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# The Scope of Preemption under the 2009 Family Smoking Prevention and Tobacco Control Act

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GEORGETOWN LAW





# The Scope of Preemption under the 2009 Family Smoking Prevention and Tobacco Control Act

SAM F. HALABI\*

## I. INTRODUCTION

Although the Patient Protection and Affordable Care Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act overshadow it, the first major law signed by President Barack Obama in his first term, the 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), competes with both health insurance and financial reform laws in terms of the human and economic cost it aimed to reduce: annually tobacco consumption kills over 400,000 Americans, sickens and injures more than 8 million and causes over \$100 billion in economic loss.<sup>1</sup> Previous legislative and regulatory efforts to curb the public health burden imposed by tobacco faltered against the industry's strong ties in Congress, strategies that emphasized ineffective self-regulatory measures, and the U.S. Supreme Court's decision in *FDA v. Brown and Williamson Tobacco Corp.*, which rejected the Clinton Administration's effort to assert FDA authority over tobacco products absent an explicit Congressional mandate to do so.<sup>2</sup> Litigation *had* succeeded, however, as states' attorneys general and private litigants slowly but steadily eroded the industry's invulnerability in the courts, resulting in the Master Settlement Agreement with 46 states and as yet uncertain tort and statutory consumer protection liabilities that may run into the billions of dollars.<sup>3</sup>

Like the Affordable Care Act and Dodd-Frank that followed, the Tobacco Control Act included benefits for the target industry. There are at least two such benefits for tobacco firms in the law. First, the law raises costly barriers to entry for new participants in the tobacco sector, many of which would not have been constrained by the terms that applied to the major manufacturers voluntarily as part of the Master Settlement Agreement, nor without the law, the significant fees now imposed on the tobacco industry to fund FDA oversight. Second, Section 916 of the law provides an explicit, statutory preemption provision that, while ambiguous in important respects explored in this article, gives preemptive effect to certain tobacco

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<sup>1</sup> Barack Obama, President of the United States, Remarks by the President at the Signing of the Family Smoking Prevention and Tobacco Control Act (June 22, 2009), *available at* <http://www.whitehouse.gov/the-press-office/remarks-president-signing-family-smoking-prevention-and-tobacco-control-act>.

<sup>2</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). For the legislative history, including multiple failures, see *infra* note 45.

<sup>3</sup> <http://time.com/3016961/23-6-billion-lawsuit-winner-to-big-tobacco-are-you-awake-now/>

products subjected to FDA premarket review.<sup>4</sup> At issue in that preemption provision is the law's authorization for "modified risk tobacco products" (MRTPs) and associated branding and labeling which, as the public health rationale goes, help current tobacco users consume products with less nicotine or fewer toxic contaminants and therefore reduce their risk of disease or death.<sup>5</sup> Authorized under Section 911 of the Tobacco Control Act, these products include but are not limited to, "low-carcinogen cigarettes, devices that heat tobacco to release nicotine, smokeless tobacco, and novel nicotine products."<sup>6</sup>

There is considerable controversy within the public health community as to the justification for giving legal sanction to MRTPs. While some public health organizations have called reduced risk of tobacco-related disease through "reducing exposure to tobacco toxicants . . . feasible" deceptive tactics used by the tobacco industry revolved around spurious claims about reduced risk especially the use of "light", "ultra-light", "low", "mild" and associated color schemes to falsely communicate the possibility of less harm or even safety of tobacco products.<sup>7</sup> In his comment to the FDA on Section 911, prominent public health scholar Stanton Glantz warned that "modified risk products have a strong potential for simply being the latest chapter in [tobacco companies'] fraud."<sup>8</sup>

This article is the first to analyze the heretofore unanswered question: what is the scope of constitutional preemption when Section 911 (modified risk tobacco products) and Section 916 (preemption of state law) are read together against the broader background of U.S. Supreme Court precedent that will shape that inquiry? The Tobacco Control Act's preemption provision implicates at least two relevant U.S. Supreme Court precedents on the scope of Article VI preemption for FDA-approved products as well as one decision specific to tobacco labeling: *Wyeth v. Levine*, *Riegel v. Medtronic, Inc.* and *Altria v. Good*.<sup>9</sup> While the U.S. Supreme Court's decision in *Wyeth v. Levine* concluded that a clear statement from Congress is necessary to preempt state law causes of action for certain pharmaceuticals, its decision in *Riegel v. Medtronic* suggests that an elaborate FDA approval process with an express preemption clause may suffice to demonstrate complete preemption in the medical device context. Indeed, Section 916's preemption provision closely tracks the preemption provision at issue in *Riegel* (and other statutory schemes) but the law adds a section, a "rule of construction", explicitly protecting causes of action

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<sup>4</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 916, 123 Stat. 1776 (2009).

<sup>5</sup> INST. OF MEDICINE, COMM. ON SCIENTIFIC STANDARDS FOR STUDIES ON MODIFIED RISK TOBACCO PRODUCTS, SCIENTIFIC STANDARDS FOR STUDIES ON MODIFIED RISK TOBACCO PRODUCTS 1-2 (2011) [hereinafter IOM MRTP Report] (citing Family Smoking Prevention and Tobacco Control Act).

<sup>6</sup> Benjamin Mason Meier & Donna Shelley, *The Fourth Pillar of the Framework Convention on Tobacco Control: Harm Reduction and the International Human Right to Health*, 121(5) PUBLIC HEALTH REPORTS 494, 494-500 (2006), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1564445/>.

<sup>7</sup> Mark Parascandola, *Lessons from the History of Tobacco Harm Reduction: The National Cancer Institute's Smoking and Health Program and the "Less Hazardous Cigarette"*, 7 (5) NICOTINE AND TOBACCO RESEARCH 779, 779-789 (2005).

<sup>8</sup> Stanton Glantz, Submission to FDA Docket on Scientific Evaluation of Modified Risk Tobacco Product Applications (September 21, 2011), available at <http://tobacco.ucsf.edu/submission-fda-docket-scientific-evaluation-modified-risk-tobacco-product-applications>.

<sup>9</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Wyeth v. Levine*, 555 U.S. 555 (2009); *Altria v. Good*, 555 U.S. 70 (2008).

based in state product liability law. That “rule of construction” adds an important lens to the statutory interpretation that will determine how extensively, if at all, Congress sought to displace state law regulating modified risk tobacco products.

There is scant guidance from the legislative history on the scope of the law’s preemption provision. In the courts, *Altria v. Good* is the Court’s last statement on preemption of state law causes of action in the tobacco product labeling context and includes important insights into how Section 916 will be construed against modified risk claims. FDA is now considering the first modified risk tobacco product produced by Swedish Match, a firm participating in a joint venture with Philip Morris International, making the question of (and answer to) preemption all the more relevant.

At stake in answering the preemption question correctly is how the tobacco industry may use Section 911 to continue historical practices with FDA’s approval and the public health implications of doing so. Tobacco consumers will inevitably use state law causes of action to allege that the content of tobacco manufacturers’ modified risk claims are misleading, that modified risk claims extend use of non-modified risk claim products, and that modified risk tobacco products are used to shape risk perception across other product lines. More broadly, construction of the preemption provision in the MRTP context will influence the relationship between the 2009 Tobacco Control Act and state law as FDA and federal courts shape the law’s implementation.

The article concludes that Section 916’s preemption provision preserves rather than prevents product liability lawsuits to regulate tobacco firms’ behavior with respect to MRTPs and, relatedly, tobacco product branding and labeling. One of the most effective ways of policing industry use of modified-risk tobacco labeling is product liability claims based on state common law which explains the presence of the statute’s “rule of construction related to product liability.” State tort law causes of action create remedies for tobacco consumers deceived or misled by proposed labeling that nevertheless survives FDA premarket review, consistent with Congress’s intent for FDA regulation to work alongside state law in providing “ongoing oversight” of the tobacco industry.<sup>10</sup>

Part II of this article provides a brief history of tobacco industry practices with respect to reduced-risk claims as well as the regulatory regimes that followed, particularly the Federal Cigarette Labeling and Advertising Act. Part II situates the Tobacco Control Act’s Section 911 premarket review and post-market surveillance processes within this broader history. Part III sets forth the Tobacco Control Act’s Section 916 provision for preserving state regulatory authority over tobacco products excluding exceptions found in Section 916(a)(2)(A). This Part analyzes the statutory text, prefatory Congressional findings, and legislative history to identify and detail the extent of Section 916(a)(2)(A)’s preemptive scope. Given the law’s revolution in Congressional perspective on the role of state law as well as the statute’s purpose and Congressional findings, the most plausible conclusion is that Congress intended to preserve state product liability suits as an additional layer of oversight of MRTP labels and branding. Using Swedish Match’s 2014 modified risk tobacco product application for snus smokeless tobacco as well as other industry documents detailing the intended effect of snus on individual consumers, Part IV demonstrates that the

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<sup>10</sup> Family Smoking Prevention and Tobacco Control Act Public Law § 2(8).

relationship between FDA premarket review of MRTPs and the Tobacco Control Act's preference for complementary state law is indistinguishable from the conclusion reached in *Wyeth v. Levine*. State product liability and related tort claims against MRTPs are therefore not preempted by the law. Part V provides a brief conclusion.

## II. THE TOBACCO HEALTH CLAIMS-REGULATION CYCLE

Before the 2009 Tobacco Control Act provided a statutory allowance for modified risk products, tobacco manufacturers anticipated the market environment that would unfold as conventional cigarettes came under heavier regulatory and tax burdens. Their broad strategy was to place cigarettes—the most hazardous tobacco products for both individual and public health—as part of a broad spectrum of tobacco products that might span a lifetime. Tobacco firms emphasized their history and experience as part of their case for MRTPs. “[T]he concept of harm reduction is well established at British American Tobacco. For decades, [our] scientists . . . have been investigating the links between tobacco and smoking-related diseases.”<sup>11</sup> Similarly, “R.J. Reynolds has a long history of efforts to reduce the harm caused by cigarettes . . . this new regulatory environment [is] an opportunity to work more closely with the government and the public health community to make significant progress in terms of tobacco harm reduction.”<sup>12</sup>

### A. Historical Practices around Reduced Risk

BAT's and RJR's statements tell some of the story. Between the 1930s and the 1950s, tobacco manufacturers steepened two related investments. The first was in national advertising and marketing campaigns which aimed at capturing larger shares of the cigarette market revolutionized by RJ Reynolds' introduction of the Camel cigarette.<sup>13</sup> This investment, in turn, shaped the trajectory of the second: research centers aimed at studying tobacco's chemical properties to generate evidence supporting the campaigns. Along the way, these research centers learned and exploited the addictive properties of nicotine and manipulated tobacco product ingredients and product designs to facilitate addiction.<sup>14</sup>

Health claims occupied central ground in tobacco firms' battle for market share (the campaigns' objective of increased consumption and initiation was shared across firms). Firms advertised that doctors preferred their brand of cigarette; mentholated cigarettes treated colds; the use of one component or another diminished throat irritation more than other brands; and, filtered cigarettes were “better for your health.”<sup>15</sup> The aim of the research was not to reduce the harms of tobacco

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<sup>11</sup> British American Tobacco, EU Social Report 2006/07, Harm Reduction, available at [http://www.batresponsibility.eu/sr0607\\_harmreduction.html](http://www.batresponsibility.eu/sr0607_harmreduction.html).

<sup>12</sup> RJ Reynolds, Harm Reduction and Product Integrity, available at <http://www.reynoldsamerican.com/harm.cfm?plank=harm1>.

<sup>13</sup> JORDAN GOODMAN, TOBACCO IN HISTORY: CULTURES OF DEPENDENCE 102 (1993).

<sup>14</sup> STANTON A. GLANTZ ET. AL., THE CIGARETTE PAPERS 26 (1996).

<sup>15</sup> *More Doctors Smoke Camels Than Any Other Cigarette*, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, TRUTH TOBACCO INDUSTRY DOCUMENTS (July 11, 1950), <http://legacy.library.ucsf.edu/tid/gig88d00>; *70 Years of Menthol Cigarette Ads*, HEALTH, 2 of 16, [http://www.health.com/health/gallery/0\\_20388015\\_00.html](http://www.health.com/health/gallery/0_20388015_00.html) (mentholated cigarettes good for colds); John Slade, *Nicotine Delivery Devices*, CONFERENCE ON THE FTC CIGARETTE TEST MODEL 4, 8 (1994), <http://legacy.library.ucsf.edu/tid>

consumption but rather to capture larger market share.<sup>16</sup> As a 1958 Philip Morris memorandum quipped:

I know this sounds like a wild program, but I'll bet that the first company to produce a cigarette claiming: a substantial reduction . . . in tars and nicotine, or an ersatz cigarette whose smoke contains no tobacco tars, and with good smoking flavor, will take the market . . . Of course, we would have to be careful to infer that the reason for the change in dress was the continuing evidence linking cigarette smoking with health, and that although the evidence is not altogether irrefutable we have decided upon this course of action in the public interest. In this way, we have protected our bridges behind us because we have not admitted there is a direct relation between smoking and health, and we are building new bridges ahead which we will need if there is a flood . . .  
”<sup>17</sup>

The earliest challenges to these health claims took three major forms: tort litigation against the major tobacco firms, findings from credible and unaffiliated medical researchers, and regulatory responses to the mounting medical evidence that contradicted tobacco firms' health claims.<sup>18</sup> In 1954, St. Louis factory worker Ira C. Lowe sued R.J. Reynolds for the loss of his lung to cancer. A lifelong smoker of Camel cigarettes, Mr. Lowe stated “[n]aturally, I didn't want to hurt my health, and naturally, through their advertising, why [R.J. Reynolds] assured me that Camels wouldn't hurt my health. In fact, that they would help me.”<sup>19</sup> During this period, independent medical researchers established an irrefutable relationship between smoking and disease, particularly lung cancer. In response to the growing evidence, tobacco companies conspired to create evidence disputing the link between smoking and health risks.<sup>20</sup> This campaign enabled tobacco manufacturers to defeat suits like Lowe's since they could successfully point to ostensibly credible evidence to question smoking's link to disease. By 1964, the first Surgeon General's Report summarized the medical evidence with greater certainty, concluding that “cigarette

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/yas85b00 (use of glycol reduces throat irritation); *Filtered Cigarette Smoke is Better for Your Health*, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, TRUTH TOBACCO INDUSTRY DOCUMENTS, <http://legacy.library.ucsf.edu/tid/gth50a99>.

<sup>16</sup> T. Abrams, et al. for Jones, Day, Reavis & Pogue, undated attorney work product for Brown & Williamson. B&Wdocument 681879254/715.

<sup>17</sup> Memorandum, *Brief Comments on a Program to Produce a Low Delivery Filter Cigarette with Flavor*, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, TRUTH TOBACCO INDUSTRY DOCUMENTS (July 24, 1958), <http://legacy.library.ucsf.edu/tid/bcf56b00>.

<sup>18</sup> Medical evidence associating cigarette-smoking with cancer had only begun to emerge. *New York Times*, Smoking Found Tied to Cancer of Lungs; 94.1 % of Males Studies Used Cigarettes, 1950, 27 May; Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation*, 107 YALE L.J. 1163, 1263-1315 (1998).

<sup>19</sup> TOBACCODOCUMENTS.ORG, [http://tobaccodocuments.org/industry\\_depositions/500502527-2585.html](http://tobaccodocuments.org/industry_depositions/500502527-2585.html).

<sup>20</sup> *United States v. Philip Morris USA, Inc.*, 449 F.Supp.2d 1, 417 (D.D.C. 2006).

smoking contributes substantially to mortality from certain specific diseases and to the overall death rate.”<sup>21</sup>

The Surgeon General’s Report opened a range of regulatory options including federal oversight by the FTC and FCC as well as regulation by the states.<sup>22</sup> Instead, tobacco firms succeeded in lobbying for the Federal Cigarette Labeling and Advertising Act (FCLAA) which required cigarette packages and advertising to contain warnings. Tobacco industry interests steered the regulatory debate away from federal agencies, state and local governments and toward Congress where it secured a labeling and warning regime understood, even in 1964, to “serve no useful purpose” in terms of affecting consumers’ behavior.<sup>23</sup> The cycle was repeated in 1969 when, facing the lapse of the 1965 warning regime, the industry again moved the regulatory debate from the FTC, the FCC and state governments to Congress, which gently strengthened the national warning.<sup>24</sup> When Congress changed the warning from cigarettes “may be hazardous” to smoking “is dangerous” they also broadened the scope of the federal warning requirement’s preemptive effect on state law.<sup>25</sup>

Federal law therefore supplied manufacturers—who from the 1940s knew significantly more about nicotine and tobacco than independent researchers or consumers – with two insurmountable defenses. First, tobacco firms argued that Congress intended to preempt any differing forms of state regulation, including common law causes of action. Failure-to-warn suits force manufacturers, who frequently possess more information about products (and how they are used) than consumers, to disclose information so as to ensure safe products and safe use. Strict liability places a financial incentive on firms to maximize investments in safe product design. Second, when their preemption arguments failed, manufacturers argued that consumers, warned by Congress, assumed the risk of smoking or contributed to their own injuries.<sup>26</sup>

In the 1970s, no longer able to assert smoking’s health benefits, manufacturers created and marketed “reduced risk” cigarettes and focused their marketing on

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<sup>21</sup> U.S. DEP’T OF HEALTH EDUC. AND WELFARE, *SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE* (1964), available at <http://profiles.nlm.nih.gov/ps/access/NNBBMQ.pdf>.

<sup>22</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513 (1992) (“the Federal Trade Commission (FTC), which had long regulated unfair and deceptive advertising practices in the cigarette industry, promulgated a new trade regulation rule. That rule, which was to take effect January 1, 1965, established that it would be a violation of the Federal Trade Commission Act ‘to fail to disclose, clearly and prominently, in all advertising and on every pack, box, carton, or container [of cigarettes] that cigarette smoking is dangerous to health and may cause death from cancer and other diseases.’ 29 Fed.Reg. 8325 (1964). Several States also moved to regulate the advertising and labeling of cigarettes. See, e.g., 1965 N.Y.Laws, ch. 470; see also 111 Cong.Rec. 13900-13902 (1965) (statement of Sen. Moss).”).

<sup>23</sup> FTC HEARING ON PROPOSED TRADE REGULATION RULES: THREE DAYS OF HEARINGS COMPLETED ON PROPOSALS FOR THE ADVERTISING AND LABELLING OF CIGARETTES 4 (1964), available at <http://legacy.library.ucsf.edu/tid/lau71b00> (citing statement submitted by the American Medical Association).

<sup>24</sup> *Cipollone v. Liggett Group*, 505 U.S. at 514-15.

<sup>25</sup> See *id.* at 515 (citing Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87, amended by 15 U.S.C. §§ 1331-1340).

<sup>26</sup> Graham E. Kelder, Jr. & Richard A. Daynard, *The Role of Litigation in the Effective Control of the Sale and Use of Tobacco*, 8 STAN. L. & POL’Y REV. 63, 98 (1997).

adolescents.<sup>27</sup> The two strategies were related. Marketing “light”, “ultra-light”, and similar brands led health-conscious consumers to choose those alternatives believing that a “light” cigarette was safer than a “full flavor” cigarette.<sup>28</sup> Marketing light cigarettes simultaneously attracted “health conscious” consumers to light cigarettes but also implicitly associated non-light brands with rebelliousness and independence in ways that appealed to adolescents.<sup>29</sup> Foreshadowing concerns with MRTPs, marketing light cigarettes was accomplished using the Cambridge Filter Method, results from which the FTC and the International Standards Organization allowed tobacco firms to use when making “light” and “low” claims. RJ Reynolds knew the test did not accurately model smokers’ tar or nicotine intake as early as 1971.<sup>30</sup> In 1974, an internal Philip Morris memorandum raised a “moral issue on FTC tar”—whether to “reveal to the FTC the fact that some cigarette smokers may be getting more tar than the FTC rating of that cigarette.”<sup>31</sup> While the FTC has abandoned the test, manufacturers still implicitly endorse the FTC/ISO standard and, in particular, advocate that the ISO serve as the global clearinghouse for measuring reduced yields of nicotine or toxic agents.<sup>32</sup>

Again, private tort litigants brought the earliest and most accurate allegations against these practices. The most famous of these, filed on behalf of Rose Cipollone—whose lifelong smoking behavior responded to the changing campaigns aimed at her -- accused the major tobacco firms of neutralizing mandatory warnings with comprehensive efforts to mislead and deceive about smoking risks. In *Cipollone v. Liggett Group*, the tobacco manufacturer was charged with producing a product it knew contained hidden risks not apparent or known to the consumer and intentionally misleading that consumer by referring to the product as “light.”<sup>33</sup> The

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<sup>27</sup> R.J. REYNOLDS, PLANNING ASSUMPTIONS AND FORECAST FOR THE PERIOD 1977-1986 14 (1976), available at <http://legacy.library.ucsf.edu/tid/bzb78d00> (“Evidence is now available to indicate that the 14-18 year old group is an increasing segment of the smoking population. RJR-T must soon establish a successful new brand in this market if our position in the industry is to be maintained in the long term.”); Memorandum from R. L. Johnson, Brand Manager, Brown & Williamson, to R. A. Pittman, Exec. Vice President, Brown & Williamson (Feb. 21, 1973), available at <http://legacy.library.ucsf.edu/tid/tqu04f00> (“KOOL’s stake in the 16 – 25 year old population segment is such that the value of this audience should be accurately weighted and reflected in current media programs. . . . [A]ll magazines will be reviewed to see how efficiently they reach this group . . . .”); Memorandum from T. L. Achey to Curtis Judge, President, Lorillard Tobacco Company (Aug. 30, 1978), available at <http://legacy.library.ucsf.edu/tid/cmt22f00> (“Our profile taken locally shows this brand being purchased by black people (all ages), young adults (usually college age), but the base of our business is the high school student. NEWPORT in the 1970’s is turning into the Marlboro of the 60’s and 70’s. It is the ‘In’ brand to smoke if you want to be one of the group.”).

<sup>28</sup> *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006). Light and low marketing was intended to “keep smokers smoking; to stop smokers from quitting; to encourage people, especially young people, to start smoking; and to maintain or increase corporate profits.”

<sup>29</sup> PHILIP MORRIS, SMOKER PERSONALITY/LIFESTYLE, available at <http://legacy.library.ucsf.edu/tid/kyu76e00>.

<sup>30</sup> UNKNOWN INDIVIDUAL AT RJ REYNOLDS, PUFF PROFILE PAPER (1971), available at <http://legacy.library.ucsf.edu/tid/dse89d00>.

<sup>31</sup> Memorandum from R. Fagan to H. Wakeham, *Moral Issue on FTC Tar* (Mar. 7, 1974), available at <http://legacy.library.ucsf.edu/tid/dra50i00>.

<sup>32</sup> British American Tobacco, Docket No. FDA-2009-N-0294 Regulation of Tobacco Products: Request for Comments (Sept. 29, 2009) available at [http://www.bat.com/group/sites/uk\\_\\_3mnfen.nsf/vwPagesWebLive/DO52AMGZ/\\$FILE/medMD7WECL5.pdf?openement](http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO52AMGZ/$FILE/medMD7WECL5.pdf?openement).

<sup>33</sup> *Altria v. Good*, 555 U.S. 70, 75 (2008).

*Cipollone* Court framed the relevant preemption question as: whether the legal duty that is the predicate of the common-law damages action constitutes a “requirement or prohibition based on smoking and health...with respect to...advertising or promotion,” giving that clause a fair but narrow reading.<sup>34</sup> The Court articulated the plaintiffs’ claim as asserting that cigarette manufacturers may have fraudulently misrepresented and concealed a material fact, and that claim was not preempted because it was ultimately a violation of the manufacturer’s duty not to deceive.<sup>35</sup> While the FCLAA broadly preempted state law torts, it did not preempt causes of action that could be articulated separately from the relationship between smoking and health, like a manufacturer’s duty not to deceive.<sup>36</sup> *Cipollone* paved the way for exposing tobacco firms’ deceptive practices through documents obtained in adversarial litigation.

*Altria v. Good* represented the last of the decisions issued by the U.S. Supreme Court on the relationship between the FCLAA and state law torts aimed at holding tobacco firms liable for tactics that either deceived consumers directly or endeavored to neutralize the Congressionally-mandated warnings.<sup>37</sup> The plaintiffs in *Altria* sued tobacco manufacturer Philip Morris claiming the manufacturer fraudulently advertised its “light” cigarettes, e.g. Marlboro Lights, as delivering less tar and nicotine to consumers than regular brands, despite the manufacturer having knowledge that this advertising was untrue.<sup>38</sup> The plaintiffs asserted that Philip Morris deliberately deceived them about the true and harmful nature of “light” cigarettes in violation of the Maine Unfair Trade Practices Act (MUTPA), by advertising such tobacco products posed fewer health risks.<sup>39</sup>

The *Altria* Court concluded the plaintiffs’ claims fell within the permissible claims authorized under *Cipollone*.<sup>40</sup> Like in *Cipollone*, deceptive statements such as the use of “light” and “lowered tar and nicotine” induced the plaintiffs in *Altria* to purchase the products and they properly alleged the violation of a duty to not deceive.<sup>41</sup> The *Altria* Court concluded that the presence of federally mandated warnings may “bear on the materiality of the fraudulent statements, but that fact does not change the case from one about the statements into one about the warnings.”<sup>42</sup>

U.S. states followed tort plaintiffs, arguing that tobacco manufacturers should pay for the health costs their products imposed.<sup>43</sup> In 1999, the U.S. government brought a RICO action against nine cigarette manufacturers and two trade groups for

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<sup>34</sup> *Id.* at 80.

<sup>35</sup> *Id.* at 81.

<sup>36</sup> *Cipollone v. Liggett Group*, 505 U.S. at 528-29 (“Such claims are predicated not on a duty ‘based on smoking and health’ but rather on a more general obligation: the duty not to deceive.”).

<sup>37</sup> *Altria v. Good*, 555 U.S. at 77.

<sup>38</sup> *Id.* at 73.

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* at 82-83.

<sup>43</sup> Jonathan Gruber, *The Economics of Tobacco Regulation*, 21 HEALTH AFFAIRS 146 (2002) (“In May 1994 the State of Mississippi filed a lawsuit against the industry to recover the lost medical costs to the state from smoking-related illness, and a number of other states soon did likewise”).

conspiring to deceive consumers about the health risks of tobacco products.<sup>44</sup> These suits led to the passage of the Tobacco Control Act in 2009.<sup>45</sup>

*B. The Tobacco Control Act's Modified Risk Tobacco Product Review Process*

Despite this history, Congress made allowance for modified risk claims in the Tobacco Control Act on the theory that such “harm reduction” products may play a role in achieving the individual and public health objectives behind the law. Section 911 of the Tobacco Control Act prohibits health claims until scientific evidence supports meaningful conclusions.<sup>46</sup> When an MRTP applicant represents that a tobacco product is less harmful than other tobacco products, that representation may only be made for a tobacco product (1) as it is used by consumers, (2) that significantly reduces the risk of tobacco-related disease, (3) to individual tobacco users; and (4) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.<sup>47</sup>

Section 911(l) requires FDA to consult with the U.S. Institute of Medicine which has issued two key reports, *Clearing the Smoke: the Science Base for Tobacco Harm Reduction* in 2001 and *Scientific Standards for Studies on Modified Risk Tobacco Products* in 2011. Generally speaking, the major tobacco firms advocate that FDA make greater use of principles articulated in the former when issuing guidance and regulations under Section 911 while public health experts favor principles consistent with the latter.<sup>48</sup>

Tobacco firms and their scientific and marketing agents advocate at least the following positions. First, FDA should demand less data about products already in the market for which “a significant amount of scientific data exists.”<sup>49</sup> Second, FDA should be “flexible” in its scientific standards so as not to erect insuperable obstacles to the introduction of new, harm-reducing tobacco products.<sup>50</sup> Third, FDA should view the introduction of MRTPs as part of a comprehensive effort to assist in the “migration” from one end of the dangerous product risk spectrum to the other.<sup>51</sup> This

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<sup>44</sup> *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006).

<sup>45</sup> In 1996, FDA asserted jurisdiction over tobacco products, but in 2000, the Supreme Court ruled that only Congress could give FDA authority over tobacco. In 2001, Senators Kennedy and DeWine introduced the forerunner of the Tobacco Control Act and re-introduced it in 2004 when it finally passed the Senate. In 2008, the House passed a companion bill too late for the Senate to act upon it. On April 2, 2009, the House approved the current legislation with 298 votes; on June 11, the Senate approved the law with 97 votes.

<sup>46</sup> *Tobacco Control Act* 2009, §911(g)(2)

<sup>47</sup> 21 U.S.C. §387(k).

<sup>48</sup> Altria Client Services, Docket No. FDA-2011-N-443 (76 Fed. Reg. 120 (Wednesday, June 22, 2011), *Scientific Evaluation of Modified Risk Tobacco Products*, p. 7 (“The 2001 IOM Report provides a basic framework that FDA can use for MRTP evaluations.”); [http://www.bat.com/group/sites/uk3mnfen.nsf/vwPagesWebLive/DOS2AMGZ/\\$FILE/medMD7WECL5.pdf?openement](http://www.bat.com/group/sites/uk3mnfen.nsf/vwPagesWebLive/DOS2AMGZ/$FILE/medMD7WECL5.pdf?openement) (BAT submission favoring use of the 2001 IOM Report).

<sup>49</sup> Jeffrey Walker, Transcript of FDA Public Workshop: Scientific Evaluation of Modified Risk Tobacco Product (MRTP) Applications (Aug. 25, 2011) p. 111.

<sup>50</sup> Altria Client Services, Docket No. FDA-2011-N-443 (76 Fed. Reg. 120 (Wednesday, June 22, 2011), *Scientific Evaluation of Modified Risk Tobacco Products*, p. 28.

<sup>51</sup> Altria Client Services, Docket No. FDA-2011-N-443 (76 Fed. Reg. 120 (Wednesday, June 22, 2011), *Scientific Evaluation of Modified Risk Tobacco Products*, p. 5.

effort includes leeway for trial-and-error to find products consumers “like and accept”, advance through “adult feedback” so that the marketplace itself will produce evidence of where “adult consumers of tobacco products will decide through their actions in the marketplace the outcome of . . . collective efforts to reduce harm.”<sup>52</sup>

Public health experts urge FDA to adopt more rigorous standards for every stage of MRTP approval including laboratory comparison between conventional products and MRTPs, animal and human studies, toxicant exposures using known biomarker measurements (but making sure to remain aware of others), as well as post-market surveillance including surveillance and consumer use, claims and messaging evaluation, epidemiology and intervention studies paying attention to how products change and how people use the different products differently over time.<sup>53</sup> Under the law, FDA must take into account the effect of all of whatever data it demands on initiation, cessation as well as individual and aggregate disease prevalence. Some public health scholars concede the extreme difficulty of capturing all relevant variables. As Ralph Caraballo, the branch chief of the Epidemiology Branch in the Office on Smoking and Health at the National Center for Chronic Disease Prevention and Health Promotion at CDC, conceded mid-way through the first day of a two-day FDA workshop “Yes, I am a little bit confused about what an MRTP is.”<sup>54</sup> However, there is an assumption in some parts of the public health community that given sufficient resources, including time, scientists will be able to create a workable, public health-oriented MRTP application, marketing and monitoring framework.<sup>55</sup> Yet even the most optimistic concede at least two important weaknesses: first, any MRTP application and review process will be product-specific<sup>56</sup> and second, post-marketing surveillance is historically an FDA weakness.<sup>57</sup>

The problem is compounded by two additional aspects of the Section 911 process. First, by its terms, Section 911 gives the MRTP applicant default control over the principal investigator, methods and objectives of the post-surveillance protocol.<sup>58</sup> While the statute gives a 30-day window for applicants to submit the protocol, it will inevitably have been developed parallel to the pre-marketing and pre-claims tests to

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<sup>52</sup> Altria Client Services, Docket No. FDA-2011-N-443 (76 Fed. Reg. 120 (Wednesday, June 22, 2011), Scientific Evaluation of Modified Risk Tobacco Products, p. 5-6.

<sup>53</sup> See U.S. Institute of Medicine, *Scientific Standards for Studies on Modified Risk Tobacco Products* 73-148 (2011).

<sup>54</sup> Ralph Caraballo, Transcript of FDA Public Workshop: Scientific Evaluation of Modified Risk Tobacco Product (MRTP) Applications (Aug. 25, 2011) p. 249.

<sup>55</sup> Timothy McAfee, Transcript of FDA Public Workshop: Scientific Evaluation of Modified Risk Tobacco Product (MRTP) Applications (Aug. 25, 2011) p. 386.

<sup>56</sup> Peter Shields, Transcript of FDA Public Workshop: Scientific Evaluation of Modified Risk Tobacco Product (MRTP) Applications (Aug. 25, 2011) p. 31-32.

<sup>57</sup> Efthimios Parasidis, *Patients over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WISC. L. REV. 5 (2011).

<sup>58</sup> Section 911(i)(2) (“Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Secretary as necessary to protect the public health.”)

maximize the chance that post-marketing data confirms the applicant's claims.<sup>59</sup> FDA's Center for Tobacco Products will have only 60 days to question the principal investigator, the research methods or other aspects of the protocol.<sup>60</sup> Second, every MRTP application must be referred to FDA's Tobacco Products Scientific Advisory Committee, (TPSAC) where tobacco industry representatives are able to influence the review of MRTP applications through argument and presentation of industry-generated data even if not through direct votes.<sup>61</sup>

The Tobacco Control Act attempts to secure the legitimacy of authorized health claims on tobacco products through specific safeguards. MRTP applicants must file an extensive application with FDA accompanied by evidence as to the MRTP's manufacture, intended marketing and effect of marketing on consumers; review under both individual and population health harm reduction standards; self-terminating authorizations; and, post-marketing surveillance.<sup>62</sup> The question is whether these safeguards are sufficient to prevent a recurrence of the "light" and "low" episode in which tobacco firms manipulated both the FTC and the consuming public into belief in a "safer" cigarette, or whether Congress must add measures to protect the public from the marketing industry built around tobacco consumption. While the law immediately subjected products described as "light" and "low" to MRTP review, it allows comparisons between product categories, such as between cigarettes and smokeless tobacco.

It is unlikely that regulators will be able, even with long-term epidemiological evidence, to comprehensively identify and prohibit practices with which the tobacco industry has far more experience and familiarity. Cigarette companies accompanied terms like "light" and "ultra-light" with color tones and contrasts and container consistency to shape health perceptions. For example, "refinements in the package consist[ing] mainly of increasing the amount of white space on the pack and lightening the brown color tones . . . [gave] the revised package the appearance of reduced strength."<sup>63</sup> Researchers at Philip Morris discovered that soft packs conveyed different levels of cigarette strength than hard packs.<sup>64</sup>

After adoption of Section 911's prohibition on these modifiers, when consumers request "Camel Lights," they are presented with "Camel Blues" and if they request "Marlboro Lights" they are presented with the familiar white and gold package that, as the law requires, no longer displays the word "Lights."<sup>65</sup> Tobacco manufacturers did not respond to recent legal prohibitions on "light" and "low"; "light" and "low" were only part of a far wider campaign to shape risk perception. Depending on

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<sup>59</sup> This is one of the reasons the IOM recommended independent third parties undertake the postmarketing surveillance studies.

<sup>60</sup> Section 911(i)(2).

<sup>61</sup> 21 U.S.C. § 387(a) (2009).

<sup>62</sup> See 21 USC § 387k(b).

<sup>63</sup> E. Etzel, Consumer research proposal: Camel Filter revised packaging Test Study. RJ Reynolds. March 2, 1979 *available at* <http://legacy.library.ucsf.edu/tid/qxb79d00>.

<sup>64</sup> See D. Dennis, Memo to CP Loh: The effects of soft pack versus box packaging of test cigarettes on consumer perceptions. Philip Morris. August 26, 1982 *available at* <http://legacy.library.ucsf.edu/tid/lfv92e00> noting that cigarettes in soft packs were perceived to be stronger than those in boxes.

<sup>65</sup> See Press Release, Frank R. Lautenberg, Lautenberg, Durbin Warn Tobacco Companies Not to Engage in Misleading Cigarette Advertising (June 17, 2010) *available at* <http://lautenberg.senate.gov/newsroom/record.cfm?id=325753>.

FDA's guidance, there will be a strong set of incentives (that have historically driven tobacco industry behavior) for MRTP applications and post-surveillance protocols to be shaped to maximize the appearance of relative reduction in risk of a given tobacco product while obscuring behavioral and environmental factors which lead to parity in overall disease risk in an individual user, dual use of hazardous tobacco products or delays in cessation.

Tobacco manufacturers and their affiliated marketers remain free to use many aspects of tobacco product packaging, labeling and advertising to increase demand for the full range of their products.<sup>66</sup> The Tobacco Control Act prohibits FDA from banning cigarettes or requiring cigarettes' nicotine yields be reduced to zero and exempts the following descriptors from regulation under Section 911: "smokeless tobacco", "smokeless tobacco product", "not consumed by smoking", "does not produce smoke", "smokefree", "smoke-free", "without smoke", "no smoke", or "not smoke."<sup>67</sup> The Tobacco Control Act attempted to address through graphic warnings and marketing restrictions the possibility that these modifiers might be misleadingly contrasted with combustible smoking products to shape health perceptions. The law provides for advertising and marketing restrictions as well as more effective warning labels covering 50% of the top half of the front and back of each package.<sup>68</sup> Tobacco manufacturers have already succeeded in blocking the graphic warnings, ensuring years will pass before they are implemented, if ever.<sup>69</sup>

The result is that tobacco companies are empowered to shape their MRTP applications' product delivery and use data, "substantial" harm reduction claims, clinical trial results, consumer use and perception studies and post-market surveillance protocols to emphasize review of the product and consumers using the product while the actual labeling, marketing and promotion of the MRTPs will occur against a backdrop of the full range of legally protected products including pricing structure, brand diffusion, packaging color, size, shape, retail store placement, implied messages between cigarette lines; between cigarettes and smokeless lines; between smokeless lines. All of this is to say nothing of the infinite number of types of claims and whether they are "substantial" within the meaning of the statute or FDA's forthcoming regulations, some or all of which tobacco firms are quite likely to challenge.

### **III. THE PREEMPTIVE EFFECT OF AN FDA-APPROVED MODIFIED RISK TOBACCO PRODUCT LABEL**

The aforementioned history strongly suggests that, after FDA approves a modified risk tobacco product label, consumers injured by tobacco consumption will identify one or more ways in which the MRTP applicant affirmatively or impliedly misled them about the tobacco consumption-promoting intent behind the label, the kind of

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<sup>66</sup> E. Etzel, Consumer research proposal: Camel Filter revised packaging Test Study. RJ Reynolds. March 2, 1979 available at [http://legacy.library.ucsf.edu/tid/qxb79d00\\_American Cancer Society, Cancer Action Network et al., Deadly in Pink: Big Tobacco Steps Up its Targeting of Women and Girls, at 2 \(2009\)](http://legacy.library.ucsf.edu/tid/qxb79d00_American Cancer Society, Cancer Action Network et al., Deadly in Pink: Big Tobacco Steps Up its Targeting of Women and Girls, at 2 (2009), available at http://www.tobaccofreekids.org/deadlyinpink), available at <http://www.tobaccofreekids.org/deadlyinpink>.

<sup>67</sup> Section 911(g)(B)(iii)(C).

<sup>68</sup> 15 U.S.C. § 1333(b)(2).

<sup>69</sup> *RJReynolds v. FDA*, 696 F.3d 1205, 1222 (D.C. Cir. 2012), overruled in part by *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

consumption the label actually caused, as well as the delay use of the MRTP caused the consumer in ultimately ceasing tobacco use. Those claims may be based on a number of theories including failure-to-warn, strict products liability, as well as common law fraud. Courts will be forced to determine whether the process Congress set forth in Section 911 was intended to prevent those claims from serving as an additional check on industry behavior.

### A. *Article VI Preemption*

Article VI of the U.S. Constitution, the Supremacy Clause, subordinates, limits, or renders void state law that conflicts with federal law adopted pursuant to constitutional authority.<sup>70</sup> Preemption effectively divides control over certain regulatory issue areas between the federal government and the states, although regulatory regimes often overlap.<sup>71</sup> While it is now regarded as an expansive doctrine for federal authority, the Framers viewed it as essential to avoid state nullification of federal law.<sup>72</sup>

Preemption of state law may be express or implied.<sup>73</sup> Courts may and do apply either or both to preempt state law whether statutory, administrative or judicially fashioned.<sup>74</sup> Express preemption occurs when a federal statute contains a preemption clause that explicitly confirms Congress's intention to preempt state law. Where a question of preemption arises, it centers on the preemption clause's scope.

Implied preemption is inferred from a federal statute's structure and purpose in the absence of an express provision.<sup>75</sup> There are three types of implied preemption: (1) impossibility preemption; (2) obstacle preemption; and (3) field preemption. Impossibility preemption applies when the state and federal law are in direct conflict, making it impossible for a party to comply with both regulations.<sup>76</sup> Obstacle preemption arises when it is possible for a party to comply with both the state and federal law, but the state law imposes an obstacle to compliance with the federal law as to hinder the advancement of the policies behind the federal law.<sup>77</sup> Field preemption arises when the federal regulatory scheme of Congress is so prevalent as to occupy the field of law to warrant an inference that Congress did not intend the states to supplement it.<sup>78</sup> Implied preemption doctrines may ultimately invalidate

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<sup>70</sup> U.S. Const. art. VI. Cl. 2. The Supremacy Clause states that "This constitution, and the Laws of the United States which shall be made in pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."

<sup>71</sup> Janelle C. Sharpe, *Legislating Preemption*, 53 WM. & MARY L. REV. 163 (2011).

<sup>72</sup> Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 231-32 (2000).

<sup>73</sup> Michael K. Carrier, *Federal Preemption of Common Law Tort Awards by the Federal Food, Drug, and Cosmetic Act*, 51 FOOD & DRUG L.J. 509, 510 (1996).

<sup>74</sup> See, e.g. 29 U.S.C. §§ 151-187 (1982) (preempting state common law prohibiting strikes); 17 U.S. Code § 301 (preempting state statutes and common law in the copyright context).

<sup>75</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) ("Congress' intent may be "explicitly stated in the statute's language or implicitly contained in its structure and purpose." In the absence of an express congressional command, state law is preempted if that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field "as to make reasonable the inference that Congress left no room for the States to supplement it."").

<sup>76</sup> *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002).

<sup>77</sup> *Crosby v. National Foreign Trade Council*, 530 U.S. 363 (2000).

<sup>78</sup> Stephen Guardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 775 (1994).

state law, even where an express preemption clause appears to “save” state regulatory authority.<sup>79</sup>

In applying a preemption analysis, courts will consider: (1) the existence of a preemption or savings clause in the statute or rule; (2) the precise wording of an applicable preemption or savings clause; (3) the comprehensiveness of the federal scheme; and (4) the opinion of the relevant federal agency.<sup>80</sup> Other factors courts consider are: (1) whether the state law at issue is positive or common in nature; (2) whether the state law is parallel to the federal law or different from or in addition to the federal law; and (3) whether preemption would leave an injured plaintiff without a remedy.<sup>81</sup> The intent of Congress is always the touchstone in both express and implied preemption analyses.<sup>82</sup>

The default presumption in most circumstances is against preemption, especially in subject areas where states have traditionally occupied principal regulatory roles like health and safety.<sup>83</sup> The presumption against preemption exists to limit the scope of preemption, even where it applies.<sup>84</sup> The presumption against preemption may be overcome by a strong indication of Congressional intent to displace state law.<sup>85</sup>

### B. *Preemption and FDA Regulated Products*

Because the FDA’s Congressional mandate is to both protect and promote public health, its activities have always overlapped with areas traditionally regulated by the states. Congress enacted the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. (FDCA) precisely because states and the general public called for a federal role in battling the sale and distribution of unsafe or fraudulently marketed medicines.<sup>86</sup> To ensure safety and efficacy, the FDCA grants FDA authority to oversee premarket approval of new drugs and high-risk medical devices.<sup>87</sup>

The FDCA contains varying preemption and savings clauses applicable to prescription drugs, non-prescription drugs, and medical devices.<sup>88</sup> Congress has not

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<sup>79</sup> Sprietsma, *supra*, note 61.

<sup>80</sup> Geier v. American Honda Motor Co., 529 U.S. 861, 868, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000) (analyzing preemption begins with explicit statutory language); Fellner v. Tri-Union Seafoods LLC, 539 F.3d 237, 244 (2008) (applying preemption analysis, courts examine comprehensiveness of federal scheme).

<sup>81</sup> Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (invoking distinction between positive and common law); Mary Davis, *The “New” Presumption Against Preemption*, 61 HASTINGS L.J. 1217, 1227 (2010) (noting Supreme Court cases in which courts analyzed availability of a remedy as a preemption factor).

<sup>82</sup> Medtronic v. Lohr, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (“ [t]he purpose of Congress is the ultimate touchstone” in every preemption case”).

<sup>83</sup> Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992); Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947); Howard L. Dorfman, Vivian M. Quinn, and Elizabeth A. Brophy, *Presumption of Innocence: FDA’s Authority to Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate*, 61 FOOD & DRUG L.J. 585, 596 (2006).

<sup>84</sup> Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).

<sup>85</sup> See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 1194 (2009).

<sup>86</sup> Food, Drug, and Cosmetic Act, ch. 866, 48 Stat. 1275 (1934).

<sup>87</sup> *Bates v. Dow AgroSciences, LLC*, 544 U.S. 431, 449 (2005).

<sup>88</sup> *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2482, 2484, 2492 (2013).

generally expressed an intent to occupy the field.<sup>89</sup> As a result, state court relief is possible without an implied conflict with the FDCA or regulations adopted pursuant thereto.<sup>90</sup> The burden of proof to show that a new drug is safe for use shifted to the manufacturer upon the 1962 amendments to the FDCA.<sup>91</sup> The 1962 amendments further included a savings clause in which the FDCA only preempted state law when it directly and positively conflicted with the FDCA.<sup>92</sup> Congress amended the FDCA again in 2007, giving the FDA statutory authority to require drug manufacturers to change their drug labels based on safety information that becomes available after the drug is approved.<sup>93</sup> In the 2007 amendments, Congress adopted a “rule of construction” to make it clear that manufacturers remain responsible for updating their labels.<sup>94</sup>

In 1976, Congress passed the Medical Device Amendments, which amended the FDCA in order to “provide for the safety and effectiveness of medical devices intended for human use, and for other purposes.”<sup>95</sup> The law gave the FDA increased authority over medical device regulation.<sup>96</sup> For high-risk Class III medical devices like pacemakers, heart valves, prostheses, and bone screws, a premarket approval process, the “the most rigorous FDA scrutiny available under federal law” aims at ensuring those devices’ safety and effectiveness.<sup>97</sup> Unlike the FDCA, which contains a savings clause, the Medical Devices Amendments include an express preemption clause that provides “no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to any requirement applicable under this chapter to the device, and . . . which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.”<sup>98</sup>

The U.S. Supreme Court has clarified the reach and scope of express and implied preemption doctrines in several FDA-regulated product categories.

### 1. *Riegel v. Medtronic, Inc.*

The plaintiff in *Riegel* was injured when an Evergreen Balloon Catheter, a Class III device which had been approved by the FDA through the pre-marketing approval process, ruptured during a coronary angioplasty procedure.<sup>99</sup> The issue addressed by the U.S. Supreme Court was whether the Medical Device Amendments’ express preemption clause “bars common law claims challenging the safety and effectiveness

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<sup>89</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

<sup>90</sup> *Id.*

<sup>91</sup> *Wyeth v. Levine*, 555 U.S. 555, 567 (2009).

<sup>92</sup> *Id.* at 567.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.* at 568.

<sup>95</sup> *Carrier*, *supra* note 58, at 590.

<sup>96</sup> *Id.* at 548.

<sup>97</sup> David A. Kessler, M.D., and David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461 (2008).

<sup>98</sup> *Riegel v. Medtronic, Inc.* 552 U.S. 312, 316 (2008); 21 U.S.C. §360k(a).

<sup>99</sup> *Id.* at 317-320.

of a medical device given premarket approval [through the PMA process] by the FDA.”<sup>100</sup>

Because the Medical Device Amendments’ express preemption clause preempts state requirements “different from or in addition to” any federal requirement, the court stated that in order to resolve the preemption issue it (1) “must determine whether the Federal Government has established requirements applicable to [the] catheter” and (2) “[i]f so . . . then determine whether the [plaintiff’s] common law claims are based upon New York requirements with respect to the device that are ‘different from, or in addition to’ the federal ones, and that relate to safety and effectiveness.”<sup>101</sup>

The court held that the pre-marketing approval process imposes “requirements” under the Medical Device Amendments because it is focused on the safety of the specific device with almost no deviations from the specifications included in its approval application.<sup>102</sup> Thus, pre-marketing approval resulted in the presence of federal “requirements” applicable to the catheter that exert preemptive force.

Addressing the second part of the analysis, the court stated that “[s]afety and effectiveness are the very subjects of the [plaintiff’s] common law claims, so the critical issue is whether New York’s tort duties constitute “requirements” under the Medical Device Amendments.<sup>103</sup> The majority then held that “[a]bsent other [Congressional] indication, reference to a state’s ‘requirements’ includes its common law duties.”<sup>104</sup> Because there was no evidence contradicting the normal meaning, the court found that plaintiff’s claims constituted “requirements” within the meaning of the Medical Device Amendments.<sup>105</sup>

The court conceded that the Medical Device Amendments’ preemption provision would not bar a state from providing a parallel damages remedy for claims premised on a violation of FDA regulations themselves. However, the plaintiff’s claims were preempted because they would have given rise to state law requirements that were different from or in addition to federal law requirements in that plaintiff asserted that the defendant had violated state common law notwithstanding the fact that the defendant had complied with the applicable federal requirements.<sup>106</sup>

In dissent, Justice Ginsburg argued that until 1976, the FDA did not engage in premarket regulation of medical devices. Because some states acted to fill the void by adopting their own regulatory systems for medical devices, the Medical Device Amendments aimed only at those state regulatory schemes, and particularly to California’s system of premarket approval for medical devices, by preempting state initiatives absent FDA permission. The law did not, she reasoned, intend to preempt state common law torts that would hold manufacturers accountable for design or label defects.<sup>107</sup>

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<sup>100</sup> *Id.* at 315.

<sup>101</sup> *Id.* at 321-22.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.* at 324.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.* at 330.

<sup>107</sup> *Id.* at 333.

## 2. *Wyeth v. Levine*

In *Wyeth*, the plaintiff contracted gangrene and lost her arm as a result of the administration of the anti-nausea drug Phenergan into her arm using the IV-push method.<sup>108</sup> The plaintiff brought an action against defendant asserting common law negligence and strict liability claims, and alleging that the drug's label was defective because it failed to instruct health care providers that the IV-drip method should be used to administer the drug rather than the higher risk IV-push method.<sup>109</sup>

Because Congress consistently refused to include an express preemption provision for prescription drugs in the FDCA, the U.S. Supreme Court was not, as in *Riegel*, interpreting the scope of a statutory preemption provision but rather various species of implied preemption.<sup>110</sup> The defendant based their preemption argument on two alternative theories. First, the defendant argued that it would have been impossible to comply with the state law's duty to modify Phenergan's labeling without violating federal law.<sup>111</sup> Second, the defendant argued that recognition of the plaintiff's common law tort claims would pose an obstacle to the policies behind the FDCA because it substitutes the opinion of a lay jury for the expert opinion of the FDA as to drug labeling requirements.<sup>112</sup>

Prior to addressing defendant's specific arguments, the court stated that its analysis must be guided by two fundamental principles of preemption law: (1) that "the purpose of Congress is the ultimate touchstone in every preemption case" and (2) that, in all preemption cases, "particularly in those in which Congress has 'legislated . . . in a field which the states have traditionally occupied,'" the court begins with the assumption that the police powers of the state are not superseded by federal statute "unless that was the clear and manifest purpose of Congress."<sup>113</sup>

The defendant argued that because of a 2008 regulatory amendment which provided that a manufacturer may only change its label to reflect "newly acquired information," the defendant could not comply with its state law obligation to modify its label without violating federal law because it did not possess any "newly acquired information."<sup>114</sup> The court rejected that argument, noting that defendant could have complied with both the federal and state requirements because the definition of "newly acquired information" includes both "new data" and "new analyses of previously submitted data."<sup>115</sup> Thus, it was not impossible for defendant to comply with both the federal and state requirements because, contrary to defendant's claims,

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<sup>108</sup> *Wyeth v. Levine*, 555 U.S. 555, 564-65. (2009)

<sup>109</sup> *Id.* at 559.

<sup>110</sup> *See id.* at 574-74.

<sup>111</sup> *Id.* at 562.

<sup>112</sup> *Id.* at 562-63. . The FDA had, historically, not sought preemptive effect be given to regulations they adopted. But such defenses had become increasingly common in the years leading up to *Wyeth*, due in part to the fact that the FDA began to support the theory that the FDCA establishes both a "floor" and a "ceiling," such that FDA approval of a drug's label preempts inconsistent state law, as opposed to merely establishing a "floor," which a state law is free to build upon. 129 S. Ct. at 573-74 (citations omitted). Lower courts had noticed the FDA's somewhat unusual turn in advocating for the application of preemption in *Wyeth*, a move that led to courts giving less weight to the agency's views.

<sup>113</sup> *Id.* at 565 (quoting *Medtronic, Inc.*, 518 U.S. at 485).

<sup>114</sup> *Id.* at 568-69.

<sup>115</sup> *Id.* at 568-74.

the applicable regulations allowed the defendant to comply with the common law duty to modify the label by providing a method for unilateral label modifications aimed at strengthening the warnings on a label.<sup>116</sup>

The court also rejected defendant's alternative argument that allowing state common law actions for failure to warn would pose an obstacle to the advancement of the FDCA's objectives and policies. The court found that Congress did not intend FDA oversight to exclusively ensure drug safety and effectiveness; rather, Congress anticipated that consumers would avail themselves of state law claims or else be left without a private remedy.<sup>117</sup> The court noted that state tort litigation generally adds another important and beneficial layer of consumer protection that "complements" FDA regulation.<sup>118</sup> In addition, the court rejected the defendant's and FDA's argument that federal labeling standards establish both a floor and a ceiling, because that position conflicted with the FDA's prior pronouncements as well as the evidence of Congressional intent.<sup>119</sup> As a result, *Wyeth* makes clear that the FDCA regulatory scheme is a floor which does not preempt state common law claims.

### C. *The Tobacco Control Act's Preemption Provision*

Under the 2009 Tobacco Control Act, courts must choose whether Section 911's process for premarket approval of modified risk claims is controlled by *Riegel*, *Wyeth*, or possible alternatives that draw from both. As with any issue involving Congress's intent to preempt state law, the inquiry must begin with the text.

#### 1. *Statutory Text and Legislative History*

Section 916 of the Tobacco Control Act, "Preservation of State and Local Authority" combines the preemptive language of the 1976 Medical Device Amendments (and other statutory schemes) with the "Rule of Construction" of the 2007 FDCA amendments:

##### In General

Preservation. Except as provided in paragraph (2)(A), nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter . . .

##### Preemption of Certain State and Local Requirements

In General. No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this

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<sup>116</sup> *Id.* at 572-73.

<sup>117</sup> *Id.* at 574-81.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

chapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products . . .

Rule of Construction Regarding Product Liability. No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.<sup>120</sup>

Not only does the law merge incongruous provisions drawn from other FDCA provisions shaping the preemptive effect of FDA regulation, it did not define “product liability” in the statute, nor did it indicate an intent to import definitions of “product liability” present in other statutory schemes like the U.S. Internal Revenue Code.<sup>121</sup> Congress instead implicitly allocated the definition to state law, which may vary in the kinds of claims qualified as “product liability”. Alternatively, Congress intended to distinguish product liability from other sorts of “positive” state law like statutes and regulations that might differ from FDA requirements applicable to “tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.” The most closely analogous mechanism in the FDCA is that regulating over-the-counter drugs which contains the preemptive language of Section 916(a)(2)(A) with the rule of construction of 916(b).<sup>122</sup> That provision also offers no definition of “product liability”, it has been infrequently litigated, and even if it did, the core inquiries relevant to preemption analysis based on Congressional intent would differ.<sup>123</sup> The official legislative history provides scant guidance in resolving the apparent tension between Section 916(a) and 916(b).<sup>124</sup>

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<sup>120</sup> Tobacco Control Act Section 916.

<sup>121</sup> IRC § 172(f)(4).

<sup>122</sup> 21 U.S.C. §379(r).

<sup>123</sup> Of five district courts that have considered preemption under 21 U.S.C. § 379(r), only one alleged personal injury as opposed purely economic loss. While the four alleging purely economic loss were preempted, the one alleging personal injury, loss of taste, was considered “saved” by the product liability savings clause. Compare *Crozier v. Johnson & Johnson Consumer Companies, Inc.*, 901 F.Supp.2d 494 (D.N.J. 2012) (purely economic loss claims preempted) with *Peters v. Astrazeneca, LP*, 417 F.Supp.2d 1051 (W.D.Wis. 2006), (personal injury claims resulting from over-the-counter drug use saved by 21 U.S.C. § 379r(e)). Claims against MRTTP labels, by contrast, will almost certainly be based on personal injury related to increased or sustained tobacco consumption.

<sup>124</sup> The most direct evidence available is from a 2007 hearing before the House Subcommittee on Health of the Energy and Commerce Committee during an exchange with Richard Bonnie, chair of an Institute of Medicine committee that authored a report entitled “Ending the Tobacco Problem: A Blueprint for the Nation.” Committee on Reducing Tobacco Use, U.S. Institute of Medicine, *ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION* (Richard Bonnie ed.) (2007). On the one hand, Mr. Bonnie testified that “An important part of this bill is actually to remove one of the obstacles that now exist to more aggressive regulation at the State and local level by loosening the preemption and allowing the States to engage in regulations that supplement whatever Federal regulations are adopted.” House Report 110-69, October 3, 2007 p. 44. On the other he noted that except “for actions that relate to fraud and deception,” the law would preempt “with regard to packages and to product regulation, direct regulation of the product by the FDA.” *Id.* at 47. To the extent it sheds light on the issue, the most plausible reading of the hearing exchange is that for “States to engage in regulations that supplement” federal law means their

#### D. Statutory Purpose and Congressional Findings

Assuming that neither the text nor the legislative history provide adequate answers, it would be possible to reach different conclusions about the scope of Section 916 preemption as it applies to state common law product liability actions. One possibility is that Section 916(a)(2)(A) provides an absolute bar to state law regulating any aspect of its covered issues: tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products. In essence, the argument would run that the MRTP approval process is as or more extensive than that for Class III medical devices, Congress included a similar express preemption provision for MRTPs as Class III medical devices, and therefore *Riegel* controls. A second possibility is that Section 916(b) divides 916(a)(2)(A) into, on the one hand, “positive” state law like statutes and regulations and, on the other, common law product liability claims which are preserved, a position closely aligned with Justice Ginsburg’s dissent in *Riegel* and the majority in *Wyeth v. Levine*.<sup>125</sup> A third possibility is that Section 916(b) was meant only to preserve current claims in state and federal courts based on state product liability law that might be affected by forthcoming FDA regulations on the issues covered by 916(a)(2)(A), an interpretation in tension with the statute’s plain text. What is almost certainly the case is that claims based on common law fraud remain entirely preserved.

Once the context of the law is considered, however, it becomes clear that Congress intended to unleash rather than constrain the role of state law in effecting the statute’s purpose. In explaining the law’s purpose, Congress noted that it intended to “to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry’s efforts to develop, introduce, and promote less harmful tobacco products.”<sup>126</sup> While that purpose might be read to mean *only* FDA enforcement, Congress did not so specify, even though it could have and did with respect to other provisions of the law. Within the broader portfolio of FDA-regulated products, it is also clear that tobacco products share little with the regulatory review process or individual health benefits Class III medical devices enjoy against state product liability claims.<sup>127</sup>

In concluding that the Medical Device Amendments preempted New York tort law, the *Riegel* majority noted that “the solicitude for those injured by FDA-approved devices . . . was overcome in Congress’s estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.” With respect to MRTPs, Congress expressed a polar sentiment:

[u]nless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals,

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statutory and administrative measures rather than judge-made common law which would largely overlap with the “fraud and deception” Bonnie identified.

<sup>125</sup> See, e.g., *Bates v. Dow Agrosciences*, 544 U.S. 431 (2005).

<sup>126</sup> H.R. Con. Res. 1256, 111 th Cong., (2009) (enacted).

<sup>127</sup> Generic drugs also enjoy such protection, but for reasons not relevant for this discussion.

who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.<sup>128</sup>

Indeed, internal industry documents made available through the Master Settlement Agreement as well as the first MRTP application itself – by Swedish Match – hint at tobacco industry practices the 2009 Tobacco Control Act sought to regulate. Given the role that private law litigation played in exposing the tactics of tobacco manufacturers to deceive consumers about the risks of tobacco use, the most plausible conclusion about the preemptive scope of Section 916 is that it is intended to operate against a narrow class of state measures that might, for example, attempt to explicitly order the alteration of FDA-approved wording for a label or add state-level regulatory review for manufacturing processes. The availability of state law claims sounding in tort are more consistent with Congress's sentiment than an alternative which might suggest that Congress sought to promote innovation in modified risk-labeled tobacco products.

In contrast to the regulatory regime imposed by the Federal Cigarette Labeling and Advertising Act, which concluded that prescribed federal (and not state) warnings were both necessary and sufficient to inform the public of the health consequences of smoking, the 2009 Tobacco Control Act fully embraced complementary regulation as the means by which the law would protect public health from deceptive industry practices.<sup>129</sup> Acknowledging that the only safe alternative to smoking is cessation, the law calls for “all interventions to help smokers quit completely.”<sup>130</sup> “As the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.”<sup>131</sup>

Although in its findings Congress stated that “the only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified”, it clarified that “[i]f manufacturers state or imply in communications directed to consumers through the media or through a label, labeling, or advertising, that a tobacco product is approved or inspected by the Food and Drug Administration or complies with Food and Drug Administration standards, consumers are likely to be confused and misled. Depending upon the particular language used and its

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<sup>128</sup> H.R. Con. Res. 1256, 111 th Cong., (2009) (enacted).

<sup>129</sup> Tobacco Control Act, Public Law 111-31 [H.R. 1256] Section 2 Findings 7 and 8.

<sup>130</sup> *Id.* at 2(34).

<sup>131</sup> *Id.* at 2(41).

context, such a statement could result in consumers being misled into believing that the product is endorsed by the Food and Drug Administration for use or in consumers being misled about the harmfulness of the product because of such regulation, inspection, approval, or compliance” and followed that qualification with three references to the U.S. Government’s lawsuit against the major tobacco manufacturers which found that the major United States cigarette companies continue to target and market to youth; dramatically increased their advertising and promotional spending in ways that encourage youth to start smoking subsequent to the signing of the Master Settlement Agreement in 1998; and designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research.<sup>132</sup>

The upshot from Congressional findings supporting the law is not only that state law represents a critical aspect of the need for “ongoing oversight” of the industry, but that historical deceptive practices continued even after the industry’s settlement with U.S. states in 1998. Given Congress’s heightened sensitivity to MRTPs’ potential to undermine the law – “dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product” – it is unlikely that Congress sought for Section 916(b) to have broad preemptive effect over MRTPs.

#### **IV. THE SWEDISH MATCH MODIFIED RISK TOBACCO PRODUCT APPLICATION**

The first modified risk tobacco product application opened for comment by FDA was submitted by Swedish Match, a firm incorporated in Sweden with its headquarters in Stockholm, on June 11, 2014 (it was considered complete on August 27, 2014) seeking amended labeling for its “snus” (pronounced “snoose”) smokeless tobacco product. Snus is a treated tobacco powder packed in pouches that look similar to a square of gum or tea bag. It is smokeless and spitless, if “correctly” used, and has a long history on the Swedish market. Early in its history, snus was consumed primarily by working class men.<sup>133</sup> Demand in Sweden was strong until World War I when cigarettes grew more popular. The company now known as Swedish Match reformed its approach to the product as evidence mounted about the health consequences of cigarette use. Adopting strategies perfected by American tobacco manufacturers, and their advertisers, for cigarettes, Swedish Match promoted snus as “the tobacco product for health-conscious but daring, sports-loving males.”<sup>134</sup> Around the later 1990s and early 2000s, demand for snus increased while that for cigarettes decreased.<sup>135</sup> The resulting tobacco consumption pattern has been

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<sup>132</sup> *Id.* at 2(46-49).

<sup>133</sup> SCENIHR, *Health Effects of Smokeless Tobacco Products*, 22nd Sess., Doc. 3116865667, at 33 (Feb. 6, 2008), available at <http://industrydocuments.library.ucsf.edu/tobacco/docs/mjcn0151>; *What is Snus?*, Camel, <https://snus.tobaccopleasure.com/Security/Login> (last visited May 17, 2015).

<sup>134</sup> *Id.* at 34.

<sup>135</sup> *Id.*

called the “Swedish Experience”<sup>136</sup>: attributing “low male smoking prevalence, and resulting low levels of tobacco-related mortality, to high rates of snus use among Swedish men.”<sup>137</sup> The argument goes that increased snus use in Sweden led to reduced cigarette consumption, with decreases in cancer rates and diseases related to carcinogens and toxins found in cigarettes.

#### A. *The Swedish Match Application and Requested Labeling Change*

Swedish Match’s requested labeling change establishes cigarettes as the benchmark tobacco product and suggests health benefits contingent on behavior that, while obtaining in the Swedish context, may not obtain where cultural, tax, and advertising environments differ. It proposes to eliminate warnings about gum disease and tooth loss or mouth cancer; more relevantly it asks that a current warning, “This product is not a safe alternative to cigarettes” be changed to “No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.”<sup>138</sup>

Aside from independent evidence that use of snus raises other risks like pancreatic cancer, preterm birth, preeclampsia and neonatal apnea, the requesting labeling changes themselves demonstrate a likelihood of consumer confusion and perhaps deception.<sup>139</sup> The statement “this product presents substantially lower risks to health than cigarettes” assumes, and would necessarily convey, that it would reduce risk if a consumer, for example, used one snus instead of one cigarette per day as opposed to completely transitioning from cigarettes to snus. Indeed, the entire phenomenon of “dual use”—that consumers of cigarettes will add another modality of nicotine consumption as opposed to reducing the other—is not only poorly understood in the credible scientific community, it provides a large incentive for firms to imply that the transition from one tobacco product to the other is seamless.<sup>140</sup> In its test marketing for snus before the 2009 Tobacco Control Act was adopted, RJReynolds found that uptake of snus was largely with “males and adult smokers under 30” suggesting, at least for the latter, dual use as opposed to transition from one to the other.<sup>141</sup>

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<sup>136</sup> Lindsay C. Dastrup & Jacqueline M. McNamara, Comment, *Tobacco Control and Snus: Time to Take a Stand*, 11 J. HEALTH CARE L. & POL’Y 127, 127-28 (2008); Matt Ritchel & David Jolly, *A Lesser Warning? Maybe*, N.Y. Times (Nov. 29, 2014), <http://nyti.ms/1FGn5LU>.

<sup>137</sup> Silvy Peeters & Anna B. Gilmore, *Understanding the Emergence of the Tobacco Industry’s Use of the Term Tobacco Harm Reduction in Order to Inform Public Health Policy*, TOBACCO CONTROL, at 1 (Jan. 22, 2014), <http://tobaccocontrol.bmj.com/content/early/2014/01/22/tobaccocontrol-2013-051502.full.pdf+html>.

<sup>138</sup> <http://www.medpagetoday.com/Washington-Watch/FDAGeneral/50920>.

<sup>139</sup> [http://www.nytimes.com/2014/11/30/business/studying-snus-a-smokeless-tobacco-from-sweden.html?\\_r=0](http://www.nytimes.com/2014/11/30/business/studying-snus-a-smokeless-tobacco-from-sweden.html?_r=0).

<sup>140</sup> Jennifer Maki, *The Incentives Created by a Harm Reduction Approach to Smoking Cessation: Snus and Smoking in Sweden and Finland*, INT’L J. OF DRUG POLICY 1, 1 (2014), <http://dx.doi.org/10.1016/j.drugpo.2014.08.003>.

<sup>141</sup> R.J. Reynolds Tobacco Company, *Camel SNUS Training Manual*, at 5-2 (Mar. 2006), available at <http://industrydocuments.library.ucsf.edu/tobacco/docs/ylxp0221>.

### B. *The Swedish Match Joint Venture with Philip Morris International*

Even if it were understandable that Swedish Match could not practically and with good faith convey the full universe of dual-use risk with a label change requested, the MRTP application and associated presentations contain aspects that display a lack of candor and fact shading reminiscent of past industry practices. For example, in a presentation to FDA Tobacco Products Scientific Advisory Committee, Swedish Match representatives asserted that they were the “right company” to secure modified risk labeling for snus because they were not “a big tobacco company.”<sup>142</sup> Yet since 2009 Swedish Match has participated in a joint venture with Philip Morris International, SMPM International AB (and briefly paired with Lorillard)<sup>143</sup> for the production and sale of snus and other smokefree tobacco products worldwide outside of Scandinavia and the United States.<sup>144</sup> Each company “own[s] a 50% stake and [licenses] their respective trademarks and intellectual property to the joint venture.”<sup>145</sup> Six board members made up of three members from each company direct the joint venture.<sup>146</sup> SMPM “sources its products from Swedish Match and sells them through [PMI]’s sales and distribution network”<sup>147</sup> and provides a way for PMI to get into the smokeless tobacco market, and allow Swedish Match to gain international presence.<sup>148</sup> In July, 2009, Philip Morris purchased Swedish Match South Africa for approximately \$222 million.<sup>149</sup> At the time of the purchase,

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<sup>142</sup><http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM443162.pdf>.

<sup>143</sup> See generally *SMPM International*, TOBACCO TACTICS, [http://www.tobaccotactics.org/index.php?title=SMPM\\_International&oldid=19393](http://www.tobaccotactics.org/index.php?title=SMPM_International&oldid=19393) (last updated Mar. 17, 2015).

<sup>144</sup> Press Release, Philip Morris International, Swedish Match and Philip Morris International Announce Global Joint Venture to Commercialize Smokefree Tobacco Products (Feb. 3, 2009), available at <http://investors.philipmorrisinternational.com/phoenix.zhtml?c=146476&p=irol-newsArticle&ID=1251102>; Press Release, Swedish Match, Swedish Match and Philip Morris International Announce Global Joint Venture to Commercialize Smokefree Tobacco Products (Feb. 3, 2009), available at <http://www.swedishmatch.com/en/Media/Pressreleases/Press-releases/2009/wedish-atch-and-hilip-orris-international-announce-global-joint-venture-to-commercialize-smokefree-tobacco-products1/>. Swedish Match and Philip Morris International Announce Global Joint Venture to Commercialize Smokefree Tobacco Products, BLOOMBERG (Feb. 3, 2009), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aRwUFOutzSyM>.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*; *SMPM Int’l*, *supra* note 16 (naming board members and starting dates).

<sup>147</sup> SWEDISH MATCH, 2013 ANNUAL REPORT at 14 (Mar. 10, 2014), available at [http://www.swedishmatch.com/Reports/Annual%20reports/2013\\_SwedishMatchAnnualReport\\_EN.pdf](http://www.swedishmatch.com/Reports/Annual%20reports/2013_SwedishMatchAnnualReport_EN.pdf); PHILIP MORRIS INT’L, *Philip Morris and JP Morgan Conference Call*, at 11-12 (June 26, 2009), available at <http://industrydocuments.library.ucsf.edu/tobacco/docs/hqjv0151>.

<sup>148</sup> Kevin Helliker, *Smokeless Tobacco to Get Push by Venture Overseas*, WALL ST. J. (Feb. 4, 2009), available at <http://www.wsj.com/articles/SB123370817484245811>; MICHAEL A. HITT ET AL., STRATEGIC MANAGEMENT: COMPETITIVENESS AND GLOBALIZATION 36, 9th ed. (2011).

<sup>149</sup> Press Release, Philip Morris Int’l, Philip Morris International Announces Agreement to Acquire Swedish Match South Africa for \$222 Million (July 2, 2009), available at [http://www.pmi.com/eng/media\\_center/press\\_releases/Pages/200907020246.aspx](http://www.pmi.com/eng/media_center/press_releases/Pages/200907020246.aspx); *Philip Morris International Announces Agreement to Acquire Swedish Match South Africa for \$222 Million*, REUTERS (July 2, 2009), <http://mobile.reuters.com/article/idUS57604+02-Jul-2009+BW20090702?irpc=932>; Guru Focus, *Mario Gabelli Comments on Swedish Match AB*, NASDAQ (July 25, 2014), <http://www.nasdaq.com/article/mario-gabelli-comments-on-swedish-match-ab-cm373750>; SWEDISH MATCH, Q2 2012: HALF YEAR REPORT at

Swedish Match South Africa was the market leader in the “other” tobacco products category.<sup>150</sup>

SMPM ran or is running test markets in Taiwan, Canada, Russia, and Israel.<sup>151</sup> According to Swedish Match’s 2012 Annual Report, the Taiwanese testing was concluded in 2012.<sup>152</sup> However, the General snus brand that was being test marketed in Taiwan is currently being used for test marketing parts of Canada.<sup>153</sup> The test market in Canada began in the Toronto area and expanded to Alberta; because Canada has continually shown positive feedback to the smokeless tobacco products, SMPM has further expanded into other cities.<sup>154</sup> As of 2014, the General brand is in approximately 3,000 stores.<sup>155</sup> In July 2012, test marketing began in Tel Aviv, Israel is for the Marlboro brand of snus.<sup>156</sup>

The test marketing campaigns appear aimed at testing a number of variables including co-branding with well-known names, modifications necessary in light of less stringent marketing restrictions, and types of metropolitan markets that show promise. In 2012, SMPM launched a test market of its Parliament brand snus in St. Petersburg, Russia.<sup>157</sup> Later in 2013, test marketing in Russia included Moscow and other cities.<sup>158</sup> In 2014, Russia’s test market was expanded to include the Chesterfield brand.<sup>159</sup> Russia was the third test market to launch, after Taiwan and Canada, and spokespersons for Swedish Match noted the relevance of laxer marketing restrictions than those in Taiwan and Canada.<sup>160</sup>

3, 5 (2012), available at <http://globaldocuments.morningstar.com/documentlibrary/document/70ca1a793f0c20e061323d0ad1e75dff.msdoc/original>; 2012 ANNUAL REPORT, *supra* note 129, at 11.

<sup>150</sup> Swedish Match, *supra* note 20; REUTERS, *supra* note 20.

<sup>151</sup> *SMPM Int’l*, *supra* note 16; *UPDATE 2-Swedish Match Sees Price War Eventually Easing*, REUTERS (Nov. 14, 2012), <http://www.reuters.com/article/2012/11/14/swedishmatch-outlook-idUSL5E8ME6MR20121114>; *Swedish Match AB Earnings Conference Call*, THOMSON REUTERS (Oct. 26, 2011), available at [http://www.swedishmatch.com/Documents/Transcripts/SWMA\\_ST-Transcript-2011-10-26T12\\_00.pdf](http://www.swedishmatch.com/Documents/Transcripts/SWMA_ST-Transcript-2011-10-26T12_00.pdf).

<sup>152</sup> 2012 ANNUAL REPORT, [https://www.swedishmatch.com/Reports/Annual%20reports/2012\\_SwedishMatchAnnualReport\\_EN.pdf](https://www.swedishmatch.com/Reports/Annual%20reports/2012_SwedishMatchAnnualReport_EN.pdf), at 11.

<sup>153</sup> *Market for Snus and Moist Snuff*, SWEDISH MATCH, <http://www.swedishmatch.com/en/Our-business/Snus-and-moist-snuff/Market-development/> (last updated Mar. 23, 2015).

<sup>154</sup> THOMSON REUTERS, *Q3 2011 Swedish Match AB Earnings Conference Call*, at 4 (2011), available at [http://www.swedishmatch.com/Documents/Transcripts/SWMA\\_ST-Transcript-2011-10-26T12\\_00.pdf](http://www.swedishmatch.com/Documents/Transcripts/SWMA_ST-Transcript-2011-10-26T12_00.pdf).

<sup>155</sup> See generally Mike Serebrinnik, *Swedish Match is a Great Stock to Chew On*, Seeking Alpha (Jan. 21, 2014), <http://seekingalpha.com/article/1956631-swedish-match-is-a-great-stock-to-chew-on>.

<sup>156</sup> SWEDISH MATCH, Q4 INVESTOR KIT at 20 (Dec. 31, 2013), available at [https://www.swedishmatch.com/Documents/Presentations/2013\\_Q4\\_InterimPresentation\\_SwedishMatch\\_EN.pdf](https://www.swedishmatch.com/Documents/Presentations/2013_Q4_InterimPresentation_SwedishMatch_EN.pdf). Q4 INVESTOR KIT, *supra* note 137, at 20.

<sup>157</sup> 2012 ANNUAL REPORT, *supra* note 129, at 11.

<sup>158</sup> INVESTOR KIT, *supra* note 137, at 20.

<sup>159</sup> *Market for Snus and Moist Snuff*, *supra* note 134.

<sup>160</sup> Silvy Peeters, *Russia: Snus Targeted at Young & Wealthy*, 21 Tobacco Control 456, 456 (Sept. 2012), available at <http://tobaccocontrol.bmj.com/content/21/5/456.full.pdf+html?sid=58d0283b-da19-4704-85a0-f4c187dbe6e4> (quoting Swedish Match CEO Lars Dahlgren); *Q3 2011 Swedish Match Conference Call*, *supra* note 135, at 9.

*C. Snus Marketing and the Problem with MRTP Premarket Review and Postmarket Surveillance*

Co-branding, promoting or at least suggesting dual use, and pairing snus with other products has already been part of the strategy tobacco firms used when introducing snus into the U.S. market before the Tobacco Control Act became law.<sup>161</sup> Consider the example of a tobacco consumer who received a free sample of Camel Snus when purchasing “Grizzly” smokeless tobacco:

I received a snus sample of frost at the gas station while buying my grizzly dip. I enjoyed the snus, but it took two pouches to satisfy me. I think it should be cheaper and stronger. Please give me some more free snus and coupons, thank you!<sup>162</sup>

This and other internet submissions and coupon-based information retrieval systems have allowed manufacturers to aggregate enormous amounts of information as to age, sex, race and geographic profile of MRTP consumers, time and place of purchase, likely dual-use products (including roll-your-own cigarettes and little cigars), pricing structure and other relevant information necessary for a comprehensive risk-reduction or public health assessment.<sup>163</sup> Firms have extensive research informing how many snus need to be in a tin, how long each packet is retained by consumers, where in the mouth it is placed, how large or small the pouch should be, how to compete on “moisture” content, likelihood of dual use, racial profile of consumers, as well as how to exploit the Swedish tradition of the product’s “Europeanness” or stereotypes of Swedish women.<sup>164</sup> It is unlikely that regulators will be able to capture the full universe of dependent and independent variables that affect the product’s ability to substantially reduce harm as well as overall effect on individual and public health. As the CDC’s Timothy McAfee noted “Once it is post-marketing, we have let the genie out of the bottle. Even with the pharmaceutical companies, that is not the FDA’s strength. Post-marketing surveillance and then calling back products takes tremendous, tremendous effort.”<sup>165</sup>

The nature of adversarial litigation itself will cast MRTP applications, and any information mistakenly or intentionally omitted or which FDA fails to request, in the light most likely to expose deceptive or misleading reduced risk claims and will be able to do so more nimbly than FDA regulatory process now contemplates. Litigation is a legitimate instrument for advancing public health; lawsuits laid much of the groundwork for the passage of the Tobacco Control Act. More importantly, the tobacco industry has already used litigation to successfully dismantle important parts of the law, subject to likely U.S. Supreme Court review. Similarly, “FDA is going to be challenged with every decision they make by industry, who is going to

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<sup>161</sup> See Camel Snus Training, December 19, 2007 available at <http://industrydocuments.library.ucsf.edu/tobacco/docs/fyxf0222> (“[Philip Morris USA is now saying that Marlboro Snus will deliver the “taste and quality that adult smokers expect from Marlboro”.”).

<sup>162</sup> <http://legacy.library.ucsf.edu/tid/fto97g00>.

<sup>163</sup> <https://industrydocuments.library.ucsf.edu/tobacco/docs/xtlv0145>.

<sup>164</sup> R.J. Reynolds Tobacco Company, *Camel SNUS Training Manual*, at 5-2 (Mar. 2006), available at <http://industrydocuments.library.ucsf.edu/tobacco/docs/ylxp0221>.

<sup>165</sup> Timothy McAfee, Transcript of FDA Public Workshop: Scientific Evaluation of Modified Risk Tobacco Product (MRTP) Applications (Aug. 25, 2011) p. 386.

sue them every step of the way because they are not going to like anything that FDA is going to do.”<sup>166</sup>

Limitations on private enforcement are additionally troublesome given tobacco industry participation on the Tobacco Products Scientific Advisory Committee (TPSAC), which advises the Commissioner of FDA on health and other issues relating to tobacco products.<sup>167</sup> Three non-voting seats on the TPSAC are delegated to tobacco industry representatives.<sup>168</sup> MRTP applications must be referred to TPSAC, giving the industry an important opportunity to influence the public health debate on MRTPs.

To be sure, there will be complicating questions surrounding whether the MRTP applicant is seeking a label for a combustible versus a smokeless product and whether the MRTP process is appropriate versus the characterization of the product as making therapeutic claims, which would trigger an altogether different regulatory pathway. Electronic cigarette marketers, for example, have subtly suggested that their products offer a lower-risk alternative to traditional cigarettes.<sup>169</sup> Smokeless products enjoy less protection from federal preemption under the Comprehensive Smokeless Tobacco Health Education Act, which would inevitably influence courts’ interpretation of Section 916’s scope.<sup>170</sup> Yet it may be stated that in either case, Congress intended state law torts to provide an important supplementary layer of consumer protection and regulatory oversight.

## V. CONCLUSION

Addison Yeaman, the general counsel for Brown & Williamson wrote in 1963, “we are, then, in the business of selling nicotine, an addictive drug . . .”<sup>171</sup> This essential aim of tobacco firms has not changed. The objective of the 2009 Family Smoking Prevention and Tobacco Control Act was to regulate the ways in which tobacco firms would be allowed to continue to sell an addictive drug. Given both Congress’s acknowledgment that private litigation played a critical role in exposing industry practices and its general and understandable hesitation to exclusively occupy the field of food and drug regulation traditionally held by states, the most loyal interpretation of Section 916(a)(2)(A) is that it was drafted to apply to a narrow class of state regulatory mechanisms like parallel and conflicting review of an MRTP label. To read it as preempting state tort and consumer protection laws would be inconsistent with the statute’s text, history and public health objectives.

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<sup>166</sup> Shields, *supra* note 48, at p. 262.

<sup>167</sup> 21 U.S.C. § 387(q) (2009).

<sup>168</sup> *Id.* § 387(q)(b)(1)(b).

<sup>169</sup> Eric Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising— and the First Amendment*, 70 FOOD & DRUG L.J. (2015).

<sup>170</sup> 15 USC 4406.

<sup>171</sup> <http://legacy.library.ucsf.edu/tid/xde02d00>.