COMMENT SUBMITTED IN RESPONSE TO FDA ON PROPOSED COLLECTION OF INFORMATION REGARDING EXEMPTIONS FROM SUBSTANTIAL EQUIVALENCE REQUIREMENTS FOR TOBACCO PRODUCTS

Docket No. FDA-2013-N-1588

Stanton Glantz, PhD
Lauren Lempert, JD, MPH
Center for Tobacco Control Research and Education
University of California San Francisco

February 17, 2014

We submit these comments in response to FDA's notice concerning the proposed collection of information regarding exemptions from substantial equivalence requirements for tobacco products. We previously submitted public comments on substantial equivalence in reference to docket 2010-D-0635 which are incorporated by reference in this comment.[1]

The FDA rule establishing procedures for tobacco companies to request exemptions from the substantial equivalence requirements of the Family Smoking Prevention and Tobacco Control Act has created an enormous loophole that gives tobacco companies, adjudicated racketeers,[2] an opportunity to claim that modifications they made to new tobacco products they wish to introduce into the market by adding or increasing toxic additives are so-called "minor modifications," although many such additives (i.e., ammonia or added sugars) make those products more attractive, appealing, and/or more addictive,[3] thereby avoiding meaningful premarket approval by the FDA.

While the proposed collection of information is necessary, it is not sufficient for FDA to properly meet its mandated responsibility to protect the public health. The public health requirement in the context of substantial equivalence exemptions and the public health standard are clearly enunciated in the Family Smoking Prevention and Tobacco Control Act (FSPTCA)[4] and in FDA's final rule establishing procedures for requesting an exemption from the substantial equivalence requirements.[5] FSPTCA requires that in reaching its determination that a tobacco product may be exempt from the substantial equivalence reporting requirements, FDA must determine not only that the product modification would be a "minor modification," but also that a report "is not necessary to ensure that permitting the tobacco product to be marketed would be

[1] Glantz S. RE: Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products; Availability (Document ID FDA-2010-D-0635-0001). December 15, 2012. Available on www.regulation.gov at 1jw-82jq-ae81; and Glantz S. Comment Regarding Power and Effect Size in Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products; Guidance FDA-201-D-0635, January 9, 2013.

[2] *United States v. Philip Morris USA, Inc.,* 449 F. Supp. 2d 1 (D.D.C. 2006)

[3] Anderson SJ, McCandless PM, Klausner K, Taketa R, Yerger VB (2011) Tobacco documents research methodology. Tob Control 20 Suppl 2: ii8-11; Stevenson T, Proctor RN (2008) The secret and soul of Marlboro: Phillip Morris and the origins, spread, and denial of nicotine freebasing. Am J Public Health 98: 1184-1194;
Wertz MS, Kyriss T, Paranjape S, Glantz SA (2011) The toxic effects of cigarette additives. Philip Morris' project mix reconsidered: an analysis of documents released through litigation. PLoS Med 8: e1001145.

[4] Family Smoking Prevention and Tobacco Control Act sections 905(j)(3) and 907.

[5] 21 CFR 1107.1

appropriate for protection of the public health," and that an exemption is otherwise appropriate. [6] It is essential for FDA to exercise this authority and require as much information as is necessary to make a determination that will protect the public health. In contrast to FDA's regulatory authority over drugs and medical devices, which requires FDA to strike an appropriate balance between the public's need to get fast access to potentially life-saving medications and the need to ensure that those products are safe and effective, FDA's regulatory authority over tobacco products is intended to protect the public from those very products, since they are known to be lethal if used as directed.[7]

Although the final rule provides that an exemption request must contain a detailed explanation of the purpose for the modification and a detailed description of the modification, including whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of the existing tobacco additive,[8] it does not explicitly require exemption requests to include statements, supported by scientific evidence, indicating the exact amount of the additives contained in the predicate product and the exact amount of the additives contained in the modified product together with compelling evidence from adequately powered studies to demonstrate that these changes do not increase health risks to individual consumers or the population as a whole.

The FDA should require this level of detail and specificity. By requiring this specificity, FDA would be better able to make an independent determination about whether the modification is indeed "minor" and whether the modified product would be appropriate for the protection of public health.

Additionally, the FDA should set a small limit on the number of "minor modification" exemptions it will permit for any one product and its successor products. Without such a limit, a manufacturer could over time request a string of "minor" modifications that, taken together, would in effect be introducing a new product that should be subject to the new tobacco product review requirements under FSPTCA section 910(a)(2), rather than making a "minor" modification that could be exempt from substantial equivalence rules under section 905(j)(3).

Moreover, FDA must make its own independent assessment about whether the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictive, or abuse liability, and must not merely rely on a certification made by an official of the company as provided in the rule.[9]

The FDA must never forget that the major tobacco companies remain under the jurisdiction of a federal court that found that the defendant companies have implemented a massive fraud on that American public and that "[t]here is a reasonable likelihood that Defendants' RICO violations will continue in most of the areas in which they have committed violations in the past.",[10] and therefore the FDA cannot and must not assume that the information

[6] Family Smoking Prevention and Tobacco Control Act sections 905(j)(3)(A); 21 CFR 1107.1

[7] U.S. Dept. of Health and Human Services. *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General.* (2014)

[8] 21 CFR 1107.1(b)(3) and (4)

[9] 21 CFR 1107.1(b)(7)

[10] *United States v. Philip Morris USA, Inc.,* 449 F. Supp. 2d 1 (D.D.C. 2006) at page 1606.

provided by these companies about their products is legitimate without doing its own independent testing.

Specifically, Judge Kessler stated in her RICO decision:

> The foregoing Findings of Fact demonstrate that, ***over the course of approximately fifty years***, different ***Defendants***, at different times, took the following actions in order to maintain their public positions on smoking and disease-related issues, nicotine addiction, nicotine manipulation, and low tar cigarettes, in order to protect themselves from smoking and health related claims in litigation, and ***in order to avoid regulation which they viewed as harmful***: they ***suppressed, concealed, and terminated scientific research; they destroyed documents including scientific reports and studies; and they repeatedly and intentionally improperly asserted the attorney-client and work product privileges over many thousands of documents (not just pages) to thwart disclosure*** to plaintiffs in smoking and health related litigation and ***to federal regulatory agencies***, and to shield those documents from the harsh light of day."[11]

Significantly, Judge Kessler also ruled that:

> Defendants [tobacco companies] have ***a continuing interest in suppressing research and information and destroying documents*** which could prove detrimental to their public and litigation positions. Although it is difficult to prove such suppression or destruction, ***the Court strongly believes such RICO violations are reasonably likely to continue.***[12]

The FDA cannot and should not ignore these findings. Indeed, they should be included explicitly in the final rule where they can be part of the record in the case of any litigation that the tobacco companies bring when the FDA denies a "minor" modification.

Most important, for these reasons the FDA cannot and should not take at face value any manufacturer's certification summarizing the supporting evidence and providing the rationale for its determination that the modification would satisfy the mandated public health standard, but rather must make its own assessment.

Unless the FDA is exceptionally careful, allowing substantial equivalence exemptions for seemingly "minor" modifications could open up a huge loophole that would undermine meaningful product regulation.

[11] *United States v. Philip Morris USA, Inc.,* 449 F. Supp. 2d 1 (D.D.C. 2006) at paragraph 4034, page 1477 (emphasis added).
[12] *United States v. Philip Morris USA, Inc.,* 449 F. Supp. 2d 1 (D.D.C. 2006) at page 1609.