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Division of Dockets Management (HFA305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2011-D-0147

To Whom It May Concern:

The undersigned groups submit these comments in the above-designated docket concerning the Draft Guidance for Industry and FDA Staff entitled “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.”

I. The regulations governing substantial equivalence applications are part of a larger regulatory framework for the regulation of New Tobacco Products.

The regulations governing substantial equivalence are among the most important regulatory policies under the FSPTCA. These regulations are part of the larger framework under which FDA regulates new tobacco products. Section 910(a)(1) of the Act defines “New Tobacco Products” to include “any product marketed after February 15, 2007 and any modification of a product marketed on that date.” The general rule is that New Tobacco Products may not be commercially marketed unless and until the FDA has granted a New Product application under the terms of Section 910. In exercising this authority, the FDA is directed to deny the application

“if there is a lack of a showing that permitting such tobacco product to be marketed would [inter alia] be appropriate for the protection of the public health.”

Sec. 910(c)(2)(A)

Critically, this provision puts the burden on the applicant to demonstrate that the new tobacco product meets the standard. The product may not be marketed until the application has been reviewed

and the FDA has issued an order permitting the product to be marketed after deciding that the manufacturer has made the required showing. The statute sets forth a set of detailed requirements describing the information the manufacturer must provide regarding the content of the product, its manufacturing, processing, and packing, and its labeling. Sec. 910(c)(2)(A)-(D). The statute requires the manufacturer to include in such an application, inter alia,

- (A) Full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;
- (B) A full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product; and
- (C) A full description of the methods used in, and the facilities used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product.

In addition, the FDA is directed to take into account, where appropriate, “well-controlled investigations, which may include 1 or more clinical investigations by” qualified experts and “other “valid scientific evidence sufficient to evaluate the tobacco product.” Sec. 910(c)(5).

The policy underlying this requirement reflects the Congressional determination that new tobacco products—all of which, when used as intended, cause death and disease—should not be marketed unless the manufacturer has demonstrated by the submission of a substantial amount of evidence that such products meet a rigorous standard. The statute requires the Secretary to deny a new product application unless the manufacturer has met its burden of establishing that the marketing of the new tobacco product is “appropriate for the protection of the public health.” The statute requires the Secretary to determine whether the manufacturer has met this burden by considering “the risks and benefits to the population as a whole, including users and nonusers of tobacco products, and taking into account

- (A) The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- (B) The increased or decreased likelihood that those who do not use tobacco products will start using such products.”

Sec. 910(c)(4)

The statute thus requires the Secretary to consider not only the health effects of the new tobacco product on those who will use it, but also how the marketing of the new tobacco product will affect decisions of users to stop using tobacco products and how its availability will affect decisions by nonusers to start using tobacco products. The burden of proving that these standards are met is on the manufacturer.

These detailed requirements demonstrate the judgment of the Congress that it should not be “business as usual” for manufacturers to introduce new tobacco products and that, before they do so,

they should have to produce a substantial amount of scientific evidence and obtain a determination from the FDA that the overall effect of marketing the product will be appropriate for the protection of the health of both users and non-users of tobacco products. Under the standards established by the statute, if there is any doubt or if the manufacturer has not met its burden, the product should not be permitted on the market.

The Congress had good reason to be skeptical about the consequences for the public health of the introduction of new tobacco products and good reason to place the burden on manufacturers to establish that the introduction of a new product would be consistent with protection of the public health. Tobacco companies have often resorted to the introduction and marketing of allegedly new types of cigarettes in order to allay the concerns of smokers about the health consequences of the product they are smoking and to persuade them to continue smoking rather than to quit. In the 1950s, following widespread publicity about scientific studies showing the dangers of smoking, tobacco companies introduced filtered cigarettes, which were widely promoted with messages designed to induce consumers into believing that they were an alternative that could safely be used. Today, 99% of the cigarettes sold in the United States are filtered.¹ Beginning in the 1970s, in response to even more persuasive evidence about the dangers of smoking, tobacco companies introduced cigarettes labeled “light”, which were widely promoted with messages designed to induce consumers into believing that such cigarettes were somehow safer than full-flavored cigarettes.² Although it turned out that such cigarettes were no safer, the marketing campaign was a success. A majority of current smokers say they smoke light, mild, or ultra-light cigarettes³ and most smokers believe that “light” and “ultralight” cigarettes are less harsh, contain less tar and nicotine and provide some reduction in risk.⁴ Moreover, in efforts to keep people smoking and to expand their customer base, cigarette manufacturers continually introduced scores of new products and continue to do so. The proliferation of brands, sub-brands and styles has been bewildering.⁵ Many of such products have been designed to appeal to specific segments of the population and, as the United States District Court for the District of Columbia found, many such products were designed to appeal to adolescents – individuals who were not yet smokers or at least not yet addicted smokers.⁶ In the decisions of tobacco companies to market new products, there is no evidence that the effect on public health was ever a concern.

The history of the tobacco industry’s development and marketing of new tobacco products is relevant in the development of an overall regulatory policy for regulation of such products. That history

¹ U.S. Federal Trade Commission (FTC), *Cigarette Report for 2007 and 2008*, 2011, <http://www.ftc.gov/os/2011/07/110729cigarettereport.pdf>.

² *United States v. Philip Morris*, 449 F. Supp. 2d 1 at 740 (D.C.D.C. 2006)), *aff’d* in relevant part, 566 F. 3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S.Ct. 3501 (2010).

³ 2003 Tobacco Use Special Supplement to the Current Population Survey (TUSCC-CPS).

⁴ Shiffman, S et al., “Smokers beliefs about light and ultralight cigarettes,” *Tobacco Control* 10 (Suppl):i17-i23, 2001.

⁵ See, e.g., the brand directory for brands that can be legally sold in the State of Kentucky. <http://revenue.ky.gov/NR/rdonlyres/1609CA5A-4364-400D-9417-3F3028D2CBD3/0/PMCERTIFICATIONLIST101211.pdf>.

⁶ *United States v. Philip Morris*, 449 F. Supp. 2d 1 at 972-980, 877-879(D.C.D.C. 2006)

shows that the tobacco companies have a far greater ability to manipulate the content and emissions of their cigarettes than they had claimed and that the introduction of new products and design modifications of existing products have been used for many decades to maintain or increase the addictiveness of cigarettes and to mislead consumers into believing that switching to a modified cigarette is a safe alternative to quitting.⁷ Judge Kessler concluded that “the Defendants have falsely denied that they can and do control the level of nicotine delivered in order to create and sustain addiction.”⁸ The evidence cited by Judge Kessler that the tobacco companies have deliberately manipulated the nicotine content of cigarettes to ensure their addictiveness is both voluminous and compelling.⁹ Other changes made the product more palatable to more consumers, thereby increasing the number of individuals at risk. Moreover, the introduction of new brands and styles gave the companies the ability to give such new products a distinctive promotional profile to appeal to separate segments of the market—including adolescents who were not yet addicted. There is no question that the continual introduction of new and modified tobacco products has increased the number of smokers in the United States and caused hundreds of thousands if not millions of additional premature deaths. Given this history, industry claims about the reasons for—and the consequences of-- the introduction of new products and the modification of existing products cannot be taken at face value. Tobacco product manufacturers must be required to demonstrate the impact of product changes on behavior, appeal, addiction and health before being permitted to market new or modified products.

Enactment of the FSPTCA—and specifically the new product standards established in section 910—was intended to change the criterion for introduction of new tobacco products and establish a new and altogether different criterion: new tobacco products should not be introduced in the absence of a persuasive demonstration by the manufacturer of specific evidence that the introduction of such products would be appropriate for the public health.

II. The statutory provisions for products demonstrated to be substantially equivalent to products marketed as of February 15, 2007 represent an exception to the general policy and require the manufacturer of such products to demonstrate that each and every statutory requirement is met in order to qualify for the exception.

The statute created an exception to these requirements for new tobacco products found by the FDA to be “substantially equivalent to tobacco products marketed on February 15, 2007.” New tobacco products that meet the requirements for “substantial equivalence” are to be subject to regulatory requirements under Section 905(j) and Section 910 that are considerable but less extensive than those applicable to new tobacco products. However, because substantial equivalence represents an exception

⁷ United States v. Philip Morris, 449 F. Supp. 2d 1 at 308-386 and 655-864 (D.C.D.C. 2006); See also, Federal Trade Commission Press Release, “*FTC Rescinds Guidance from 1966 on Statements Concerning Tar and Nicotine Yields*”, November 26, 2008. <http://www.ftc.gov/opa/2008/11/cigarettestesting.shtm>; WHO, 2007 World Health Organization, *The Scientific Basis of Tobacco Product Regulation*; Report of a WHO Study Group (TobReg). WHO Technical Report Series, No. 945, Geneva, 2007. http://www.who.int/tobacco/publications/prod_regulation/tsr/en/index.html

⁸ 449 F. Supp. 2d 1 at 515.

⁹ 449 F. Supp. 2d 1 at 515-571.

to a well-founded general rule, requirements to qualify for the exception should be strictly construed and aggressively enforced.

A new product that is the subject of a report under Section 905(j) is “substantially equivalent” to a predicate product if

It has the same characteristics as the predicate tobacco product or;

If it has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product [as a new product] because the new product does not raise different questions of public health.

Sec. 910(a)(3)(A)

The term “characteristics” is defined by the statute as “the materials, ingredients, design, composition, heating source, or other features of a tobacco product.”

Sec. 910(a)(3)(B)

Comments filed by the American Cancer Society Cancer Action Network, the American Lung Association, and the Campaign for Tobacco-Free Kids in March 2011, set forth a framework for the evaluation of substantial equivalence claims under section 905(j). The undersigned groups endorse that framework and urge the FDA to adopt it in administering the rules for substantial equivalence. A full copy of those comments is attached hereto.

That submission reached the following conclusions:

1. In determining whether a new product has the “same characteristics as the predicate product,” the “same characteristics” has quantitative as well as qualitative meaning.
2. Any physical aspect of the tobacco product that is intended to be consumed and any physical aspect of its combustion product is a “characteristic” and thus must be “the same” as in the predicate product.
3. Products containing or delivering greater quantities of harmful or potentially harmful or potentially addictive substances than the predicate product “raise different questions of public health.”
4. Products containing greater quantities of substances that, while not harmful or addictive in themselves, may contribute to an increase in the presence of a harmful or addictive substance in smoke constituents “raise different questions of public health.”
5. Products containing increased levels of substances that FDA has not found to be harmful or potentially harmful or addictive in themselves but which may have health effects

such as changing the particle size of smoke constituents “raise different questions of public health.”

6. Products containing or delivering other substances that are not present in the predicate product or that are present in the predicate product in lower quantities may also “raise different questions of public health.”
7. In examples #3 and #4, such a product is not “substantially equivalent.” In examples #5 and #6, the burden of proof is on the manufacturer to present sufficient evidence to rebut the presumption that the product “raises different questions of public health.”

The undersigned groups strongly encourage the FDA to apply these criteria in the evaluation of substantial equivalence filings under section 905(j).

III. The Availability of a Substantial Equivalence Exception to the Requirements of a New Product Application Should NOT be Used to Displace the General Rule Applicable to New Tobacco Products.

As noted above, the statute created a general rule applicable to the marketing of new tobacco products (section 910) and an exception to that rule for certain qualifying new tobacco products (section 905(j)). The statute establishes two categories for products for which substantial equivalence filings are made. Products that were marketed on or before March 22, 2011 may remain on the market unless and until the FDA rejects an application for substantial equivalence. Products that were marketed after March 22, 2011 may not be marketed unless and until FDA grants an application for substantial equivalence.

Because of the advantages conferred by section 905(j) and because manufacturers were free to elect a filing under that section regardless of the merits of their claims, a well-founded concern exists that the availability of section 905(j) could lead to a large number of applications under this provision in an effort by the tobacco industry to circumvent the requirements of section 910 as the proper method for bringing a new product to market. Moreover, concerns are particularly acute with regard to products claimed to have been marketed on or before March 22, 2011 because such products remain on the market—and capable of inflicting death and disease—indefinitely despite the absence of any affirmative regulatory action on an application.

Indeed, it appears that the tobacco industry is carefully using the “substantial equivalence” exception to evade the “new product” requirements and will continue to do so until FDA takes strong action. These concerns deepened when it was revealed that as of earlier this year (approximately the March 22, 2011 demarcation date) more than 2,500 substantial equivalence applications had been filed—and not a single new product application.¹⁰ These concerns have grown with the revelation that

¹⁰ Letter from FDA to Dr. Gregory Connolly in response to Freedom of Information Act request of August 12, 2011.

the number of pending substantial equivalence applications has more recently grown to over 3,700—and still not a single new product application.¹¹

The incentives for a manufacturer to misclassify a product as “substantially equivalent” are obvious. Apparent examples of such misclassification include products such as Camel strips, sticks, and orbs. Moreover, numerous new cigarette brands, including Newport Red, have been introduced and achieved significant market presence with no new product applications filed under Section 910. Unless and until FDA takes action to reject applications that do not meet the exacting criteria of the statute for the application of the substantial equivalence standard, the more than 2,000 new products introduced on or before March 22, 2011 will remain on the market and the increasing number of new products for which substantial equivalence applications were filed subsequent to March 22, 2011 will not be subject to the requirements of section 910.

Moreover, the industry will continue to avoid providing the FDA the kind of information required under the new product standards and FDA will increasingly find itself unable to protect consumers from these lethal products. This result is a far cry from the regulatory regime Congress provided for new and modified products. FDA should enforce the substantial equivalence requirements to prevent the proliferation of products whose effects on the public health have not been properly examined prior to their marketing.

IV. The absence of publicly available information about pending substantial equivalence filings or FDA actions taken with regard to such filings does not serve the public interest in ensuring that regulatory policies are transparent.

Very little information is available concerning the status of substantial equivalence filings. It is our understanding, however, that no applications have been definitively acted upon. We urge FDA to establish a procedure to maximize the amount of information available to the public regarding substantial equivalence filings in a manner consistent with applicable statutory requirements for protection of commercially confidential information. It should be possible for information to be released that would show by category what products have been the subject of applications, or what type of changes have been proposed or that would show by category the number of products with changes involving different ingredients. Information regarding any rulings by FDA—either final or preliminary—should be made publicly available promptly so that the public can be made aware of how this important authority is being exercised. This information should be made available on FDA’s website without the requirement of the filing of a Freedom of Information Act request.

We recognize that the promulgation of these questions and answers is designed, at least in part, to address concerns about the need for the public to understand FDA’s conclusions regarding the application of the substantial equivalence standard. Promulgation of such questions and answers is not, however, an adequate substitute for decisions on pending applications that would make clearer the actual requirements for establishing substantial equivalence and for the publication of such decisions in

¹¹ Letter of Oct. 22, 2011 from FDA to Dr. Gregory Connolly in response to Freedom of Information Act request.

a manner that would be informative to the public but consistent with the protection of confidential information.

V. Comments on Specific Questions and Answers

Questions 1 and 2. FDA states that it will not enforce the premarket requirements of section 905(j) and 910 with regard to a product marketed on February 15, 2007 if no change was made to the product other than the elimination of the designation “light,” “mild,” or “low” pursuant to the statutory requirement of section 911 or the affixing of new warning labels pursuant to regulations published on June 22, 2011 under the authority of the Federal Cigarette Labeling and Advertising Act, as amended by the Family Smoking Prevention and Tobacco Control Act. We concur with the agency’s conclusion that if the only change in a product is the elimination of these designations pursuant to the statutory requirement or the affixing of new warning labels pursuant to statutory and regulatory requirements the FDA should not require either a new tobacco product application or a substantial equivalence application on the basis of such change alone. We believe, however, that the agency correctly notes that the label and packaging of a tobacco product is a “part” of that product.

However, the FDA should inform the public how many substantial equivalence filings are based on the elimination of these designations alone or a change based exclusively on the new warning label requirements and thus how many such applications would be rendered moot by the announced policy.

Question 3. FDA states that a change in a package from soft pack to hard pack (or vice versa), made after February 15, 2007 without any other modification of a product would not render the product a new tobacco product. The FDA states, however, that if such a modification changed the product in another way, such as a change in moisture content, shelf life, ingredient composition, nicotine delivery, or harmful/potentially harmful constituents, the modification would make the product a “new product” with different characteristics. We believe FDA’s response correctly applies the statutory language.

Question 4. FDA states that if a change is made to the font size, color, or background color for packaging or labeling after February 15, 2007, the FDA will not enforce the requirements of either section 910 of 905(j) “provided the modification does not raise different questions of public health.” FDA should make clear that any such change (except changes to reduce font size made in connection with introduction of the new warning labels) requires at least submission of sufficient data to show that the change did not “raise a question of public health.” It is at least conceivable that changes in font size, color, or background color could, for example, make the product more attractive to youth or suggest to consumers that a product reduces harm or contains a reduced level of harmful substances.¹² In such a case, the change would “raise a different question of public health.” The burden is on the manufacturer to demonstrate that any such change does not do so.

¹² The broader issue of whether misleading messages continue to be sent by color-coding of packages even after the removal of verbal designations such as “light” remains a matter of concern.

Question 5. We agree with the FDA that changing the name of a product subsequent to February 15, 2007 makes the product a “new tobacco product” and subject to the premarket requirements of sections 905(j) and 910. Changing the name of a product constitutes a modification of the tobacco product within the meaning of Section 910(a)(1). A name change can alter the appeal of a product, its target consumer, or its image or lead to different ways of smoking that impact health or the number of users.

Question 6. FDA concludes that if a manufacturer markets a cigarette as Brand X on February 15, 2007 and after that date continues to market the identical cigarette under the additional name Brand Y, Brand Y would be a “new tobacco product.” FDA’s conclusion is in our view correct. The considerations applicable to question 6 require the same result as for question 5.

Question 7. FDA concludes that, for a cigarette marketed on February 15, 2007, if a new supplier for an additive is substituted after that date but the specification of the additive remains the same and the change does not result in a change in any component, part, constituent, additive or ingredient, the change would not render the product a new tobacco product. FDA notes that if the new supplier uses a new additive or if there is a change in any component, part, constituent, additive, or ingredient, the change would constitute a “modification.” FDA’s conclusion is correct. The key is whether the supplier change results in any change to the contents of the product, including quality and purity of ingredients used.

Question 8. FDA reiterates the statement it made in its previous guidance that it does not intend to enforce the requirements of sections 910 and 905(j) for tobacco blending changes required to address the natural variation of tobacco in order to maintain a consistent product. We believe, as stated in our March comments, that a company relying on this provision should be required to demonstrate that the change in tobacco for blending was not only intended to maintain a consistent product but that it had this effect. The manufacturer’s intent is not enough to exempt the product. It must verify that the blending change has not resulted in an alteration of the product, including a requirement that there be no increase in the level of a hazardous or potentially hazardous constituent. Moreover, given the potential for such blending changes to result in alterations in nicotine delivery to the customer, it is important for FDA to insist on provision of proof that such blending changes do not have this effect.

FDA’s own tobacco investigation in 1994-1996 which led to its Final Rule on tobacco, concluded that “Leaf blending is one of the primary means the industry uses to control nicotine levels in cigarettes.”¹³ The FDA then made clear that it understood that the addictiveness of tobacco products and the targeting of populations with the intent of creating addiction and sustaining addiction was accomplished across brands and manipulated within brands over time, by tobacco blending.¹⁴ Thus, any variation in blending that could alter nicotine content, delivery, free nicotine fraction, or other substances that may contribute to addiction (e.g., acetaldehyde emission) should be considered in determination of whether the product is appropriately considered a new tobacco product. The burden

¹³ FDA, 1996, Federal Register 61, No. 168, Aug. 28, p. 44983.

¹⁴ FDA, 1996, Federal Register 61, No. 168, Aug. 28, p. 4492-4494.

should be on the manufacturer to provide data on content and emissions of nicotine, whether the unprotonated (i.e., “free base”) fraction is altered, and other substances that may alter addictiveness. If there are variations, FDA may require companies to conduct studies to evaluate potential differences in behavioral and physiological effects.

Question 9. FDA states that any modification to the level of an additive in a product after February 15, 2007 makes the product a “new tobacco product” but that changes in controls on production that do not affect the actual level of an additive would not make the product a new tobacco product. This conclusion is correct in our view.

Question 10. FDA states that a change subsequent to February 15, 2007 to Fire-Safe Compliant cigarette paper would make the product a new tobacco product. Although it might be appropriate to exempt from enforcement some changes required by law (such as elimination of the designation “light’), a change in cigarette paper could affect a smoker’s intake of smoke constituents and therefore have health effects. FDA’s conclusion is correct. The burden should be on the manufacturer to demonstrate that the new paper does not alter the content of the cigarette or its smoke. Indeed, cigarette manufacturers have themselves said previously that changing the paper in a way that impacts its porosity or the ventilation flow alters the content of the smoke.¹⁵

Question 11. FDA states that a change in the processing aid for a sub-component of the cigarette could have an impact on other characteristics within the tobacco product and therefore would be a modification of the product. FDA’s conclusion is correct. Again, the manufacturer should be required to meet its burden of proving that the change had no impact on the content of the product or its smoke or that the manufacturer had tested the effect of the change on what consumers receive and its impact on consumers and their health.

Question 12. The question asks whether FDA would be willing to create a mechanism whereby companies can contact the agency to determine if certain modifications convert an existing tobacco product into a “new tobacco product” and require a substantial equivalence filing. We believe that it is appropriate for FDA to meet with manufacturers to advise on the standards and criteria it is using to make such decisions, but informal or oral communications should not substitute for requiring the manufacturer to formally submit a written record of any change so that it is part of FDA’s database and can be used by FDA in evaluating product changes at that time and in the future. If FDA provides a manufacturer any advice, the advice should be promptly posted on the FDA website in a manner that discloses the substance of the question, the information on which it was based and the advice given without identifying the questioner. FDA should ensure that it makes clear that provision of such advice does not constitute approval of any application.

Moreover, it is important for FDA to consult with stakeholders other than manufacturers on the same questions. Whatever arrangements FDA affords to manufacturers for such discussions should be available to other interested organizations.

¹⁵ Comments on substantial equivalence submitted in March, 2011 by R.J. Reynolds at 8. (Hereinafter “Reynolds comment”).

Question 13. Without providing an opinion on the specific question, we believe that if FDA allows any rounding of data, it should make public such decision and the factual and scientific basis for the decision and should establish a procedure for monitoring the impact of any such decision.

Question 14. FDA's states that a manufacturer may submit one substantial equivalent report for all identical products that have different names. FDA should monitor the impact of its conclusion but FDA's answer appears unobjectionable

Question 15. FDA's response regarding whether a characteristic should be reported as a material or an ingredient is consistent with the statute. The key element is inclusiveness and consistency.

Question 16. FDA concludes that a modification of glue used in a cigarette renders the product a new tobacco product. FDA's conclusion is correct. Any other response would open a potentially dangerous loophole.

Question 17. The FDA's answer regarding the reporting of harmful and potentially harmful constituents appears consistent with the statute, but it will be critical for FDA to establish a system for how this information is reported to allow it to make the kind of comparisons between products that it will need to make to evaluate the impact of different product changes.

Question 18. FDA's response regarding the need for an environmental assessment is consistent with the statute.

VI Comments on the Industry's March comments on guidance for substantial equivalence.

Numerous tobacco product manufacturers submitted comments on the FDA's proposed guidance on substantial equivalence in Docket Number FDA-2010-D-0635 and FDA-2010-0646 in March, 2011. Many of these comments criticized the FDA's proposed guidance. We believe that the large majority of these comments misinterpret the provisions of the statute, misconceive the purpose of the statutory framework for the regulation of new products and the requirements for demonstrating substantial equivalence, and, if implemented, would undermine the fundamental goal of the statute—the protection of the public health.

A. The framework for substantial equivalence of tobacco products is fundamentally different from that for drugs and devices and requires a different regulatory approach.

Several manufacturers criticized the guidance issued earlier this year on substantial equivalence because they said that the policy on substantial equivalence adopted by FDA with regard to tobacco products differs from the policy toward substantial equivalence adopted by FDA with regard to drugs and devices.¹⁶ As we noted in our prior comments, there are fundamental differences between drugs

¹⁶ Comments on substantial equivalence submitted in February, 2011 by Lorillard at 2-3. (Hereinafter "Lorillard comment"); Comments on substantial equivalence submitted in February, 2011 by Altria at 5 (Hereinafter "Altria comment"); Reynolds comment at 37; Comments on substantial equivalence submitted in June, 2011 by Liggett at

and devices on the one hand and tobacco products on the other, that make it highly inappropriate to apply standards of substantial equivalence developed in the regulation of drugs and medical devices to tobacco products. There is a strong public interest in making drugs and medical devices available for use so long as they are safe and effective. Drugs and medical devices can cure or treat diseases and they can save or prolong lives. By contrast, *no* tobacco product is safe and *no* tobacco product is effective to treat disease. All tobacco products cause death and disease. The statutory standard for tobacco products focuses on the protection of the public health. Determination of what is appropriate to protect the public health with regard to a product that kills when used as intended is different from what is appropriate with regard to a potentially lifesaving drug. In establishing the public health standard and making its findings about the deadly effect of cigarettes, Congress recognized the difference between tobacco products and drugs and developed a statute specifically designed to deal with the unique characteristics of tobacco products.

Moreover, unlike the medical device industry where there are accepted scientific methods for evaluating whether safety and effectiveness have been adversely affected by new technology in a new device, the methods for determining whether a new tobacco product poses no greater risk to the public than a predicate product are less well developed precisely because the tobacco industry was unregulated until 2009. This means it is even more important that the burden be placed on the manufacturer and that manufacturers be required to provide FDA enough information for FDA to conduct the necessary evaluations. These considerations compel the conclusion that the FDA should take into account the harmful nature and lack of public benefit of tobacco products in making its determinations and that it should impose a rigorous burden on the industry to supply the science it needs to make its decisions.

B. The smoke constituents of a cigarette are “features” (and therefore “characteristics”) of a tobacco product within the meaning of Section 910(a)(3)(B).

Section 910(c)(3)(B) provides that a tobacco product can be substantially equivalent to a predicate product if it has “the same characteristics” as the predicate product. “Characteristics” is defined to mean “the materials, ingredients, design, composition, heating source, or other features of a tobacco product.” Altria has argued that smoke constituents are not “characteristics” because they are not specifically mentioned and should not be considered an “other feature” of the product.¹⁷ This contention has no merit. In multiple places the statute makes clear that tobacco smoke and smoke constituents are as important as the ingredients in the product. The FDA’s position is also consistent with that of the World Health Organization’s Expert Study Group, which emphasizes the vital importance of assessing tobacco product emissions (i.e., smoke) qualitatively and quantitatively because it is the emissions that determine the toxic and addictive effects of the product.¹⁸ Although the statute

3-6 (Hereinafter “Liggett comment”); Comments on substantial equivalence submitted in March, 2011 by Commonwealth, et al. at 8-11 (Hereinafter “Commonwealth comment”).

¹⁷ Altria comment at 7-8.

¹⁸ The World Health Organization, *The Scientific Basis of Tobacco Product Regulation; Report of a WHO Study Group (TobReg)*. WHO Technical Report Series, No. 945, Geneva, 2007.

enumerated several different elements in defining “characteristics,” by using the highly inclusive term “other features,” the statute made clear an intention to include elements beyond those that were specified. It is irrelevant whether such other elements might or might not have been referred to individually elsewhere in the statute. Smoke constituents—and any other elements not specifically enumerated that could affect the public health—are “other features” of a tobacco product as that term is used in Section 910(c)(3)(B).

The essential purpose of the entire Act is to protect the public health. In determining whether “smoke constituents” should be deemed to be a “feature” of the product (and hence a “characteristic”), the relevant question is whether a product with different smoke characteristics could have a different impact on public health. Nothing in a cigarette has a greater impact on public health than the constituents in its smoke. It would be contradictory to the express language of the statute and the purpose of the statute to read “other features” not to include smoke constituents.

C. The requirement that the characteristics of a new product must be the same as the characteristics of the predicate product should be given its literal meaning.

Several cigarette manufacturers have argued that the statutory requirement that a product have “the same characteristics” as a predicate product cannot be interpreted to require that a product have “the identical characteristics” because by definition a modification must change a “characteristic of the product,” thereby making it impossible for a modified product to meet the requirement.¹⁹ This contention has no merit. The comparison is to the predicate product, not just the product that is being modified and it is entirely possible for a modified product to have “characteristics” that are identical to a predicate product. However, characteristics are “the same” only if they are “identical” and if the characteristics of a new product are not identical to a predicate product, the product does not have “the same characteristics.” However, FDA has indicated that there are several ways in which a product could be “modified” that do not constitute a modification of its “characteristics” for purposes of the statute. For example, a change in packaging from hard pack to soft pack that has no other effect on the physical properties of the cigarettes (Question 3); a change in tobacco blending due to variation in growing conditions in order to maintain a consistent product (Question 8); a change in quality control that does not affect the level of an additive in the product (Question 9). These examples are illustrative and not exhaustive of the ways in which a product can have been modified but still have “the same characteristics” as a predicate product. It is evident that FDA is correctly interpreting the term “characteristics” to mean those elements that could have an effect on the public health impact of the product. Such effects include, but are not limited to, potential effects on the toxicity, addictiveness or the appeal of the product.

http://www.who.int/tobacco/publications/prod_regulation/tsr/en/index.html; The World Health Organization, Study Group on Tobacco Product Regulation (TobReg) Recommendation: Guiding Principles for the Development of Tobacco Product Research and Testing Capacity and Proposed Protocols for the Initiation of Tobacco Product Testing. Geneva, Switzerland, 2004.

http://www.who.int/tobacco/publications/prod_regulation/goa_principles/en/index.html

¹⁹ Altria comment at 5; Liggett comment at 8-10.

In this case, as in others, FDA is making practical decisions based on the statutory language and its assessment of the potential public health impacts of different types of modifications. Given the fact that the tobacco industry has long hidden from the public and government regulators the impact of different product changes, the agency's case-by-case approach is amply justified at the present time.

Cigarette manufacturers also complain that the requirement that characteristics be "identical" provides no leeway for small quantitative alterations in the content of additives or other elements.²⁰ As with other issues, FDA has appropriately sought to address such questions on a case-by-case basis. Determination of appropriate levels of tolerance in measurement will vary depending upon the nature of the substance at issue and the test methodology. If a tobacco product manufacturer has solid scientific evidence about the impact of small quantitative changes, it should present that information to the FDA in a manner that is responsive to the full range of considerations that the statute requires FDA to consider. If it does not have such evidence, the statute makes clear that the tobacco industry will no longer be allowed to use the American public as guinea pigs.

As the industry provides FDA with the scientific research it possesses and FDA is able to evaluate that research and develop standards and criteria that assure the public that any changes will not adversely impact public health, FDA will be in a position to provide broader guidance. Development of an overall policy should be based on practical experience and incorporate additional scientific information and technological progress. However, given the potential harm tobacco products can cause, it is appropriate for regulatory decisions to be based on the recognition that no increase in the delivery of a toxic or addictive substance can be presumed to be without an impact on the public health.

D. The requirement that a tobacco product must be substantially equivalent to a single predicate product rather than to various aspects of multiple predicate products is both consistent with the statute and necessary for the protection of the public health.

In its previous guidance FDA stated that in making substantial equivalence determinations, a single predicate product should be used for comparison purposes because "a meaningful scientific comparison intended to determine whether the characteristics of the products are the same or are different but present no different questions of public health cannot be made between a new tobacco product and multiple tobacco products." All the major cigarette manufacturers took issue with this statement.²¹

FDA's interpretation of the statute is correct and necessary for the protection of the public health. In the absence of a requirement that a new tobacco product be compared only to a single product, it would be possible for a manufacturer to argue that such a product was substantially equivalent to a product that had never before been on the market and the health effects of which are unknown. Under the interpretation urged by the manufacturers, a new product could be deemed to be "substantially equivalent" to a predicate product if each of the components of the new product had been found in no greater quantity in one predicate product or another. It would be unnecessary for the

²⁰ Lorillard comment at 2; Altria comment at 5; Reynolds comment at 33-37.

²¹ Altria comment at 4; Lorillard comment at 4; Reynolds comment at 3; Liggett comment at 7-8.

particular combination of components to have been present in a single predicate product. Thus, a new tobacco product could be found to be “substantially equivalent” to a predicate product that had never existed.

The cigarette manufacturers’ own statements demonstrate why such a rule would not protect the public health. In its comments, R.J. Reynolds Tobacco Company, in describing its own quality control program, makes the following statement.

“Because one product change may affect other properties of the tobacco product and multiple product changes may occur at once (e.g., a change in the cigarette paper may affect the ventilation of the cigarette), the configuration of the final tobacco product is evaluated as a complex, integrated system.”²²

This statement succinctly describes the reason why, for purposes of a substantial equivalence determination, a new product must be compared to a single predicate product. Even if a new product did not contain any element in a quantity greater than that present in multiple predicate products, there could be no assurance that such a product would not present a greater risk to the public health than any such predicate products.

Altria’s comments purport to find support for its position in a statement made by the Institute of Medicine in its 2001 Report, *Clearing the Smoke*, to the effect that cigarette manufacturers should be permitted to market new or modified products in the absence of any claim of reduced exposure or reduced risk so long as they certified that the product could not reasonably be expected to increase the risk of disease.²³ This statement provides no support for the use of multiple predicate products. To begin with, the statute rejects the approach taken by the 2001 Report and adopts a completely different regulatory standard. Moreover, in a later 2007 report, the Institute of Medicine dropped this recommendation.²⁴ Third, the statement provides no support whatsoever for the policy position urged by Altria. In the absence of an express comparison between a new tobacco product and a single, identified predicate product there can be no reasonable expectation that the new product will not pose an increased risk to the public health.²⁵ Moreover, given the history of the industry’s duplicity in the marketing of new and modified products, a manufacturer’s certification that the product could not reasonably be expected to increase the risk of disease would be wholly lacking in credibility. The statute requires scientific evidence—not unsupported assertions.

The FDA’s interpretation is fully consistent with the language of the statute, which requires that a new product be compared to “a [predicate] tobacco product.” (emphasis added) Sec. 905(j)(1)(A) Nothing in the statutory language would warrant a different interpretation.

²² Reynolds comment at 13.

²³ Altria comment at 9.

²⁴ Institute of Medicine, *Ending the Tobacco Problem, A Blueprint for the Nation*, 2007.

²⁵ Institute of Medicine, *Clearing the Smoke: The Science Base for Tobacco Harm Reduction*, February 2001; Altria comment at 5.

E. The statute requires affirmative premarket action by the FDA for the designation of a product as “substantially equivalent”—not simply premarket notification.

The major cigarette manufacturers urge that the statute does not require affirmative premarket FDA action for a product to be designated “substantially equivalent” to a predicate product, but rather only premarket notification by the manufacturer to the agency.²⁶ This position is contradicted by the statutory language. The statute provides that a new product can be considered “substantially equivalent” to a predicate product only if “*the Secretary by order has found that the tobacco product*” [meets the statutory standard]. Sec. 910(a)(3) (emphasis added) Nothing could be more clear.

The cigarette manufacturers argue that the provisions of Section 905(j) are inconsistent with this requirement because they provide that a tobacco product manufacturer must file a report at least 90 days prior to introducing the product into commerce. The manufacturers argue that this provision makes no sense if a manufacturer must await the Secretary’s determination before introducing the product.²⁷ As shown above, however, such an interpretation is explicitly contradicted by the language of section 910(a)(3). Moreover, there is no conflict between the two sections. Both requirements apply. A manufacturer may not market a tobacco product found by the Secretary to be substantially equivalent to a predicate product until 90 days after its 905(j) report was filed even if the Secretary makes such a finding within 90 days. If, after the passage of 90 days from the date the report was filed, the Secretary has not made the required finding, the manufacturer may not market the product until such a finding is made.

The cigarette manufacturers also cite the reporting requirements under section 904(c) as support for the argument that the statute somehow does not require premarket action before a product alleged to be substantially equivalent to a predicate product can be marketed.²⁸ These provisions require tobacco product manufacturers to report new additives or increases in additives at least 90 days prior to taking such action and decreases in additives no more than 60 days after such decrease is implemented. The manufacturers argue that these provisions are inconsistent with the requirement of premarket action because they contemplate such changes being made without such premarket action. However, there is no such inconsistency. The statute does not require premarket action by the Secretary for products (1) marketed on or before March 22, 2011 and (2) for which reports were filed under Section 905(j) on or before March 22, 2011. Thus, with respect to the hundreds of products modified between the date of enactment and March 22, 2011, these provisions would have been applicable and such changes could have been made without premarket action by the Secretary. Any such change made after March 22, 2011 would be prohibited in the absence of affirmative premarket action by the Secretary. Moreover, it is not unreasonable for decreases in additives to be governed by a different standard.

²⁶ Lorillard comment at 5-6.

²⁷ Lorillard comment at 7.

²⁸ Lorillard comment at 5; Altria comment at 10-11.

F. Industry arguments that a wide range of product modifications should be permitted without premarket action by the Secretary are unpersuasive in light of the industry's history of abuse.

The statute requires premarket action on any change, however small, in cigarette design but gives FDA discretion to adopt limited exceptions that do not impact the public health. The industry is attempting to pressure the FDA to grant a set of broad exceptions that are inconsistent with the statute and that would permit it to operate essentially as it did prior to the enactment of the statute and continue to modify and introduce new products without regard to public health concerns, all the while assuring FDA and the public that none of these changes has any impact on public health.²⁹ Quite correctly, however, FDA has concluded that statute establishes a different regime and that it is only authorized to grant limited exceptions where it has sufficient scientific evidence to insure that such exceptions do not impact the public health. Unlike the manufacturers of thousands of other products, tobacco product manufacturers have never before been required to prove to government officials the impact of different ingredients in its products and different changes in its products. The new statute clearly changes that situation. Product changes may not be made in the absence of sound evidence independently reviewed by FDA that the change does not harm the public health. The industry bears the burden of proving the effect of a new product on the public health and if it lacks the evidence to demonstrate what will be the impact of its changes it will not be permitted to market the product. The day when the industry can benefit from hiding the truth or failing to conduct the type of rigorous scientific research other industries have long been required to conduct for far less dangerous products has been ended by the new statute.

Strict enforcement of the statutory requirements is required in order to ensure that the purpose of the statute is served. Under a standard of substantial equivalence, any mistaken ruling that a product is substantially equivalent to another creates a potential chain effect. Moreover, the industry's history of misconduct demonstrates that here is no reason for FDA to trust that any exception will not be abused.

The cigarette manufacturers make various arguments designed to limit the requirement of premarket action by the Secretary on a substantial equivalence report filed under section 905(j) as a precondition for marketing. Thus, Altria argues that new tobacco products with conventional designs comprising new combinations of ingredients would have "the same characteristics" as previously marketed products with regard to smoke toxicity. Altria advises that close scrutiny should be reserved for "truly novel compositional or design features of a new tobacco product which might have the potential to alter toxicity."³⁰ R.J. Reynolds makes a similar argument that "modifications within the 'marketplace range' do not increase the inherent public health risks associated with tobacco products."³¹ None of these assertions are supported by the language of the statute. R.J. Reynolds also

²⁹ Reynolds comment at 22; Altria comment at 5-6, 10-11.

³⁰ Altria comment at 6.

³¹ Reynolds comment at 33-37.

cites several studies that it asserts show that certain changes in tobacco products do not increase what it describes as “inherent public health risks” associated with tobacco products

Furthermore, R.J. Reynolds describes its Stewardship Program, which it describes as “especially rigorous” and designed to ensure that changes in cigarettes did not increase the inherent public health risks of smoking.³² Other companies allege that they have similar programs. Reynolds asserts that it employs a sophisticated method to assign various levels of risk to proposed changes and that, if it deems the modification to be major, it increases the amount of testing to determine whether, in the judgment of the company evaluators, it poses “an increase in the inherent risks associated with tobacco products.”³³ According to Reynolds, if the company evaluators determine that a change does increase the inherent risks associated with tobacco products, Reynolds does not implement the change.³⁴ This describes the discredited process that prevailed prior to enactment of the FSPTCA and that failed to protect the public health against the rapacious practices of the tobacco industry. That Reynolds—or any tobacco company—could possibly believe that any such process provides adequate protection for the public health is astonishing. Reynolds ingeniously tries to turn the unassailable proposition that there is no such thing as a safe cigarette (a proposition it steadfastly denied for more than fifty years) on its head by arguing that since cigarettes are inherently lethal changes in cigarette design that may increase the delivery of toxic substances have no public health consequences. This argument rests on the assumption that if it is not possible to quantify an increase in death from an increase in the level of a toxicant, such an increase can somehow be presumed to be harmless. In fact, however, the statute reverses this presumption: no increase in toxicants should be presumed to be appropriate for the protection of the public health and the burden should be on the manufacturer to demonstrate that the effect of any change in the product meets this standard.

The Reynolds argument also ignores evidence that shows how such changes increase the addictiveness of cigarettes or the manner in which nicotine is delivered. In addition, it ignores evidence that shows how such changes affect the consumer acceptability of such products. As a result, the argument ignores the effect of such changes on decisions by existing smokers to quit or decisions by non-smokers to initiate use.

In fact, the overwhelming weight of the historical evidence demonstrates that the companies have frequently and knowingly altered the design of cigarettes in ways that intentionally increased the inherent public health risks of smoking by deliberately designing their products and marketing them to provide the false impression that they presented a reduced risk of harm and in order to discourage existing smokers from quitting and to encourage non-users to initiate tobacco use.

As extensively documented in the decision of the United States District Court for the District of Columbia in *U.S. v. Philip Morris*, 449 F. Supp. 2d 1 (D.C.D.C. 2006) and in an authoritative review of the evidence by the National Cancer Institute, the major cigarette manufacturers, over a period of many decades, deliberately designed their cigarettes to increase the inherent public health risks of smoking.

³² Reynolds comment at 12-14.

³³ Reynolds comment at 35.

³⁴ Reynolds comment at 12.

The major cigarette manufacturers made design changes in cigarettes labeled as “light” or “low-tar” with the intention to produce cigarettes that would show substantially lower tar and nicotine delivery on machine-measured tests while knowing that the actual delivery of tar and nicotine to customers was higher.³⁵ As the National Cancer Institute found, “the dichotomy of delivery between smokers and machines was the intended result of the engineering effort to design elasticity of delivery into cigarettes.”³⁶ These changes involved, inter alia, the introduction of ventilation holes in cigarette filters, changes in paper, and the use of additives to facilitate the delivery of nicotine. The companies had an extensive and sophisticated understanding that consumers would alter their smoking behavior to get the amount of nicotine they needed and made design changes in their cigarettes to facilitate such changes.³⁷ The companies understood that by labeling their cigarettes “light” or “low-tar” they were encouraging consumers to use them in the belief that by smoking such cigarettes they were using a safer product and lowering their disease risk. The companies were aware that these cigarettes were not in fact any safer than full-flavored cigarettes and that consumers were being misled by their claims to the contrary. Moreover, as the District Court found, the companies recognized that smokers relied on the claims made for low tar/light cigarettes as a rationale for not quitting smoking.³⁸ Critically, the industry was able to get away with this fraud precisely because it was not required to share all of its research with the government and because it was not required to conduct the kind of scientific research needed for the government to evaluate the actual impact of how it was designing so-called low tar cigarettes.

As extensively documented in *U.S. v. Philip Morris*, the major tobacco companies developed the capability to precisely control the level of nicotine in cigarettes and to produce cigarettes with a high ratio of nicotine to tar.³⁹ Over a period of many decades, they have designed their cigarettes with the deliberate intention of providing doses of nicotine sufficient to create and sustain addiction. They have done so by altering the blend of tobacco leaf and by using many other design techniques, such as using reconstituted tobacco material, burn accelerants, ash conditioners, and buffering substances in order to affect nicotine levels and delivery. In addition, they incorporated various design elements such as filter design, paper selection and perforation, ventilation, and the use of additives to control the pH of cigarette smoke and increase the delivery of free nicotine.

Given the ability of tobacco manufacturers to control the level of nicotine in their products to ensure delivery of a dose sufficient to sustain addiction, the fact that the level of nicotine in cigarettes rose appreciably in the period 1997-2005, cannot be seen as accidental.⁴⁰

³⁵ *United States v. Philip Morris*, 449 F. Supp. 2d 1 (D.C.D.C. 2006); National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Yields of Tar and Nicotine; Report of the NCI Expert Committee*. Smoking and Tobacco Control Monograph 13.

³⁶ National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Yields of Tar and Nicotine; Report of the NCI Expert Committee*. Smoking and Tobacco Control Monograph 13 at 6.

³⁷ *United States v. Philip Morris*, 449 F. Supp. 2d 1 at 515-633 (D.C.D.C. 2006).

³⁸ *United States v. Philip Morris*, 449 F. Supp. 2d 1 at 843-863 (D.C.D.C. 2006).

³⁹ *United States v. Philip Morris*, 449 F. Supp. 2d 1 at 516-560 (D.C.D.C. 2006).

⁴⁰ Connolly, GN, et. al., “Trends in Smoke Nicotine Yield and Relationship to Design Characteristics Among Popular U.S. Cigarette Brands 1997-2005,” *Tobacco Control* 16(5), October 2007.

This history demonstrates that the industry has a far greater capability to engineer the contents of its product than has been claimed; that the industry has a much more sophisticated understanding than regulators of the effects of product design changes on consumer behavior; and that the industry is willing to develop and market products that increase the inherent risks of smoking and mislead consumers about the risks posed by such products.

These facts have important policy implications. No effective regulatory policy can be based on the acceptance of industry claims that product modifications do not increase the inherent risks of smoking. The statute appropriately places the burden on tobacco product manufacturers to demonstrate the truth of any and all its assertions regarding the effect of product changes on the public health and in the absence of such demonstration they should not be entitled to market any new product. Such changes include not only changes that might implicate changes in toxicity, but also changes that might implicate changes in addictiveness or enhance the appeal of the product to new users. The industry complains that such a requirement would compel substantial changes in the way it has always done business. But this complaint misses the point: the purpose of the statute was to require fundamental changes in the way the industry does business and in what it discloses to the government in order to protect the public health.

Most important, the drafters of the statute emphatically rejected an approach that would have permitted the manufacturers to market new or modified products without prior affirmative action by the regulatory agency.⁴¹

G. FDA should demand production of all documents from the Reynolds Stewardship Program and similar programs operated by other major tobacco companies.

⁴¹ Philip Morris cites a recommendation in the Institute of Medicine's 2001 Study, *Clearing the Smoke*, in support of its contention that the statute should be interpreted to give the industry broad discretion in determining what kinds of changes in cigarette design require premarket approval and to permit a wide range of changes in cigarette design so long as the changes were not "truly novel." This conclusion was reached, however, before massive amounts of evidence became available about the industry's manipulations of cigarette design with regard to light cigarettes, or about the deliberate increases in nicotine levels with the express purpose of making cigarettes more addictive, or about other changes in cigarette design that increased the risk to public health. The National Cancer Institute monograph that chronicled the history of the industry's deception regarding the marketing of light cigarettes was not published until months after the release of the Institute of Medicine Study. Most important, the District Court had not yet made its extensive findings regarding the industry's conduct over many decades. When the Institute of Medicine issued its next report on tobacco policy in 2007, *Ending the Tobacco Problem*, it did not make any similar recommendation. Most importantly, however, the statute rejects the inadequate standard stated in the 2001 Institute of Medicine Study.

In its comments submitted to the FDA, R.J. Reynolds describes its Stewardship Program for the evaluation of the effects of changes in cigarette design and composition on the health risks of tobacco products. According to R.J. Reynolds, the program has produced a wealth of information and provides a basis for reaching a number of important conclusions.⁴² It also alleges that the other major tobacco product manufacturers have similar programs. Pursuant to section 904(a)(4), each tobacco product manufacturer should have submitted “all documents developed after 6 months after the date of enactment of the Tobacco Control Act that relate to the health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.” The statute also permits FDA to require the manufacturers to produce many older documents that are highly relevant to substantial equivalence questions. These include the following:

- (1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives;
- (2) Any and all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.

FDA should require production of all such information and commission a review of what can be learned from it about the public health impacts of product design.⁴³ Of particular interest would be any documents relating to the effect of additives and ingredients on the delivery of nicotine, the addictiveness of cigarettes, or the consumer acceptability of cigarettes. As noted above, changes in any of these parameters would be highly relevant in determining whether or not a product is substantially equivalent to a predicate product.

H. The statute does not limit the application of the substantial equivalence standards to changes that increase toxicity, but rather includes all changes that could affect public health.

The major tobacco manufacturers seek to limit the application of the substantial equivalence standards to changes that increase toxicity.⁴⁴ However, the statutory standard is not so limited. Under the statute, unless a product “has the same characteristics as the predicate product,” it can qualify as substantially equivalent to a predicate product only if the manufacturer demonstrates “that it is not appropriate to regulate the product as a new product because the product does not raise different questions of public health.” In determining when a product “raises different questions of public health,” several issues are relevant.

⁴² Reynolds comment at 33-37. According to Reynolds, “If the Stewardship Program determines that a proposed change is likely to increase the inherent risks associated with tobacco products, R.J. Reynolds does not implement the change.”

⁴³ Reynolds invites the agency to make use of the Stewardship Program as a model. Reynolds comment at 14.

⁴⁴ Altria comment at 8-10; Reynolds comment at 33-37.

First, the product should be evaluated as it is actually used by consumers and as it affects consumers in actual use. Thus, for example, if a cigarette design change causes smokers to smoke it differently, resulting in delivery of different quantities of various constituents, such a change could raise a different question of public health.

Second, products that increase the delivery of addictive substances “raise different questions of public health,” whether or not such changes increase the toxicity of cigarettes. Just as quitting smoking reduces a smoker’s risk of death and disease, so continued smoking increases that risk. Therefore, product changes that make the product more addictive by affecting the delivery of nicotine make it less likely that existing users will quit and make it more likely that those who initiate smoking will become addicted. Therefore such product changes affecting the delivery of nicotine raise different questions of public health. Third, changes that make it more likely that non-smokers will start smoking or that existing users will not quit “raise different questions of public health.” The public health standard is specifically defined in several sections of the statute to include these considerations. Some tobacco companies argue that the failure to include specific mention of these factors in section 905(j) means that they should not be considered. However, there is no rational argument that the use of the term “public health” in section 905(j) has a meaning different from that in other sections of the statute. Moreover, increases in smoking initiation and decreases in cessation undeniably have effects on public health. There is no reason why changes in initiation or decreases in cessation should be excluded from consideration when evaluating whether a change in cigarette design raises a different question of public health. Thus, modification of a product in a way that made it more likely than the predicate product to encourage smoking initiation would “raise a different question of public health” and preclude its classification as “substantially equivalent” to the predicate product.

These considerations require that FDA consider variations in smoke characteristics that could affect initiation, dependence, and cessation as required by the statute and these characteristics can include nicotine emission, the free base fraction and quantity in emissions, other pharmacologically active substances such as acetaldehyde, and any substances that may make it easier to inhale addictive levels of smoke into the lung.

Finally, Altria once again seeks to rely on the Institute of Medicine 2001 study for the proposition that substantial equivalence evaluations should be limited to toxicology studies and clinical studies.⁴⁵ As noted above, the Institute of Medicine 2001 report was not adopted by Congress, nor was its standard included in the Act. As shown above, *supra*, note 1, the statute adopted more rigorous standards for premarket review of proposed product modifications than those stated in that Report. Indeed, the tobacco industry argued unsuccessfully that Congress should adopt several of the standards in the 2001 report--which makes it even more significant that Congress did not do so. In addition, the IOM recommendation states that the evaluation should be made not only on the basis of toxicological

⁴⁵ Altria comment at 9.

information, but on the basis of epidemiological information as well.⁴⁶ Such epidemiological information would include consideration of effects on initiation and cessation.

I. The suggestion that FDA should establish a deadline for resolution of each substantial equivalence filing should be rejected.

The statute establishes no deadline for resolution of a substantial equivalence filing. Several tobacco product manufacturers suggest that the FDA should establish such a deadline. If the industry's recommendation were adopted, it would benefit from its own failure to provide FDA sufficient information in a timely fashion and it would benefit from the fact that it has long failed either to conduct the kind of studies that FDA will need to be certain that it is reaching the correct conclusion or has failed to disclose such studies. FDA must be given the time to collect the information it needs and evaluate that information. The statute makes clear that FDA should act expeditiously but it also does not limit the time FDA has to make decisions because products should not be allowed on the market until the industry has met its burden.

J. The fact that a manufacturer lacks information regarding substances and constituents in predicate tobacco products is not an argument for bypassing statutory requirements.

Several tobacco product manufacturers complain that they lack full information on the characteristics of products marketed as of February 15, 2007 but still argue that they should be permitted to market new products because they are allegedly substantially equivalent to such products. This argument is entirely inconsistent with the statute. It is astonishing that manufacturers assert that lethal and addictive new products should be permitted on the market because they are allegedly "substantially equivalent" to products as to which comparison is impossible.⁴⁷ The burden of establishing substantial equivalence is on the manufacturer. If the manufacturer lacks sufficient information to carry this burden, FDA cannot act affirmatively on the application. The consequence is that the manufacturer must pursue a different avenue to market the product.

K. The fact that the FDA has not completed the promulgation of a list of harmful or potentially harmful constituents in tobacco products does not mean that the FDA cannot or should not require manufacturers to provide evidence regarding the levels of designated substances as a condition of approval of substantial equivalence applications.

There is nothing in the statute that limits FDA's review of products to constituents that it has identified as harmful or potentially harmful. The time lines in the statute require submission of information regarding harmful and substantially harmful constituents as of December 19, 2009 for all products. As part of its consideration of a substantial equivalence filing or a new product application, FDA is free to consider the levels of such constituents in both the new product and the predicate product and to require submission of such information whether or not the constituent has been formally designated as harmful or potential harmful.

⁴⁶ Institute of Medicine, *Clearing the Smoke: The Science Base for Tobacco Harm Reduction*, February 2001.

⁴⁷ Commonwealth, et al. comment at 5-6.

L. The statute does not require FDA to exempt any class of modifications from the requirements of Section 905(j) and FDA should not issue any such exemptions until it is satisfied that such exemptions are consistent with its obligation to protect the public health.

Reynolds complains that FDA has not issued regulations for exemptions from the substantial equivalence filing requirements pursuant to section 905(j)(3) that go beyond the language of the statute. It argues that the failure to do so violates the agency's obligations.⁴⁸

Once again, Reynolds makes assertions that are inconsistent with the requirements of the statute. There is no statutory obligation for the agency to issue such exemptions. The statute permits but does not require FDA to issue such exemptions. As noted previously, FDA is dealing with an extraordinarily complex and difficult set of issues. The development of policy standards should be informed by experience and factual analysis. It is not surprising that the agency has chosen to require the industry to first provide it with the information and scientific studies in its possession and indicated that it will study this information carefully in making decisions, initially on a case by case basis, until it has more information and a better scientific database base upon which to make broader conclusions.

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ORGANIZATIONAL SIGNATURES ON FOLLOWING PAGE

⁴⁸ Reynolds comment at 35.



Christopher W. Hansen
President
American Cancer Society Cancer Action
Network



Nancy Brown
Chief Executive Officer
American Heart Association




Charles D. Connor
President and Chief Executive Officer
American Lung Association



Matthew Myers
President
Campaign for Tobacco-free Kids



Cheryl G. Heulton, Dr. P.H.
President and Chief Executive Officer
Legacy



Norman Anderson, Ph.D.
Chief Executive Officer
American Psychological Association



Michael Barry
Executive Director
American College of Preventive Medicine



Stephen C. Crane, PhD, MPH
Executive Director
American Thoracic Society



Jeannette Noltenius, MA, PhD
National Director
National Latino Tobacco Control Network



Jud Richland, MPH
President and Chief Executive Officer
Partnership for Prevention



Robert West, PhD
President
Society for Research on Nicotine and Tobacco