January 31, 2012

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

RE: Docket No. FDA-2011-N-0493

To Whom It May Concern:

The undersigned organizations offer the following comments on the Food and Drug Administration's (FDA) proposed amendments to the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* (Rule).

The currently effective regulation prohibits manufacturers of tobacco products from using a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for tobacco products whose trade or brand name was on both a tobacco and nontobacco product sold on January 1, 1995.[1] The proposed amendments would:

1. Change the grandfather date from January 1, 1995 to June 22, 2009;
2. Permit a manufacturer to use the trade or brand name of its cigarette or smokeless tobacco product if such cigarette or smokeless tobacco product is sold before the trade or brand name of the non-tobacco product is registered with the United States Patent and Trademark Office (USPTO) or in any situation where the brand name is not registered with the US Patent and Trademark Office ; and
3. Permit manufacturers to request an exemption from the restriction based on information that adequately demonstrates that their proposed trade or brand name does not substantially appeal to children or adolescents.[2]

The proposed amendments would create an unnecessary exemption that would expose children, adolescents, and the public to precisely the kind of marketing that helped create the very problems the Tobacco Control Act was designed to address. Furthermore, these amendments reflect an inadequate understanding of the fundamental purpose of the Tobacco Control Act and the Rule and the potential consequences of the proposed amendment and a failure to appreciate the scope of the FDA's obligation to protect the public health of all Americans by the Act. Moreover, the proposed analysis of costs and benefits fails to take any

1 21 CFR §1140.16(a), 75 FR 13225

2 76 FR 71281

account of the additional burden of death and disease that this exemption could create. The undersigned groups urge FDA to reconsider this poorly-conceived proposed rule.

I. The purpose of the existing rule is to protect the public health against actions by tobacco product manufacturers that exploit the imagery or consumer identification of existing non-tobacco products.

The marketing of tobacco products has contributed greatly to the scope of tobacco usage in the United States. The major tobacco companies have spent and continue to spend many billions of dollars to promote their brands and to create favorable associations between their brands and lifestyles that will be attractive to the consuming public. Many non-tobacco brands enjoy wide public acceptance and tobacco companies recognized early on that they could promote their own brands and increase the sale of cigarettes by associating their products with popular non-tobacco brands. The notice accompanying the proposed rule recognizes that such "brand-stretching" can be a highly effective way to promote brand equity. [3] The existing rule was designed to prevent such brand-stretching.

FDA correctly states that young people are particularly vulnerable to "forming impressions of product owners based on the image and meanings of the brand name identified with the product" and that

> the restriction on the use of a nontobacco brand name sought to limit the elements of marketing and advertising ``that resonate most strongly with the needs of those under 18 to establish an appropriate image and to create a sense of acceptance and belonging.'' 61 FR 44396 at 44444 (1996). For example, the name of a popular motorcycle or cosmetic brand, if used on a tobacco product, may create immediate interest and appeal in the youth market. This would allow the tobacco companies to again capitalize on the susceptibility of this age group to certain advertising and marketing practices, and to the appeal of brands in particular. Page 71283

FDA errs, however, in failing to recognize that "brand-stretching" is also an effective marketing strategy with regard to adults. The Congressional directive to FDA to re-promulgate the 1996 Rule, which includes the prohibition on brand-stretching, was contained in a much larger piece of legislation the purpose of which is not only to protect children and adolescents, but also to protect the public health of all Americans.

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)[4] gave the FDA broad authority to regulate the manufacture, marketing, and distribution of tobacco products in order to protect the public health. The Congressional intent in promulgating these regulations was to "address the public health crisis created by actions of the tobacco industry," and the restrictions on the sale and distribution of tobacco products contained in those regulations are "substantially related to accomplish the[se] public health goals."[5] In enacting the Tobacco Control Act, Congress made extensive legislative findings regarding the lethal nature of tobacco products, and found, among other things, that: tobacco use is the foremost preventable cause of premature death in America, causing more than 400,000 deaths each year, and

[3] Notice of Proposed Rulemaking at 76 FR 71281 et seq

[4] Pub. L. 111–31, June 22, 2009 (Tobacco Control Act)

[5] Tobacco Control Act, Sec. 2 (29), (30)

approximately 8,600,000 Americans have chronic illnesses related to smoking; advertising, marketing, and promotion of tobacco products especially directed to attract young people to use tobacco products have resulted in increased use of tobacco products by youth; cigarette manufacturers spend billions of dollars a year to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use; and it is in the public interest for Congress to adopt legislation to address the public health crisis created by the actions of the tobacco industry.[6]

While Congress recognized in enacting the Tobacco Act that the Federal Government has a "substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use"[7], the Tobacco Control Act set the standard to guide the act as one that is based on protection of the public health standard[8], a standard that extends beyond young tobacco users to non-users, past-users, present users, and potential future or returning users of every age, sex, and ethnic or racial group. The tobacco industry's well documented, deliberate, and insidious strategies to target children, adolescents, young adults, African Americans and other racial groups, and women in order to get them addicted to cigarettes, is also designed to keep them as sustained customers of cigarettes and other tobacco products, and discourage tobacco users from quitting. These broader concerns are reflected in the Tobacco Control Act's findings,[9] and underscore the need for regulations that restrict marketing and promotional efforts to these groups. In order to determine whether a particular regulation would be "appropriate for the protection of the public health," the FDA must consider "the risks and benefits to the *population as a whole*, *including users and nonusers of the tobacco product,"* and the following factors must be taken into account:

> "(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
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> "(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products."[10]

The FDA would make a grave mistake by adopting amendments based upon the false premise that its authority is limited to the protection of children and adolescents when the regulatory mandate assigned to the FDA under the Tobacco Control Act carries with it an obligation to protect the population as a whole.

II. FDA Should Not Create an Exemption from the Prohibition on Brand Stretching.

The Rule that Congress incorporated into the FSPTCA [11] was originally promulgated in August 1996. The text of the final rule states:

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6 Tobacco Control Act, Sec. 2(13), (15), (16), (29)

7 Tobacco Control Act, Sec. 2 (31)

8 Tobacco Control Act, Sec. 906(d)(1)

9 Tobacco Control Act, Sec. 2

10 Tobacco Control Act, Sec. 906(d)(1) (emphasis added)

11 Currently numbered as 21 CFR §1140.16(a) (75 FR 13225)

(a) *Restriction on product names.* A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.[12]

As mandated by the Tobacco Control Act, FDA reissued the Rule in March of 2010. Congress was explicit that the regulation was to be re-issued without change except where specified in the FSPTCA.[13]

When it formulated the proposed rule in August 1995[14] and the final rule in August 1996,[15] the FDA considered the overwhelming scientific evidence available at the time regarding the tobacco industry's deliberate tactics to market its dangerously addictive tobacco products and the immense public harm that results. Since the publication of the original Rule, even more scientific evidence and industry data has become available demonstrating the billions of dollars and considerable effort expended by the tobacco industry to maintain its current customers and attract new customers.[16] The more recent evidence continues to demonstrate the necessity for these regulations and the need for the FDA to use the full scope of its authority to restrict both direct and indirect marketing (such as brand extensions anticipated by the original Rule) of tobacco products. Any limitations to or exemptions from the FDA's broad authority to protect the public health would violate the plain meaning of the Tobacco Act and the intent of Congress.

The FSPTCA appropriately reinstated the restriction on manufacturers of tobacco products from using a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product. However, inconsistent with the mandate of Congress and with no factual basis, FDA's current proposal to the Rule would permit manufacturers to request an exemption from the restriction based on information "that adequately demonstrates that their proposed trade or brand name does not substantially appeal to children or adolescents,"[17] The proposed rule ignores Congress' explicit determination that the record already justifies prohibiting the use of trade or brand names of a nontobacco product as the trade or brand name of a tobacco product. Moreover, it further ignores the statutory directive that the correct standard to be applied is the protection of public health.[18]

Even if the only purpose of the prohibition on brand-stretching were to protect children and adolescents, the proposed exemption would constitute an abdication of regulatory responsibility. To begin with, the definition of "substantial appeal to children or adolescents" is far too vague to serve as an effective standard. Moreover, the idea that an exemption would be appropriate if there were evidence of the type FDA and Congress previously relied on —

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12 Originally numbered as 21 CFR 896.16(a) (61 FR 44615)

13 21 CFR §1140.16(a) (75 FR 13225)

14 60 FR 41314

15 61 FR 44615

16 National Cancer Institute, "The Role of the Media in Promoting and Reducing Tobacco Use," NCI Tobacco Control Monograph Series, Monograph 19, NIH Publication No. 07-6242, 2008 (*http://cancercontrol.cancer.gov/TCRB/monographs/19/index.html*) (Monograph 19)

17 76 FR 71281-71282

18 76 FR 71285

whether "substantial" or not — that children or adolescents would thereby be lured into addiction by the use of confusing brand imagery is appalling. A manufacturer's interest in adopting a brand name that it is not even currently using is not worth the life of a single child. There is simply no warrant at all for any exemption.

III. The FDA Should Not Change the Grandfather Date from January 1, 1995 to June 22, 2009.

A. When it Enacted the Tobacco Control Act, Congress Chose Not to Change the Grandfather Date Even Though it Changed Other Dates in the Regulation.

When it enacted the Tobacco Control Act in 2009, Congress made clear in its findings that its intent was to expand the FDA's authority to impose restrictions on tobacco companies, not to limit it, and to "eliminate potential loopholes," not to create new ones. There is no evidence that the specific date of January 1, 1995, after which manufacturers are prohibited from using a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, was an error or an oversight, and there is no indication whatsoever that Congress intended FDA to change this specific date every or any time an amendment to the Marketing Rule was made. The plain meaning of the language clearly provides that the sole exception to the prohibition on using nontobacco brand names on tobacco products was for products sold on January 1, 1995.

Furthermore, the rules of statutory construction provide that where, as here, Congress enumerated certain exceptions, additional exceptions are not to be implied. For example, while the original Marketing Rule prohibits the distribution of free samples of cigarettes, smokeless tobacco, or other tobacco products, a specific exception was added in to Tobacco Control Act allowing the distribution of free samples of smokeless tobacco in a qualified adult-only facility.[19]

B. The Proposed Change in the Grandfather Date Inappropriately Grants a Preference to Manufacturers Who Have Refused to Join the Tobacco Master Settlement at the Expense of Manufacturers Who Have Done So.

Subsequent to the promulgation of the 1996 FDA Rule, the major tobacco product manufacturers entered into the Master Settlement Agreement of November 23, 1998, with 46 States, the District of Columbia, Puerto Rico and four U.S. territories. Since that time, approximately 50 additional manufacturers have entered into the agreement, becoming "Participating Manufacturers."[20] Participating Manufacturers represent approximately 95 percent of the market for cigarettes in the United States. Section III (j) of the Master Settlement Agreement, to which all the Participating Manufacturers have agreed, addresses the issue of brand-stretching. It provides,

> **III. (j) Ban on Non-Tobacco Brand Names.** No Participating Manufacturer may, pursuant to any agreement requiring the payment of money or other valuable consideration, use or cause to be used as a brand name of any Tobacco Product any nationally recognized or nationally established brand name or trade name of any non-tobacco item or service or any nationally recognized or nationally established sports team, entertainment group or individual celebrity. Provided, however, that the

19 Tobacco Control Act, Sec. 102(a)(2)(G)(d)

20 A list of Participating Manufacturers can be found at www.naag.org.

> preceding sentence shall not apply to any Tobacco Product brand name in existence as of July 1, 1998. For the purposes of this subsection, the term "other valuable consideration" shall not include an agreement between two entities who enter into such agreement for the sole purpose of avoiding infringement claims.[21]

There are no exemptions permitted in the MSA, other than for tobacco product brand names that were in existence as of July 1, 1998. While section III(a) of the MSA specifically prohibits targeting youth in the advertising, promotion or marketing of tobacco products, or taking any actions whose primary purpose is to initiate, maintain, or increase the incidence of youth smoking, the provision concerning the prohibition on using non-tobacco brand names is in addition to that prohibition, is not specifically directed to youth, and is not limited to brand-stretching designed to appeal to any particular group of users, non-users, potential users, or returning users, or to any age group, ethnic group, or gender. Rather, MSA section III(j) applies to "any" tobacco product and "any" non-tobacco item or service, or "any" nationally recognized or nationally established sports team, entertainment group or celebrity.[22]

The existing regulation in part overlaps the coverage of MSA section III(j) and thus imposes on the companies that have refused to join the MSA ("Non-Participating Manufacturers") restrictions on brand-stretching, most of which were already applicable to Participating Manufacturers under the MSA. As a practical matter, the proposed change in the grandfather provision would thus benefit only those companies that have refused to join the MSA and would do so to the competitive disadvantage of the companies that are Participating Manufacturers. If manufacturers that have 95 percent of the market share for cigarettes are able to comply with the original Rule as reflected in the MSA, there is no reason to carve out an unjustified exception for those few who have irresponsibly refused to agree to the MSA. The FDA should not provide a windfall benefit to manufacturers that refused to agree to the Master Settlement Agreement. The products of Non-Participating Manufacturers are as dangerous as the products of Participating Manufacturers.

IV. The Rule Should Not be Amended to Permit Use of Non-Tobacco Brand Names Not In Use Prior to the First Sale of the Tobacco Product but Not Registered with the US Patent and Trademark Office.

The existing regulation prohibits a tobacco product manufacturer from using as a cigarette or smokeless tobacco product brand name the trade name of a non-tobacco product if such trade name is in use for the non-tobacco product prior to the first sale of the tobacco product. The prohibition thus applies to brand names of non-tobacco products whether or not they are registered with the United States Patent and Trademark Office ("USPTO"). When it promulgated the original rule, the FDA stated that it intended that it "would apply to trade names *in use* in the United States" and the FDA emphasized that it would construe this exception narrowly.[23] The original rule did not include any exceptions limiting its application to brand names of non-tobacco products previously registered with the USPTO.

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[21] Tobacco Master Settlement Agreement of November 23, 1998, http://www.naag.org/backpages/naag/tobacco/msa/participating_manu/2012-01-05%20PM%20List.pdf.

[22] MSA, Sec. III(j)

[23] 61 FR 44445 (emphasis added)

The proposed amendment would permit tobacco product manufacturers to use such trade names even if they were already in use for non-tobacco products, even if they were well known, provided such trade names were not registered with USPTO prior to the first sale of the tobacco product. Such an amendment is unnecessary and undesirable. The stated purpose of the amendment is to create a clear line of demarcation between names that can be used and those that cannot. However, the amendment would permit a tobacco product manufacturer who was actually aware that a brand name was already in use for a non-tobacco product to use that brand name provided that the name was not registered with the USPTO. In fact, the category of trade names in use is broader than the category of trade names registered with USPTO. There are several commercial services that offer to search for trade names in use and provide a report. At a minimum, a tobacco product manufacturer should not be permitted to use the brand name of a non-tobacco product if it is actually aware that such trade name is already in use. Moreover, a tobacco product manufacturer should not be permitted to use such a brand name unless it has first obtained a report from a reputable trade name search firm that confirms that such brand name is not in use. The MSA does not contain the limitation proposed by FDA and manufacturers have not had a problem complying. The experience with the MSA demonstrates that no reason exists for the proposed exemption.

Congress instructed the FDA to consider "the risks and benefits to the population as a whole" and to consider whether the proposed rule would increase or decrease the likelihood that existing tobacco users would stop using tobacco products, or increase or decrease the likelihood that nonusers of tobacco would start using tobacco products.[24] These considerations apply in the FDA's consideration of the scope of the brand-stretching regulations. Since the proposed amendment to the rule would have the potential to make it easier for tobacco companies to exploit the brand imagery on nontobacco products, FDA's proposal would not advance these important public health goals, and any argument the FDA might posit about the protection of tobacco companies from any kind of "unfair exploitation" from other companies is irrelevant.

V. FDA's Analysis of Costs and Benefits is Wrong.

FDA's analysis of the costs and benefits of the proposed rule ignores substantial potential costs to the public. In analyzing the cost to the public in changing the grandfather date, FDA concludes that the cost to the public would be "negligible" because the seventeen brands it has identified allegedly have a low market share and permitting the continued use of the brand name would be unlikely to result in image enhancement that would cause many young people to use tobacco products. This analysis is inadequate, however, because it ignores the effect of the use of brand names on the general public or the potential growth of these brands once authorized by FDA. Moreover, the superficial conclusion that none of the brands has substantial market presence based on national market share ignores an important fact. At least one of the cigarette brands, Tahoe, has an appreciable market presence in several regional markets and its manufacturer has successfully created a distinct brand image. In addition, the fact that for this brand FDA has failed to identify a highly conspicuous and popular non-tobacco brand (Chevrolet Tahoe vehicles) raises questions about the completeness of the list on which FDA bases its conclusions.

Moreover, FDA's cost-benefit analysis focuses only on the change in the grandfather provision and fails to address the public health costs associated with either the proposed exemption or

[24] Tobacco Control Act, Sec. 906(d)(1)

the limitation of the prohibition to include only non-tobacco brands registered with the USPTO. As shown above, a proposal that would permit an exemption based on a showing that a brand is unlikely to have a "substantial" appeal to youth implies that exemptions could be granted if such brands had an appeal to youth that was somehow less than "substantial." As this comment has previously suggested, any such appeal—whether "substantial" or not—should outweigh the alleged benefits of the suggested exemption. Moreover, in analyzing the costs and benefits of the change in the rule, FDA should consider not only the effect on the use of tobacco products by young people, but also by the general public, including the effect of the rule in regional or demographic sub-markets.

Moreover, both the proposed exemption and the change in the rule that would permit brand-stretching with regard to non-tobacco brands not registered with the USPTO would apply to all tobacco product manufacturers—not just to the few brands that allegedly would benefit from the proposed change in the grandfather provision. Thus, FDA's assumption that its proposal applies only to a very small portion of the tobacco product market is unwarranted.

The superficial and inadequate cost-benefit analysis presented by FDA is indicative of the agency's failure to consider the full implications of the changes it has proposed. Moreover, FDA's dismissal of increased death and disease attributable to tobacco products that does not somehow rise to the level of "substantiality" represents a fundamental misunderstanding of the purpose of the statute and the proper approach FDA should adopt in implementing it.

VI. The Tobacco Industry's Promotion of Strong Brand Images has Successfully Increased the Overall Number of Tobacco Users.

The tobacco industry's branding and promotion efforts have been remarkably effective. *Advertising Age*, the leading advertising trade journal, ranked Philip Morris's Marlboro Man as the top advertising icon of the century, recognizing that this brand image had the most powerful resonance in the marketplace with respect to effectiveness, longevity, recognition, and cultural impact.[25] *Business Week* ranked Marlboro as the world's ninth most valuable global brand.[26]

The Marlboro Man is a good example of a brand or trademark that has been successfully linked to consistent imagery over a long time. The Marlboro leathered cowboy brand image of rugged masculinity has been communicated consistently for several decades, and adjusted over time. Philip Morris has invested heavily in sponsoring auto-racing to extend Marlboro's overall brand positioning and brand imagery. Since the Marlboro brand image is rugged, hyper-masculine, individualistic, and heroic, as is this style of auto racing, the company saw Formula One and Indy car racing as adding a modern-day dimension to this image.[27] During the early 2000s, Philip Morris spent roughly $23 million each year to sponsor a Formula One race-car driver, and about $54 million each year to have Marlboro placed in multiple locations on the race car, helmet, and overall of the driver and his teammate.[28] Other complementary message strategies include: the "Marlboro Country" visual images of cowboys and the American West; a lifestyle magazine entitled "Unlimited," which is hailed as an "action, adventure, and good times" magazine

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[25] Monograph 19, p. 54; The advertising century. Advertising Age, 2005. http://adage.com/century

[26] Monograph 19, p. 54; The 100 top brands. Business Week, August 4, 2003

[27] The business of racing: Corporate America has discovered motor racing, and CART in particular, as a marketing tool. New York Times, July 9, 1989; Monograph 19, p. 66

[28] Monograph 19, p. 68

consistent with the psychographics of the target market; Marlboro Classics clothing line labels which emphasize the garments' "strength" and "endurance," implying that the garments can endure harsh outdoor activities like those expected of a cowboy; Marlboro Unlimited Gear, including branded trail watches, transportable gas grills, and gear bags that are promoted as durable, "without limits," and "built for adventure."[29]

In the face of Marlboro's success in dominating market share, R.J. Reynolds' (RJR) instituted design changes in 1980 and 1981 and introduced the Joe Camel brand and advertising campaign for Camel cigarettes, lasting from 1988 to the mid-1990s. Camel was repositioned to become the contemporary younger adult smoker brand. Joe Camel is another infamous example of the insidious power of branding. RJR's introduction of the Joe Camel "Smooth Character" cartoon figure was so successful that the character Joe Camel was virtually as recognizable to preschoolers as the beloved Mickey Mouse. As a result, between 1989 and 1993, when advertising for the new Joe Camel campaign jumped from $27 million to $43 million, Camel's share among youth increased by more than 50 percent, while its adult market share did not change at all.[30] Youth smoking prevalence rates shot up during the early 1990s. Between 1991 and 1997, 30-day adolescent prevalence rates rose from 28 percent to 36 percent, and several analyses have linked this increase in prevalence to marketing and advertising in general, and to the introduction of the Camel "Smooth Character" campaign in 1988 in particular. Youth market share increased more significantly for Camel than for other popular youth brands (Marlboro, Newport) during this period.[31]

Evidence collected from tobacco industry documents explicitly discussing their strategies aimed at young adults demonstrates that tobacco companies capitalized on the importance of brand names to young people since they understood that the transition from smoking the first cigarette to becoming a confirmed pack-a-day smoker may take years and span a series of stages that may extend to age 25. Therefore, they developed strategies not only to encourage initial experimentation, often by teens, but also to carry new smokers through each stage of this process. The industry encourages increased tobacco consumption by focusing on key transition periods when young adults adopt new behaviors – such as entering a new workplace, school, or the military – and especially by focusing on leisure and social activities. Moreover, tobacco companies study young adults' attitudes, social groups, values, aspirations, role models, and activities and then infiltrate both their physical and their social environments.[32] Both RJR and Philip Morris developed cigarette brands for each stage of smoking.[33] For example, in 1994, Philip Morris's advertising agency, Young & Rubicam, presented the following model to illustrate evolution of brand choice as the young adult smoker matures:

Choice of "starter" brand → youthful conformity/rebellion
"Break-away brand" → early maturation: individuation and self-assertion

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[29] Monograph 19, p. 67

[30] CDC, "Changes in the Cigarette Brand Preference of Adolescent Smokers, U.S. 1989-1993," *MMWR* 43(32):577-581, August 19, 1994, http://www.cdc.gov/mmwr/preview/mmwrhtml/00032326.htm.

[31] How cigarette design can affect youth initiation into smoking: Camel cigarettes 1983-93, `G Ferris Wayne, G N Connolly. Tobacco Control 2002;11(Suppl I):i32–i39. Down-loaded from tobaccocontrol.bmj.com on January 4, 2012

[32] Why and How the Tobacco Industry Sells cigarettes to Young Adults: Evidence from Industry Documents. Pamela Ling and Stanton Glantz, Am. J. Public Health. 2002;92: 908-916

[33] Ling and Glantz, id.

Choice of "mature" brand(s) → later maturation: self-management/tradeoffs[34]

The industry documents further show that the tobacco industry not only tries to cultivate new smokers, but has also positioned brands for established smokers who are thinking about quitting. An RJR 1981 segmentation study presentation showed how brands were positioned for each life stage (see attached figure). RJR attempted to match a brand image – such as "macho, strong and masculine" or "low tar, health concerned" to the smoker's life stage.[35]

In addition to the substantial evidence in the tobacco industry's internal documents about their knowledge of the importance of branding and promotional strategies to entrap youth in a lifetime addiction to their harmful tobacco products, there is ample evidence in the literature demonstrating the importance of brand names to children and adolescents. For example, a study measuring the product logo recognition by children as young as 3 – 6 years old was reported in the Journal of the American Medical Association in 1991. This study demonstrated high rates of logo recognition in very young children for products that are targeted to both children and adults. It found that children can properly match the McDonald's arches to a hamburger, and have a high recognition of the Chevrolet and Ford logos, which are obviously targeted to adults, not kids. And even though at the time of the study, cigarette advertising was no longer on television and very young children usually cannot read print ads, the study found that by the age of 6 years, "Old Joe [Camel] is as well recognized as Mickey Mouse."[36] Of particular relevance, the study found that:

Children's knowledge of cigarette brand logos is most likely the result of their exposure to "environmental tobacco advertising." Camel and Marlboro brand advertising is ubiquitous, appearing in movies, on billboards, promotional displays at youth-oriented events, on television during sporting events, and on "line extenders," such as T-shirts, posters, and caps. In addition to this paid advertising, Camel and Marlboro brand logos appear on video arcade games, children's toys, and candy products. [Emphasis added, citation omitted.][37]

The authors of this study found that children are referred to by marketing researchers as "consumers in training." Therefore, in addition to the market directly under the control of children (e.g., kids spending their own money on candy) and the market for products in which children influence household purchasing decisions (e.g., children convince their parents to buy particular brands of breakfast cereal), research has identified a third market for products that children will consume when they become adolescents and adults. Market researchers believe that brand awareness created in childhood can be the basis for product preference later in life, and children will exhibit a preference for products that they are currently too young to use.[38]

Therefore, even when cigarette and smokeless tobacco brands and promotions are supposedly not intended for children, they still impact children's preferences and choices. As the authors of

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[34] Ling and Glantz, referencing Philip Morris Tobacco Company document. March 24, 1994. Bates No. 2500086977/7024. Available at http://www.pmdocs.com

[35] Ling and Glantz, referencing R.J. Reynolds Tobacco Company document. 1981. Bates No. 501233021-3038. Available at http://www.rjrtdocs.com

[36] P. Fischer et al., Brand Logo Recognition. JAMA. 1991;266(22):3145-3148, pp. 3147-3148

[37] Fischer et al., p. 3148

[38] Fisher et al, p. 3147

this study stated, "It is obviously impossible to predict how the exposure of children to environmental tobacco advertising [which includes brand stretching and line extenders] might influence their later smoking behavior. While cigarette companies claim that they do not intend to market to children, their intentions are irrelevant if advertising [including brand stretching and line extenders] affects what children know. R. J. Reynolds Tobacco Company is as effective as The Disney Channel in reaching 6-year-old children."[39]

A more recent study confirmed these findings, and found that even toddlers and preschool-aged children were shown to be heavily influenced by brands and branding. In this study, a pediatrician looked at what methods of persuasion are being used to sell food products to the youngest television viewers. She found that the majority of child-oriented food advertisements took a branding approach, focusing on creating lifelong customers rather than generating immediate sales. The study found that brand recognition begins as early as 2 years of age, particularly when cartoon or cartoonish (e.g., Tony the Tiger or Ronald McDonald) characters are used to sell products. Marketers are eager to reach very young children not necessarily to promote specific products, but to build brand loyalty on the theory that the younger the age at which brand awareness is established, the stronger the brand loyalty will be as a child grows. The study quotes an expert in children's consumer behavior who said, "'Brand marketing must being with children. Even if a child does not buy the product and will not for many years…the marketing must being in childhood.'"[40] The study found that advertisements aimed at very young children focused on building brand recognition through the use of licensed characters, logos, and slogans, and that ads seemed to be designed to build social or emotional association with products or brands. In the case of fast food advertising, the advertisements did not focus on the food itself, or on its taste or nutritional value, but rather the ads focused on building familiarity and brand loyalties.[41] This approach was adopted by RJR in its Joe Camel advertising campaign, building brand loyalty with young people by building a social or emotional association with the cartoonish Joe Camel figure to make smoking seem "cool" and interesting.

Most companies, especially tobacco companies, go to great lengths and expense to zealously protect their trademarks and brand names. The FDA's argument that its proposed regulation is necessary because it would prevent companies from unfairly exploiting the rule to the detriment of tobacco companies is clearly unsubstantiated in the case of large tobacco manufacturers for whom the costs of trademark searches and possible names changes is *de minimis* when one considers the $34 million per day they spend on marketing. But small tobacco manufacturers are no less responsible for producing, distributing, and marketing cigarettes and smokeless tobacco products that addict and kill those whom are reached and influenced by their branding and advertising.

In 2008, the five largest smokeless tobacco manufacturers spent $547.9 million dollars advertising and marketing their products, the most ever reported to the Federal Trade Commission. As cigarette smoking prevalence, sales, and advertising and promotion expenditures decrease, the amount spent on smokeless tobacco has increased rapidly. Since

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[39] Fischer et al., p. 3148

[40] S. Connor., Food-Related Advertising on Preschool Television: Building Brand Recognition in Young Viewers, Pediatrics 2006;118,1478-1485, p. 1479

[41] Connor, page 1483

2003, the last year in which expenditures for smokeless tobacco advertising and promotion decreased, this amount has increased by almost 2.4 times.[42]

Given these practices, the FDA should not create unnecessary exemptions from the restrictions contained in the tobacco regulations. If anything, FDA should be tightening them in order to achieve the Tobacco Control Act's public health goals. Moreover, the size and/or market share of the tobacco manufacturers whose branding and marketing activities are restricted by this regulation is irrelevant.[43] The FDA was given broad authority to restrict these branding and marketing activities by all tobacco manufacturers; there is no good reason or public health imperative to limit this authority, and no legal justification to do so.

Indeed, one of the stated purposes of these regulations is "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco."[44] The intent of Congress to *expand*, rather than limit, the authority of the FDA to regulate the manufacturing, marketing, and distribution of tobacco products was made crystal clear in these findings: "Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations."[45]

VII. Because Brand Stretching is an Effective Way for Tobacco Companies to Circumvent Other Restrictions, the FDA Should Not Permit Additional Exceptions or Exemptions to its Non-Tobacco Brand Name Regulations.

The tobacco industry spends extraordinary resources on cigarette and smokeless tobacco promotion. Cigarette companies spent $10.86 billion on advertising and promotional expenditures in 2007, and $9.94 billion in 2008. While these expenditures have been gradually decreasing, in the most recent report cigarette companies spent approximately double the $5.11 billion spent on advertising and marketing in 1996, the year the original regulations were enacted. The money cigarette companies spent on U.S. marketing in 2008 amounted to approximately $27 million per day.[46] The five major U.S. smokeless tobacco manufacturers spent a total of $411.2 million on smokeless tobacco advertising and promotion in 2007, and these expenditures rose to $547.9 million in 2008, a 55% increase from the $354.1 million spent in 2006.[47] While cigarette sales are predominantly dominated by the larger tobacco manufactures, many smaller tobacco manufacturers have become major players in the smokeless tobacco market. Given the new emphasis on smokeless tobacco and the grave danger to public health that its mounting use represents, it is important that the FDA not loosen its restrictions and thereby provide a loophole that would allow any tobacco manufacture, including the smaller smokeless tobacco manufacturers, to use brand names of nontobacco products on their tobacco products in circumvention of the law and Congressional intent.

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42 American Lung Association. *Trends in Tobacco Use.* Table 19: Total U.S. Advertising and Promotional Expenditures for Cigarettes and Smokeless Tobacco, 1975-2006. American Lung Association Research and Program Services Epidemiology and Statistics Unit, July 2011.

43 61 FR 44444

44 Tobacco Control Act, Sec. 3(2)

45 Tobacco Control Act, Sec. 2 (31)

46 Federal Trade Commission Cigarette Report for 2007 and 2008, issued 2011, Federal Trade Commission, Washington; http://www.ftc.gov/os/2011/07/110729cigarettereport.pdf

47 Federal Trade Commission Smokeless Tobacco Report for 2007 and 2008, issued 2011, Federal Trade Commission, Washington; http://www.ftc.gov/os/2011/07/110729smokelesstobaccoreport.pdf

Although the total dollars spent on cigarette advertising and promotion have declined slightly in recent years, expenditures for smokeless tobacco advertising and promotion have increased dramatically. When one form of promotion has been proscribed or restricted by regulations or court actions, tobacco firms have tended to create other marketing strategies to continue communicating messages and images for their respective brands and trademarks. For this reason, partial restrictions on the sale and distribution of tobacco products have proven ineffective.[48] For example, when the Public Health Cigarette Smoking Act prohibited broadcast advertisements for cigarettes in January 1971, U.S. cigarette advertising expenditures doubled for magazines and increased more than fourfold for newspapers in just one year,[49] and companies shifted their resources toward sport and cultural sponsorship marketing in the 1970s and 1980s.[50] The MSA's 1998 prohibition on cigarette billboard advertising has prompted an increase in the prevalence of both interior and exterior point-of-sale tobacco advertising at retail outlets.[51] Thus, while partial restrictions limit the promotional options for the tobacco industry, the total amount of promotional spending dollars persists, allowing the industry to respond with alternatives.

Using brand stretching or extensions is an effective strategy still available to tobacco companies to circumvent other tobacco promotion restrictions, and the FDA should use it authority to prevent tobacco manufacturers from exploiting this opportunity. There are many documented examples of tobacco companies using brand extension in European and Asian countries as well as in the United States to circumvent tobacco advertising prohibitions or restrictions. For example, after enactment of a cigarette advertising bar in Norway in 1975, Camel boots were introduced in that country with advertisements that were virtually identical to earlier ads for Camel Cigarettes. "Marlboro Classics" clothing is sold in at least 29 countries. Marlboro and Camel lighters, all Mall matches, and Camel footwear were introduced in France following the tobacco advertising restrictions imposed by the *Loi Veil* legislation in 1976. Camel boots were sold in Finland after direct tobacco advertising was proscribed in 1976. "Camel adventures" travel tours were sold in Sweden after tobacco advertising was restricted there in 1979. Liggett & Myers matches, Camel scooters, Gauloises travel excursions, and Bastos cassettes were sold in Belgium after the enactment of advertising limits under the Royal Decree of 20 December 1982. Although direct tobacco advertising is forbidden in Malaysia, Benson & Hedges opened a Bistro in Kuala Lumpur. Camel Trophy "adventure boots" were sold in Turkey after it outlawed tobacco advertising in 1997.[52]

Tobacco control research has shown the connection between brand stretching and promotion of the sponsoring tobacco products, and demonstrated that advertising for the nontobacco product or service is consistently seen as advertising for the sponsoring tobacco brand. Therefore, interchanging the names of tobacco products and nontobacco products helps

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[48] Monograph 19, p. 82

[49] Monograph 19, p. 82

[50] Monograph 19, p. 83

[51] Mongoraph 19, p. 83

[52] Monograph 19, p. 105

tobacco companies maintain their product brand identity, especially when other more traditional advertising and promotional channels have been blocked.[53]

Conclusion

It is clear from the long history of tobacco company efforts to use branding and other promotional strategies to mislead consumers into initiating and sustaining tobacco use and from the grave toll these successful efforts have taken on public health that the FDA must not create loopholes in its regulations, but rather must insist that all tobacco manufacturers refrain from using nontobacco product names on their tobacco products. The bottom line for the FDA must be the protection of public health as outlined in the Tobacco Control Act; therefore, it should not promulgate the proposed amendments.

Sincerely,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
American Public Health Association
Campaign for Tobacco-Free Kids
Partnership for Prevention

[53] Monograph 19, p. 106