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

Comments on Docket No. FDA-2017-N-5095, Review of Existing Center for Tobacco Products Regulatory and Information Collection Requirements

The undersigned organizations submit these comments in the above-designated docket.

The notice in this docket asks commenters to “identify those regulations that merit repeal, replacement or modification” in order to “alleviate regulatory burdens.” The notice specifies a number of ways a regulation might be subject to such designation: (1) the regulation might be “outdated, unnecessary or ineffective”; (2) the regulation might impose costs in excess of benefits; (3) the regulation might have been superseded by other events; (4) the regulation might be rendered unnecessary due to the existence of voluntary industry standards; (5) the regulation imposes unnecessary burdens for compliance; (6) the regulation requires the unnecessary collection of data; and (7) the regulation unnecessarily eliminates jobs.

After reviewing the existing regulations of the Center for Tobacco Products (“CTP”), the undersigned believe that there are no regulations issued by CTP that meet any of these criteria and that implementation of Executive Order 13771 does not justify elimination of any such regulations.

The Center for Tobacco Products, created in 2009 pursuant to the authority of the Family Smoking Prevention and Tobacco Control Act of 2009 (“Tobacco Control Act” or “TCA”), is the newest center at FDA. Congress enacted the TCA following the Supreme Court’s decision in *Brown & Williamson Tobacco Corp. v. FDA*, 520 U.S. 120 (2000), in which the Supreme Court invalidated FDA’s attempt to subject cigarettes to FDA jurisdiction under the Food, Drug and Cosmetic Act (“FDCA”). The Supreme Court held that, despite the fact that tobacco usage constituted “perhaps the largest preventable cause of death in the United States,” Congress had not intended the FDCA to subject tobacco products to FDA regulation. In response, in 2009 Congress enacted the TCA, which provided the statutory basis for the regulation of tobacco products and created the Center for Tobacco Products to administer the TCA.

The TCA contains an extensive recitation of findings and purposes that defines and informs the CTP's mission. In addition, the statute provides FDA with an extensive array of authorities, including but not limited to the authority to set standards for tobacco products, to grant marketing orders to permit the sale of new tobacco products, to regulate the advertising and promotion of tobacco products, to require reporting of the ingredients of tobacco products and of the level of hazardous and potentially hazardous components in tobacco products, and many others.

In order to fulfill these functions, the TCA required FDA to promulgate regulations in some areas and authorized FDA to do so in others. Pursuant to this authority, FDA has promulgated only a few final rules. The principal such rules are those concerning the sale, promotion and advertising of tobacco products to youth that FDA was explicitly required to promulgate by the statute; a rule requiring graphic warning labels for cigarettes, also required by the statute, that was subsequently invalidated by the United States Court of Appeals for the District of Columbia Circuit in *R.J. Reynolds Tobacco Company v. FDA*, 696 F. 2d 1205 (D.C. Cir. 2012); a rule to establish user fees to finance the operations of the CTP; and a rule pursuant to which FDA asserted jurisdiction over e-cigarettes, cigars, pipe tobacco, hookah and other tobacco products by deeming them subject to the agency's authority (the "deeming rule"). One proposed rule is under review following submission of public comments: a rule that would establish a product standard setting a maximum level for Nitrosonornicotine ("NNN") in smokeless tobacco products.

I. Brief Description of Regulations Issued by the Center for Tobacco Products

A. Regulations Regarding the Sale and Promotion of Tobacco Products to Underage Users.

When FDA first asserted jurisdiction over tobacco products in 1996, FDA promulgated regulations designed to reduce the advertising and promotion of cigarettes and other tobacco products to underage users. These regulations were invalidated in 2000 when the Supreme Court held that the FDCA did not confer on FDA the jurisdiction to regulate tobacco products. When Congress enacted the TCA in 2009 it directed FDA to promulgate the 1996 rules except to the extent that courts had found such rules conflicted with constitutional requirements. Accordingly, in 2010 FDA promulgated rules that prohibited the sale of tobacco products to underage users and required age verification for such purposes; prohibited or restricted the sale of tobacco products in non-face-to-face transactions; prohibited the distribution of free samples of tobacco products; prohibited the distribution of brand-name merchandise and promotion of sports and entertainment events with tobacco product brand names. 75 Fed. Reg. 13225 (March 19, 2010). Tobacco product manufacturers brought suit to invalidate these provisions but most of the

provisions of the rule were upheld in *Discount Tobacco City & Lottery Ltd. v. FDA*, 674 F. 3d 509 (6th Cir. 2011), *cert. denied*, 133 S.Ct. 1996 (2013).¹

The restrictions on sales and promotion to adolescents are contained in 21 CFR 1140 ff. Because these regulations were issued pursuant to a statutory mandate, and because “EO 13771 applies only to the extent permitted by law,” these regulations cannot be considered for modification or repeal to implement that Executive Order.² The undersigned organizations have submitted comments in support of such regulations and incorporate those comments by reference herein. The positions urged in these comments remain as relevant and important today as they were when they were originally filed and there is no question that these regulations serve an important public purpose.

B. Regulations regarding warning labels on cigarette packs and advertising.

The TCA required FDA to promulgate revised warning labels on cigarette packs and cigarette advertising that would have required new revised textual warnings, increased the size of the warnings and included color graphics to illustrate the text. FDA promulgated regulations to implement this requirement but the rule establishing such warning labels was vacated by the United States Court of Appeals for the District of Columbia Circuit in *R.J. Reynolds Tobacco Co. v. FDA*, 696 F. 3d1205 (D.C. Cir. 2012) because the court found that the specific images selected by FDA to illustrate the text did not meet applicable constitutional standards. Five years later, FDA still is in the process of developing alternative warning labels to meet this statutory requirement.³

The TCA also established requirements for revised warning labels for smokeless tobacco products but the statutory requirements took effect without the establishment of new regulations.

C. Regulations establishing jurisdiction over other tobacco products.

The TCA also gave FDA authority to assert regulatory jurisdiction over other tobacco products, such as e-cigarettes, cigars, pipe tobacco and hookah by the promulgation of a rule. In 2011 FDA announced its intention to promulgate a rule asserting jurisdiction over other tobacco products, including cigars and e-cigarettes. In 2014 FDA proposed regulations to deem such products subject to FDA jurisdiction, 80 Fed. Reg. 23142 (April 25, 2014) and in 2016 FDA issued final regulations, 81 Fed. Reg. 28974 (May 10, 2016). The undersigned organizations

¹ The court invalidated a requirement that all cigarette advertising be text-only and in black and white as well as a provision prohibiting customer loyalty programs. 674 F. 3d at 544, 548.

² Memorandum: Implementing Executive Order 13771, Titled “Reducing Regulation and Controlling Regulatory Costs,” Office of Information and Regulatory Affairs, Office of Management and Budget (answer to Q18).

³ The undersigned organizations have filed a lawsuit alleging that FDA’s failure to issue a new rule requiring graphic health warnings constitutes “agency action unlawfully withheld or unreasonably delayed” in violation of the Administrative Procedure Act. That lawsuit is pending. See *American Academy of Pediatrics, et al v. FDA*, CA No. 16-cv-11985 (D. Mass, October 4, 2016).

filed extensive comments on both the proposed regulations and the final regulations. These comments are also incorporated by reference herein.

D. Regulations implementing user fees.

The TCA provided that the functions of the CTP should be financed exclusively through user fees paid by regulated tobacco product manufacturers. 21 USC 387s(a). FDA has promulgated regulations to implement this requirement 21 CFR §1150 ff.

E. Proposed regulation establishing a product standard setting a maximum level of Nitrosonornicotine (“NNN”) in smokeless tobacco products.

FDA has proposed a regulation that would establish a product standard pursuant to 21 U.S.C. § 387g setting a maximum level of the carcinogen, Nitrosonornicotine (“NNN”) in smokeless tobacco products. 82 Fed. Reg. 8004 (January 23, 2017). The comment period on this proposed regulation closed in June, 2017 and FDA is considering the comments. The undersigned groups filed comments in support of the proposed rule and those comments are incorporated by reference.

F. Other guidances and draft guidances.

FDA has promulgated guidance and draft guidance documents with respect to a number of other matters, principally those establishing procedures and requirements for the submission of applications for the marketing of tobacco products. The OMB Memorandum Implementing Executive Order 13771 states that an “EO 13771 regulatory action” includes a “significant guidance document reviewed by OIRA under the procedures of EO 12866 that has been finalized and that imposes total costs greater than zero.” No guidance or draft guidance documents promulgated by FDA pursuant to the Tobacco Control Act have been reviewed by OIRA under the procedures of EO 12866 and none of them constitutes an EO 13771 regulatory action.

II. None of the regulations issued by the Center for Tobacco Products should be altered in response to Executive Order 13771.

A. None of the CTP regulations are “outdated, unnecessary, or no longer current” and they have not been “superseded by other events.”

The requirement for agencies to examine their regulations, evaluate the need for such regulations, and eliminate unnecessary regulations is premised in part on the assumption that many federal regulatory regimes have been in existence for decades and may retain features that have not been subject to evaluation for many years. Whatever the applicability of such considerations may be to other regulatory regimes, they have no relevance to the regulation of tobacco products, which is premised on a recently enacted statute and a very limited set of regulations very recently promulgated. The regulations concerning tobacco products have quite

recently been subjected to review and have, with certain exceptions withstood legal challenge. All the existing tobacco regulations are necessary to protect the public health and should be retained. As noted above, the regulations prohibiting marketing practices for cigarettes and smokeless tobacco products targeted to adolescents were specifically required by the Tobacco Control Act, enacted in 2009. The regulations deeming cigars, e-cigarettes, and other tobacco products subject to FDA jurisdiction were promulgated on May 9, 2016 and became effective on August 8, 2016.

Pursuant to the TCA, FDA's regulatory functions are financed exclusively by users' fees paid by tobacco product manufacturers. The aggregate amount of such fees is fixed by statute. FDA has promulgated regulations to determine how such fees should be apportioned among the regulated entities. The apportionment of such fees does not affect the aggregate impact of the fees.

B. The regulations do not impose costs in excess of their benefits.

1. The rule prohibiting the marketing of cigarettes and smokeless tobacco products to adolescents does not impose costs in excess of its benefits.

The 1996 marketing rule, 61 Fed. Reg. 44396 (August 28, 1996), was the culmination of the most extensive rulemaking proceeding in FDA history, in which the agency reviewed more than 700,000 comments. In announcing the rule, FDA stated that "the need for action stems from the agency's determination to ameliorate the enormous toll on the public health that is directly attributable to the consumption by adolescents of cigarettes and smokeless tobacco products . . . FDA finds that the pervasiveness and imagery used in industry advertising and promotional programs often obscure adolescent perceptions of the significance of the associated health risks and the strength of the addictive power of tobacco products." *Id.* at 44571. Because the rule met the criteria for a major federal action under Executive Order 12866, FDA conducted a Regulatory Impact Analysis pursuant to that Order, *Id.* at 44568-44606, that concluded that the "substantial benefits of this regulation will greatly exceed the compliance costs" associated with the rule. *Id.* at 44571. In reaching this conclusion FDA stated that it had "considered other alternatives and determined that the current rule is the least burdensome." *Id.*

As noted above, the Tobacco Control Act directed FDA to promulgate the 1996 rule except to the extent that provisions may have been rendered unconstitutional by court decisions subsequent to 1996. When FDA promulgated the rule it relied on the extensive Regulatory Impact Analysis that had been completed when the rule had initially been promulgated. *See* 75 Fed. Reg. at 13229.

Moreover, as noted above, smoking imposes massive economic costs on the American economy and requires large governmental expenditures. Medicare spends \$45 billion annually, Medicaid spends \$39.6 billion annually, and other government programs spend \$23.8 billion

annually to treat smoking-related disease.⁴ Regulations that reduce the incidence of smoking, such as the 2010 rule promulgated pursuant to the Tobacco Control Act, mitigate these costs and thereby have a positive economic impact.

2. The deeming rule does not impose costs in excess of its benefits.

As noted above, the deeming rule, promulgated in 2016, was the culmination of a five-year process of review by FDA of the scientific literature on the newly-deemed products, consideration of 275 scientific studies and other reports and 135,000 public comments. 81 Fed. Reg. at 28982. Brief of the FDA in *Nicopure Labs, Ltd. v. FDA*, No. 16-cv-878 (D.D.C.) (FDA Brief) at 38. FDA concluded, on the basis of overwhelming evidence, that regulation of cigars, e-cigarettes and other newly-deemed products pursuant to the provisions of the Tobacco Control Act is necessary due to their potential for harm to public health. 81 Fed. Reg. at 28983. FDA documented its conclusions in the notice accompanying the rule. 81 Fed. Reg. at 28974-29106. In a judicial challenge to the validity of the deeming rule, the United States District Court for the District of Columbia concluded that FDA had considered the relevant factors and properly considered both benefits and costs and concluded that the benefits of the regulation outweighed the costs. *Nicopure Labs, LLC v. FDA*, 2017 WL 3130312 (DDC July 21, 2017).

FDA's deeming of additional tobacco products, including e-cigarettes and cigars, subject to its jurisdiction, automatically subjected those products to the same regulatory requirements previously imposed by the TCA on cigarettes, cigarette tobacco, roll-your-own-tobacco and smokeless tobacco. 81 Fed. Reg. at 28976. For example, manufacturers of the newly-deemed products become subject to the product review requirements established by section 910 of the TCA, 21 U.S.C. § 387j. *Nicopure Labs, Ltd. v. FDA, supra*, at 29. "Pre-market review is a creature of statute and not a new regulatory requirement dreamed up and imposed...by the FDA." *Id.* FDA noted the proliferation of e-cigarette products and the lack of information concerning their contents and concluded that "without a regulatory framework, users who expect consistency in these products may instead be subject to significant variability in nicotine content among products, raising potential public health and safety issues." 81 Fed. Reg. at 28984.

With regard to e-cigarettes, FDA cited "a dramatic rise in the use of ENDS products," with current "e-cigarette use among high school students increas[ing] nearly 800 percent" from 2011 to 2014 and "2.4 million middle and high school students report[ing] current use of e-cigarettes." *Id.* With regard to cigars, FDA found that "nearly 2,500 youth under the age of 18 smoke their first cigar each day, nearly as many as those who smoke their first cigarette each day (more than 2,600)." *Id.* at 28985.

In describing the scope of the deeming rule, FDA noted that the statutory requirements that will apply to the newly deemed products include establishment registration and product listing, ingredient listing, testing and reporting for harmful and potentially harmful components,

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC460/3661>.

premarket submissions prior to the introduction of new products, and labeling requirements. 81 Fed. Reg. at 28980.

For those aspects of the deeming rule that were not automatically imposed by virtue of deeming the additional products subject to FDA jurisdiction, but rather were imposed through the exercise of FDA discretion under other provisions of the TCA, FDA documented the reasons why it was necessary to extend regulations to the newly deemed products. For example, FDA extended some, but not all, of the prohibitions on marketing to adolescents applicable to cigarettes to the newly deemed products, including the requirement of 18 years as the minimum age of purchase. With regard to the prohibition on free samples, FDA noted that at least eight e-cigarette companies promote their products through sponsored or sampling events, many of which appear to be youth-oriented and “in 2012 and 2013 alone, 6 e-cigarette companies sponsored or provided free samples at 348 events, many of which were music festivals and motorsport events geared toward young people.” *Id.* at 28986. FDA concluded that “prohibiting free samples eliminates a pathway to tobacco products for youth, which can help to reduce initiation and thus decrease morbidity caused by use of tobacco products” *Id.* at 28987, and cited the conclusion of the Sixth Circuit upholding the constitutionality of the prohibition on distribution of free samples of cigarettes in *Discount Tobacco City*, that free tobacco samples constitute an easily accessible source for youth. *Id.*, citing 674 F. 3d at 541. Moreover, because e-cigarettes contain nicotine, FDA required a warning label on product packaging and advertising. 81 Fed. Reg. at 28976. FDA also required larger warning labels for cigars. *Id.* at 28979.

When it promulgated the deeming rule FDA not only identified important reasons for asserting jurisdiction over the newly deemed products, but also provided a regulatory impact assessment pursuant to Executive Order 12688 that concluded that the benefits of asserting jurisdiction over these products outweighed the costs. 81 Fed. Reg. 29074 ff. Because benefits are difficult to quantify, FDA used a breakeven approach in the formulation of a regulatory impact assessment and considered four alternatives to the rule. 81 Fed. Reg. 29075-76.

Subsequent to the promulgation of the deeming rule, manufacturers of both e-cigarette products and cigars brought suit against FDA to invalidate the rule in several federal courts. The first of these cases to reach decision was *Nicopure Labs, LLC. v. FDA*, 2017 WL 3130312, (D.D.C. 2017), in which e-cigarette companies challenged the application to e-cigarettes of no fewer than eight separate provisions of the Act, including challenges to the premarket review, warning labels, and modified risk provisions of the rule. The court rejected each and every one of the challenges and noted, “the agency expressly considered both the burdens the decision would impose on the vaping industry and the benefits to the public” and “contains a discussion of all the required topics.” 2017 WL at 33-37. The court noted that the FDA had concluded, after conducting this analysis, that the costs were outweighed by the welfare gains. Notably, the court expressly found that the methodology utilized by FDA in conducting its regulatory impact assessment was appropriate: “The administrative record reflects that the agency expressly

considered both the burdens the decision would impose on the vaping industry and the benefits to the public....” 2017 WL 3130312 at 33, 37.

FDA itself, in defending the validity of the deeming rule, argued strongly that it had properly considered benefits and costs pursuant to Executive Orders 12866 and 13563. FDA Br. at 50-60. FDA’s brief properly concluded that whatever requirement existed for a cost/benefit analysis, the requirement arose from the Executive Orders and not from the TCA or the Administrative Procedure Act. FDA Br. at 50. FDA argued that “the agency provided an extensive, qualitative discussion of the rule’s benefits, as well as the benefits of several regulatory alternatives... and provided summaries of quantifiable costs as well as a thorough, qualitative discussion of other costs in which the agency described all costs, whether quantitatively or qualitatively.” *Id.* at 59

Cigar manufacturers have also filed lawsuits challenging the deeming rule but none of the cigar cases has yet gone to judgment. In the most advanced of these cases, *Cigar Ass’n of America v. FDA*, 16-cv-1460 (D.D.C.), plaintiffs have filed a motion for a preliminary injunction to enjoin four aspects of the deeming rule as they apply to cigars, most prominently the warning label requirements. FDA’s brief opposing the motion notes, inter alia, the FDA’s finding that the health risks of cigars are widely unappreciated, that many users believe that cigars are not addictive unless the user inhales, and that cigars are a safe alternative to cigarettes. Memorandum in Opposition to Plaintiffs’ Motion for a Preliminary Injunction and for Partial Summary Judgment and in Support of Defendants’ Cross-Motion for Partial Summary Judgment, *Cigar Association of America v. FDA*, C.A. No. 16-1460, at 11; 81 Fed. Reg. at 28988, 29070.

The proposed regulation to establish a standard for NNN in smokeless tobacco products was the subject of recently completed Regulatory Impact Analyses pursuant to Executive Order 12866 that concluded the benefits of the proposed regulation exceeded their costs. The Regulatory Impact Analysis accompanying the NNN rule will be re-examined if and when FDA issues a final rule and there is no justification for an additional re-examination in connection with this docket. The Regulatory Impact Analysis accompanying the deeming rule was recently completed and re-examining it in the context of this docket would itself constitute a wasteful and unnecessary expenditure of regulatory resources.

C. The regulations cannot be displaced by voluntary industry standards.

In the TCA, Congress gave FDA broad regulatory authority over tobacco products because it had unique scientific and the regulatory expertise and made clear the reasons for its decision to do so in the Findings at the beginning of the TCA. Congress found,

The Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate

the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health. In connection with its mandate to promote health and reduce the risk of harm, the Food and Drug Administration routinely makes decisions about whether and how products may be marketed in the United States.

Pub. L. 111-31, Sec. 2 (44).

Many regulatory decisions under the TCA depend upon determinations by the FDA that the marketing of certain products or promotional claims about products are “appropriate for the protection of the public health,” (the “public health standard”). In evaluating such claims, FDA is directed to consider, inter alia, scientific evidence about the population-wide effect of products and promotional claims, taking into account the risks and benefits to both users and non-users of tobacco products.

None of the CTP regulations could feasibly be displaced by voluntary industry standards. No non-governmental organization has the breadth of expertise and experience or the disinterested perspective necessary to make such decisions. To the contrary, in the many years during which tobacco products were not subject to FDA regulation, voluntary organizations created by the industry facilitated the industry’s misconduct by providing a false public impression that the industry was acting in the public interest. *See U.S. v. Philip Morris*, 449 F. Supp. 2d 1, 281, 286, (D.D.C. 2006), *aff’d in relevant part*, 566 F.3d 1095 (D.C. Cir. 2007). Rather, as the findings in the Tobacco Control Act make clear, many of the issues the legislation was designed to address resulted from the misconduct of the tobacco industry, aided and abetted by voluntary organizations, which concealed evidence that smoking was lethal, denied for decades that nicotine was addictive in the face of conclusive evidence to the contrary, marketed tobacco products to children in an effort to addict them to a deadly product, misrepresented the dangers posed by “light” cigarettes, and destroyed and concealed evidence of their misconduct. An industry with such a record could never be trusted to develop or enforce standards to protect the public health.

Moreover, the presence of the issues that impelled FDA to deem e-cigarettes, cigars, and other tobacco products (e.g., the substantial uptake of these products by children, promotional appeals directed toward children, the lack of consistency in the nicotine content of e-cigarettes, etc.) demonstrates that, in the absence of FDA regulation, serious public health problems will continue to exist.

D. The regulations do not impose unnecessary burdens for compliance.

FDA’s assertion of jurisdiction over other tobacco products through the deeming rule has been the subject of intensive examination since 2010 and the reasons why these products must be made subject to regulation under the Tobacco Control Act are set forth in the FDA’s statements accompanying the deeming rule.

As noted above, FDA's assertion of jurisdiction over e-cigarettes was recently upheld against judicial challenge in *Nicopure Labs, LLC. v. FDA* and several other challenges to the rule are pending in other federal courts. These challenges encompass virtually all the provisions of the rule. As both FDA and the *Nicopure* court made clear, FDA's assertion of jurisdiction over these products triggers the application of numerous provisions of the Tobacco Control Act to the regulation of these products, including requirements for the registration of manufacturing establishments and product lists, the submission of information about product ingredients and the levels of harmful and potentially harmful constituents, requirements for marketing orders for the sale of new products and products alleged to be substantially equivalent to existing products, and requirements for the making of modified risk and reduced exposure claims. In determining whether marketing orders should be issued, the statute requires FDA to determine, according to scientific evidence, whether the marketing of such products is "appropriate for the protection of the public health" considering both the benefits and the risks to the population as a whole. Making such determinations requires FDA to consider a substantial body of scientific evidence, including data that must be provided by manufacturers. The information required to be submitted in connection with such determinations has been the subject of intense scrutiny and debate in the course of the consideration of the deeming rule.

As noted above, on July 28, 2017, FDA Commissioner Gottlieb announced that FDA would initiate rulemaking proceedings to establish the requirements for new product and substantial equivalence applications and the standards applicable to such products. Thus, detailed examination of the regulatory process for the issuance of marketing orders is already in process.

Compliance with the regulatory requirements of the Tobacco Control Act will undoubtedly impose costs on tobacco product manufactures. However, Congress recognized that tobacco products are both lethal and addictive and that the benefits of comprehensive regulation of such products under the public health standard would outweigh the costs. A process that considers the costs of compliance with such a regulatory regime without considering the benefits of regulation to the public health would be incomplete and would contravene statutory requirements.

E. The regulations do not require unnecessary collections of data.

As noted above, FDA has in process a full consideration of the requirements for submission of data in connection with applications for marketing orders. In order to fulfill its statutory function, FDA must require sufficient data to establish all the likely effects of such products on the health of individuals as well as on the population as a whole, including users and non-users of tobacco products.

F. The regulations do not unnecessarily eliminate jobs and may have a net positive impact on economic growth.

It is important to note at the outset that regulations that reduce tobacco consumption can have a substantial positive effect on the economy and thus that considering the costs of such regulations without taking account of their benefits would lead to policies that are counterproductive and harmful to the economy. Tobacco use imposes enormous economic burdens not only for the treatment of tobacco-related disease but also by impairing the health of millions of Americans. According to the authoritative Surgeon General's Report for 2014, the productivity loss for smoking mortality is \$151 billion per year and the productivity loss for smoking mortality for nonsmokers was more than \$5 billion. Because these figures exclude any productivity loss due to smoking morbidity, they understate the economic burden attributable to smoking. In addition to these effects, the cost of providing medical care for smoking-related disease is \$130 billion per year.⁵ These figures make it clear that the economic cost attributable to smoking is staggering. Any evaluation of the effects of smoking on employment (presumably a cost) must be balanced against the benefits that accrue when regulation reduces smoking. Thus, programs that reduce tobacco use have a large positive impact on economic growth.

The effect of the deeming rule on jobs and economic growth is unclear. Assertion of FDA regulatory jurisdiction to cigars and other combusted products through the deeming rule is likely to lead to a reduction in the consumption of such products. Although there may be a reduction in jobs associated with the manufacture and sale of such products, the economic benefits resulting from a reduction in their use is likely to be far greater than any such loss. Regular cigar smoking was responsible for approximately 9,000 premature deaths and more than 140,000 years of potential life lost among US adults aged 35 years or older in 2010. These years of life had an economic value of approximately \$23 billion.⁶

It is not at all clear, for example, that FDA regulation will reduce the sale of e-cigarette products. Even if some e-cigarette products come off the market as a result of FDA regulation, total consumption of e-cigarettes may rise and jobs associated with the manufacture and marketing of e-cigarettes may increase rather than decrease. If, for example, FDA requires e-cigarette manufacturers to demonstrate that their products actually help smokers switch completely to e-cigarettes, or to demonstrate that their products enable smokers to quit tobacco use entirely, products capable of meeting this standard may prove highly attractive. Jobs associated with products that cannot meet this standard may be lost but that loss may well be offset by increased job opportunities associated with products that meet the standard.

Moreover, if the deeming rule results in identification of products that actually help smokers switch completely away from smoking or quit use of tobacco products entirely, it could have a strong positive impact on economic growth. As noted above, smoking has an enormous negative economic impact and regulatory action that facilitates the identification of products that can reduce smoking and expansion of their market opportunities could significantly benefit

⁵ U.S. Dept. of Health and Human Services, *The Health Consequences of Smoking – 50 Years of Progress, A Report of the Surgeon General* (Executive Summary), at 11 (2014).

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4151956>.

economic growth. By contrast, the manufacture of products that are not proved to be effective in helping smokers to switch completely to e-cigarettes or to quit tobacco use entirely is detrimental to economic growth because it does nothing but perpetuate the negative impact of tobacco use on the economy.

In any event, however, it is not the purpose of the Tobacco Control Act to contribute to economic growth but rather to reduce the toll of death and disease resulting from the use of tobacco products. No regulation that FDA believes is effective at reducing that toll should be withdrawn or limited because of concerns that jobs in the tobacco industry will be lost or economic growth deterred.

III. In evaluating whether to issue, withdraw, or amend rules issued under the Tobacco Control Act, FDA must apply the statutory standards and may not make such decisions by considering the costs resulting from a rule without considering the benefits.

FDA derives its authority to regulate tobacco products from Congress's delegation of authority in the Food, Drug and Cosmetic Act, as amended by the Tobacco Control Act. In issuing, withdrawing, or amending regulations under the Tobacco Control Act, FDA must comply with the standards specified in the statute as well as the requirement of the Administrative Procedure Act, 5 U.S.C. § 706, that such action not be arbitrary or capricious. The Tobacco Control Act gives FDA a broad array of authorities. As the United States District Court held in the *Nicopure* case, each section of the statute specifies the factors FDA is directed to consider in exercising its authority and FDA may not disregard these statutory requirements or apply an alternative standard that nullifies them. For example, the section of the statute conferring authority to issue product standards provides that FDA must consider both the risks and the benefits of such a standard to the population as a whole, including both users and nonusers of tobacco.

Executive Order 13771 requires federal agencies, including the Department of Health and Human Services (1) to eliminate at least two existing regulations for each new regulation that it issues and (2) to limit the incremental costs of all regulations to an arbitrarily established ceiling without regard to the benefits such regulations may provide.

The Executive Order provides that “no regulations exceeding the agency’s total incremental cost allowance will be permitted in [any] fiscal year, unless required by law or approved in writing by the Director of the Office of Management and Budget.” Executive Order, Sec. 2(b). The Executive Order does not prevent an agency from issuing regulations “required by law,” such as the 2010 regulations prohibiting marketing practices directed at minors or the requirement for graphic warning labels on cigarette packs and advertising. However, the cost even of new regulations required by law must be offset by reductions elsewhere.

This requirement imposes a limitation on agency action that is inconsistent with the statutory standard under the TCA and is arbitrary and capricious within the meaning of the Administrative Procedure Act. If, for example, a product standard FDA had determined was “appropriate for the protection of the public health” could not be issued unless two other regulations, which may be completely unrelated, were withdrawn, the statutory standard would effectively have been rewritten. Moreover, it would be equally arbitrary and capricious—and contrary to the Tobacco Control Act—to withdraw or amend a rule previously issued simply to offset the cost of a rule that might not involve tobacco regulation at all. In promulgating, amending, or withdrawing regulations, FDA must adhere to statutory standards in all cases; application of a directive to consider the cost of rules without considering their benefits cannot be squared with this principle.

In addition, the requirement that costs of new rules be offset without regard to their benefits creates a powerful disincentive for agencies to issue new rules even where the statutory standards for issuance of such a rule are met. A decision not to issue a rule that would otherwise meet the statutory standard simply in order to avoid having to repeal totally unrelated rules would also violate statutory standards and would be arbitrary and capricious. The proposed rule to sharply reduce the carcinogen NNN in smokeless tobacco products is a particularly compelling example. FDA already has determined that its proposed NNN product standard meets the statutory public health standard. Indeed, the agency found that the standard would, in the first 20 years following its implementation, prevent approximately 12,700 new cases of oral cancer and approximately 2,200 oral cancer deaths, with a gain of approximately 15,200 life years over that time period. 82 Fed. Reg. at 8005. It also has determined that the benefits of such a standard would exceed the costs by approximately \$15 billion over the next twenty years. *Id.* at 8006. It would be contrary to the statutory standard, and arbitrary and capricious, to fail to issue the NNN rule because its cost must be offset by the repeal of other rules within the jurisdiction of the Department of Health and Human Services, which themselves may have benefits that far exceed their costs.

Thus, the Executive Order could prevent the agency from fulfilling statutory requirements either because an existing rule would have to be withdrawn as a result of the issuance of another unrelated rule or because a rule, otherwise meeting statutory standards, might not be issued because other unrelated rules would have to be withdrawn as a result. In either case, the agency would have been prevented from implementing the statute in accordance with statutory standards. Regulatory decisions—whether to withdraw or amend an existing regulation or to refrain from issuing a new regulation-- based on cost without regard to benefits would thus be arbitrary and capricious and inconsistent with the statute.

IV. FDA should provide for a reopened comment period to allow the public to respond to suggestions given for repealing or weakening regulations

The Federal Register notice of September 8 directs commenters to address questions designed to elicit suggestions for FDA regulations that should be rescinded or weakened. It does not expressly direct commenters to advance reasons why existing regulations should be retained or strengthened, although it obviously permits such comments to be filed. Given the one-sided nature of the questions asked, FDA should provide for a second comment period, of at least 30 days, to allow the public the opportunity to respond to the suggestions given by industry and others of regulations to be rescinded or weakened.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Tobacco Control Legal Consortium

Truth Initiative