Packaging colour research by tobacco companies:

The pack as a product characteristic

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Supplemental File:

Implications for FDA Review of New Tobacco Products

The 2009 Family Smoking Prevention and Tobacco Control Act[1] (FSPTCA) requires tobacco companies to obtain premarket authorization from the U.S. Food and Drug Administration (FDA) before they can legally market a "new tobacco product" in the United States. A "new tobacco product" is defined as a tobacco product that was not commercially marketed in the U.S. on February 15, 2007, or that has been modified, including but not limited to changing any part or any other additive or ingredient.[2] The companies can obtain this authorization using one of three pathways, described more fully below and spelled out in FSPTCA sections 905(j) and 910:

(1) Submit a premarket tobacco product application (PMTA); [3]

(2) Submit a "substantial equivalence" (SE) report;[4]or

(3) Demonstrate that the product is exempt from new product or SE requirements. [5]

As of September 2015 (the most recent data posted by FDA as of April 2016), FDA had received a total of 5,333 product submissions, including 1,721 regular SE submissions (including 662 streamlined applications), 3,517 provisional SE submissions, and 68 SE exemption submissions, as well as 12 premarket applications for new tobacco products and 15 modified risk tobacco product applications.[6] [7]Of the 5,306 SE submissions it had received,[6] as of April 2016 the agency had issued 555 SE orders, 176

Not Substantially Equivalent (NSE) orders, and 37 “Refuse to Accept” orders (for incomplete SE reports), 23 SE order rescissions, and 982 manufacturers had withdrawn their applications. Of the 3,517 provisional SE applications, as of April 2016 FDA has issued 48 provisional NSE orders (4 in February 2014, 7 in August 2014, 10 in May 2015, 1 in August 2015, 5 in September 2015, 10 in October 2015, and 11 in February 2016, leaving 3,469 new tobacco products that were introduced between February 2007 and March 2011 and had not been evaluated by FDA remaining on the market while awaiting SE review.[8]

Products that do not have pre-market authorization as required by FSPTCA section 910 are deemed “adulterated” under FSPTCA section 902. [9] Products with labeling that is false or misleading in any particular are deemed “misbranded” under FSPTCA section 903. [10] Products that FDA determines are “not substantially equivalent” (NSE) and for which it issues NSE orders are considered both adulterated and misbranded. [11] When a tobacco product is deemed adulterated or misbranded, it is illegal to sell or distribute the product in interstate commerce or import the product into the United States. [11, 12]

Premarket Tobacco Product Application

Under the premarket tobacco product application (PMTA) pathway, manufacturers must present data and information sufficient to enable FDA to make a finding that the marketing of a new tobacco product is "appropriate for the protection of the public health," and the product and its manufacture and labeling conform to requirements in the Act and related rules. [3] The public health standard requires FDA to

consider the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, 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.[13]

Importantly, FSPTCA 910(b)(1)(F) requires new tobacco product applications to contain "specimens of the labeling proposed to be used for such tobacco product" [14] in addition to reports of health risks; statements of components, ingredients, additives, properties, and principles of operation; descriptions of manufacturing methods; and other relevant information and product samples.[15] This statutory requirement establishes that Congress intended product labeling, like other tobacco product characteristics, to be an important factor in FDA's determination of whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health. FDA highlighted this statutory requirement in its September 2011 *Guidance for Industry, Applications for Premarket Review of New Tobacco Products* [16] ("PMTA Guidance"), further specifying that the requirement includes "labels, inserts/onserts, instructions, and other accompanying information or materials."

In addition to implementing the public health standard, FDA is required to deny any PMTA if the product's package labeling is "false or misleading in any particular." [17] Therefore, in its September 2011 PMTA Guidance, FDA recommends that manufacturers submit adult human subject studies that provide evaluations of "consumer perceptions including risk perceptions based on the product itself, *as well as on the packaging and labeling of the new tobacco product* [emphasis added]" to enable FDA to determine whether the product's packaging or labeling is false or misleading in any particular and

whether allowing the product on the market would be appropriate for the protection of the public health.[16]

As of April 2016, FDA had received just 12 PMTA applications[6] for which it issued four "Refuse-to-File" (RTF; i.e., refuse to undertake an extensive new product review) final actions and eight PMTA marketing orders in October 2015 (for Swedish Match snus products).[8] FDA may refuse to file an application if it is missing one or more items required by FSPTCA section 910(b) (e.g., a full statement of the components ingredients, additives, and properties of the product; samples of the product; or specimens of the labeling). [7, 15] In its "Brief Summary of Refusal-to-File Determinations," [7]FDA cited a failure to provide an adequate example ("specimen") of the proposed labeling as a deficiency in one or more of the PMTA applications it reviewed. Notably, FDA stated that one or more of the submitted labeling specimens were deficient and triggered a RTF action because the specimen was not reproduced in color.[7] These RTFs are significant because they show that FDA has not been willing to authorize the marketing of a new tobacco product under the PMTA route if it is unable to properly evaluate the package, including the color of the package.

Substantial Equivalence

Manufacturers may avoid the PMTA process if they use the SE pathway. To obtain an SE order, the manufacturer must submit an SE report to FDA and demonstrate that the product has the "same characteristics" as a tobacco product commercially marketed in the U.S. on February 15, 2007, or its different characteristics do not raise "different questions of public health" compared to the 2007 product, and the product is otherwise in compliance with the Act. [18] If the new product raises different questions of

public health, the product is not SE. The FSPTCA defines "substantial equivalence" in terms of "characteristics," and defines "characteristics" as the "materials, *ingredients*, design, composition, heating source, or *other features* of a tobacco product [emphasis added]." [19, 20] The statute does not further define each of the terms used in the definition of "characteristics." However, the fact that the definition is not limited to "materials" and "ingredients," and also includes "design" and "other features," suggests that packaging and labeling, and their coloring, are included, especially given that labeling is included in PMTA reviews along with ingredients and other features, [15]and given the provision's goal of protecting against any product changes or differences of any kind that could cause new or increased public health harms.

Exemption from Substantial Equivalence

Under the exemption from SE pathway, a manufacturer that modifies a legally sold product by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be exempt from submitting a SE report if the modified version of the product is "minor," the product's marketing "would be appropriate for protection of the public health," and an exemption is "otherwise appropriate." [5] As of April 2016, FDA received 73 SE exemption submissions,[6] issued one exemption from SE action, 50 "refuse to accept" (RTA) letters for exemption requests, and received two withdrawals. [8] In its decision summary for the exemption from SE request, [21] FDA does not discuss whether there were any packaging or color changes or public health impacts of the new tobacco product.

FDA Guidances on Substantial Equivalence

FDA's Center for Tobacco Products issues guidance documents for industry and

FDA staff that, while not legally binding requirements, represent FDA's current thinking on a particular topic and provide information to assist those who must understand and comply with the law.[22, 23] Before issuing a final guidance, FDA often publishes a draft guidance to solicit comments from industry, other stakeholders, and the general public. Both draft and final guidances are only guidelines and are not binding on FDA or the companies. In particular, FDA can later adopt and use "an alternative approach [even if it contradicts a published guidance] if the approach satisfies the requirements of the applicable statutes and regulations." [24]

FDA stated in its September 2011 *Draft Guidance for Industry and Food and Drug Administration Staff. Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* [25]that FDA considered the label and packaging of a tobacco product to be a "part" of that product, and that a change to any part of a tobacco product after February 15, 2007 makes that product a "new tobacco product." Thus, FDA indicated that a cigarette would be considered a "new tobacco product" subject to enforcement under requirements for SE reports and PMTA applications (FSPTCA sections 905(j) and 910) if a modification to the font size, ink color, or background color of a tobacco product's packaging raised different questions of public health. [25]The standard FDA described in its September 2011 draft guidance was consistent with the industry practices described in our paper. [26]

Perhaps anticipating the tobacco industry's First Amendment commercial speech claims and imminent lawsuits, FDA softened this policy in its March 2015 *Guidance for Industry, Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* [24]by stating that a label is not a "part" of the

tobacco product, unless the label is modified in a way that renders the product "distinct" from the predicate product. The language of the March 2015 guidance is confusing because it says that a product can both have the "same characteristics" as a predicate product and also be "distinct" from that product.[24] FDA explained that a product with a label change might be considered a "distinct product" depending on the circumstances, for example, if changes were made to a product's logo, "identifiable patterns of color," product descriptors, or any combination thereof.[24] Importantly, when a company changes the tobacco product's label, FDA believes it is a "new product" subject to the SE provisions if the label change would "lead consumers to believe that the product is different from the predicate" or if consumers are "likely to perceive it as 'new' by virtue of the different label." [24] In this regard, we have documented that actual industry practices treat color changes in packaging and labels as "distinct" changes to the product.[26]

FDA's March 2015 guidance offers a muddled description of its current thinking on how color changes in packaging may make a tobacco product "distinct" and therefore a "new product." FDA indicates that if a product is new because it is "distinct" but otherwise has the "same characteristics" as the predicate product, FDA thinks the manufacturer may comply with the law by submitting a streamlined "Same Characteristics SE Report" in lieu of submitting a full SE report or premarket application under section 910(b).[24] (The "Same Characteristics" report, unanticipated in the FSPTCA, is an invention of FDA and intended to be easier for the manufacturer to prepare and for FDA to review.) In contrast, if a change to a logo, colors, product descriptors or other aspects of the label is unlikely to lead consumers to believe that the

product is different from the predicate, then the guidance indicates that FDA would not consider the product a "new tobacco product" subject to the related statutory requirements. [24] As an example, FDA suggests in the guidance that a change in background color from green to red may result in a "distinct product," but a change from white to cream likely would not.

If a company changes the label on a product that is being legally marketed because a "provisional SE report" was previously filed, the guidance indicates that FDA will allow the changed product to remain on the market so long as a new Same Characteristics SE Report was filed by April 3, 2015. For products that are not already on the market, the guidance indicates that a manufacturer may legally market a product that is otherwise "identical" except for a change in the label 90 days after it submits a Same Characteristics SE Report. According to the process suggested by the guidance, the product may then remain on the market unless and until FDA issues a not substantially equivalent (NSE) order. [24]

Industry Lawsuit and Subsequent Submissions

Even though FDA's guidance indicated that FDA would be taking a considerably more permissive approach to label changes than a plain reading of the statute might suggest and was not legally binding, Philip Morris, R.J. Reynolds, Lorillard, and three other tobacco companies sued FDA in April 2015, claiming that FDA's more permissive approach to label changes in its March 2015 guidance was still an abuse of discretion that infringed the companies' free speech rights under the First Amendment to the United States Constitution.[27] In May 2015, FDA issued an interim enforcement policy on new tobacco products,[28] added as a footnote to the agency's March 2015 guidance,[24] stating

that for tobacco products in which the only modification or difference is "a label change that creates a distinct product with identical characteristics to the predicate product," FDA would *not* take any actions against the manufacturers for not first obtaining a premarket authorization and would not issue any "not substantially equivalent" orders.[28] In June 2015, after FDA weakened its enforcement policy, the companies dropped their lawsuit.[29]

Shortly after FDA announced its new enforcement policy, the companies submitted and FDA accepted and issued orders on, the new streamlined shorter, easier Same Characteristics SE reports. On July 17, 2015, FDA announced[30] it had issued 125 SE orders in June 2015, which included final actions on streamlined Same Characteristics SE reports for 105 products.[31]

Legal Implications of Using Color to Change Consumers' Perceptions of the Taste, Strength, and Texture of Tobacco Products

FDA's original September 2011 thinking was correct and supported by the tobacco companies' own research and marketing activities,[26]as well as by the legal framework for new product and SE reviews established in FSPTCA sections 910 and 905(j).[32] Because consumers perceive tobacco products in packages with changed label colors (including labels with slightly lightened colors or more white space) to taste and feel different from products in their original packages, [26] FDA should treat products in packages with changes in label colors as "new products" subject to the SE provisions requiring regular SE reports, and should conduct social science evaluations of the packaging changes. In contrast, FDA's March 2015 policy[24] is inconsistent with the tobacco companies' actual product characteristic decisions[26] in which the companies

sometimes change pack colors to alter consumers' perceptions and experiences about the taste, strength, and texture of the cigarettes inside the pack just as when they make changes in the rod length, tobacco blend, or additives. Cigarette packaging and labels modified in this way operate as cigarette "characteristics" or ingredients and are "part" of the tobacco products. When tobacco companies change these product characteristics, they create distinct and "new tobacco products." Indeed, the companies explicitly acknowledge this fact in some of their internal discussions of product changes.[33-36] Under the FSPTCA such new products require premarket authorization.[32]

A change to the tobacco blend, rod length, or additives would not be subject to First Amendment protection. Likewise, a change to package colors is not subject to First Amendment protections if it is regulated not to restrict commercial speech, but as a product change that changes how consumers experience the taste or texture of the cigarettes when smoked.

Ingredient and product changes, including changes to packaging and labeling, that influence consumers' experiences of smoking the cigarettes contrast with packaging and labeling changes that include new communicative text or images that are used to *communicate accurate product information to legal consumers*, which may trigger First Amendment protections if regulated to restrict commercial speech. However, even if FDA's treatment of color changes to packaging or labeling were seen as regulating commercial speech that might be subject to First Amendment protections, it could not qualify for such constitutional protections because such color changes are false and misleading. The common industry practices documented in our paper[26] demonstrate that pack and labeling colors, by changing the way consumers experience the cigarettes' taste

and texture, can mislead consumers into thinking inaccurately that some cigarette brands or sub-brands are significantly less or more harmful than others. This conclusion is further supported by other research finding that smokers think cigarettes are less harmful than other cigarettes if they perceive them to taste and feel "lighter," "smoother," less "harsh," or less "full-flavored,"[37].

Moreover, if color changes that alter consumers' harm or risk perceptions are considered commercial speech, products making such changes would also likely violate FSPTCA section 911[38] if the manufacturer did not first obtain a "modified risk tobacco product" (MRTP) order from FDA. FSPTCA section 911 prohibits tobacco companies from marketing tobacco products with labeling that represents explicitly *or implicitly* that the product presents a lower risk of disease or is less harmful than other tobacco products unless FDA issues an MRTP order stating that the product actually would reduce harm and benefit the public health.[38] Products that violate FSPTCA section 911 are deemed "adulterated" under FSPTCA section 902,[9] and products with labeling that is false or misleading in any particular are deemed "misbranded" under FSPTCA section 903.[10]

Summaries of FDA Final Actions on New Tobacco Product Submissions

While FDA has the authority and capacity to do "Social Science" reviews,[39] which would include consideration of color in packaging and its impact on the population using the "public health standard," it is not clear if FDA is regularly doing any such reviews or how FDA is considering any information it might be receiving from any such reviews. FDA posts summaries of selected SE, NSE, and other marketing orders on its Tobacco Product Marketing Orders website, but these postings suggest that FDA has not regularly been doing social science reviews of color or labeling changes, and they provide little

insight into the agency's current thinking on how it treats changes in packaging and label colors in PMTA and SE reviews.[8] Large sections of the reports are redacted to prevent disclosure of unsubstantiated trade secrets claimed by the industry ("(b)(4)" redactions).[40] In many cases, so much of the report is redacted that it is difficult to understand the basis for FDA's SE determination. (See, for example, the April 2015 Technical Project Lead (TPL) Review for SE0010167-SE0010171,[41] the March 2015 TPL Review for SE0010365-SE0010369 and SE0010422,[42] and the June 2014 Technical Project Lead (TPL) Memorandum: SE Reports SE0003503-SE0003524 & SE0010338-SE0010359.[43])

Most SE reports include Chemistry, Engineering, and Toxicology reviews, with only a few including Social Science reviews. One example of a SE evaluation that did include a Social Science review is the SE report on eight SE applications for Swedish Match loose moist snuff products sold in plastic cans,[44] which appears to consider whether the darker color of the new tobacco products compared to the corresponding predicate tobacco products increases the appeal of the new products. However, while the report states that the SE reports submitted by the manufacturer included information about consumer perception testing, the submitted information did not actually address the specific color differences between the new and corresponding predicate products.[44] The report stated that at the time the social science reviews were conducted (July 2012, January 2013, August 2013, and September 2013), "the available scientific evidence is not sufficient to establish that the product color differences in this case are significant enough to cause the new tobacco products to raise different questions of public health,"[44] and therefore concluded that the differences in product appeal between the predicate and corresponding new tobacco products did not raise different questions of public health.[44]

FDA's conclusion ignores and contradicts the fact that tobacco companies use color differences to influence consumers' perceptions of the taste, strength, and general appeal of their tobacco products.[26] At the very least, the darker color of the product in the Swedish Match SE application[44] raises different questions of public health in regard to how consumers will perceive its taste compared to the predicate and how that might affect existing and potential new consumers' purchase and use decisions.

Conclusion

The routine industry practices documented in our paper[26] -- using color changes and differences in packaging and labels as ingredients that alter consumers' perceptions of the cigarettes' taste, texture, and strength -- support the position originally taken by FDA in its September 2011 guidance on SE,[25] in which FDA considered cigarette packaging and labeling as a "part" (i.e., a "characteristic") of the new tobacco product in the same way it considers other tobacco product ingredients when it evaluates SE reports. Analogous to changes in rod length, tobacco blend, or additives, color changes in packaging and labels that operate as ingredients changes are not entitled to First Amendment protections. While FDA is not legally bound by its guidances, the agency should follow the guidelines it articulated in its original September 2011 guidance, rather than the convoluted recommendations in its March 2015 guidance.[24] Moreover, even if FDA relied on its March 2015 interpretation, color changes in tobacco product packaging and labels render tobacco products "distinct" by FDA's definition[24] since they lead consumers to believe that the products in one pack are different from identical products in another pack with different colored labeling.[26] Therefore, FDA should consider any tobacco product with color changes in its packaging and labels as a "new product"

subject to rigorous SE review. FDA should require full-length SE reports, rather than streamlined "Same Characteristics" reports, for all SE submissions with any color changes to the product's packaging and labeling, and should conduct Social Science reviews that consider the public health impacts of new tobacco products as actually used by consumers for all SE submissions.

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