The attached document represents CTP's then-current thinking on certain aspects of tobacco regulatory science. The information contained herein is subject to change based on advances in policy, the regulatory framework, and regulatory science, and, is not binding on FDA or the public. Moreover, this document is not a comprehensive manual for the purposes of preparing or reviewing tobacco product applications. FDA's review of tobacco product applications is based on the specific facts presented in each application, and is documented in a comprehensive body of reviews particular to each application.

Given the above, all interested persons should refer to the Federal Food, Drug, and Cosmetic Act, and its implementing regulations, as well as guidance documents and webinars prepared by FDA, for information on FDA's tobacco authorities and regulatory framework. This document does not bind FDA in its review of any tobacco product application and thus, you should not use this document as a tool, guide, or manual for the preparation of applications or submissions to FDA.

Supporting Memorandum

DATE: August 12, 2016

FROM: David Portnoy, PhD, MPH

Digitally signed by David B. Portnoy -S **Social Science Team Lead** Date: 2016.08.12 09:39:53 -04'00'

THROUGH: Conrad Choiniere, PhD Digitally signed by Conrad J. Choiniere -S

> Date: 2016.08.17 13:24:20 -04'00' **Director, Division of Population Health Sciences**

TO: File

SUBJECT: Effect of Tobacco Product Package Shape on Consumer Perceptions, Initiation, and

Cessation

This memorandum addresses how a change in a tobacco product's package shape may impact product initiation and cessation, which would raise different questions of public health. No research to our knowledge has directly assessed whether package shape directly leads to tobacco use initiation or delayed cessation. However, research indicates that tobacco package shape influences appeal and perceived harm, and changes in these outcomes are likely to lead to use initiation and delayed cessation. However, not all tobacco package shapes are equally attractive, and not all changes in package shape may influence perceptions of harm of tobacco products.

Currently, there is no scientific evidence that directly addresses whether changing the shape of a tobacco product's package directly causes non-users of tobacco to initiate use of tobacco or directly causes current users of tobacco to delay cessation. In the absence of direct evidence on these behavioral outcomes, research on the effects of package shape on product appeal and consumer perceptions may provide insight into how a package shape change would influence product initiation and cessation.

Package Shape Background

Product packaging can attract consumers' attention to a product, ¹ increase their attraction to the product, ¹⁻³ and affect their beliefs about the product (e.g., beliefs about whether the product is appropriate for use by men vs. women and what category the product belongs to). ² Through effects on attention, attraction, and beliefs, packaging can influence consumer behavior, which includes 'approach' responses (e.g., purchasing the product, sharing it with others) and 'avoidance' responses (e.g., being unwilling to purchase the product). ² As Bloch sums up, "The goal of product design is to elicit more positive than negative responses among consumers, especially the target segment," in order to maximize approach and minimize avoidance responses among consumers. ^{2, p. 20}

Packages that deviate from the traditional package style in a product category, such as through a novel shape, attract and maintain consumers' attention. When changing a package shape, the degree of incongruity between a new and existing package can affect whether consumers' positive and negative evaluations of the existing product will transfer to the new product. Packages that are highly different from other packages in the product category make it less likely that consumers will transfer their positive and negative affective responses (i.e., feelings of goodness or badness⁴) from the product category to the specific product. Thus, although a drastic change in package shape will attract consumers' attention, it may either increase or decrease the product's appeal, depending on consumers' attraction to the current product. For an established, market-leading product, a large change may have the unintended consequence of *reducing* the appeal of the product, whereas a moderate change (e.g., such that there is only a slight incongruity between the new and old package) may increase the appeal of the product. Marketing researchers recommend using a new package style that is much different from the traditional style when seeking to change consumers' product perceptions, such as when seeking to revitalize a brand or improve consumer attitudes toward a product. Assessment of the consumer of the product of the product. Assessment of the product of the produc

There is limited evidence that particular package shapes are inherently more appealing to consumers than other shapes. For rectangular shaped packages, whether consumers prefer a more vs. less elongated package shape may depend on the type of product.³ Soaps and detergents in more elongated rectangular packages tend to have greater market share within their categories than those in less elongated packages, whereas the opposite is true for cereal and cookies.³ This analysis did not control for other differences across products aside from package shape (e.g., type of cookie).³ However, a separate study in the same paper assessed preferences for invitation cards that varied in shape but were identical on other characteristics, finding that card shape influenced appeal.³ We are unaware of any research on whether preferences for shapes may change over time or whether consumers have preferences regarding the proportions of other package shapes (e.g., circular vs. oval).

Package shape can also influence consumers' perceptions of product volume.^{6,7} People tend to perceive containers that are elongated (e.g., a beer bottle) as containing more product than equal-volume containers that are shorter (e.g., a beer can).⁷ Accordingly, consumers tend to purchase lower quantities

of elongated containers when seeking to meet a given level of desired consumption (e.g., when purchasing beer for a given number of party-goers).⁷

In addition to the general information above, there is some information about the role of package shape and individual types of tobacco products. Specifically, package shape can influence consumers' attraction to tobacco products and their perceptions of the products, which are factors that play a role in tobacco product initiation and cessation. There is evidence on the role of package shape for both cigarettes and smokeless tobacco; however there are no published studies concerning the package shape of other tobacco products such as roll-your-own tobacco, cigars, pipe and waterpipe tobacco, or liquid nicotine.

Cigarette Pack Shape

Novel cigarette pack shapes may increase the appeal of cigarettes to non-smokers and current smokers. Studies have examined the appeal of cigarette packs with an "innovative slim shape and size," sometimes called lipstick packs because of their resemblance to cosmetics. For example, a study of youth never smokers in the UK (aged 11-16 years) found that a lipstick pack was rated more positively than a standard pack on all attributes examined, including the extent to which it tempted them to smoke, was attractive, eye-catching, cool, fun, worth looking at, meant for someone like me, childish, and liked. Additional studies among youth and young adult female non-smokers and smokers also suggested that lipstick packs were seen as more appealing and less harmful than cigarette packs with standard shapes. It lipstick packs were seen as more appealing and less harmful than cigarette packs with existence of other differences between packs aside from their shape (e.g., colors, logos), Sill-13 or a qualitative study design. However, together, the studies form a consistent pattern of results indicating increased appeal and lower perceived harm of cigarettes in lipstick packs compared to traditionally shaped packs among youth and young adult females.

Another study asked young adult Australian ever-smokers to rank a set of plain cigarette packs differing in shapes, including a traditional pack (7-6-7 organization of cigarettes), a wider pack (10-10 organization of cigarettes), a squarer pack (5-5-5-5 organization of cigarettes), a pack with beveled edges, and a pack with rounded edges. ¹⁰ The rounded pack tended to be ranked highest on attractiveness and quality of cigarettes, including significantly higher than the traditional pack. ¹⁰ Conversely, the wider pack and squarer pack were rated equally least attractive and lowest in quality. Also, the standard pack shape tended to be rated as less distracting from health warnings than alternative pack shapes including the squarer pack, beveled edge pack, and rounded edge pack, but not the wider pack. ¹⁰ The generalizability of this study to the U.S. context was limited by the fact that the packs were plain and included graphic health warnings. ¹⁰

Analyses of trade journals suggested that package shape changes were among the strategies used by cigarette brands to increase their market share in the UK from 2004-2011, a 'dark' market with a comprehensive ban on advertising, promotion, and sponsorship.¹⁵ During this period, companies introduced cigarettes in slim packs, hexagonal-shaped packs, beveled-edged packs, and a limited-edition V-pack with an innovative opening.^{15, 16} It is unknown whether the companies increased their market share by attracting new users or by encouraging current smokers of other brands to switch to their brands.

A review of tobacco industry consumer research suggested that cigarette packs with novel shapes (such as rounded or beveled edges) tended to be more appealing to smokers than traditional packs. ¹⁷ One

industry document stated that the "round edge pack will add youthfulness, leading edge savvy to brand [and] will attract entry level users."^{17, p. 1662} Packages that had slim dimensions were especially appealing to young women and were also liked because they were easier to carry by hand or purse. ¹⁷ Cigarette packs with rounded corners, octagonal shapes, and slim shapes may lead smokers to perceive the cigarettes as 'lighter.'¹⁷ In turn, some consumers may use lightness to infer the harmfulness of a cigarette product. ¹⁸ Furthermore, industry documents suggested that the introduction of cigarette products in new package shapes has led to increased purchases in some cases. ¹⁷ However, it is unknown what proportion of purchases were from new smokers versus those switching from other brands. ¹⁷

Taken together, these studies indicate that certain changes in package shape can increase the appeal and reduce the perceived harm of a cigarette product to current users and non-users of cigarettes. Package shape changes may be especially likely to increase appeal and reduce perceived harm of cigarettes when they are targeted toward particular groups (e.g., cigarette packs with unique slim shapes for young females). Given that the attractiveness and perceived harm of cigarettes predict smoking initiation among current non-smokers, ¹⁹⁻²³ certain cigarette pack shape changes can influence product use initiation.

Smokeless Tobacco Package Shape

One reason why many people in the U.S. are not receptive to using smokeless tobacco products may be negative associations with the overall product category. These associations are related to perceived negative characteristics of the product including being "gross," "disgusting," and associated with negative stereotypes of users of the products (e.g., "rednecks"). Thus, changing the shape of a smokeless tobacco package in order to distinguish the product from the overall smokeless tobacco product category could decrease negative associations, which could make it more likely that people would start using the product. Indeed, focus groups and qualitative interviews found that smokeless tobacco users in rural Ohio believed novel smokeless products such as Camel snus, which is packaged in an oblong can, are targeted at people who are not current users of smokeless tobacco. Participants commented that a non-round can shape was more discreet and not associated with negative stereotypes:

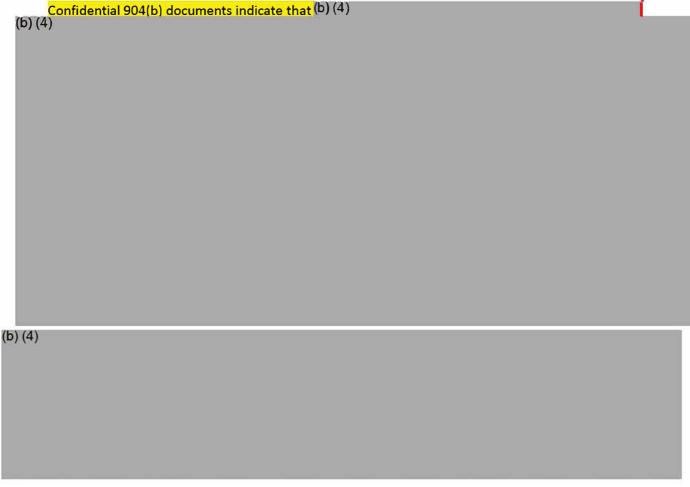
These novel products fit better in pockets and did 'not have the redneck status of the ring in the pocket.' An adult shared, 'I just like that it is a little tin you can put in your pocket and it doesn't look like a circle and people be like, 'Oh he chews.' 27, p. 4

People also noted that packages for Camel Snus and Camel Orbs (which came in a similar oblong-shaped tin) looked like mint or candy containers.²⁷

In another qualitative study, snus packages were described as more appealing than those of other smokeless tobacco products by cigarette smokers who were non-users of smokeless tobacco.²⁵ Snus packages were referred to as "'fashionable', 'cool', 'modern', 'sexy', 'flashy', 'sharper' and more 'noticeable' in stores."^{25, p. 3} However, it is unknown whether smokers were referring to snus packages with novel shapes (such as market-leader Camel Snus) or other varieties of snus.

Industry research on cigarette packaging reviewed above ¹⁷ raises the possibility that a novel package shape could cause a smokeless tobacco product to be perceived as 'lighter' in taste and nicotine compared to other smokeless tobacco products. Focus group research indicated that Camel snus products (packaged in an oblong can) may be perceived to be weaker than traditional smokeless

tobacco products by current users of smokeless tobacco.²⁷ Some of these focus group participants suggested that the weakness and added flavors may be aimed at enticing non-tobacco using youth into trying the product.²⁷ The researchers noted that Camel snus had a similar total nicotine level as traditional smokeless products, and the perception of Camel snus as weaker "may stem from their candy-like taste and packaging."^{27, p. 5} However, no research to our knowledge has examined whether package shape influences people's perceptions of smokeless tobacco product strength.



A publicly available Camel Snus market performance update from 2006 lamented the round package shape, stating that, "Current packaging shape is a trial barrier," and "Smokers assume it's dip."³¹ This suggests that round snus packages discourage initiation of snus use by current non-users of smokeless tobacco, and that changing the shape of a snus can would increase appeal and encourage snus use by cigarette smokers who do not currently use smokeless tobacco products.

Package Shape for Other Tobacco Products

To our knowledge, no prior studies have examined the effects of package shape on consumer appeal, perceptions, or use of tobacco products other than cigarettes and smokeless tobacco products. Research on package shape for cigarettes, smokeless tobacco, and other general consumer products would be applicable to understanding how package shape could potentially influence the appeal and perceptions of other tobacco products (e.g., roll-your-own, cigars, pipe, waterpipe, liquid nicotine).

Synthesis of the Evidence

Package shape matters for the appeal of tobacco products. Changing the shape of a tobacco product's package is likely to attract attention, as humans are drawn to novel stimuli from an early age. Novelty-seeking is considered one of the fundamental drives underlying much consumer behavior. Novelty of a product may be particularly relevant to young people because youth who rate highly on the personality trait "novelty-seeking" are more likely to smoke and use other substances and more likely to be early adopters of smoking behavior. Indeed, personality traits, including novelty-seeking and risk-taking, are among the most important predictors for initiation of tobacco use. Moreover, adolescence is a developmental period characterized by heightened sensitivity to novelty. Finally, theories of persuasion suggest that novelty can be a factor that predicts positive attitude change in situations where individuals are not able or willing to think deeply. These considerations support the conclusion that a novel tobacco package shape is likely to increase the appeal of the product, particularly among young people, which is likely to lead to increased initiation.

In addition to creating appeal through novelty, package shape also influences the appeal of a tobacco product by affecting the associations that people make with the product. Drastically changing the shape of a package distances the product from the positive and negative associations that people have with the product and product class. When people hold negative associations with the product (e.g., it is seen as harmful or stigmatized), a new package shape would be expected to make the product more appealing and therefore remove a barrier to initiation among current non-users. Research indicates that certain cigarette pack shape changes can increase the appeal of cigarettes among youth non-smokers. And reduce the perceived harm of cigarettes among non-smokers. Putthermore, qualitative research suggested that a smokeless tobacco package with a novel shape was appealing to adolescent and adult smokeless tobacco users. Changes in appeal and perceived harm are likely to lead to increased initiation by current non-users of the product.

Through effects on perceived harm, changes in tobacco package shape may also lead to delayed cessation among current users of products. Research suggests that particular cigarette pack shapes can reduce the perceived harm of cigarettes among current smokers.^{8, 9, 11, 14, 17} In turn, lower perceptions of the harmfulness of smoking may discourage smokers from attempting to quit smoking.^{42, 43}

The outcomes described here – attention to tobacco products, appeal of tobacco products, and perceptions of harm from tobacco use – are precursors to tobacco use behaviors. Studies by public health researchers and tobacco companies alike indicate that the newness of a product and people's accompanying curiosity about it are a common reason for trial. 44-50 Accordingly, tobacco companies have sought to generate awareness of their products as a first step toward trial 44, 51 and have assessed their packages and advertisements based on whether they are "eye-catching," "attractive," and "cool." 52 Tobacco packages are designed to create appealing brand images that make people want to use the products.⁵³ Youth who are receptive to tobacco advertising and promotions are more likely to become established smokers by young adulthood.⁵⁴ A review of the evidence that tobacco promotion causes tobacco initiation focused on the mediating role of psychological factors such as product appeal and imagery, stating, "Promotion makes children curious about tobacco use," and "promotion changes many children's attitudes about tobacco use from negative to positive and increases their susceptibility and intentions to use tobacco, thereby increasing their likelihood of initiating or of progressing from minimal experimentation to regular use." 55, p. e1243 Perceiving tobacco products as harmful appears to act as a barrier to initiating tobacco use, as people who see tobacco products as less harmful are more likely to begin using the products.^{23, 56-58} Moreover, among tobacco product users, concerns about health are one

of the primary reasons given for quitting,^{46, 59, 60} and mistaken beliefs about the reduced harm of particular tobacco products may lead current users to continue using the products.^{43, 61}

Conclusions

Package shape plays an important role in the appeal of tobacco products and consumers' perceptions of harm from the products. These outcomes are likely to influence product initiation and cessation. Not all tobacco package shapes are created equal: that is, different package shapes may have different effects on tobacco use. Not all tobacco package shapes are equally attractive, and some novel package shapes (i.e., shapes that are unconventional for a particular product type) may be either more or less attractive than the traditional shape for a given product class. ¹⁰ Similarly, not all novel package shapes may lead to lower perceptions of harm among users and non-users of the product.

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