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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-0189, RIN 0910-AG38, 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 Campaign for Tobacco-Free Kids (CTFK) submits these comments in response to the Proposed Rule of the Food and Drug Administration (FDA) deeming various tobacco products subject to the Federal Food, Drug and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA).[1] These comments are in addition to the comments submitted today by CTFK jointly with 23 other organizations.

In Section III of its Notice of Proposed Rulemaking (NPRM), FDA discusses what it calls the "continuum of nicotine-delivering products."[2] FDA also requests public comment on "how e-cigarettes should be regulated based on the continuum of nicotine-delivering products (as discussed in section III) and the potential benefits associated with e-cigarettes."[3] As FDA correctly notes, "cigarette smoking is the major contributor to the death and disease attributable to tobacco use."[4] In establishing a regulatory policy for all tobacco products, FDA must account for the net public health impacts at the population level, including impacts on initiation, cessation, addiction, and product harm.

The term "continuum of nicotine-delivering products" is used by FDA to refer to the fact that there are gradations in individual harm produced by different tobacco products and that if an individual who smokes cigarettes, and who would otherwise not quit, switches entirely to a

[1] Throughout these comments, the terms "Tobacco Control Act" or "TCA" will refer to the Food, Drug and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act.
[2] 79 Fed. Reg. at 23147-48.
[3] *Id*. at 23152.
[4] *Id*. at 23147

product whose use is demonstrably and significantly much less hazardous, that person will reduce his/her risk of disease. If the content of e-cigarettes were regulated carefully, the marketing were strictly limited to focus on already addicted cigarette smokers, and post-market surveillance were put into place to monitor who is using these products and with what result, the risk of harm to an individual who has switched entirely from cigarettes to using e-cigarettes exclusively is likely to be considerably lower than that from continuing to use cigarettes, even though that risk may exceed that resulting from using nicotine replacement therapy (NRT) products or not using any product containing nicotine.

In taking account of the "continuum of nicotine delivering products," FDA's task is to consider not only individual effects but also the population level effects of the marketing of products. The impact of a product on the public health is determined not only by its impact on the individual user, but also by the way its marketing may affect initiation, cessation, and relapse. Thus, the determination that a product may be less harmful to an individual than cigarettes is only a part of the statutory criteria FDA is required to apply. As FDA's notice in this docket explains, "If . . .products result in minimal initiation by children and adolescents while significant numbers of smokers quit, then there is potential for the net impact at the population level to be positive. If, on the other hand, there is significant initiation by young people, minimal quitting or significant dual use of combustible and non-combustible products, then the public health impact could be negative."[5]

The challenge for FDA is how to identify and implement a set of policies that will most effectively fulfill its statutory obligation to protect and promote the public health. How should FDA respond to products that the manufacturer claims pose less of a risk to individual consumers than smoking cigarettes and that the manufacturer claims have the potential to move many consumers away from smoking cigarettes? FDA should be guided by two core principles: 1) It should not lower its scientific standards because the costs of a mistake are great, as we have seen from past experience; and 2) It should consider procedures that will expedite and provide an incentive for innovation that promotes the public health. FDA can design a regulatory policy that is consistent with both these objectives.

This is not the first time in our history that those concerned about tobacco have been confronted by claims that certain products are less hazardous than traditional cigarettes and it is vital to learn from earlier experiences.[6] The claims now being made for e-cigarettes are reminiscent of those made a generation ago for "light" cigarettes, including claims that switching to a different product is an acceptable alternative to quitting. In the absence of government testing and rigorous science, those claims nurtured false hopes that led millions of Americans to switch to cigarettes falsely marketed as low risk, often instead of quitting, with tragic

[5] 79 Fed. Reg. at 23147.

[6] National Cancer Institute, R*isks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, NCI Smoking and Tobacco Control Monograph 13, U.S Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute, 2001; *U.S. v. Philip Morris USA, Inc.*, 449 F.Supp.2d at 560.

consequences. With regard to other products, such as smokeless tobacco products, the manner in which those products were marketed resulted in more people using smokeless tobacco products, but there is no solid evidence they led to fewer people smoking cigarettes.

The Tobacco Control Act establishes standards, review processes and measurable burdens precisely so that millions of Americans do not become human guinea pigs for a massive experiment with no control. FDA protects the public by requiring good science before products are marketed and health claims are made about them. There is no acceptable substitute.

FDA should not alter the substantive standards applied in considering marketing applications for new or substantially equivalent products or product claims, nor should it alter who has the burden of proof of each element, even for products that may pose a lower risk of individual harm than cigarettes. The argument that some manufacturers lack the resources to adequately conduct the necessary science is one that has properly been rejected for other products regulated by FDA. FDA's obligation is to protect the public health and the marketing of products that is not consistent with that objective should not be permitted, regardless of who the manufacturer is. To protect the public health, FDA should not weaken its requirements for rigorous science, nor its requirements that the manufacturer provide sufficient science to enable FDA to evaluate the health impact of a product under review.

Although FDA should not compromise the substantive standards it applies, it can still recognize that some technologies and products both have lower risk than cigarettes and have a demonstrated potential to reduce tobacco-related death and disease if used to completely displace cigarette smoking by an individual. In such cases it would be appropriate for FDA to develop clear guidelines for the science that will be necessary for it to review the safety and health impact of specified products and to accelerate the review of marketing applications for such products. Procedures developed by FDA in the regulation of drugs demonstrate that FDA has the ability to implement procedural changes to expedite the availability of new drugs for patients with serious conditions where effective alternatives do not already exist. FDA has created several avenues for such action through procedures known as fast track, breakthrough therapy, accelerated approval, and priority review.[7] Although the drug approval process differs in numerous respects from procedures for tobacco regulation, the use of procedural innovations to serve important regulatory purposes is instructive.

Creation of these avenues focuses not on changes in substantive standards of review, but on the establishment of procedures for making sound scientific decisions in an expedited time frame. In all cases, they involve a request by the manufacturer for a designation of eligibility and a preliminary determination that a product meets the threshold standards for expedited review.

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[7] See generally http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccesstoImportantNewTherapies/ucm128291.htm.

In making determinations of relative risk and eligibility for expedited review, FDA needs to recognize that:

- the use of any tobacco product, including a well regulated e-cigarette, poses a greater risk than using no tobacco product; and

- the scientific evidence does not demonstrate a substantial health benefit or reduction in harm to an individual from the use of an e-cigarette or other tobacco product if consumers (current cigarette smokers) use an e-cigarette or other tobacco product while continuing to use cigarettes (dual use), except when dual use is a short-term pathway to quitting smoking cigarettes.

Determination of Eligibility for Expedited Consideration

FDA has discretion to and must carefully determine which products qualify for expedited consideration. Products should be considered for expedited consideration only if the manufacturer is able to demonstrate that: a) the use of the product presents "minimal" health risk to the user compared to traditional tobacco products, such as cigarettes; b) adequate manufacturing controls are in place so that the consumer will receive the consistent yields of the same substances that have been tested and have been assessed by FDA and that adequate controls are in place to insure that the product consistently meets specifications and is free of other contaminants, including harmful and potentially harmful constituents (HPHCs); c) the product as actually used is likely to substantially and measurably reduce the consumer's risk of tobacco-related disease based upon the best available, reliable scientific evidence without conducting long term epidemiological studies; and d) the product as it is proposed to be sold and marketed does not appeal to significant numbers of youth or individuals who are not current cigarette smokers.

A key factor in determining whether a product when actually used will measurably and substantially reduce a cigarette smoker's risk of death and disease from tobacco use is evidence about whether the individual consumer will use the product exclusively or continue to smoke cigarettes while using the product. Only a cigarette smoker who switches to using e-cigarettes exclusively will meet this criterion.

One factor in determining the likelihood that a product will stimulate youth initiation is the way a product is advertised and marketed. FDA can rely on scientific evidence about prior campaigns involving tobacco products that use similar tactics, venues, themes, images and messages to reach scientifically valid conclusions about the impact of campaigns for e-cigarettes and other tobacco products. A product that is marketed by presenting celebrities popular with adolescents, promoted at sporting events or rock concerts, that features sexual innuendo, uses cartoons, or has been shown in prior research to appeal to adolescents, should not meet the criteria for expedited consideration. A manufacturer seeking expedited review should be required to provide detailed information on the profile of its users, and a protocol for post-market surveillance to determine who is using the product and the actual effects of the marketing of the

product. Creating a strong regulatory incentive not to market tobacco products in ways that appeal to adolescents should be an essential and necessary precondition to expedited review.

Procedural Advantages of Expedited Consideration

Products that qualify for expedited consideration would be accorded priority in the scheduling of consultations with FDA and priority in consideration of materials submitted for review. In addition, FDA would be expected to provide prompt guidance to the manufacturer on the nature of the scientific evidence and other information required for consideration of such an application.

In establishing what scientific evidence will be required, the scientific burden of proof and the conditions for being able to access the expedited procedure, the FDA should establish a public process for review and comment on what should be required to protect the public health while not impeding the introduction of genuinely innovative products with a substantial potential to serve as an alternative to cigarette use by cigarette smokers who can't or otherwise would not quit.

Relationship to Nicotine Replacement Therapy Products

Although products marketed as therapeutic products for cessation of tobacco use are not regulated as tobacco products under the Tobacco Control Act, they are also nicotine delivery products and have a place in any analysis of the continuum of nicotine-delivering products. Evaluation of the potential impact on cessation of tobacco products seeking expedited review should take into account the relative likelihood that smokers who would use them would otherwise have stopped smoking cigarettes on their own or done so using FDA approved NRTs successfully. FDA should take steps to coordinate the regulation of tobacco products seeking expedited review with the regulation of NRTs in a manner best designed to protect the public health. The goal of such a regulatory program should be to assist cigarette smokers to stop smoking cigarettes while creating the smallest risk of negatively impacting the behavior of non-cigarette smokers and former cigarette smokers.

Respectfully Submitted,

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