apply several other important sales and marketing restrictions currently applicable to cigarettes. First, FDA does not propose to prohibit self-service displays of tobacco products in retail stores, which means that displays of cigars and electronic cigarettes with candy and fruit flavors, in brightly-colored packaging, could still be placed next to the candy aisle in retail stores. Second, the proposed regulation would impose no minimum pack size to prevent the sale of inexpensive single cigars or other products that are appealing to price-sensitive kids. Third, the rule would not prohibit the distribution of non-tobacco merchandise carrying a tobacco product logo. Fourth, it would permit brand sponsorship of athletic or musical events that may have significant youth attendance.

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<sup>3</sup> 79 Fed. Reg. at 23150.

<sup>4</sup> *Id.* at 23151.

<sup>5</sup> *Id.* at 23150.

<sup>6</sup> *Id.* at 23151.

<sup>7</sup> *Id.*

In addition, although FDA's proposed prohibition on the sale of the deemed products to minors applies to all retailers, including internet retailers, the proposed rule does not explicitly impose any age verification requirements on internet sellers. Given the easy accessibility of the deemed products to underage purchasers over the internet and the inherent difficulty of enforcing adequate age verification on internet purchases, FDA should simply prohibit internet sales of the deemed products as a step toward prohibiting internet sales of all tobacco products. At the very minimum, FDA should adopt age verification procedures for internet sellers of deemed products analogous to the procedures required for internet sales of cigarettes and smokeless tobacco products in the Prevent All Cigarette Trafficking Act of 2009 (PACT Act).

Public comments should be submitted pointing out the need to apply the same sales restrictions to deemed products that apply to cigarettes and smokeless tobacco products, as well as stronger provisions to prevent youth access to the deemed products through the internet, including, preferably, a prohibition on internet sales or, at a minimum, application of PACT Act age verification procedures to internet sales of the deemed products.

### ***Advertising Restrictions***

Section 906 of the TCA gives FDA the authority to impose restrictions on the marketing of tobacco products to the maximum extent permitted by the First Amendment. Pursuant to this authority FDA imposed the specific marketing restrictions for cigarettes and smokeless tobacco products first adopted by FDA in 1996.<sup>8</sup> Despite FDA's broad authority under the TCA to impose restrictions on the advertising and promotion of tobacco products, if appropriate for the protection of public health, the proposed rule does not address the advertising of the newly-deemed products, including cigars and electronic cigarettes, in ways and in venues that may be targeting youth, or make any specific proposals for restricting the advertising and promotion of these products.

Electronic cigarette manufacturers like Lorillard have been using advertising that closely mimics the advertising strategies long used by the tobacco industry to attract youth, including the use of celebrities, the use of cartoon characters, and the portrayal of e-cigarettes as glamorous, masculine and rebellious.<sup>9</sup> A recent study found that a significant majority of teenagers have been exposed to e-cigarette advertising, with 73% of 12 to 17-year-olds being exposed to Lorillard's print and TV ads for its product blu.<sup>10</sup> Not surprisingly, youth usage of electronic cigarettes has been increasing dramatically. The Centers for Disease Control and Prevention reported that the percentage of high school students who reported ever using e-cigarettes doubled in one year from 2011 to 2012; ever usage also doubled among middle school students.<sup>11</sup> Despite these troubling facts, the proposed rule does not extend to the newly-deemed products reporting requirements on advertising that are currently applicable to cigarettes.

<sup>8</sup> The 1996 marketing restrictions had been invalidated by the Supreme Court's decision in 2000 ruling that FDA could not assert jurisdiction over tobacco products in the absence of additional legislation. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

<sup>9</sup> *See Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth*, A Report by the Staff of Senator Richard Durbin, Representative Henry Waxman, et. al. (April 14, 2014).

<sup>10</sup> *Vaporized: E-Cigarettes, Advertising, and Youth* (Legacy 2014), at 7.

<sup>11</sup> U.S. Centers for Disease Control and Prevention, "Tobacco Product Use Among Middle and High School Students – United States, 2011 and 2012, 62 *Morbidity and Mortality Weekly Report (MMWR)* (November 15, 2013), at 895.

It would be valuable for public comments to be submitted demonstrating how e-cigarettes and cigars are currently being advertised and marketed, urging that FDA adopt for the deemed products the same or similar advertising reporting restrictions currently applied to cigarettes and smokeless products, and recommending that FDA consider the way products are advertised and marketed in evaluating applications for the marketing of such products.

### ***Warning Labels***

The proposed rule would mandate a health warning about the addictiveness of nicotine for all nicotine-containing tobacco products, including cigars and electronic cigarettes. It also would require four additional rotating health warnings for cigars, addressing (1) the risk of cancer of the mouth and throat, (2) the risk of lung cancer and heart disease, (3) the risk of lung cancer and heart disease from secondhand smoke, and (4) that cigars are not a safe alternative to cigarettes. The four additional cigar warnings would be identical to those already required under the 2000 Federal Trade Commission (FTC) consent orders involving the seven largest cigar manufacturers and would thus require those warnings for other cigar manufacturers as well. The required warnings would be on packaging and advertising. However, FDA is not proposing to require the fifth FTC warning addressing the increased risk of "infertility, stillbirth and low birth weight" because "FDA is not aware of studies specifically linking cigars to these reproductive effects."<sup>12</sup>

Given the severe addictiveness of nicotine, and particularly the vulnerability of adolescents to nicotine addiction, FDA's proposed nicotine warning should be mandated for all tobacco products, including premium cigars. FDA's proposed cigar warnings also should be required for all cigars, including premium cigars, and those warnings should include the fifth FTC warning concerning the reproductive risks of cigars. Recent data from CDC's National Youth Risk Behavior Survey shows that cigar smoking prevalence among high school students is declining at a far slower rate than cigarette smoking prevalence. Indeed, high school boys now smoke cigars at the same rate as cigarettes (16.5 percent for cigars and 16.4 percent for cigarettes).<sup>13</sup>

It also should be noted that, after the proposed rule went to OMB for review, the period for compliance with the health warning requirements was increased from 12 months to 24. The 24-month compliance period exceeds that given industry by the TCA on cigarette textual and graphic warnings (15 months) and smokeless tobacco textual warnings (12 months). Particularly given that the new cigar warnings are already carried on the products of the seven largest cigar manufacturers by virtue of the FTC consent orders, the 24-month compliance period is excessive.

Thus, public comments should urge FDA to mandate its proposed nicotine warning for all tobacco products and require all five of the FTC warnings (in addition to the nicotine warning) for all cigars. Moreover, the comments should indicate that the warnings should be implemented no later than 12 months after the date of the final rule.

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<sup>12</sup> 79 Fed. Reg. at 23168.

<sup>13</sup> CDC, "Youth Risk Behavior Surveillance – United States, 2013, *MMWR* 63 No. 4, June 13, 2014.

### *Use of Flavors in Cigars and Electronic Cigarettes*

Despite the fact that the Tobacco Control Act bans the use of characterizing flavors (other than tobacco flavor and menthol) in cigarettes and despite the mounting evidence of youth usage of cigars and e-cigarettes, FDA is not proposing any restrictions on the sale of flavored cigars or e-cigarettes.

In recent years, cigar consumption has increased dramatically at the same time cigarette consumption has declined. The increase in cigar use has been driven primarily by an increase in the consumption of small, flavored cigars, including candy and fruit flavors that go by names like "Purple Haze," "Hush Honey," "Banana Split" and "Pinkberry."<sup>14</sup> Indeed, a recent study found that 75% of the growth in cigar sales from 2008-2011 represents growth in sales of flavored cigars.<sup>15</sup> Every day, more than 2,700 kids try cigar smoking for the first time, approaching the 3,200 who try cigarettes for the first time every day.<sup>16</sup> Indeed, high school boys now smoke cigars at the same rate as cigarettes. In 2013, 16.5% of high school boys smoked cigars, compared to 16.4 % who smoked cigarettes.<sup>17</sup> There is little doubt that sweet, fruity flavors are especially appealing to kids. According to the Florida Youth Tobacco Survey, of high school cigar smokers, nearly 69% smoke flavored cigars.<sup>18</sup> Although FDA is proposing to extend its jurisdiction over cigars (with the possible exception of so-called "premium cigars"), it is proposing no action at the present time to prohibit kid-friendly flavors in cigars.

As FDA itself notes, electronic cigarettes also are "available in numerous flavors, including vanilla, chocolate, peach schnapps, bubblegum and cola."<sup>19</sup>

In connection with its proposed deeming rule, FDA requested public comments on possible regulatory actions addressing the use of characterizing flavors in newly-deemed products.<sup>20</sup>

Public comments should be submitted documenting the flavors being used in cigars and e-cigarettes and the reasons this poses a public health concern, while recommending that FDA should either incorporate provisions prohibiting characterizing flavors (other than tobacco) in the final deeming rule or issue a proposed rule prohibiting such flavors so that a final rule restricting flavors can be issued immediately following publication of a final deeming rule.

<sup>14</sup> See *Not Your Grandfather's Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation of Kids* (Campaign for Tobacco-Free Kids 2013), at 9.

<sup>15</sup> Delnevo, Cristine D. et al., "Preference for flavoured cigar brands among youth, young adults and adults in the USA," *Tobacco Control*, published online first April 10, 2014 doi: 10.1136/tobacco control-2013-051408.

<sup>16</sup> Substance Abuse and Mental Health Services Administration (SAMHSA), *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*, 2013.

<sup>17</sup> <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DefTabs/NSDUH-DetTabsSect4peTabs1to16-2012.htm#Tab4.10A>. Cigars are defined as cigars, cigarillos or little cigars.

<sup>18</sup> CDC, "Youth Risk Behavior Surveillance – United States, 2013," *MMWR* 63 No. 4, June 13, 2014.

<sup>19</sup> 2013 Florida Youth Tobacco Survey, <http://www.floridahealth.gov/reports-and-data/survey-data/fl-youth-tobacco-survey/reports/2013-state/index.html>

<sup>20</sup> 79 Fed. Reg. at 23157.

<sup>20</sup> 79 Fed. Reg. at 23157.

### ***Mislabeling of Cigarettes as Cigars***

During FDA's long delay in extending its regulatory authority over cigars, manufacturers have labeled products "cigars" that are, in fact, cigarettes, in order to avoid the TCA's prohibition of characterizing flavors in cigarettes and other regulations applicable to cigarettes. The proposed rule does not propose a specific solution but does ask for comment on which characteristics or other factors FDA should consider in determining whether these products are cigarettes, as defined in the TCA.<sup>21</sup>

Public comments should be submitted noting that FDA need not await the completion of the deeming rule before taking enforcement action, under its authority over cigarettes, against unscrupulous manufacturers who are selling cigarettes disguised as "cigars" in defiance of FDA regulations that apply to cigarettes.

### ***Sale of Nicotine Liquid in Uncontrolled Quantities and Without Child-Proof Containers***

With the dramatic recent increase in the use of electronic cigarettes and nicotine-laced "e-juice," there also has been a disturbing increase in incidents of nicotine poisoning involving children, in part because liquid nicotine is not being sold in childproof containers.

Nicotine is a powerful neurotoxin and even tiny amounts absorbed through the skin can cause vomiting and seizures. Indeed, the warning label on Altria's MarkTen e-cigarette product states: "Nicotine is addictive and habit forming and is very toxic by inhalation, in contact with the skin, or if swallowed." CDC recently reported that the number of calls to poison control centers involving e-cigarette products and their components increased from one per month in September, 2010 to 215 per month in February, 2014.<sup>22</sup> In its discussion of the proposed deeming rule, FDA itself noted that in February, 2014, 41.7% of the combined calls to poison control centers for conventional cigarettes and e-cigarettes were for e-cigarette exposures. It further noted that over 51% of those exposures involved children 5 years and younger.<sup>23</sup> The fact that e-cigarettes are sold with candy flavors makes the threat even more acute. As the Director of one poison control center in California put it, "It's not a matter if a child will be seriously poisoned or killed. It's a matter of when."<sup>24</sup>

Despite FDA's expression of concern about nicotine poisoning of children, the agency's proposed rule would do nothing to address the widespread availability of the candy-flavored, nicotine-laced liquid used in e-cigarettes and related products in containers with no child-resistant features.

Public comments should be submitted urging FDA to act swiftly to address this issue. Given the urgency of this threat to our nation's children, FDA should issue a proposed rule to

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<sup>21</sup> 79 Fed. Reg. at 23144.

<sup>22</sup> CDC, "Calls to Poison Center for Exposures to Electronic Cigarettes – United States, September 2010-February 2014, 63 *MMWR* (April 4, 2014) at 292.

<sup>23</sup> 79 Fed. Reg. at 23158.

<sup>24</sup> Matt Richtel, "Selling a Poison by the Barrel: Liquid Nicotine for E-Cigarettes," *New York Times* (March 23, 2014).

require child-resistant packaging of e-liquids and related products in time so that a final rule can be issued at the same time as the publication of a final deeming rule.

### ***Premarket Review of New Products***

Because of the tobacco industry's long history of introducing new products into the market that are more dangerous, more addictive and more appealing, particularly to young people, the TCA prohibits the introduction of new tobacco products unless FDA determines, prior to their marketing, that their introduction would be "appropriate for the protection of the public health." Under Sections 910 and 905j of the statute, new products are those introduced, or modified, after February 15, 2007. The statute also provides for an alternative pathway to market if it can be shown that the new product is "substantially equivalent" to a product already on the market as of February 15, 2007. The TCA allowed products introduced by March 22, 2011 to remain on the market indefinitely unless and until FDA rejected a substantial equivalence application if the application was submitted by that date. More than 3,100 substantial equivalence applications were filed by that date; virtually all these products remain on the market despite the fact that FDA has not yet granted a single application.

The proposed deeming rule would apply the premarket review requirements to the newly-deemed products, but FDA would exercise its enforcement discretion to address the unique status of deemed products. If the provisions of the statute were applied literally to the deemed products, no new products introduced after February 15, 2007 would be permitted to remain on the market because no substantial equivalence applications would have been filed in time to meet the March 22, 2011 deadline. This would mean that probably all e-cigarettes and any cigars that have been changed since February 2007 would be illegal. Thus, FDA is proposing to suspend enforcement of the premarket review provisions for those products that would otherwise be illegal until two years following the issuance of a final deeming rule. As a result of FDA choosing to exercise its enforcement discretion in this way, manufacturers will be permitted to keep existing deemed products on the market and introduce new deemed products until two years after promulgation of a final deeming rule. Moreover, a manufacturer that files a new product application or a substantial equivalence application by that date would be permitted to market the product unless and until FDA denied the application.

The provisions of the proposed deeming rule on new products and substantial equivalence need to be tightened to limit the harm new tobacco products can inflict prior to FDA determinations on substantial equivalence or new product applications.

The period for submitting the application should be shortened to one year from the date the deeming rule became final. This period, during which FDA will not enforce the premarket review requirements, was extended to 24 months after the proposed rule went to OMB for review. In addition, FDA should take concrete steps to avoid undue delay in resolving these applications, including giving priority to applications filed within the one-year deadline in order to ensure that products that do not meet statutory requirements can promptly be removed from the market. In order to avoid manufacturers flooding the market with unmeritorious applications, FDA should promptly review and reject applications that do not provide complete information at the time of filing. FDA must establish a new system to avoid a continuation of its record of

lengthy delays in resolving applications while potentially lethal products remain on the market during FDA review.

As a condition of FDA allowing newly deemed products that would otherwise be illegal to remain on the market, FDA should require that manufacturers of these products meet certain conditions to receive the benefit of the period in which FDA will not enforce the existing statutory provisions. FDA should require manufacturers of such products to adhere to all the sales and marketing restrictions in the 2010 rule as a condition of receiving the benefit of FDA's enforcement forbearance. In addition, FDA should require new product manufacturers to submit ingredient information within 90 days of the final rule and should require manufacturers to meet standards for good manufacturing practices to ensure consistency in nicotine content and other components. FDA should also require manufacturers to supply all advertising and promotional materials and relevant marketing research as part of any marketing application.

Public comments on this section of the deeming rule should emphasize the importance of applying the new product and substantial equivalence standards to the deemed products, but should advocate no more than a one-year period from the final rule during which manufacturers can file substantial equivalence and new product applications while keeping their products on the market. Comments should also urge FDA to place marketing and other restrictions on new products as a condition of receiving the benefit of FDA enforcement forbearance. Comments should also urge FDA to establish a system to ensure that products not remain on the market for a lengthy period while FDA considers the merits of substantial equivalence or new product applications.

#### ***Application of Statutory Standards for Modified Risk Claims***

Because of the tobacco industry's history of responding to health concerns about tobacco by marketing products with false and misleading claims of "reduced risk," the TCA prohibits a manufacturer from making claims that its product presents a lower risk of tobacco-related disease unless the basis for such a claim is thoroughly substantiated to FDA and the agency grants an application permitting the claim to be made. FDA's proposed deeming rule would apply the modified risk provisions to the deemed products.

Public comments should emphasize the importance of applying the modified risk provisions with rigor, particularly in light of the health claims often made for electronic cigarettes. The modified risk provisions of the TCA both protect against the adverse public health consequences of misleading reduced risk claims, while providing a pathway to market for evidence-based modified risk claims.

#### ***Possible Exemptions for Small Manufacturers***

FDA is seeking comments on "any unique challenges" faced by small manufacturers of the deemed products in complying with the proposed rule, specifically noting the concerns of small manufacturers in complying with the proposed registration requirements and the reporting of harmful and potentially harmful constituents.<sup>25</sup> Given the important implications for public health of all the newly-deemed products, there is no justification for weakening the rules for

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<sup>25</sup> 79 Fed. Reg. at 23148.



manufacturers of a certain size. The products made by small manufacturers are no less lethal or addictive than those manufactured by large manufacturers and even a small manufacturer of tobacco products has the capability of causing great damage to public health.

Therefore, it is important that public comments be filed opposing any exemption from the deeming rule for small manufacturers of tobacco products.

### ***Discounting Benefits from Smoking Cessation in Cost/Benefit Analysis***

By Executive Order and statutory mandate, agencies like FDA are required to prepare, for economically significant regulatory actions, a Regulatory Impact Analysis (RIA) assessing the costs and benefits of available regulatory options to allow the agency to select regulatory approaches that maximize net benefits. In its Preliminary RIA for the proposed deeming rule, FDA repeats an error it made in the RIA for its 2011 graphic warnings rule: FDA substantially discounts the benefits to individuals from smoking cessation to account for lost "consumer surplus," i.e., the lost "pleasure" smokers give up by not smoking. Thus, although it is clear that individuals would derive substantial benefits from improved health and longevity if they stopped smoking due to the impact of the deeming regulation, FDA proposes to consider only 30% of those benefits, thus discounting by 70% the benefits from smoking cessation.

FDA's analysis is deeply flawed, in part because the concept of consumer surplus legitimately applies only where the buying decisions of consumers represent thoroughly rational and fully informed choices. However, as FDA acknowledges in the proposed rule, the vast majority of smokers begin smoking and become addicted while they are still underage. The age minimum is based on the premise that the decision of an underage person to begin smoking is neither fully-informed nor rational. It is well established that adolescents are not fully aware of the health consequences of smoking, have little conception of their own mortality and heavily discount the threat of addiction. Moreover, once a consumer becomes addicted, the decision to continue buying cigarettes is no longer rational. The vast majority of smokers say they would quit smoking if they could. It is therefore perverse to consider the satisfaction of an addiction to smoking as a "pleasure." For most smokers, it is an unwelcome burden, with enormous psychic costs from the inability to quit.

It is vitally important that FDA receive public comment objecting to the inappropriate application of the "consumer surplus" concept to smoking and to FDA's proposal to substantially discount the health and welfare benefits to smokers from quitting in response to the issuance of the deeming rule.

### ***The Issue of Delay***

It is important that public comment be submitted to FDA that sets out the harms caused by the three-year delay in issuing the proposed regulation and urges FDA to act without further delay to both issue the final deeming rule and close the gaps left open by the proposed rule. From the time FDA first indicated its intention to deem all tobacco products subject to its regulatory authority under the TCA, it took three full years for a proposed deeming rule to be published. During that period, the market for flavored cigars exploded and electronic cigarette companies began promoting their highly addictive products using techniques long-ago perfected

by the cigarette companies to promote their products to young people. It is very clear that the inexcusable delay in extending FDA's regulatory authority has had real, and continuing, public health consequences.

It is imperative that FDA issue a final deeming rule within one year of publishing its proposed rule, i.e., no later than April 25, 2015.

In addition, FDA must take all necessary steps, beginning immediately, to issue additional proposed regulations to close the gaps left by the proposed deeming rule, including the failure to address the problems caused by current advertising and sponsorship of deemed products and the use of flavors in these products that make them appealing to youth. FDA should either address these issues in the final deeming rule or issue a proposed rule covering these issues so that it is ready to finalize those regulations immediately following issuance of a final deeming rule. For every day that passes without FDA action, there will be more young people exposed to the risk of nicotine addiction and tobacco-related disease.