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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Commissioner Hamburg:

As the leading architect of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) and as members with a longstanding interest in tobacco control, we applaud FDA for issuing its *Proposed Rule on Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*.

The proposed Deeming Rule takes some important steps forward. It will bring a large set of dangerous tobacco products under FDA's regulatory umbrella. For the first time, FDA will regulate e-cigarettes, cigars, and a variety of other types of tobacco products when the rule is finalized.

Ultimately, however, the proposal does not go far enough to protect our nation's youth from the harms of tobacco. The proposed Deeming Rule should be improved through the adoption of an enforcement policy that prevents manufacturers of newly deemed products from using flavorings or marketing tactics that appeal to children. Under this approach, newly deemed products would remain on the market for adults, but children would be protected from unscrupulous manufacturers who target them in their product design and marketing practices.

I. FDA Should Use Its Enforcement Discretion to Protect Youth

In recent years, there has been a dramatic increase in the marketing of novel tobacco products to nonsmokers, especially teenagers. All of these products contain a highly addictive drug, nicotine. E-cigarettes and flavored cigars, in particular, are examples of proposed newly deemed products that are exploding in popularity among youth. The manufacturers of these

products use advertising and promotional techniques that resemble those once employed by cigarette companies to prey upon children.

This makes it urgent for FDA to impose restrictions right away that will keep these and all other newly deemed tobacco products out of the hands of kids. Once FDA finalizes its deeming rule and brings the newly deemed tobacco products under its regulatory purview, the agency will have the authority to bring immediate enforcement actions against irresponsible manufacturers that target youth. FDA should take full advantage of this authority.

The key point is that once e-cigarettes, flavored cigars, and all other newly deemed products are brought under FDA's jurisdiction via the Deeming Rule, they become illegal to market because they are new "tobacco products" that have not received the required FDA premarket authorization. FDA acknowledged this in the proposed Deeming Rule and proposed using its enforcement discretion to give manufacturers of newly deemed tobacco products two years to apply for FDA authorization to market their products. FDA also solicited comments on whether it should limit the application of its enforcement discretion only "[w]hen marketing of the new tobacco product is limited to existing adult users of the product," "[w]hen marketing of the new tobacco product is unlikely to be seen or received by youth," or "to certain categories of products ... based on their relative impact on public health" such as "nonflavored" products.[1]

Given the risks to children, FDA should use its enforcement discretion to allow newly deemed tobacco products, like e-cigarettes and flavored cigars, to remain on the market only if their marketing is restricted to adults. E-cigarettes and cigars should not be allowed to be flavored or promoted in a way that would make these products more attractive to kids. Federal law and FDA regulations have established a set of restrictions to protect children from conventional cigarettes. These restrictions include the ban on flavorings, the ban on self-service displays, and the ban on sponsorships of music and sporting events. Because children can become as addicted to any of the newly deemed tobacco products as they can to conventional cigarettes, FDA should extend its enforcement discretion only to newly deemed products that comply with these same youth access restrictions.

This approach would offer significant advantages over the alternative of waiting for a subsequent rulemaking. The most important advantage is speed. FDA can describe its enforcement policy in the final deeming regulation or through guidance issued contemporaneously with the final regulation. This would have the effect of immediately preventing manufacturers of newly deemed tobacco products from targeting children. The alternative of waiting to impose these restrictions through a separate rulemaking would take years. If the agency has concerns that regulations may be needed to provide permanent protection to children from some categories of newly deemed products, these regulations should

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[1] Department of Health and Human Services, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 79 Fed. Reg. 23142, 23176 (Apr. 25, 2014) (proposed rule).

be promulgated expeditiously. But FDA does not need to wait for these regulations to start protecting children.

In addition, courts give great deference to agency exercises of prosecutorial discretion, which would put the youth access restrictions on a sound legal footing.

A. Youth E-Cigarette and Flavored Cigar Use

All of the newly deemed products contain a highly addictive drug, nicotine, which can have lasting adverse consequences for the developing brain of children.[2] Unlike cigarettes, however, such products are not currently subject to FDA oversight of their manufacturing, sale, and marketing. Manufacturers of e-cigarettes and flavored cigars, in particular, have used this loophole to make and market flavored products to appeal to teenagers.

According to CDC, e-cigarette use by high school students more than doubled between 2011 and 2012.[3] FDA has likewise found that "[m]ore youth who report they would never have used a tobacco product are experimenting with e-cigarettes."[4]

In April, Rep. Waxman and Rep. Pallone released a report with Senator Durbin, Senator Harkin, and other members of Congress that found e-cigarette companies use various marketing practices that appeal to youth, including making e-cigarettes in flavors like Cherry Crush, Chocolate Treat, Peachy Keen, and Grape Mint.[5] The report also found that marketing expenditures by e-cigarette manufacturers more than doubled between 2012 and 2013. In an earlier investigation, we detailed how e-cigarette manufacturers are taking advantage of the absence of regulation to market their products using the same strategies cigarette manufacturers once used to use to target children, including television advertisements, sports and event sponsorships, and even cartoon imagery.[6]

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[2] Department of Health and Human Services, *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General* (2014) (online at www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf).

[3] Centers for Disease Control and Prevention, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students – United States, 2011-2012,* MMWR 62(35);729-730 (Sept. 6, 2013) (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm).

[4] *Supra* note 1 at 23147 (Apr. 25, 2014).

[5] Sen. Richard Durbin, Rep. Henry A. Waxman, Sen. Tom Harkin, et al., *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth* (Apr. 14, 2014) (online at http://democrats.energycommerce.house.gov/sites/default/files/documents/Report-E-Cigarettes-Youth-Marketing-Gateway-To-Addiction-2014-4-14.pdf).

[6] Letter from Rep. Henry A. Waxman, et al. to Margaret Hamburg, Commissioner of Food and Drugs (Nov. 4, 2013) (online at http://democrats.energycommerce.house.gov/index.php?q=news/ranking-members-warn-of-dangers-of-e-cigarette-advertising).

A May report issued by the Legacy Foundation confirms that e-cigarette advertising is reaching teenagers.[7]

The situation is similar, if not worse, with flavored cigars. As noted in the proposal, there is a common misperception that young people do not smoke cigars.[8] In fact, young adults aged 18 to 24 smoke cigars at a rate three times that of older adults.[9] As the proposed rule details, a survey examining the number of people in 2010 who first smoked a cigar found that 37% of them were under the age of 18. Some 3,000 youth begin smoking cigars every day in the United States. Studies of high school students in Massachusetts and Ohio found that cigars were more popular than cigarettes. The most popular kinds of cigars with teens are small cigars and cigarillos because of their sweetened flavors.[10]

In March 2011, Rep. Waxman sent FDA a letter providing detailed evidence obtained by the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations on how a company introduced flavored cigars as a way of circumventing the FDA ban on flavored cigarettes.[11] The company's aim was to foster a seamless transition from smoking flavored cigarettes to smoking flavored cigars that were in fact cigarettes in all respects except name and wrapper.

The Surgeon General and CDC have made similar findings. In March 2012, the Surgeon General reported on the increase in flavored cigars, noting that "flavored cigarettes are reemerging as flavored cigars" due to the fact that they are not presently covered under the Tobacco Control Act flavoring ban.[12] CDC reported that 60% of young cigar smokers smoke cigars with candy, fruit, and other flavors.[13]

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[7] Legacy Foundation, *Vaporized: E-Cigarettes, Advertising, and Youth* (May 2014) (online at http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf).

[8] *Supra* note 1, at 23167.

[9] Dr. Brian A. King, Dr. Shanta R. Dube, Michael A. Tynan, *Flavored Cigar Smoking Among U.S. Adults: Findings From the 2009-2010 National Adult Tobacco Survey*, Nicotine & Tobacco Research (Aug. 27, 2012).

[10] *Supra* note 1, at 23167.

[11] Letter from Rep. Henry A. Waxman to Margaret Hamburg, Commissioner of Food and Drugs (March 28, 2011) (online at http://democrats.energycommerce.house.gov/index.php?q=news/rep-waxman-urges-fda-to-ban-clove-flavored-cigars).

[12] U.S. Department of Health and Human Services, Office of the Surgeon General, *Preventing Tobacco Use Among Youth and Young Adults* (March 2012) (online at www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf).

[13] *Supra* note 9.

B. The FDA Proposed Deeming Regulation

The Tobacco Control Act defines a new tobacco product as any tobacco product that was not commercially marketed in the United States as of February 15, 2007. In the proposed regulations, FDA states that "most proposed deemed tobacco products would be considered new tobacco products and would be required to obtain an order from FDA prior to marketing."[14] FDA further states that the absence of FDA authorization would make these products "adulterated" and subject to FDA enforcement action.[15]

To allow the continued marketing of newly deemed tobacco products after they are brought under FDA's jurisdiction, FDA proposed a "compliance policy." Under this policy, FDA would exercise its enforcement discretion and establish a 24-month period during which a manufacturer could continue to market its tobacco products. If the manufacturer submits an application for FDA authorization during this period, the compliance period would be extended until FDA acts on the application.[16]

FDA also sought comment on whether a more restrictive compliance policy would be in the public interest. FDA specifically asked for comment on these questions:

> [I]s there a justification for having the compliance period instead apply to the following circumstances: When marketing of the new tobacco product is limited to existing adult users of the product? When marketing of the new tobacco product is unlikely to be seen or received by youth?[17]

FDA also asked for comment on whether the compliance policy should be available "only to certain categories of products, such as based on their relative impact on public health."[18] FDA delineated examples of factors the agency could take into account to determine a product's impact on public health, including whether the product is "nonflavored."[19]

During the compliance period, newly deemed tobacco products would not be completely unregulated. Under the proposed Deeming Rule, all such products would become subject to the following Federal Food Drug and Cosmetic Act provisions that apply to conventional cigarettes:

(1) Enforcement action against products determined to be adulterated and misbranded;

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[14] *Supra* note 1, at 23174.

[15] *Supra* note 1, at 23175.

[16] *Id.*

[17] *Supra* note 1, at 23175-6.

[18] *Supra* note 1, at 23176.

[19] *Id.*

(2) Required ingredient listing submission and reporting of harmful and potentially harmful constituents;
(3) Required registration and product listing;
(4) Prohibition against use of modified risk descriptors (e.g., ''light" and ''low'') and claims unless FDA issues an order permitting their use;
(5) Prohibition on the distribution of free samples;
(6) Required minimum age of purchase (18 years of age or older);
(7) Health warnings for product packages and advertisements; and
(8) Prohibition of vending machine sales, unless the vending machine is located in an adults-only facility.[20]

However, there are many youth access restrictions that apply to conventional cigarettes that would not apply to newly deemed tobacco products during the compliance period as proposed by FDA. These include the prohibition on characterizing flavors that appeal to kids, such as cherry and chocolate; the prohibition of tobacco brand-name sponsorships of sports and entertainment events; and the prohibition on self-service displays.[21]

C. A More Protective Compliance Period

FDA's proposed 24-month compliance period puts the nation's youth at risk. During this period, manufacturers of newly deemed tobacco products would remain free to continue to market flavored products that appeal to teenagers and to do so using marketing strategies that target them. This could reverse decades of gains in reducing youth tobacco use and lead to a surge of nicotine addiction among teenagers.

FDA should instead use its enforcement authority to take immediate action to protect children. As FDA suggested in the proposal, the agency could do this by bringing enforcement cases against manufacturers of newly deemed tobacco products that are marketing products or using advertising strategies that appeal to children. Under this approach, the FDA compliance period would be reserved for manufacturers of tobacco products that market their products only to adult smokers.

FDA does not have to "reinvent the wheel" in deciding what additional restrictions should be made conditions of the compliance period. Federal law and FDA regulations have established a set of restrictions for cigarette manufacturers that are designed to protect children from conventional cigarettes. FDA can use its enforcement discretion so that only those newly deemed tobacco products that comply with these same restrictions may remain on the market during the compliance period. This approach makes sense because all newly deemed tobacco

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[20] *Supra* note 1, at 23143-23144.

[21] *See* Section 907(a) of the Tobacco Control Act (P.L. 111-31) (codified at 21 U.S.C. § 387g(a)); Department of Health and Human Services, *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 75 Fed. Reg. 13227 (Mar. 10, 2010) (final rule).

products contain the same addictive drug, nicotine, as conventional cigarettes, and because these restrictions have been proven to be effective.

There are five specific youth access restrictions that apply to manufacturers and distributors of conventional cigarettes that should also be applied to manufacturers and distributors of newly deemed tobacco products during the compliance period. These are:

(1) The ban on the use of all flavorings except traditional tobacco flavorings;[22]
(2) The prohibition of tobacco brand-name sponsorships of sports and entertainment events;[23]
(3) The prohibition on self-service displays;[24]
(4) The requirement that audio advertisements use only words, with no music or sound effects:[25] and
(5) The prohibition on delivery through the mail and the requirement of age verification at the time of both sale and delivery when the seller is not in the physical presence of the buyer.[26]

The rationale for incorporating these restrictions as conditions of any compliance period is compelling. Section 907 of the Tobacco Control Act prohibits the use of characterizing flavorings in cigarettes, reflecting the congressional understanding that the tobacco industry manufactured these products with sweet and fruity flavors as a key part of its strategy to addict young people to its lethal products. These banned flavorings are now being used in e-cigarettes and flavored cigars, and the result is the same: they are enticing youth to try these products. Bad actor companies that are using flavorings that appeal to children in newly deemed products should not receive the benefit of FDA's enforcement discretion.

The same reasoning applies to the other restrictions that Congress enacted to protect children from tobacco products. The compliance period should be available only to responsible manufacturers that take basic steps to keep their products away from kids.

D. Childproof Packaging

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[22] Section 907(a) of the Tobacco Control Act (P.L. 111-31) (codified at 21 U.S.C. § 387g(a)).

[23] *See* Department of Health and Human Services, *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 75 Fed. Reg. 13227 (Mar. 10, 2010) (final rule).

[24] *Id.*

[25] *Id.*

[26] Prevent All Cigarette Trafficking Act of 2009 (P.L.111-154) (codified at 15 U.S.C. § 375).

Another way the regulatory void surrounding e-cigarettes has endangered our children is through exposure to liquid nicotine, a dangerous toxin. Poison control centers across the country have reported a significant increase in the number of exposures to e-cigarette devices and liquid nicotine. From 2012 to 2013, there was a 219% increase in such exposures.[27] According to the U.S. Centers for Disease Control and Prevention, calls related to poisoning from the liquid nicotine used in e-cigarettes ran at a rate of roughly one a month in 2010, but jumped to 215 in February of this year alone.[28] Doctors at the Einstein Medical Center in Philadelphia say that just "one teaspoon of a 1.8 percent nicotine solution could be lethal" to a 200-pound person.[29]

More than half of these exposures have occurred in young children under the age of six.[30] According to the American Association of Poison Control Centers, some children and toddlers who come in contact with e-cigarette devices or liquid nicotine have become very ill, and some have required emergency room visits with nausea and vomiting.[31] The use of child-friendly flavors, like "gummy bear," makes these products even more likely to attract children and exacerbates the threat of poisonings.

This is an urgent threat. The director of CDC's Office on Smoking and Health warned earlier this year, "[w]e have not had an unintentional poisoning death from e-cigarettes yet in the United States that we know of, but the potential is there given the amount of concentrated nicotine in these solutions -- it would not take a lot for a child death to occur."[32]

This danger can also be addressed through FDA's enforcement discretion. As part of its compliance policy, FDA should allow the sale and marketing of e-cigarettes and liquid nicotine products for adults only if they are packaged in child-resistant containers.

E. Legal Authority for Using Enforcement Discretion

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[27] American Association of Poison Control Centers, *E-Cigarette Devices and Liquid Nicotine*, (online at: http://www.aapcc.org/alerts/e-cigarettes/).

[28] Centers for Disease Control and Prevention, *Calls to Poison Centers for Exposures to Electronic Cigarettes – United States, September 2010-February 2014,* MMWR 63(13):292-293 (April 4, 2014) (online at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm?s_cid=mm6313a4_w).

[29] Bassett, R, et al., *Nicotine Poisoning in an Infant*, New England Journal of Medicine, 370;23 (June 5, 2014) (online at: http://www.nejm.org/doi/pdf/10.1056/NEJMc1403843).

[30] *Supra* note 28.

[31] *Supra* note 27.

[32] U.S. News & World Report, *Nicotine Poisoning of Infant Highlights 'E-Cig' Dangers, Docs Report,* (May 7, 2014) (online at: http://health.usnews.com/health-news/articles/2014/05/07/nicotine-poisoning-of-infant-highlights-e-cig-dangers-docs-report).

Judicial deference to federal agencies is at its highest when the agencies are exercising their prosecutorial discretion, which is what FDA would be doing if it prioritized its enforcement efforts by going after newly deemed products targeted at children while allowing those aimed at adult smokers to remain on the market.

The seminal case on agency use of enforcement discretion is *Heckler v. Chaney,* 470 U.S. 821 (1985). In *Heckler*, the Supreme Court stated: "This Court has recognized on several occasions over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion. This recognition . . . is attributed in no small part to the general unsuitability for judicial review of agency decisions to refuse enforcement."[33] The Court further elaborated on the reasons that enforcement discretion is generally unsuitable for judicial review:

> First, an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all. An agency generally cannot act against each technical violation of the statute it is charged with enforcing. The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities.[34]

In *Heckler,* the Supreme Court created a presumption against judicial review of an agency's exercise of enforcement discretion. According to the Court, the presumption may be rebutted "where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers"[35] or where Congress has "indicated an intent to circumscribe enforcement discretion, and has provided meaningful standards for defining the limits of that discretion."[36] Lower courts have interpreted this to allow review when there is a claim that the enforcement policy unlawfully construed a statute.[37]

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[33] 470 U.S. at 831.

[34] 470 U.S. at 831-832.

[35] 470 U.S. at 832-833.

[36] 470 U.S. at 834-835.

[37] *See, e.g., Edison Electric Institute v. EPA*, 996 F.2d 326, 333 (D.C. Cir.1993) (explaining that petitioners are challenging EPA's interpretation of the statute and its implementing regulations, which "clearly ... [have] to do with the substantive requirements of the law; it is not the type of discretionary judgment concerning the allocation of enforcement resources that [*Chaney*] shields from judicial review"). Most recently, the district court in D.C. rejected the argument that an FDA guidance document spelling out the agency's enforcement plan for companies engaged in compounding was reviewable. *See K-V Pharm. Co. v. FDA*, 889

In this case, there is little likelihood that a challenge to FDA's application of its enforcement discretion could succeed. If FDA adopted the approach recommended in these comments, it would announce an enforcement policy that says the agency will not take enforcement action during the compliance period against responsible manufacturers that do not use flavorings or marketing tactics that appeal to children. There is no provision in the Tobacco Control Act that prohibits FDA from adopting this policy. To the contrary, the enforcement policy furthers one of the core objectives of the law: the protection of children from addictive tobacco products. As stated in section 3 of the Tobacco Control Act, one of the primary purposes of the law is "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people."[38]

The importance of protecting children is reflected even in the short title of the Act, which provides that official title of the law is the "Family Smoking Prevention and Tobacco Control Act."[39] Congress intended the Tobacco Control Act to be a broad grant of authority to FDA to regulate tobacco products in order to protect the public health, especially the health of children. FDA should use this authority to narrow the compliance policy laid out in the proposed Deeming Rule in order to fulfill the congressional intent to protect children that underlies the Tobacco Control Act. FDA's enforcement policy should be to take immediate action against manufacturers of newly deemed tobacco products that use marketing approaches or flavors that will entice children and addict them to nicotine.

F. Providing Permanent Protection to Children

The enforcement policy recommended in these comments will provide immediate protection to children. This is needed to prevent the newly deemed products from continuing their explosive growth among youth. It is also important, however, to ensure that these protections remain in place at the end of the compliance period.

The Tobacco Control Act has two primary pathways that a manufacturer of a newly deemed product could elect to seek authorization from FDA to market its product. Many of the newly deemed products such as e-cigarettes are unlikely to have a predicate product that was on the market before February 17, 2007. These manufacturers will need to seek "new product" authorization under section 910 of the Tobacco Control Act. Under this section, FDA will have the authority to continue the restrictions on targeting children when it acts on the new product application. Section 910(c)(1)(B) of the Act allows FDA to impose restrictions on "the sale and distribution of the tobacco product" as a condition of FDA authorization "to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section

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F. Supp. 2d 119, 137 (D.D.C. 2012), *vacated*, 2014 WL 68499 (D.C. Cir. Jan. 7, 2014) (the vacatur resulted from a settlement).

[38] 21 U.S.C. 387 note.

[39] 21 U.S.C. 301 note.

906(d)."[40] Section 906(d) authorizes "restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of public health."[41] Any restrictions established during the compliance period to protect children would be restrictions on the sale and distribution of the product that FDA could make permanent by making them conditions of any authorization to market.

The other pathway for premarket approval is the "substantial equivalence" route. FDA's authority to impose conditions on manufacturers that seek FDA authorization under section 905 for products that are "substantially equivalent" to products on the market prior to February 15, 2007, is constructed differently. The definition of "substantially equivalent" in section 910(a)(3) requires either that the products have the same "materials, ingredients, design, composition, ... and other features" or that the different characteristics are not sufficiently different to make it "appropriate to regulate the product" because "the product does not raise different questions of public health."[42] Few, if any, newly deemed products are likely to have exactly the same characteristics as products on the market before February 15, 2007. For those that have differing characteristics, FDA will likely have substantial authority under the "appropriate to regulate" standard to deny or condition authorization for products that are appealing to children.

In the event that the agency has concerns about the extent of its authority to protect children when manufacturers seek authorization under the substantial equivalence pathway, FDA has several available options. The worst offenders likely to seek substantial equivalence authorization are manufacturers of the flavored cigars that children smoke instead of cigarettes. These products are not used like traditional cigars. They are manufactured to be virtually indistinguishable from cigarettes. The Maryland Department of Health and Mental Hygiene makes a compelling case that FDA has the authority to classify them as cigarettes under the definition in section 900(3) of the Act. This would permanently extend all the restrictions in the compliance period to these products.

Alternatively, as several public health groups recommend, FDA could expeditiously promulgate final regulations extending the flavorings ban and other marketing restrictions to the products. A compliance period that protects children would give FDA a window of time to complete this rulemaking.

II. The Deeming Rule Should Apply To All Cigars

FDA's proposed Deeming Rule proposes two options for regulating cigars. Option 1 would deem all cigars to be subject to FDA's oversight as "tobacco products," while Option 2 would exempt so-called "premium cigars."[43] Option 1 is the superior option.

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[40] Codified at 21 U.S.C. § 387j(c)(1)(B).

[41] Codified at 21 U.S.C. § 387f(d).

[42] Codified at 21 U.S.C. § 387j(a)(3).

[43] *Supra* note 1, at 23150-52.

In the proposal, FDA provides no evidence to support differentiating premium cigars from any other cigars on the basis of product safety. Nor does FDA provide any evidence to suggest that cigars are safe. To the contrary, FDA explains that all cigars are harmful and addictive, and it cites numerous studies documenting this. FDA notes that a large cigar may contain as much tobacco as a whole pack of cigarettes and that premium cigars have almost eight times as much nicotine as unfiltered cigarettes. According to the National Cancer Institute, "cigar smoke is as, or more, toxic and carcinogenic than cigarette smoke; and differences in disease risks produced by using cigarettes and cigars relate more to differences in patterns of use, and differences in inhalation, deposition and retention of cigar smoke than to differences in smoke composition."[44] Given that nearly 17 million adults smoke cigars, these public health concerns are significant.[45]

One danger of exempting premium cigars is the risk that manufacturers will develop new products that exploit this loophole. This is not a theoretical concern. In August, 2012, Rep. Waxman sent FDA a letter providing detailed evidence from internal company documents that showed tobacco companies continually invent new ways to circumvent public health protections. These documents revealed how tobacco manufacturers manipulated their existing products and introduced new ones to avoid FDA regulation and higher federal tax rates.[46] The tobacco industry has a long history of exploiting any loophole, including shifting customers from regulated or taxed tobacco products to those that are unregulated or more lightly taxed. An exemption for premium cigars could invite similar practices.

The proposal states that it could be difficult for small businesses that make premium cigars to fulfill certain requirements, such as ingredient listing and reporting, and asks for comments on how FDA should address these concerns.[47] Exempting premium cigars from FDA's jurisdiction altogether is unnecessary to meet these concerns. FDA could instead consider whether to tailor any requirements to the needs of small businesses.

However, FDA should not waive or loosen any requirements that could imply that premium cigars are safer than other tobacco products or that could be used to encourage the smoking of such cigars. Thus, FDA should not waive requirements for health warnings or

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[44] *Supra* note 1, at 23151.

[45] Centers for Disease Control and Prevention, *Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012–2013*, MMWR 63(30); 650-654 (August 1, 2014) (online at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6330a2.htm).

[46] Letter from Rep. Henry A. Waxman to Margaret Hamburg, Commissioner of Food and Drugs (August 27, 2012) (online at http://democrats.energycommerce.house.gov/index.php?q=news/ranking-member-waxman-releases-new-tobacco-documents-and-calls-on-fda-to-protect-youth-by-closi).

[47] *Supra* note 1, at 23148.

prohibitions on the use of modified risk descriptors, distribution of free samples, or vending machine or other non-face-to-face sales.

III. FDA Should Revise Its Regulatory Impact Analysis

On August 6, 2014, we joined with Senators Blumenthal, Durbin, and many other members of the House and Senate to urge revisions of the regulatory impact analysis. As explained in that letter, which is attached, FDA's regulatory impact analysis of the proposed Deeming Rule should be revised to more accurately reflect the benefits from smoking cessation.

IV. Conclusion

Tobacco policy in the United States is at a crossroads.

New products are being marketed that some believe have a potential to reduce risks for adult smokers. Although these products become technically illegal to sell once they are deemed to be tobacco products, we do not object to their continued availability during a short compliance period for adult smokers so long as they are marketed solely and responsibly to adults. Rigorous FDA review will be needed to separate genuine advances in health from novel ways to maintain dangerous addiction to tobacco.

But we cannot allow our children to become collateral damage. Unless prompt action is taken, the recent trends of soaring use by teenagers of these products will continue. The new products will become so entrenched that our opportunity to protect children from becoming lifelong addicts of these products vanishes.

A multi-step rulemaking – deeming followed by a second round of rulemaking to impose restrictions on flavorings and marketing practices – will take too long. That is why it is so urgent that FDA utilize its ample enforcement discretion as described in these comments until such time as FDA promulgates a regulation to accomplish all of these critical restrictions to protect children. FDA has the authority to craft a compliance policy that fully protects our youth and should do so without delay.

Sincerely,

Henry A. Waxman
Ranking Member

Frank Pallone, Jr.
Ranking Member
Subcommittee on Health

Diana DeGette
Ranking Member
Subcommittee on
Oversight and
Investigations