

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division**

RENEGADE TOBACCO COMPANY, INC., <i>et al.</i>)	
)	
Plaintiffs,)	
)	
v.)	Case No. 3:10-cv-00265-HEH
)	
U.S. FOOD AND DRUG ADMINISTRATION, <i>et al.</i> ,)	
)	
Defendants.)	

**MEMORANDUM IN SUPPORT OF
MOTION FOR PRELIMINARY INJUNCTION**
[CORRECTED]¹

This memorandum is filed by Plaintiffs Renegade Tobacco Company, Inc.; Alternative Brands, Inc.; Renegade Holdings, Inc. (collectively, “Renegade”), and Seneca-Cayuga Tobacco Company (“Seneca-Cayuga”), by counsel, in support of their Motion for Preliminary Injunction.

INTRODUCTION

Plaintiffs have brought a complaint seeking to prevent the U.S. Food and Drug Administration (“FDA”) from enforcing a regulation, 21 C.F.R. § 1140.16(a) (“the Product Name Restriction”), which was adopted by the FDA as a final rule on March 19, 2010, with an effective date of June 22, 2010. *See* 75 Fed. Reg. 13225-13232 (March 19, 2010). As written, the regulation will stop many small cigarette manufacturers from selling cigarettes under well-established brand names if those names also are used on non-tobacco products, while protecting the big tobacco companies that have long-dominated – and that continue to dominate – the cigarette market in the United States.

¹ This corrected memorandum is filed by Plaintiffs in order to comply with page limits of the local rules of court. *See* Local Civil Rule 7(F)(3).

Although the FDA admitted that its regulation was problematic, *see* 75 Fed. Reg. 13225, the agency did nothing to solve any of the problems. Then, on May 4, 2010, the FDA announced a new policy with respect to the *enforcement* – albeit not the *terms* or the *interpretation* – of the regulation; and it is likely that the FDA will argue that its May 4 announcement shields the agency against a preliminary injunction. The argument is misguided.

Superficially, the FDA’s announcement may seem to address Plaintiffs’ concerns; however, the FDA’s published assurances are wholly illusory. Indeed, the same announcement makes it clear that the FDA is *not bound* by its assurances, and that the public – including Plaintiffs – are still at risk of seeing their rights violated and their businesses destroyed.

FACTS

The Regulation and Its Effects

The Product Name Restriction, which is at the crux of this case, provides as follows:

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.

21 C.F.R. § 1140.16(a).

Products that fail to comply with the Product Name Restriction are considered “misbranded” under federal law. *See* 21 C.F.R. §1140.1. As such, they may be seized and destroyed, and severe civil and criminal penalties – including substantial fines and imprisonment – may be imposed on the manufacturers and sellers. *See* 21 U.S.C. §§ 333 and 334.

This is not the first time the FDA has sought to restrict the use of brand names on cigarettes. In 1995, the FDA gave notice of its intent to adopt such a regulation, *see* 60 Fed. Reg. 41314, 41374 (August 11, 1995), and in 1996, the FDA adopted the proposed regulation, *see* 61

Fed. Reg. 44396, 44616 (August 28, 1996) (adopting Final Rule). The 1996 Regulation, 21 C.F.R. § 897.16(a), used exactly the same text found in the 2010 regulation now at issue. The 1996 Regulation (along with many other tobacco-related regulations) was later struck down when the U.S. Supreme Court decided that the FDA had no authority to regulate tobacco. *See Food and Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

In 2009, Congress adopted new legislation, for the first time giving the FDA authority to regulate tobacco. *See* P.L. 111-31 (June 22, 2009), now codified at 15 U.S.C. §§ 1333 *et seq.* As part of this act, Congress directed the FDA to adopt a regulation “identical in its provisions” to the regulations adopted by the FDA in 1996. *See* 75 Fed. Reg. 13225, 13229 (March 19, 2010). At the same time, however, Congress directed the FDA to “include such modifications to [the 1996 regulations] that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court in *Lorillard Tobacco Co. v. Reilly*, [533 U.S. 525 (2001)].” P.L. 111-31, § 102(a)(2)(E); *see also* 75 Fed. Reg. at 13226.

In *Lorillard*, the Court held that “so long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information.” 533 U.S. at 571. One of the lessons of *Lorillard* is that marketing cigarettes constitutes commercial speech protected under the First Amendment. It is a lesson the FDA chose to ignore.

As explained in the Complaint, the Product Name Restriction, as written, will impact small tobacco companies in at least six ways:²

² These examples apply to companies, such as Plaintiffs, that are not eligible for the 1995 Names-In-Use Exception. *See* discussion *infra* at 5-6.

First, the Product Name Restriction is not limited to cases where a *single manufacturer* produces both a tobacco product and a non-tobacco product using the same trade or brand name. Instead, a cigarette manufacturer will be forced to abandon use of its trade name if a *wholly-unrelated* manufacturer uses that name on a non-tobacco product.

Second, the Product Name Restriction applies regardless whether there is any *likelihood of confusion* on the part of consumers.

Third, the Product Name Restriction applies regardless whether the cigarette manufacturer used its trade name first and regardless whether that cigarette manufacturer has a *trademark registration*.

Fourth, the Product Name Restriction applies regardless whether the tobacco product and the non-tobacco product are sold in the same *geographic market*.

Fifth, the Product Name Restriction is not limited to names appearing on a readily accessible *list of non-tobacco products*, such as a list of federally-registered trademarks. Instead, it applies to names appearing on non-tobacco products offered for sale anywhere in the economy. Thus, a cigarette manufacturer has no way of knowing with any assurance that its existing brand name – or a name it contemplates using – complies with the regulation.

Sixth, the Product Name Restriction is not limited to names adopted in the future by tobacco product manufacturers; it also applies to names *already in use* when the regulation was adopted on March 19, 2010. Thus, a cigarette manufacturer who has been using a trademarked brand name for many years before the adoption of the regulation will be forced to abandon the name if a non-tobacco manufacturer uses the same name for a non-tobacco product (as long as the name was not being used on both a tobacco product and a non-tobacco product as of January 1, 1995).

These Effects Impact the Plaintiffs

As explained in the attached Declarations of Michael Mebane and Chief Leroy Howard, small cigarette manufacturers – including Plaintiffs – will be harmed by the Product Name Restriction. Summarized below, those explanations are incorporated by reference.

Renegade – Renegade’s principal brand names include “Tucson,” “Tracker,” and “Barton.”³ Renegade has invested significant funds in developing each of these brand names and accompanying goodwill and has an established property interest in these brand names. Mebane Decl. ¶ 4. Renegade has not marketed any non-tobacco products under these brand names, nor does it intend to market any non-tobacco products under these brand names. *Id.* ¶ 5. Nonetheless, Renegade is subject to the Product Name Restriction and is not eligible for the 1995 Names-In-Use Exemption for any of its principal cigarette brands because none of the foregoing Renegade brand names was being used on a cigarette product on January 1, 1995.

One or more other manufacturers – having no connection with Renegade – now use the names “Tucson,” “Tracker” and “Barton” for their non-tobacco products. According to the USPTO: the trademark “Tucson” is used on, *inter alia*, automobiles (Serial No. 78295857); the trademark “Tracker” is used on, *inter alia*, handheld computers used for playing bingo (Serial No. 78844526); and the trademark “Barton” is used on, *inter alia*, alcoholic beverages (Serial No. 75699796). *Id.* ¶¶ 8, 10, 12. Thus, effective June 22, 2010, Renegade will be in violation of the Product Name Restriction unless it abandons the Tucson, Tracker and Barton trademarks.

³ Renegade Tobacco Company, Inc. holds the following trademarks for these names: “Tucson,” Serial No. 76156510, registered September 7, 2004; “Tracker,” Serial No. 76525463, registered March 1, 2005; and “Barton,” Serial No. 76547561, registered December 4, 2007. Mebane Decl. ¶¶ 6, 9, 11.

Seneca-Cayuga – Seneca-Cayuga’s only brand of cigarettes is “Skydancer.”⁴ Howard Decl. ¶ 5. Seneca-Cayuga also serves as a contract manufacturer for cigarettes sold under the brand name “Golden Bay.” *Id.* ¶ 10. Seneca-Cayuga has invested significant funds in developing the “Skydancer” brand name and accompanying goodwill, and it has an established property interest in this brand name. *Id.* ¶ 5. Seneca-Cayuga has not marketed any non-tobacco products under the Skydancer brand name, nor does it intend to do so. *Id.* ¶ 6. Because the Skydancer brand name was not being used on a cigarette product on January 1, 1995, that name is subject to the Product Name Restriction and is not eligible for the 1995 Names-In-Use Exemption.

Seneca-Cayuga is aware of another business that uses and/or has used “Skydancer” on a non-tobacco product – inflatable action figures. *Id.* ¶ 9. Other businesses also might choose to use the “Skydancer” name for other non-tobacco products, and Seneca-Cayuga would have no legal recourse to prevent such use, so long as the use is not likely to cause confusion or mistake, or to deceive. Indeed, if the non-tobacco business did not apply for a federal trademark, Seneca-Cayuga might not even know that the name was being used by someone else.

The 1995 Names-In-Use Exception

Part of the problem with the new Product Name Restriction can be traced to a “grandfather” clause contained in the old 1996 FDA regulation. That clause gave certain protections to names in use as of January 1, 1995 – *i.e.* at the beginning of the calendar year when the regulation was first proposed. If the FDA had followed the same approach in its current regulation, it would have used January 1, 2009, as the date for giving “grandfather”

⁴ Seneca-Cayuga holds the registered trademark “Skydancer,” Serial No. 78172235, registered March 21, 2006, for use on, *inter alia*, cigarettes. Howard Decl. ¶ 7.

clause protection to names in use. Instead, in its new regulation, the FDA leapt all the way back to January 1, 1995 – a date *fourteen years* earlier. Thus, although the new regulation uses the *same text* as the earlier regulation, it does so with a radically *different effect*: it destroys the brand names – and associated goodwill – developed by small cigarette manufacturers in reliance on the Supreme Court’s decision in *Brown & Williamson*.

While the Product Name Restriction will have catastrophic effects on small manufacturers, its impact will be negligible on the largest manufacturers, who dominate the tobacco market. In 1995, the cigarette market in the United States was dominated by four large companies: Philip Morris Inc., R.J. Reynolds Tobacco Co., Brown & Williamson Tobacco Corp. and Lorillard Tobacco Co. In 1995, these four companies collectively accounted for 97.8 percent of the national cigarette market. J. Maxwell, *Premiums Up*, Tobacco Reporter, March 1996, at 16. Today, these same companies collectively account for approximately 90 percent of the national cigarette market.⁵ (The number was reduced from four to three when Brown & Williamson merged with R.J. Reynolds in July 2004, creating Reynolds American, Inc.).

As reported by the Centers for Disease Control (“CDC”), the six top-selling brands in the United States and their respective market shares are as follows: **Marlboro** – 41.0%; **Newport** – 9.7%; **Camel** – 6.7%; **Doral** – 3.8%; **Basic** – 3.5%; **Winston** – 3.2%. See http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/brand_preference/index.htm (reporting data from 2008). These six top-selling brands collectively account for 67.9 percent of the cigarette market in the United States, and they include the three most heavily advertised brands, Marlboro, Newport and Camel. *Id.* Yet, each of these six top-selling brand names was being used on both

⁵ This percentage is drawn from data reported annually to the Securities and Exchange Commission. These “Form 10-K” reports are available at <http://www.sec.gov>.

tobacco and non-tobacco products prior to January 1, 1995, and therefore each is protected by the 1995 Names-In-Use Exception. Thus, *at least* two-thirds of the cigarette market is not subject to the Product Name Restriction.⁶ In fact, the majority (and perhaps all) of the cigarette brand names currently used by the three large tobacco companies are protected by the 1995 Names-In-Use Exception, thereby insulating approximately 90 percent of the current cigarette market in the United States from the Product Name Restriction.

The principal effect of the Product Name Restriction will be to protect the large tobacco companies from competition by (a) destroying the ability of the new, smaller cigarette companies to market their products using their current brand names, (b) preventing the new, smaller cigarette companies from building brand identities using new names, and (c) protecting the ability of the large, pre-1995 tobacco companies to market their major brands.

The FDA's Recognition of Flaws – and Its Flawed Response

When it adopted the Product Name Restriction, the FDA acknowledged that the regulation is problematic, stating “*FDA is aware of concerns regarding this provision and is considering what changes, if any, would be appropriate.*” 75 Fed. Reg. 13225 (emphasis added). When the Complaint was filed, the FDA had done nothing to address those concerns. Then, on May 4, 2010, the FDA announced what it termed “Guidance for Industry and FDA Staff: Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco” (the “Guidance”) (copy attached as **Exhibit A**). In the Guidance, the FDA announced:

⁶ See, e.g., “Marlboro” clothing (Serial Nos. 73253754, 71494855); “Newport” hip braces (Serial No. 74350881); “Camel” glassware (Serial No. 74115594), “Doral” sedatives and sleep aids (Serial No. 73813871), “Basic” surgical shoe covers (Trademark Serial No. 74491696), and “Winston” tires (Serial No. 72378552).

[The FDA] intends . . . not to commence enforcement actions under this provision for the duration of its consideration [of possible changes to the regulation] where:

(1) The trade or brand name of the cigarette or smokeless tobacco product was registered, or the product was marketed, in the United States on or before June 22, 2009; or

(2) The first marketing or registration in the United States of the tobacco product occurs before the first marketing or registration in the United States of the non-tobacco product bearing the same name; provided, however, that the tobacco and non-tobacco product are not owned, manufactured, or distributed by the same, related, or affiliated entities (including as a licensee).

All of the brands owned by Plaintiffs were registered, or the product was marketed, on or before the date cited in the Guidance, June 22, 2009; however, despite any superficial assurances, the Product Name Restriction remains highly problematic:

First, there is nothing to prevent the FDA from changing its mind and enforcing 21 CFR § 1140.16(a) even where its present “intention” is not to do so. A court date is scheduled on May 27, with the effective date of the regulation occurring about one month later. There is no assurance that, if the FDA changed its mind, there would be enough notice or Plaintiffs to obtain a timely court date for a preliminary injunction. Knowing that the FDA could change its mind any day, distributors and retailers are unlikely to keep much of Plaintiffs’ products on hand.

Second, if the FDA were to change its mind and adopt a new enforcement policy – one harmful to Plaintiffs’ interests – there is nothing in the Guidance to state that the FDA would apply the new policy only *prospectively*. That is to say, the Guidance leaves the FDA free to begin enforcement at any time for actions that occurred while the current policy is in effect.

Third, the foregoing concerns would be less troubling were it not for the fact that the Guidance prefaces the apparently helpful language with a sweeping and emphatic disclaimer: “*This guidance . . . does not create or confer any rights for or on any person and does not operate to bind the FDA or the public.*” (Emphasis added.)

In short, it would be unreasonable to rely on the Guidance when that document says it *cannot* be relied upon. As the Supreme Court explained, “the First Amendment protects against the Government; it does not leave us at the mercy of *noblesse oblige*. We would not uphold an unconstitutional statute merely because the Government promised to use it responsibly.” *United States v. Stevens*, No. 08-769, 2010 U.S. LEXIS 3478, at *34-35 (Apr. 20, 2010). A preliminary injunction is needed to protect Plaintiffs from the unconstitutional regulation.

REASONS THIS COURT SHOULD ISSUE A PRELIMINARY INJUNCTION

Legal Standard

In order to obtain a preliminary injunction, “[a] plaintiff must establish ‘[1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.’ And all four requirements must be satisfied.” *Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 346 (4th Cir. 2009) (quoting *Winter v. NRDC, Inc.*, 129 S. Ct. 365, 374 (2008)). In this case, each of these requirements is satisfied.

I. Plaintiffs Are Likely to Succeed on the Merits of their Claims.

A. The Plaintiffs Are Likely to Succeed on Their Claim that the Product Name Restriction Violates the First Amendment.

Plaintiffs’ selection and use of brand names constitutes commercial speech. *E.g.*, *San Francisco Arts & Ath. v. United States Olympic Comm.*, 483 U.S. 522, 535 (1987) (holding that use of the word “Olympic” is “commercial speech” when it is “for the purpose of trade [or] to induce the sale of any goods or services” (internal quotation marks and citation omitted)); *Friedman v. Rogers*, 440 U.S. 1, 11 (1979) (holding that t “use of trade names in connection with optometrical practice . . . is a form of commercial speech”). Commercial speech – including tobacco-related speech – is protected by the First Amendment. *Lorillard*, 533 U.S. at 571

1. The Regulation Violates the *Central Hudson* Test.

A government regulation of commercial speech is invalid if it fails to satisfy the four-part test in *Central Hudson Gas Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 (1980). This test requires a court to ask: (1) whether the speech concerns lawful activity and whether the speech is misleading; (2) whether the governmental interest served by restricting the speech is substantial; (3) whether the speech restriction directly and materially advances the asserted governmental interest; and (4) whether the speech restriction is more extensive than necessary to serve the asserted governmental interest. *See Greater New Orleans Broadcasting Assoc. v. United States*, 527 U.S. 173, 174 (1999) (applying *Central Hudson* test).

a. Plaintiffs' Brand Names Are Lawful and Not Misleading: Plaintiffs' selection and use of brand names to identify and advertise their products concerns a lawful activity – cigarette smoking. Plaintiffs' use of their brand names is not misleading, nor does the Product Name Restriction require that a brand name be misleading in order for that regulation to apply. Thus, the burden is on the government to “identify[] a substantial interest and justify[] the challenged restriction.” *Greater New Orleans*, 527 U.S. at 174 (applying *Central Hudson*).

b. The FDA Lacks a “Substantial Interest” in Preventing Smoking by Adults: It is likely the FDA will say that its interest is in preventing smoking by *minors*. *See* 60 Fed. Reg. 41,314, 41,315 (Aug. 11, 1995). If so, Plaintiffs agree that such an interest qualifies as substantial. *See Lorillard*, 533 U.S. at 564 (“State’s interest in preventing underage tobacco use is substantial...”). It is not enough, however, that government has a “substantial interest” in the abstract; it must have a substantial interest in regulating the speech at issue.

In *Psinet, Inc. v. Chapman*, 362 F.3d 227 (4th Cir. 2004), the Fourth Circuit applied these principles when it struck down an attempt by Virginia to regulate sexually explicit internet

content. In that case, Virginia tried to justify its restrictions on grounds that it only sought to restrict the availability of such content to minors. The court held that even though the *intent* of the law may have been to prevent access by minors, the *effect* was to create a “blanket prohibition of adult commercial speech.” *Id.* at 238. This, the court held, “violates the First Amendment.” *Id.* “When the government defends a regulation of speech as a means to redress past harms or prevent anticipated harms, it must do more than simply ‘posit the existence of the disease sought to be cured.’” *Id.* at 238 (quoting *Turner Broad. Sys. v. F.C.C.*, 512 U.S. 622, 664 (1994)). It is the government’s interest in the speech *actually targeted* by the regulation that matters, not its interest in another category of speech that it *intended to target*.

In this case, the FDA claims it intends to target the marketing of cigarettes to minors, but the Product Name Restriction actually targets *all* marketing of cigarettes. Most of the affected speech is heard by adults, and there is no substantial interest in preventing cigarette use. “[T]obacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products.” *Lorillard*, 533 U.S. at 564. There is nothing untruthful about a manufacturer applying its own registered trademark to its own cigarette packages.

The Supreme Court has compared sweeping restrictions on cigarette advertising to overly-aggressive restrictions on “indecent speech,” noting that “the governmental interest in protecting children from harmful materials . . . does not justify an unnecessarily broad suppression of speech addressed to adults.” *Id.* (quoting *Reno v. ACLU*, 521 U.S. 844, 875 (1997)). Thus, “[a]s the State protects *children* from tobacco advertisements, *tobacco manufacturers and retailers and their adult consumers still have a protected interest in communication.*” *Id.* (emphasis added).

c. The Regulation Does Not “Directly and Materially Advance” the Goal of Preventing Underage Smoking: The regulation is also invalid because does not “directly and materially advance” the FDA’s asserted interest in discouraging underage smoking. Even where “the Government’s asserted interests are important in the abstract [that] does not mean... that the [regulation] will *in fact* advance those interests.” *PSINet Inc. v. Chapman*, 167 F. Supp. 2d 878, 884 (W.D. Va. 2001) (emphasis added) (quoting *Turner Broad. Sys. v. F.C.C.*, 512 U.S. 622, 664 (1994)). The FDA has the burden of proving that the regulation will substantially deter smoking by minors. This it cannot do, because the regulation is underinclusive.

More than 90 percent of the cigarettes sold in the United States are exempt from the Product Name Restriction. *See* discussion *supra* at 7-8. Young people prefer brands popularized by the large tobacco companies, and those brands are protected by the 1995 Names-In-Use Exception. According to a recent federal study, 91 percent of youths ages 12 to 17 prefer cigarettes manufactured by the largest three tobacco companies, with most preferring just three brands: Marlboro (48 %), Newport (23 %), and Camel (10 %).⁷ Perversely, however, the FDA has given these youthful brands-of-choice immunity from its regulation, focusing instead on brands that young people rarely smoke.

The underinclusiveness of the Product Name Restriction refutes any claim that the regulation “directly and materially advances” any interest in preventing smoking by minors. “[A] classification that is substantially ... *underinclusive* tends to undercut the governmental claim that the classification serves legitimate political ends.” *Cabell v. Chavez-Salido*, 454 U.S. 432, 440 (1982) (emphasis added); *accord Carey v. Brown*, 447 U.S. 455, 465 (1980) (holding

⁷ *See* 2005 National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration (“SAMHSA”) of the Department of Health and Human Services, *data available at* <http://www.oas.samhsa.gov/nsduh/2k5nsduh/tabs/Sect7peTabs58to67.pdf>.

that “a statute’s over- and under-inclusiveness ‘undermine [the] claim that the prohibition ... can be justified by reference to the State’s interest’”). Or, as the Fourth Circuit has explained, “an underinclusive restriction of speech [is] impermissible . . . where the underinclusiveness is so severe that it “raises serious doubts” about whether the government is actually serving the interests it invokes.” *National Fed’n of the Blind v. FTC*, 420 F.3d 331, 346 (4th Cir. Md. 2005) (citing *Florida Star v. B.J.F.*, 491 U.S. 524, 540, (1989)). In other words, the goal of preventing underage smoking may be legitimate, but the underinclusiveness of the Product Name Restriction means that the regulation is not actually serving that goal. Thus, the regulation fails to meet the third prong of the *Central Hudson* test.

d. The Regulation is “More Extensive than is Necessary:” The Product Name Restriction is “more extensive than is necessary to serve [the government’s] interest” in preventing underage smoking. This is so for two fundamental reasons. First, the government has means to pursue its goal without ever touching the brand names. Second, even if *some sort* of brand name regulation were required, a narrower regulation would do the job just as well.

First, there are many ways the government may prevent underage tobacco use, and many of those methods are already in place or were adopted by the FDA as part of the same regulatory package that contains the Product Name Restriction. *See, e.g.*, 21 C.F.R. § 1140.14 (preventing sales to minors and requiring identification); 21 C.F.R. § 1140.16 (limiting vending machine sales); 21 C.F.R. § 1140.32 (prohibiting certain advertising targeted at teens in magazines, radio and television and at points of sale).

Second, even if there were some current need for the FDA to interfere with brand names, the Product Name Restriction is far too broad. When the FDA first adopted a product name restriction in 1996, it explained: “If a firm could use a popular nontobacco product trade name

and put it on a tobacco product, the firm could attempt to exploit the imagery or consumer identification attached to the nontobacco product to make the tobacco appeal to young people.” 61 Fed. Reg. at 44,444. The FDA speculated that such a marketing strategy would promote smoking of that brand by young people and that the Product Name Restriction would prevent that marketing strategy from being used. *Id.*⁸ Yet, even if such e marketing strategies were effective, the regulation is more extensive than necessary to deter such marketing strategies.

First, where the *cigarette manufacturer uses* the brand name *first*, that manufacturer clearly is not trying to take advantage of the image associated with a pre-existing, non-tobacco product. Yet, the Product Name Restriction applies regardless who used the name first. Renegade used and trademarked the name “Tucson” years before Hyundai gave that same name to a vehicle. Even so, that use by Hyundai is enough to force Renegade to abandon its brand.

Second, the regulation applies whether or not the non-tobacco product is popular among adolescents. For example, “Northern” is a brand of toilet paper, hardly a glamour product. Yet, because there is a toilet paper named “Northern,” no cigarette manufacturer can use that name. Various non-tobacco products use and/or have used “Tucson,” “Tracker,” “Barton,” and “Skydancer,” but Plaintiffs are unaware of any such products will appeal to adolescents. Even so, the Product Name Regulation imperils their right to use those names.

Third, if a youth-oriented, non-tobacco product is so widely popular as to tempt a cigarette manufacturer to use the same brand name on its cigarettes, the name at issue almost

⁸ The FDA cited no evidence that a tobacco product bearing a non-tobacco name would especially appeal to young people. Indeed, the evidence showed that the brands cited by the FDA either represented only a small market share, or were not sold in the United States. Moreover, the government’s own studies show that young smokers overwhelmingly prefer brands of the major tobacco companies: Marlboro, Newport and Camel. *See supra* at 17-18.

certainly will be trademarked. Yet, the regulation is not limited to trademarked names. Instead, it applies to all products, whether trademarked or not.

In sum, if the FDA wishes to prevent a cigarette manufacturer from deliberately using the same name as a popular youth-oriented product, the agency can achieve that goal by a regulation far narrower than the one at issue here. For this reason, too, the Product Name Restriction fails to meet the *Central Hudson* test and must be struck down as unconstitutional.

2. The Regulation Is Discriminatory and It Fails Strict Scrutiny

Even if the Product Name Restriction were to meet the *Central Hudson* test, it still would be invalid because it fails to meet other applicable First Amendment tests. Because the 1995 Names-In-Use Exception *discriminates* based on the identity of the speaker and/or the content of the message, the regulation must be evaluated under strict scrutiny. *Lorillard*, 533 U.S. at 577 (“[C]ontent-discriminatory regulation [of commercial speech] – like all other content-based regulation of speech – must be subjected to strict scrutiny.”). That is to say, the FDA must show that it has a compelling interest that is advanced by the discrimination, and that the discriminatory provision is narrowly tailored to advance that interest.

The government may have an interest in providing a grandfather clause for brand names that were trademarked and/or in use at the time the FDA promulgated the regulation in *March 2010*. But there is no legitimate, let alone, compelling, interest in reaching back to *1995* to decide who is and is not protected. Such discrimination is irrational.

B. The Regulation Is Void for Vagueness.

Separate from its other constitutional defects, the Product Name Restriction is void for vagueness. A statute is unconstitutionally vague if it “fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages

seriously discriminatory enforcement.” *United States v. Williams*, 553 U.S. 285, 304 (2008). In First Amendment cases, a statute also may be considered vague and overbroad if “it is unclear whether it regulates a substantial amount of protected speech.” *Id.* In this case, the regulation’s vagueness violates the First Amendment and the Due Process Clause of the Fifth Amendment.

A cigarette manufacturer cannot know with reasonable certainty that a name it selects will be lawful. When it originally adopted the Product Name Restriction in 1996, the FDA admitted, in effect, that its proposed regulation was unreasonably vague:

It would be unreasonable for the regulation to encompass all possible nontobacco product trade names, regardless of their nationality *or* whether the trade name was a registered trademark. Neither FDA nor manufacturers would be able to ensure that a name was not used elsewhere.

61 Fed. Reg. at 44,445 (emphasis added). The FDA addressed the *first part* of the problem, but not the *second*. It limited the sweep of the regulation to the *United States*, but it did not limit the regulation to names that are *trademarked*. As a result, a cigarette manufacturer will violate the regulation if it uses the same name as the non-trademarked name of a non-tobacco product anywhere in the United States. As the FDA admitted in 1996, the manufacturer can only guess, and if it guesses wrong, it will be subject to civil and criminal penalties.

Even standing alone, this defect would make the regulation void for vagueness; however, the regulation is vague in other ways, too. For example, key terms in the regulation at issue are undefined – and its application in certain situations is unclear – leaving cigarette manufacturers to guess at their meaning. Among the ambiguous terms are the following:

- **“Product”** – The term “non-tobacco product” may include those goods which, like cigarettes, are tangible in nature. But what about intangibles, and what about services? Does the FDA intend to include hotel and restaurant names? Nobody knows.

- **“Name”** – The gist of the regulation is that it is unlawful to use a brand name on a cigarette if that name is used on a non-tobacco product. But when are two names close enough to be treated as the same for purposes of the regulation?
- **Other Issues** – The regulation may apply when a manufacturer is *currently* manufacturing and selling non-tobacco products under a particular name, but what happens if that manufacturer discontinues production? And, do sales in the secondary market count for purposes of the Names-In-Use Exception?

Given the vagueness of the regulation, manufacturers can only guess at the answers. If read too narrowly, the regulation exposes them to fines and imprisonment. If read too broadly, the regulation abolishes their brand names, prevents the adoption of available new ones and ruins their businesses unnecessarily. The constitution condemns such vagueness, especially where the First Amendment is concerned. *See Stevens*, No. 08-769, 2010 U.S. LEXIS 3478, at *34-35; *see also Hill v. Colorado*, 530 U.S. 703, 732 (2000) (regulation is void for vagueness if it “fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits,” and/or “authorizes or even encourages arbitrary and discriminatory enforcement”).

C. The Regulation Violates Plaintiffs’ Right to Equal Protection under the Due Process Clause.

The Due Process Clause of the Fifth Amendment contains an equal protection component applicable against the federal government. *See Bolling v. Sharpe*, 347 U.S. 497, 499 (1954); *Buckley v. Valeo*, 424 U.S. 1, 93 (1976) (*per curiam*). The Product Name Restriction provides unequal treatment for different cigarette manufacturers depending whether their cigarette brand names (and names of non-tobacco products) were in use on January 1, 1995. For the same reasons that the regulation fails to pass strict scrutiny under the First Amendment, *see supra* at 16-18, it also violates the equal protection component of the Due Process Clause.

D. The Product Name Restriction Destroys Plaintiffs' Property Interests Without Authorization and Without Due Process of Law.

The Product Name Restriction violates Plaintiffs' due process rights because it oversteps the authority granted by Congress. When told to adopt a regulation "identical in its provision" to the regulation introduced in 1996, 75 Fed. Reg. at 13229, the FDA adopted a regulation identical in language, but dramatically different in results. The earlier regulation protected names in use as of January 1, 1995 – *i.e.* the beginning of the calendar year when the regulation was first proposed. Rather than follow this approach in its current regulation, and using January 1, 2009, as the "grandfather" date, the FDA again used January 1, 1995 – a date *fourteen years* earlier. This result was radically different from the one intended by Congress. The FDA's interpretation was *ultra vires* results in Plaintiffs' deprivation of property without due process of law.

E. The May 4, 2010 "Guidance" Issued by the FDA Underscores the Unconstitutional Nature of the Product Name Restriction.

In its May 4 "Guidance," the FDA said it "intends to exercise its enforcement discretion concerning 21 CFR 1140.16(a) not to commence enforcement actions under this provision for the duration of its consideration . . ." of modifications to the Product Name Restriction. Exhibit A. The promise to "exercise discretion" does not mitigate the regulation's unconstitutionality.

A similar issue arose in *Stevens*, 2010 U.S. LEXIS 3478. In that case, the government sought to defend a statute that banned creation, sale or possession of any "depiction of animal cruelty." Recognizing that the regulation was facially overbroad, because it would potential implicate, *inter alia*, hunting videos and worthwhile documentaries, the government claimed it would exercise "prosecutorial discretion" to reach only depictions of "'extreme' cruelty." *Id.* at *34. The Court held that the government could not redeem an unconstitutional provision simply by promising to exercise discretion in enforcement:

[T]he First Amendment protects against the Government; it does not leave us at the mercy of *noblesse oblige*. We would not uphold an unconstitutional statute merely because the Government promised to use it responsibly. . . . The Government’s assurance that it will apply [a statute] far more restrictively than its language provides is pertinent only as an implicit acknowledgment of the potential constitutional problems with a more natural reading.

Id. at *35 (citations omitted). Likewise, the FDA’s announcement that it will “exercise discretion” highlights rather than mitigates the regulation’s unconstitutionality.

For the foregoing reasons, the Product Name Restriction is invalid on its face and as applied to Plaintiffs. While Plaintiffs are almost certain to prevail on these arguments at trial, they need not show such certainty to obtain a preliminary injunction. Under *Winter*, Plaintiffs need only show they are “likely” to prevail on the merits. That standard has been met.

II. Plaintiffs Are Likely to Suffer Irreparable Harm if an Injunction Is Not Granted.

The second prong of the *Winter* test focuses on the likelihood that the party seeking an injunction will suffer irreparable harm if the injunction is not granted. The prevention of irreparable harm is one of the primary purposes of a preliminary injunction. *Sun Microsystems, Inc. v. Microsoft Corp. (In re Microsoft Corp. Antitrust Litig.)*, 333 F.3d 517, 525 (4th Cir. 2003). In this case, Plaintiffs face three types of harms if the FDA enforces the Product Name Restriction: (1) a loss of trademark rights; (2) a deprivation of First Amendment rights; and (3) destruction of their businesses. Each of these types of harms Plaintiffs is considered irreparable *as a matter of law*. Moreover, each of these harms is not only likely; it is certain.

A. A Loss of Trademark Rights Constitutes Irreparable Harm.

First, a loss of trademark rights constitutes irreparable harm. In trademark lawsuits, once a party makes a *prima facie* showing of trademark infringement, that party is entitled to a presumption of irreparable harm. *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 273 (4th Cir. 2002) (In “cases involving trademark infringement, a presumption of irreparable injury is

generally applied once the plaintiff has demonstrated a likelihood of confusion. . . .”). This is because it can be difficult, if not impossible, to quantify lost sales and goodwill due to trademark diminution. *Black & Decker (U.S.) Inc. v. Pro-Tech Power Inc.*, 26 F. Supp. 2d 834, 862 (E.D. Va. 1998); *see also JTH Tax, Inc. v. H&R Block Eastern Tax Servs., Inc.*, 128 F. Supp. 2d 926, 948 (E.D. Va. 2001) (“[A] demonstration that the competitor’s advertising tends to mislead consumers satisfies the [Lanham] Act’s irreparable harm requirement.”).

If mere *infringement* of a trademark is enough to establish irreparable harm, then certainly *destruction* of a trademark also constitutes irreparable harm. In this case, the Product Name Restriction will extinguish Plaintiffs’ trademark rights in their brands. Even if Plaintiffs could establish new brand names – a highly doubtful prospect, *see* Mebane Decl. ¶ 21; Howard Decl. ¶ 16 – it would be impossible to quantify Plaintiffs’ lost sales and goodwill before new brands could be brought to market. Plaintiffs’ harm from lost trademark rights is irreparable.

B. A Deprivation of First Amendment Rights Constitutes Irreparable Harm.

Second, Plaintiffs’ use of their brand names constitutes commercial speech protected by the First Amendment. *See Central Hudson*, 447 U.S. at 566 (if commercial speech concerns lawful activity and is not misleading, it is covered by the First Amendment). As explained above, the FDA’s Product Name Restriction violates Plaintiffs’ First Amendment rights. *See supra* at 10-18. The result is irreparable harm to Plaintiffs. As this Court stated in *Stuart Circle Parish v. Board of Zoning Appeals*, 946 F. Supp. 1225 (E.D. Va. 1996), “it is clear that ‘violations of First Amendment rights constitute *per se* irreparable injury.’” *Id.* at 1235 (citing *J. Doe v. Shenandoah County School Bd.*, 737 F. Supp. 913, 916 (W.D. Va. 1990)). Plaintiffs have shown that the FDA’s Product Name Restriction regulation violates their First Amendment commercial speech rights. This showing is all that is necessary to establish irreparable harm.

C. The Destruction of Plaintiffs' Businesses Constitutes Irreparable Harm.

Third, enforcement of the Product Name Restriction will force Renegade and Seneca-Cayuga to stop doing business. The inability to sell Renegade's brands beginning June 22, 2010, will cause a negative cash balance by not later than August 2010. Mebane Decl. ¶ 20. Additionally, Renegade will face claims against it of approximately \$3.5 million for goods which will be deemed "misbranded" under the Product Name Restriction, and therefore cannot legally be sold. *Id.* Renegade also will be forced to write-off of approximately \$1.2 million in finished goods and raw materials, which currently are listed as assets of Renegade. *Id.* These factors will force Renegade to stop doing business and close its doors. *Id.* Seneca-Cayuga, too, faces destruction if the Product Name Restriction goes into effect. If it cannot be established that non-tobacco products named Skydancer are no longer being sold, then Seneca-Cayuga will have to shut down or risk prosecution as well as both civil and criminal penalties. Howard Decl. ¶ 14.

"It is well-settled that harm to a company's ability to continue its business and preserve its existence is irreparable." *Federal Leasing, Inc. v. Suburban Trust Co.*, 650 F.2d 495, 500 (4th Cir. 1981). This is because even if the Court somehow were able to *partially* measure the damage caused by the destruction of a business in dollars, "[t]he right to continue a business is not measurable *entirely* in monetary terms; the [owners of the company] want to sell [products], not to live on the income from a damages award." *Id.* (citing *Semmes Motors, Inc. v. Ford Motor Co.*, 429 F.2d 1197, 1205 (2d Cir. 1970)) (emphasis added).⁹

⁹ Indeed, even if one or both Plaintiffs were able to survive the damaging blow the FDA proposes to deal them, they still would suffer irreparable harm. Where damage to a company "endangers its relations with customers and investors, the good will built up by a heretofore successful enterprise; such damage is 'incalculable not incalculably great or small, just incalculable.'" *Federal Leasing*, 650 F.2d at 500 (quoting *Blackwelder Furniture Co. of Statesville v. Selig Manufacturing Co.*, 550 F.2d 189, 197 (4th Cir. 1977)).

D. The May 4, 2010 FDA “Guidance” Does Not Prevent Irreparable Harm.

In its May 4, 2010 Guidance, the FDA made clear that its announcement “does not create or confer any rights for or on any person and does not operate to bind FDA or the public.” Exhibit A. The Guidance leaves enforcement entirely in the “discretion” of the FDA and is subject to revocation at any time. *Id.* Plaintiffs’ distributors and retailers will be unwilling to rely on the Guidance in making investment decisions given these broad caveats. Mebane Dec. ¶ 35. These distributors and retailers know that if the FDA reverses its position, any of Plaintiffs’ cigarettes they have on hand will be deemed “misbranded” and thus unsellable. Rather than invest in substantial inventories of cigarettes that may run afoul of the Product Name Restriction, distributors and retailers instead will stock, at most, only small quantities of these cigarettes, while stocking up, instead, on cigarettes from the largest manufacturers that are not subject to the Product Name Restriction. *Id.* ¶ 36. Such caution on the part of distributors and retailers will result in lost sales, market share and goodwill by Plaintiffs and other small manufacturers. Finally, due to the uncertainty created by the FDA, Plaintiffs and other small manufacturers will be unable to invest in additional equipment, hire employees or attract investment. *Id.* ¶ 37. In short, while enforcement of the Product Name Restriction as originally written is a sentence to a quick death, the Product Name Restriction as modified by the Guidance is a sentence to a slow death. Each ultimately will lead to the death of Plaintiffs’ businesses. Such harm is irreparable.

The types of harms faced by Plaintiffs – extinguishment of trademark rights, violation of First Amendment rights and destruction of their businesses – have been recognized as irreparable as a matter of law. The FDA’s May 4 Guidance does not mitigate these harms. Plaintiffs therefore have satisfied the second prong of the *Winter* test.

III. The Balance of the Equities Tips in Plaintiffs' Favor.

The balancing of equities typically involves balancing the harm to Plaintiffs without an injunction against the harm to Defendants if an injunction is issued. *See, e.g., Allegra Network LLC v. Reeder*, No. 1:09-cv-912, 2009 U.S. Dist. LEXIS 103688, at *10 (E.D. Va. Nov. 4, 2009) (“The balance of the equities favors a preliminary injunction as there has been no evidence that Defendants will suffer irreparable harm. . . .”); *Quesenberry v. Volvo Group N. Am., Inc.*, No. 1:09cv00022, 2009 U.S. Dist. LEXIS 22468, at *52 (W.D. Va. Mar. 10, 2009) (considering harms to both parties as part of balancing the equities); *Safeway Inc. v. CESC Plaza Ltd. P’ship*, 261 F. Supp. 2d 439, 472 (E.D. Va. 2003) (same).

As Plaintiffs have explained, the regulation will cause them great, irreparable harm, including the destruction of Plaintiffs’ products, closure of their businesses and the termination of their employees. On the other hand, the regulation does not advance the FDA’s purported goal of preventing smoking by minors. *See supra* at 13-14. Moreover, there are numerous ways in which the FDA could pursue its goal without imposing on Plaintiffs the harms that the Product Name Restriction will cause. *See supra* at 15-16 (describing other avenues open to the FDA). Thus, the balance of the equities tips in favor of Plaintiffs. Indeed, that balance is further tipped in Plaintiffs favor by the “Guidance” issued by the FDA, implying that it intends to change the regulation and to sharply curtail its enforcement in the meantime. While that Guidance is filled with loopholes, the FDA cannot credibly claim to be harmed by a preliminary injunction that prevents the agency from using those loopholes in a way that would violate the constitution and damage Plaintiffs’ businesses. .

C. The Equities Favor Protecting Plaintiffs' Constitutional Rights.

The fact that the regulation violates Plaintiffs' constitutional rights favors granting the injunction. "When the government fails to demonstrate its compelling interest in burdening a constitutional right, courts routinely find that, in the absence of a compelling justification for interference, the balance of harms and public interest also favor protecting the moving party's burdened rights." *O Centro Espirita*, 389 F.3d at 1027 (citing *Eisenberg v. Montgomery County Public Schools*, 197 F.3d 123, 127 n.11, 133 (4th Cir. 1999); *Stuart Circle Parish*, 946 F. Supp. at 1235-36) (other citations omitted). Plaintiffs have established that the FDA lacks a compelling justification for interfering with their constitutional rights. *See* discussion *supra* at 11-16. Thus, this factor, too, weighs in Plaintiffs' favor.

D. The May 4, 2010 "Guidance" Issued by the FDA Tilts the Balance of the Equities Further in Plaintiffs' Favor.

In its May 4, 2010 Guidance, the FDA says that it will "exercise its enforcement discretion" by declining to "commence enforcement actions" for trade or brand names of cigarettes and smokeless tobacco registered or marketed on or before June 22, 2009. Exhibit A. In offering this Guidance, the FDA implicitly has admitted that the Product Name Restriction, as currently written, is unconstitutional. *See* discussion *supra* at 19-20 (citing *Stevens*, No. 08-769, 2010 U.S. LEXIS 3478 at *34-35). It would be absurd for the FDA to claim that it will be harmed if it is prevented from fully enforcing a regulation that the FDA now implies – albeit unconvincingly – it will not enforce as written.

In sum, considering traditional equitable factors as well as the relative harms to Plaintiffs and the government, the balance of the equities favors granting the injunction.

III. The Public Interest Favors Granting an Injunction.

The final factor considered by courts in determining whether to issue an injunction is the public interest. The harm to the public interest would be great if the regulation is enforced, while enforcement of the regulation would provide little or no benefit to the public interest.

A. The Public Interest Would Be Harmed if the Regulation Is Enforced.

First, the preliminary injunction sought by Plaintiffs will preserve the status quo. Plaintiffs do not ask that they be allowed to do anything new. They ask only that the Product Name Restriction not be enforced against brand names already trademarked and in use on March 19, 2010, the date the FDA announced its new regulation.¹⁰

Neither Renegade nor Seneca-Cayuga sells any non-tobacco product bearing their brand names, and neither Renegade nor Seneca-Cayuga intends to do so. Mebane Decl. ¶ 5; Howard Decl. ¶ 6. Moreover, in order to assure the Court that the status quo will be preserved, Renegade and Seneca-Cayuga will readily agree *not* to sell any non-tobacco product bearing any of these names during the pendency of the preliminary injunction, and they have no objection to the Court's including such a restraint in this preliminary injunction. The "*raison d'être*" for a preliminary injunction "is to preserve the status quo during the course of a litigation in order to prevent irreparable injury to the moving party and in order to preserve the ability of the court to render complete relief." *Federal Leasing, Inc. v. Underwriters at Lloyd's*, 650 F.2d 495, 499

¹⁰ While a preliminary injunction covering *all* cigarette brands, regardless of manufacturer, would be in order, and is included in the relief Plaintiffs seek, in the alternative, Plaintiffs ask that such relief be granted simply with respect to *their own* brands that were trademarked and in use as of March 19, 2010. These brands include: **Renegade** – "Tucson," registered September 7, 2004; "Tracker," registered March 1, 2005; and "Barton," registered December 4, 2007; and **Seneca-Cayuga** – "Skydancer," registered March 21, 2006, and "Golden Bay," for which Seneca-Cayuga serves as a contract manufacturer.

(4th Cir. 1981) (internal quotation omitted). Thus, the injunction sought by Plaintiffs is consistent with the purpose of preliminary injunctions.

Second, an injunction will preserve competition and consumer choice, a result decidedly in the public interest. *See, e.g., Direx Israel, Ltd. v. Breakthrough Medical Corp.*, 952 F.2d 802 (4th Cir. 1991) (recognizing “public interest in free competition in the marketplace”); *Lasercomb America, Inc. v. Reynolds*, 911 F.2d 970 (4th Cir. 1990) (same); *Signature Flight Support Corp. v. Landow Aviation Ltd. P’ship*, 2009 U.S. Dist. LEXIS 2541 at *35 (E.D. Va. Jan. 14, 2009) (holding that the public interest calls for “a diverse marketplace” with multiple sources of product from which to choose).

Without an injunction, the regulation will sharply reduce competition, consumer choice and diversity by forcing many existing products off the shelves. For example, in Virginia alone, there are 118 cigarette brands manufactured by 33 different small manufacturers (*i.e.*, not one of the top four companies – Philip Morris, Reynolds American, Lorillard and Liggett) approved for sale. Virginia Tobacco Directory, Office of the Attorney General (April 2, 2009), available at http://www.oag.state.va.us/LEGAL_LEGIS/Tobacco/Tobacco_By_Brand.pdf. Of these, at least 77 did not exist on January 1, 1995, and thus are ineligible for the Names-In-Use Exemption. *Id.* Many if not all of these 118 cigarette brands will become unlawful under the regulation, either because another non-tobacco product with the same name was not being sold on January 1, 1995 (for the 41 brands that existed at that time), or because someone else uses the same name on a non-tobacco product somewhere in the national economy (for the other 77 brands).

Moreover, it is not just a question of product taste. It is also a question of price. The newer brands are typically cheaper than the major brands. For example, the six most popular major brands currently sell at wholesale in the range of \$27.81 to \$33.60 per carton, Mebane

Decl. ¶ 18, see also Howard Decl. ¶ 12, while minor brands, such as Renegade's wholesale for about \$18.50 and \$21.50 per carton, Mebane Decl. ¶ 17, and Skydancer wholesales for about \$13.09 to \$15.07 per carton, Howard Decl. ¶ 12. As the Product Name Restriction forces the newer brands from the shelves, retailers and consumers will be forced to turn to the more expensive, major brands. Such a drain of consumer income is not in the public interest.

Third, the regulation not only eliminates diversity in the marketplace, it does so by restricting speech. This greatly magnifies the public interest in a preliminary injunction. *E.g.*, *Ctr. for Individual Freedom, Inc. v. Ireland*, 613 F. Supp. 2d 777, 807-08 (S.D. W. Va. 2009) ("Obviously, the protection of First Amendment rights is very much in the public's interest.").

Fourth, the Product Name Restriction would not only force many existing products off the shelves, it would force out of business many small manufacturers whose soon-to-be prohibited brands are the mainstay of their economic livelihood. The result would be felt not only by the manufacturers, but by employees who would lose their jobs and creditors who would go unpaid. The Plaintiffs in this case furnish salient examples of these ripple effects.

Renegade: Renegade has 144 employees and an annual payroll of approximately \$5.4 million, including payroll taxes, health insurance and other benefits. If Renegade is forced to close its doors, the loss of jobs will have a detrimental impact on these employees and their families. Mebane Decl. ¶ 24. If Renegade closes, this will have ripple effects on other companies, since Renegade will be unable to pay creditors, including banks, suppliers and vendors. *Id.* ¶ 23. The regional economy will suffer, too. Renegade is headquartered in the Town of Mocksville, in Davie County, North Carolina. According to the Davie County Economic Development Association, Renegade's closure would result in a total of 734 jobs lost regionally (including direct job losses and "spin off" job losses), and a loss of over \$17 million

annually from the local economy. *Id.* ¶ 35 & Exhibit F. This result would be disastrous for Davie County, which already has a 12.8 percent unemployment rate. Bureau of Labor Statistics, unemployment rate for Davie County, NC, February 2010, available at <http://www.bls.gov/lau/laucntycur14.txt>.

Seneca- Cayuga: The Seneca-Cayuga Tribe manufactures cigarettes on reservation lands in the sparsely-developed northeast corner of Oklahoma. Howard Decl. ¶ 4. During the first two quarters of the 2010 fiscal year, Seneca-Cayuga's cigarette sales in the U.S. market totaled \$31,018,281. Out of this sum, it paid \$24,512,090 in excise taxes. Seneca-Cayuga's gross sales for the last fiscal year (October 1, 2008 – September 30, 2009) totaled \$51,122,195. Out of this sum, it paid \$41,347,783 in excise taxes. *Id.* ¶ 10. Seneca-Cayuga has 67 employees, approximately 85 percent of whom are either members of the Tribe or spouses of tribal members. Seneca-Cayuga has an annual payroll of about \$2.5 million, including payroll taxes, health insurance and other benefits. If Seneca-Cayuga is forced to close, the loss of jobs will have a detrimental impact on these employees and their families. *Id.* ¶ 19. This also will affect other companies and the surrounding community. First, Seneca-Cayuga will be unable to pay its creditors, including banks, suppliers and vendors. *Id.* ¶ 18. Second, such closure will have a detrimental impact on the Tribe, which has experienced a higher unemployment rate than the surrounding area. The loss of jobs at Seneca-Cayuga likely will have a ripple effect, causing the loss of other area jobs, including jobs held by other tribal members and non-members. *Id.* ¶ 20.

B. Enforcement of the Regulation Would Provide No Benefit to the Public Interest.

While the public interest would be harmed by enforcing the Product Name Restriction against Plaintiffs, the harm to the public if the regulation is not enforced is non-existent. The FDA's stated rationale for imposing the regulation – that the Product Name Restriction will

reduce youth smoking – rings hollow. The regulation is designed to *protect* the major brands by giving them the benefit of the 1995 Names-In-Use Exemption, but it is the *major* brands – *not* the newer, lower tier brands – that young smokers typically choose. *See supra* at 13.

C. The FDA’s May 4, 2010 “Guidance” Shows that the Public Interest Favors Issuing the Injunction.

With its May 4 “Guidance,” the FDA offers protection to small tobacco manufacturers with one hand while, with the other hand, it takes such protection away. By its plain terms, the “Guidance” confers no rights on anyone, leaves enforcement entirely within the FDA’s discretion, provides for exercise of such discretion only during the duration of the reconsideration of the regulation (an unknown period of time) and reserves the right at any time to begin enforcing the regulation as originally written. The public interest disfavors such a recipe for arbitrary enforcement. *See Stevens*, No. 08-769, 2010 U.S. LEXIS 3478, at *35. The public interest favors knowing the law and how it will be interpreted and enforced. Otherwise, the public will be left to the whims of a capricious government.

CONCLUSION

Plaintiffs have established that: (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in their favor; and (4) an injunction is in the public interest. The requested preliminary injunction should be issued.

RENEGADE TOBACCO COMPANY, INC.,
ALTERNATIVE BRANDS, INC., RENEGADE
HOLDINGS, INC., and SENECA-CAYUGA
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CERTIFICATE OF SERVICE

I hereby certify that the foregoing was filed electronically with the Clerk of the Court, using the CM/ECF system, which sent notification of such filing to the following counsel for U.S. Food and Drug Administration and Margaret Hamburg, M.D., Commissioner of Food and Drugs, this 7th day of April, 2010:

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