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TOBACCO INGREDIENTS AND SMOKE CONSTITUENT REPORTING AND DISCLOSURE LAWS: THE CASE FOR EXPANSION

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INTRODUCTION

Tobacco ingredients and smoke emissions reporting and disclosure laws should be expanded in three fundamental ways. First, reporting and disclosure of specific quantities of ingredients and smoke emissions on a brand-by-brand basis ought to be required. Current federal law merely requires tobacco companies to submit aggregated lists of ingredients, information which has literally no public health value. Second, expanded tobacco product reporting and disclosure laws should also encompass cigars. Although cigars are enjoying an unprecedented upswing in use, especially by young people, the existing federal reporting law covers only cigarettes and smokeless tobacco.

Third, the primary purpose of recent proposals to expand tobacco reporting laws in the United States, including most attempts by states to fill the void in federal law, has been to obtain information about tobacco constituents in their unburned state. While requiring reporting and disclosure of unburned ingredients in specific brands is a desirable public health objective, shifting to a strategy directed at smoke emissions may be more effective, at least as an initial step. Focusing on smoke emissions makes sense from a public health perspective because the harmful effects of both mainstream smoke (inhaled by smokers) and side-stream smoke (environmental tobacco smoke exposure)¹ are more readily docu-

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1. Environmental tobacco smoke ("ETS") "is formed from the smoldering of a cigarette or other [burning] tobacco product, and from smoke exhaled by the smoker." OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, CALIFORNIA ENVTL. PROTECTION AGENCY, HEALTH EFFECTS OF EXPOSURE TO ENVTL. TOBACCO SMOKE 1-2 (1997). Approximately one-half of the complex mixes of chemicals formed, in weight, by smoking tobacco are emitted from the smoldering product as side-stream smoke, which diffuses into the environment. *See id.* at 2-2. Furthermore, "[o]ver [fifty] compounds have been identified in tobacco smoke which are recognized as known or probable human carcinogens." *Id.* at 2-4.

mented and understood than the effects of unburned tobacco additives. Moreover, from a legal perspective, the tobacco industry's trade secret claims, (which it is asserting to fend-off more stringent reporting and disclosure laws in the U.S. and Canada) may be more easily defeated with regard to smoke emissions.

Furthermore, even if disclosure of ingredients and smoke emissions have a limited effect on overall tobacco consumption (because users are addicted), disclosure could be justified as a tool to encourage competitive consumer comparison and create a genuine industry incentive to reduce or eliminate harmful ingredients and emissions. The recent Winston "no additives" advertising campaign indicates that tobacco companies believe consumers are influenced to change brands based on unproven claims that their products are additive free.² The tobacco industry may well respond to enforceable, stringent reporting and disclosure requirements by altering their products, instead of just their advertising.

This Article consists of several sections, each of which explores a particular development related to recent attempts to expand tobacco product ingredients reporting and disclosure laws. In Part IA, the Article describes the contours and severe limitations of the current federal ingredients reporting law and policy. Part IB discusses recent proposals to strengthen federal law in this area, including those emanating from the failed June 20, 1997 proposed national tobacco litigation settlement. In Part II, the Article analyzes state laws enacted to fill some of the gaps in federal tobacco products ingredients reporting and disclosure laws, and the industry response to these efforts. Part III describes the very recent, and thus far more successful, efforts by the Canadian government to obtain and (at least in British Columbia) release detailed information about tobacco ingredients and emissions through new regulations. Finally, in

2. The Winston "no additives" campaign has reportedly revived a brand that had been dropping in popularity for more than a quarter of a century. In a December 1997 article ("All-natural killers"), *Fortune* magazine reported that Winston had grown from 5.4% to 5.8% in the third quarter of 1997. It's not surprising that Mr. Goldstone was so "encouraged", especially when a single point of market share equals US\$80 million [sic] in pre-tax profits. Stan Shatenstein, *Thank you for not smoking additives*, TOBACCO CONTROL, Summer 1998, at 187. One of a series of Winston advertisements beckons "Thank you for not smoking additives," claiming that Winstons are "100% Tobacco." *Id.* at 188. Another depicts a young man intently gazing at a Playboy centerfold and boasts: "I don't know if they're real, but my smokes are." *Id.* At least one state, Arizona, has filed suit against Winston's manufacturer, R.J. Reynolds, charging that the advertising campaign violates consumer protection laws "because it implies that Winston is somehow more healthful than competitors." *Id.* at 187. At this writing the FTC is poised to accept a settlement of its deceptive advertising charges against R.J. Reynolds' "no additives" campaign for Winston cigarettes. *The Federal Trade Commission* (visited Mar. 3, 1999) <<http://www.ftc.gov>>. The Proposed Settlement would require Reynolds to include the following prominent disclaimers in a variety of ads: "No additives in our tobacco does NOT mean a safer cigarette" or "No additives in our tobacco does NOT mean safer." In the Matter of R.J. Reynolds Tobacco Co., File No. 992-3025, Agreement Containing Consent Order, FTC (Mar. 3, 1999), *enforced*, In the Matter of R.J. Reynolds Tobacco Co., Docket No. C-3892, Decision and Order, FTC (Aug. 16, 1999).

Part IV the author suggests strategies for maximizing the likelihood that efforts to enhance tobacco ingredients reporting and disclosure laws will produce useful results.

I. TOBACCO PRODUCTS INGREDIENTS REPORTING AND DISCLOSURE

A. *Current Federal Reporting Requirements for Cigarettes and Smokeless Tobacco*

The Federal Cigarette Labeling and Advertising Act ("FCLAA")³ requires cigarette manufacturers, packagers and importers to "annually provide the Secretary [of Health and Human Services] with a list of the ingredients added to tobacco in the manufacture of cigarettes which does not identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients."⁴ Another federal law, the Comprehensive Smokeless Tobacco Health Education Act ("CSTHE"),⁵ imposes similar reporting requirements on the manufacturers of smokeless tobacco.⁶ Additive lists required under both laws are of no public health value, however, since they do not identify specific quantities, the tobacco companies using particular ingredients, or the brands containing specific ingredients.⁷

The federal laws also provide strong confidentiality protections for the reported ingredients information. Specifically, the laws applying to cigarettes and smokeless tobacco require any ingredients information submitted to the Secretary to be "treated as trade secret or confidential information subject to [United States Code] section 552(b)(4) of Title 5 and section 1905 of Title 18."⁸ In addition, the Secretary is required to maintain special written procedures for assuring the confidentiality of reported data, including appointing a custodian to keep the lists locked in a cabinet or file and "to maintain a complete record of any person who inspects or uses the information."⁹

Both federal laws applicable to cigarettes and smokeless tobacco include weak Congressional reporting requirements with respect to the aggregated information required from tobacco manufacturers.¹⁰ Not sur-

3. Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1341 (1994).

4. *Id.* § 1335a(a).

5. Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. §§ 4401-4408 (1994).

6. *See id.* § 4403. The smokeless law also requires manufacturers to report nicotine quantities. *Id.* § 4403(a)(1)(B).

7. *See* 15 U.S.C. §§ 1335a; 15 U.S.C. § 4403(a)(1)(B).

8. 15 U.S.C. § 1335a(b)(2)(A) (1994). *See also* 15 U.S.C. § 4403(b)(2)(A).

9. *See* 15 U.S.C. § 1335a(b)(2)(C); 15 U.S.C. § 4403(b)(2)(C).

10. *See* 15 U.S.C. § 1335a. § 1335a(b) provides:

(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a) of this section, respecting—

prisingly, neither the FCLAA, the CSTHE, nor the legislative history of either Act, acknowledge that the reporting system is virtually useless from a public health perspective because it merely requires manufacturers to report aggregated ingredients lists, while shielding specific information about quantities and brands. Permitting companies to aggregate reportable information compounds the difficulty of assessing health risks and identifying potentially responsible parties.¹¹ The legislative histories of the current federal reporting laws articulate no rationale for protecting tobacco companies from adhering to any meaningful ingredients disclosure requirements.¹²

The cigarette and smokeless tobacco industries subject to these laws have gone to great lengths to guard against disclosure of ingredients information. Elaborate and presumably expensive procedures employed by the industry to protect ingredients information throughout the reporting process were cited by the First Circuit Court of Appeals in an opinion upholding an order barring enforcement of a Massachusetts ingredients reporting and disclosure law.¹³ Specifically, with regard to company aggregation of additive data, the First Circuit noted that manufacturers "typically comply with the Labeling Act's strictures through an internuncio; they submit information to a law firm which acts as a clearinghouse The law firm maintains the secrecy of the ingredients used in a particular brand from both the government and the brand's competitors."¹⁴ Smokeless tobacco manufacturers follow similar procedures, utilizing law firms to protect against disclosure of their products' ingredients.¹⁵

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- (A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of cigarettes and the findings of such research;
 - (B) information pertaining to any such ingredient which in the judgement of the Secretary poses a health risk to cigarette smokers; and
 - (C) any other information which the Secretary determines to be in the public interest.

15 U.S.C. § 1335a(b); *see also* 15 U.S.C. § 4403(b).

11. *See* 15 U.S.C. § 1335a. § 1335a(a) provides: "A person or group of persons required to provide a list by this subsection may designate an individual or entity to provide the list required by this subsection." *See also* 15 U.S.C. 4403(a)(2).

12. *See* H.R. REP. NO. 98-805 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3718; S. REP. NO. 99-209 (1986), *reprinted in* 1986 U.S.C.C.A.N. 7. *Cf.* the Kennedy Report discussed *infra* at notes 88-91.

13. *See* Philip Morris, Inc. v. Harshbarger, 159 F.3d 670, 673 (1st Cir. 1998) (upholding a preliminary injunction obtained by the tobacco industry to restrain enforcement of a state ingredients reporting and disclosure statute based on the industry's trade secrets claim). *See infra* notes 110-112 and accompanying text.

14. *Harshbarger*, 159 F.3d at 672.

15. *See id.* at 672 n.2.

1. Applying Federal Ingredients Reporting Laws to Cigars

No federal law requires cigar manufacturers to report any type of ingredients information to federal health officials. Nothing in the statutes or legislative history of either FCLAA or CSTHE suggests any reason for excluding manufacturers of other tobacco products, such as cigars, from ingredients reporting or regulation.

Indeed, the rationale articulated in the Senate Report accompanying the enactment of the federal law regulating smokeless tobacco (requiring, *inter alia*, reporting of ingredients lists) applies to cigars today.¹⁶ For example, the Senate Report asserts that the hazards of smokeless tobacco have been “neglected” and that the smokeless tobacco industry “has staged a resurgence in recent years.”¹⁷ Citing mounting evidence of the health risks of using smokeless tobacco and “gains in production and sales,” the report states that it is essential for Congress and the federal government to take action.¹⁸ Alarming increases in the use of smokeless tobacco and youth consumption were the primary rationales for enacting the law.¹⁹ Moreover, the report acknowledges that many young consumers of smokeless tobacco “are under the mistaken impression that the use of smokeless tobacco carries no significant risk to health.”²⁰

The parallels to cigars are obvious. First, cigars have historically been neglected in federal, state, and local regulatory schemes. For example, on the federal level, cigars are excluded from labeling requirements,²¹ the prohibition on television and radio advertising,²² FDA jurisdiction,²³ and ingredients reporting laws.²⁴ Second, new information

16. See generally S. REP. NO. 99-209, pt. 1, at 1-3 (1986), reprinted in 1986 U.S.C.C.A.N. 7. In addition to mandating ingredients reporting, CSTHE requires, *inter alia*, warning labels on smokeless tobacco products. See *id.* at 2-3. See also 15 U.S.C. § 4402(a)(1) (1994) (requiring warning labels on smokeless tobacco products).

17. S. REP. NO. 99-209, at 3 (1986).

18. See *id.* Interestingly, as a justification for requiring, *inter alia*, reporting requirements and warning labels, the Senate Report also expressly acknowledges the inherently harmful nature of tobacco products. *Id.* “Tobacco products are unique in that, unlike other products which may be only hazardous when misused, these products pose a health hazard when used as intended.” *Id.* at 13. See also Daniel Givelber, *Cigarette Law*, 73 IND. L.J. 867, 898-900 (1998) (discussing the curious treatment of tobacco under product liability law).

19. See S. REP. NO. 99-209, at 4 (1986).

20. *Id.*

21. See Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1333 (1994); Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. § 4402 (1994). Recently, companion reports issued by the Office of Inspector General recommend, *inter alia*, “pursuing a collaborative effort with the Federal Trade Commission and Congress to initiate a Surgeon General’s Warning Label for cigars.” U.S. DEP’T OF HEALTH AND HUM. SERVS. OFF. OF INSPECTOR GEN., YOUTH USE OF CIGARS: FEDERAL, STATE REG. AND ENFORCEMENT ii (1999); U.S. DEP’T OF HEALTH AND HUM. SERVS. OFF. OF INSPECTOR GEN., YOUTH USE OF CIGARS: PATTERNS OF USE AND PERCEPTION 25 (1999).

22. See 15 U.S.C. § 1335 (1994). Only cigarettes and “little cigars” are covered under the electronic communication ban. See *id.* § 1332(7) (1994) for the definition of “little cigar.”

23. See *infra* notes 48-55 and accompanying text.

about the serious health risks of cigar smoking has emerged. A recent report of the National Institutes of Health warned: "Cigar smoking can cause oral, esophageal, laryngeal and lung cancers."²⁵ Third, cigar use has risen dramatically since 1993, following a period of intensive, and apparently, successful marketing and promotion campaigns.²⁶ Fourth, startling rates of cigar use by children and teenagers has been documented.²⁷ Similar conditions prompted the federal government to treat smokeless tobacco as a public health threat akin to cigarettes more than ten years ago.

In short, significant expansion of tobacco ingredients reporting and disclosure requirements is needed to ensure health officials and the smoking and non-smoking public are better informed about the health risks posed by all types of tobacco products, including cigars. In addition to influencing smokers, non-smokers who must contend with environmental tobacco smoke ("ETS"),²⁸ and public health regulators, disclosure of tobacco ingredients and emissions data could spark competition among manufacturers to reduce or eliminate harmful constituents and emissions. While the likelihood of meaningful federal action currently

24. See *supra* notes 3-6 and accompanying text.

25. U.S. DEP'T OF HEALTH AND HUM. SERVS., CIGARS: HEALTH EFFECTS AND TRENDS 19 (1998). "Regular cigar smokers who inhale, particularly those who smoke several cigars per day, have an increased risk of coronary heart disease and chronic obstructive pulmonary disease." *Id.* See also Paolo Boffetta et al., *Cigar and Pipe Smoking and Lung Cancer Risk: A Multicenter Study From Europe*, 91 J. OF NAT. CANCER INST. 697 (1999) (concluding that smokers of cigars and pipes consume less tobacco than cigarette smokers, and therefore have less risk of lung cancer than cigarette smokers); Carlos Iribarren et al., *Effect of Cigar Smoking on the Risk of Cardiovascular Disease, Chronic Obstructive Pulmonary Disease, and Cancer in Men*, 340 NEW ENG. J. MED. 1773 (1999) (finding that cigar smoking raises the smoker's risk of smoking-related diseases, including upper aerodigestive tract and lung cancers).

26. See David M. Burns, *Cigar Smoking: Overview and Current State of the Science*, in CIGARS: HEALTH EFFECTS AND TRENDS 1, 1-3 (U.S. DEP'T OF HEALTH AND HUM. SERVS. ed., 1998). Some recent data suggest that "cigar sales have flattened, up only 0.4 percent in 1998 to 3.3 billion after three consecutive years of growth exceeding 10 percent." Ted Jackovics, *Cigar With NFL Tie Aims for End Zone*, TAMPA TRIBUNE, Mar. 15, 1999, at 1. Notably, the figures were generated and released by a cigar trade group that is publicizing this apparent slowing of sales. "The bloom is off the rose. The craze is over," said Norman Sharp, head of the Cigar Assn. of America, which reported this week that net sales of cigars increased by just 0.4% in the United States last year." Kurt Streeter, *Sometimes a Cigar Craze is Just a Fad*, L.A. TIMES, Mar. 11, 1999, at C1.

27. See David M. Burns, *Cigar Smoking: Overview and Current State of the Science*, in CIGARS: HEALTH EFFECTS AND TRENDS 1, 13-14 (U.S. DEP'T OF HEALTH AND HUM. SERVS. ed., 1998); Karen K. Gerlach et al., *Trends in Cigar Consumption and Smoking Prevalence*, in CIGARS: HEALTH EFFECTS AND TRENDS 21, 42-48 (U.S. DEP'T OF HEALTH AND HUM. SERVS. ed., 1998). Moreover, while males are still more likely than females to smoke cigars, the gender difference for teens is less pronounced than for adults. See Burns, *supra*, at 13.

28. See *infra* Part B. Focusing on emissions may be advantageous to regulators. For example, even if disclosure of ingredients and emissions information has a limited effect on smokers, due to their addiction, release of emissions information could galvanize non-smokers who have been the driving force behind the growing number of ETS restrictions nationwide.

appears to be low,²⁹ recent developments in the state of Minnesota, discussed below, are more encouraging.³⁰ Ingredients reporting and disclosure may prove to be yet another area where the states lead the way in pioneering effective tobacco control regulations.³¹

B. Proposals to Expand Federal Reporting and Disclosure Requirements

Among its many controversial provisions, the proposed national tobacco settlement of June 20, 1997 (hereinafter Proposed Settlement or June 20, 1997 Proposed Settlement), included significant changes to the reporting and disclosure requirements applicable to cigarettes and smokeless tobacco under FCLAA and CSTHE³² Essentially, under the Proposed Settlement, cigarette and smokeless tobacco manufacturers would have been required to “disclose ingredient information to the public under regulations comparable to what current federal law requires for food products, reflecting the intended conditions of use.”³³ In an earlier publication this author summarized the 1997 proposed revisions to federal ingredients disclosure laws and concluded: “while the new federal requirements may be an improvement over the current federal reporting system, the long delays, permissive substantive standards, burdens of proof, and procedures appear to afford the tobacco industry significant advantages.”³⁴

Further, the June 20, 1997 Proposed Settlement would have explicitly preempted state regulations and enforcement in a number of key areas, including ingredients reporting and disclosure.³⁵ While states would have been permitted to apply for exemptions from the federal ingredients law five years after it became effective,³⁶ and states with existing laws

29. See *infra* notes 32-42 and accompanying text. Questions about federal preemption of state laws governing tobacco ingredients reporting and disclosure could further arise if amendments to federal law are proposed.

30. See *infra* Part II for a discussion of the Minnesota ingredients reporting and disclosure law.

31. See generally Russ Freyman, *Butting In*, GOVERNING, Nov. 1995, at 55 (describing legislative measures passed in several states restricting places tobacco may be used).

32. See Proposed Resolution, (last modified June 25, 1997) <<http://www.usatoday.com/news/smoke/smoke02.htm>> [hereinafter Proposed Resolution]. The June 20, 1997 Proposed Settlement was superseded by a less comprehensive and more industry-favorable multi-state settlement. Notably the multi-state settlement, otherwise known as the Master Settlement Agreement (“MSA”), does not contain any provisions related to FDA authority or tobacco ingredients reporting and disclosure. *Master Settlement Agreement* (Nov. 20, 1998) <<http://www.naag.org/settle.htm>>.

33. *Id.*

34. Peter D. Enrich & Patricia A. Davidson, *Local and State Regulation of Tobacco: The Effects of the Proposed National Settlement*, 35 HARV. J. ON LEGIS. 87, 104 (1998). For example, the industry would have enjoyed a five-year moratorium on submission of safety assessments for tobacco additives. See *id.*

35. See Proposed Resolution, *supra* note 32, at title I(F) & title V(B)(2). For a thorough discussion of the preemption issues embedded in the June 20, 1997 Proposed Settlement see Enrich & Davidson, *supra* note 34.

36. See Proposed Resolution, *supra* note 35, at title V(B)(2).

under which public disclosure had already occurred would have been "grandfathered,"³⁷ neither of these provisions would have adequately preserved state authority to regulate ingredients in tobacco products.³⁸ In fact, this author's prediction that states with existing ingredients reporting laws would not enjoy any real protection under the grandfather clause because the tobacco industry would continue to use dilatory tactics to prevent any meaningful public disclosure, has thus far been accurate.

In a comprehensive analysis of the Proposed Settlement, the Institute for Health Policy Studies [hereinafter I.H.P.S.] also criticized both the minimal existing federal reporting requirements for tobacco ingredients, and the expansion contemplated by the Proposed Settlement.³⁹ First, the report stated "[m]any have criticized the current process for disclosure of tobacco ingredients as insufficient."⁴⁰ The report went on to conclude that while the changes set forth in the Proposed Settlement "are a substantial improvement over the status quo,"⁴¹ the new procedures favored the industry and that the public disclosure requirements were inadequate for public health purposes. The I.H.P.S. report also objected to the potentially preemptive effects the proposed change in federal law might have on states with potentially stronger reporting and disclosure laws, such as Minnesota and Massachusetts.⁴²

1. Covering Cigars Under Ingredients Reporting and Disclosure Law

While neither the 1997 Proposed Settlement nor the I.H.P.S. Report addressed the issue of including cigars in federal ingredients reporting and disclosure laws, each recognized the need to expand reporting requirements and to mandate some public disclosure. The arguments supporting more detailed reporting of ingredients, health and safety assessments of tobacco additives, and public disclosure of health and safety information apply to cigars as well as to cigarettes and smokeless tobacco.

37. The proposed grandfather clause provided as follows: "However, manufacturers would be required to disclose all ingredients *which they have been compelled to publicly disclose* with respect to a particular brand in order to comply with a statute or regulation (e.g., MA Ch 94 § 307B)." Proposed Resolution, *supra* note 35, at title I(F) (emphasis added).

38. See Proposed Resolution, *supra* note 35, at title I(F). See also Enrich & Davidson, *supra* note 34, at 104-106.

39. See BRION J. FOX, ET AL., INSTITUTE FOR HEALTH POLICY STUDIES, UNIVERSITY OF CALIFORNIA, ANALYSIS OF THE PROPOSED RESOLUTION OF THE UNITED STATES TOBACCO LITIGATION (1997) [hereinafter I.H.P.S. REPORT].

40. *Id.* at 29.

41. *Id.* at 30. Under the current federal system information about tobacco ingredients submitted by cigarette and smokeless tobacco manufacturers to the U.S. Department of Health and Human Services is not subject to any form of public disclosure. See 15 U.S.C. § 1335a (1984); 15 U.S.C. § 4403 (1994). See also *supra* Part I.A.

42. See Fox, et al., *supra* note 39.

Indeed, another comprehensive analysis of national tobacco policy released shortly after the terms of the June 20, 1997 Proposed Settlement were announced, explicitly called for including cigars, as well as other forms of tobacco, in the FDA's regulatory framework.⁴³ The Koop-Kessler Report strongly opposed federal preemption of state and local authority to regulate public health, preferring instead that states have ample room to develop and enforce their own ingredients and smoke constituent reporting and disclosure laws.⁴⁴

The American Medical Association ("AMA") also called for including cigars in the federal regulation of tobacco products in its analysis of the Proposed Settlement.⁴⁵ "All tobacco products should be subject to a single, comprehensive, regulatory scheme."⁴⁶ Moreover, the AMA Report commented on the recent rise in cigar smoking, particularly among youth, and suggested that settlement-induced price increases for cigarettes could have the undesired effect of accelerating the cigar trend.⁴⁷

Cigars were not expressly excluded from the terms of the June 20, 1997 Proposed Settlement. However, it is highly unlikely that the drafters intended the settlement to cover them. Notably the proposal called for legislation that "would supersede the current often-criticized federal ingredient law and confirm FDA's authority to evaluate all additives in tobacco products."⁴⁸ But the ingredients disclosure provisions of the Proposed Settlement did not define the term "tobacco products" or mention cigars.⁴⁹

Finally, nothing in the Preamble to the Proposed Settlement suggests that the drafters considered cigars. Indeed, references to the pending lawsuits against manufacturers of cigarettes and smokeless tobacco

43. See C. EVERETT KOOP & DAVID A. KESSLER, ADVISORY COMM. ON TOBACCO POL. AND PUB. HEALTH, FINAL REPORT (1997) [hereinafter Koop-Kessler Report].

44. See *id.* at 16.

45. See TASK FORCE ON THE PROPOSED TOBACCO SETTLEMENT AGREEMENT, AMERICAN MEDICAL ASSOCIATION, ANALYSIS, REPORT, AND RECOMMENDATIONS (1997).

46. *Id.* at 5.

47. See *id.* Notably, a Senate bill purporting to implement the terms of the June 20, 1997 Proposed Settlement (which was ultimately rejected by the Senate) also apparently recognized the possibility that underage smokers might switch to cigars and pipes if deterred by new restrictions on cigarettes. Senate Bill 1415 provided: "The Secretary shall notify the Congress if the Secretary determines that underage use of pipe tobacco and cigars is increasing." S. 1415, 105th Cong. § 7 (1998). See *infra* notes 58-62 and accompanying text.

48. Proposed Resolution, *supra* note 35, at Title I (F). Moreover, as discussed herein, the "often-criticized federal ingredient law" referred to is limited to cigarettes and smokeless tobacco. See 15 U.S.C. § 1335a (1994); 15 U.S.C. § 4403 (1994).

49. However, the section of the Proposed Settlement pertaining to regulation of tobacco product development and manufacturing expressly adopted the FDA rule's definition of "tobacco products" and also would have covered "Roll Your Own, Little Cigars, Fine Cut, etc." Proposed Resolution, *supra* note 35, at Title I(E). Compare the various definitions of "tobacco products" contained in proposed federal legislation intended to implement the June 20, 1997 Settlement. See *infra* discussion accompanying notes 56-69.

and the 1996 FDA Rule,⁵⁰ which did not cover cigars,⁵¹ strongly suggest that cigars were not intended to be included in the terms of the Proposal.⁵² The FDA's 1996 jurisdictional statement noted:

The proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act. FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products.⁵³

Furthermore, in testimony before Congress regarding the 1997 proposed national tobacco settlement, Norman Sharp, President of the Cigar Association of America, relied on the absence of FDA jurisdiction over cigars to buttress his argument that cigars should not be subject to the provisions of comprehensive tobacco legislation.⁵⁴ Mr. Sharp characterized the FDA position as follows:

The FDA specifically chose not to regulate cigar and pipe tobacco products, most importantly, because it found no credible evidence that children and adolescents use these products to any significant degree. It also cited no evidence of nicotine manipulation and indeed concluded cigars and pipe tobacco were not nicotine delivery devices.⁵⁵

2. Legislation Proposed to Implement the June 20, 1997 Deal

Federal legislation filed to implement the terms of Proposed Settlement varied considerably, *inter alia*, with regard to the treatment of ci-

50. On August 28, 1996, the FDA published a final rule titled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," 61 Fed. Reg. 44,396 (1996) (to be codified at 21 C.F.R. pt. 801). However, based on an industry appeal, the rule was struck down by a three-panel judge of the U.S. Court of Appeals for the Fourth Circuit, which decided that the FDA does not have jurisdiction to regulate tobacco products. *See Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 176 (4th Cir. 1998). The United States Supreme Court recently upheld the Fourth Circuit ruling in a 5-4 decision. *See FDA v. Brown & Williamson Tobacco Corp.*, 120 S.Ct. 1291 (2000).

51. *See* 21 C.F.R. 897.1 (1998). With regard to nicotine levels in cigars, a subject beyond the scope of this Article, a petition has been filed with FDA seeking regulation of nicotine in cigars. *ASH Petitions FDA to Also Regulate Nicotine in Cigars*, 11 MEALEY'S LITIG. REP.: TOBACCO 24 (1997).

52. *See* Proposed Resolution, *supra* note 32, at 4. The recently invalidated FDA Rule, which is listed as the "source/precedent" for the proposal's advertising and marketing restrictions did not cover cigars. *See id.* at title I(A). *See also* 60 Fed. Reg. 41,313, 41,322 (1995) [hereinafter FDA's Jurisdictional Statement].

53. 60 Fed. Reg. 41,322 (1995).

54. *See Telecommunications, Trade and Consumer Protection Subcomm. of the House Commerce Comm.*, 105th Cong. (1998) (statement of Norman F. Sharp, on behalf of the Cigar Ass'n of America, Inc. and the Pipe Tobacco Council, Inc.).

55. *Id.* Notably, since the FDA Rule was promulgated, new data documenting alarming rates of youth cigar use has emerged. *See supra* note 53. Moreover, any lack of evidence to support

gars. For example, one of the first bills filed, Senate Bill 1530, clearly did not intend to cover cigars in any way.⁵⁶ The bill contained no definition of or reference to any type of cigar. Furthermore, key terms such as “tobacco product” and “manufacturer” included only cigarettes, cigarette tobacco and smokeless tobacco.⁵⁷

Similarly, Senate Bill 1415, the McCain Committee Bill, evinced no legislative intent to cover most types of cigars.⁵⁸ However, the bill did include little cigars⁵⁹ in its definition of “tobacco products,” thereby extending some of its regulatory provisions to this discrete class of cigars.⁶⁰ For example, Senate Bill 1415 would have apparently banned vending machine sales of little cigars, along with cigarettes and smokeless tobacco.

Notably, however, S. 1415’s definition of the key term “tobacco product manufacturer” was limited to manufacturers of cigarettes and smokeless tobacco.⁶¹ Thus the bill would have excluded even little cigars from many of its provisions, including its expanded ingredients reporting requirements.⁶²

jurisdiction over cigars as a drug delivery device could arguably be attributed, at least in part, to their exemption from ingredients reporting and disclosure laws, as well as the alleged dearth of proven testing protocols. A recent report of the Inspector General on youth use of cigars called for additional research to determine “whether the FDA should initiate the investigatory process for asserting jurisdiction over cigars comparable to that exercised by the FDA over cigarettes and/or have Congress expressly affirm FDA’s authority to regulate cigars.” U.S. DEP’T OF HEALTH AND HUM. SERVS. OFF. OF INSPECTOR GEN., YOUTH USE OF CIGARS: FEDERAL, STATE REG. AND ENFORCEMENT 17-18 (1999).

56. See Placing Restraints on Tobacco’s Endangerment of Children and Teens Act, or the “PROTECT Act,” S. 1530, 105th Cong. (1997). Notably, the bill’s ingredients reporting and disclosure provisions, which were limited to cigarettes and smokeless tobacco, would have potentially preempted state regulations and enforcement in this area. *Id.* §§ 900, 902, 904, 910. See also PETER D. ENRICH & PATRICIA A. DAVIDSON, IMPACT OF S. 1530 ON STATE AND LOCAL REGULATORY AND ENFORCEMENT AUTHORITY, (Tobacco Control Resource Ctr. Working Paper No. 7, 1998) (discussing the potentially preemptive effects of Senate Bill 1530).

57. See S. 1530, 105th Cong. § 5 (1997).

58. See generally S. 1415, 105th Cong. § 6 (1997) (addressing only “little cigars” as the type of cigars relevant under this bill).

59. “Little cigars” were defined by S. 1415 in accordance with the “Little Cigar Act of 1973” (Pub. L. 93-109 § 3) which amended the Federal Cigarette Labeling and Advertising Act (“FCLAA”) to include little cigars in its ban on electronic advertising. S. 1415, 105th Cong. § 6(9) (1997). See also FCLAA, 15 U.S.C. § 1335 (1994).

60. National Tobacco Policy and Youth Smoking Reduction Act, S. 1415, 105th Cong. (1998) (Manager’s Amendment of May 18, 1998). Senate Bill 1415 was the only piece of legislation purporting to implement the 1997 Proposed Settlement that was debated and voted on by Congress. It was defeated in the Senate on a procedural vote, after the tobacco industry disavowed the bill and spent millions of dollars campaigning against it, on June 17, 1998. See generally Graham Kelder, *Fight the Future—Or Everything You Always Wanted To Know About How The Tobacco Industry (a.k.a. The Cigarette Smoking Men) Killed the McCain Bill But Were Afraid To Ask*, 2 TOBACCO CONTROL UPDATE 5 (1998) (detailing the argument that the tobacco industry was responsible for the defeat of the McCain Bill).

61. See S. 1415, 105th Cong. § 6 (1997).

62. See *id.* § 904.

By contrast, another Senate bill purporting to implement the June 20, 1997 deal, Senate Bill 1638, included cigars in its definition of "tobacco products"⁶³ and would have established some significant federal regulatory authority over cigars. For example, immediately following sections establishing FDA authority to issue new, detailed warning label requirements for cigarettes⁶⁴ and smokeless tobacco,⁶⁵ the bill provided that "[t]he Secretary may prescribe such regulations as may be necessary to establish warning labels for other tobacco product packaging, labeling and advertising."⁶⁶ The FDA title of the bill also explicitly defined tobacco products to include cigars.⁶⁷ Hence, under Senate Bill 1638, cigars could have been subjected to packaging, labeling, and advertising regulations.

Similarly, FDA authority to establish performance standards which could, *inter alia*, include the reduction or elimination of nicotine, "other constituents" or "harmful components" also would have applied to all tobacco products, including cigars, under Senate Bill 1638.⁶⁸ Notably, the bill's new detailed requirements for reporting and disclosure of tobacco and non-tobacco ingredients would have applied to cigars by virtue of the expansive definition of tobacco products. Moreover, Senate Bill 1638 would have apparently preserved state and local authority in a number of areas regulated by the FDA, including ingredients reporting and disclosure provisions.⁶⁹

3. Other Recent Federal Cigar Legislation

In addition to prompting the introduction of a series of complex, multi-issue bills purporting to implement the terms of the June 20, 1997 Proposed Settlement, the spotlight on the Attorneys General litigation may have inspired the introduction of other tobacco legislation in the mid-to-late nineties. A number of these more narrowly focused bills included cigars in their definitions of tobacco products. While only one of the bills contained ingredients reporting and disclosure requirements (and new warning labels for packages as well as advertising),⁷⁰ the strategy of sweeping cigars under federal law through a shift in definitions is in-

63. S. 1638, 105th Cong. § 4(20) (1997). Cigarillos, little cigars, and pipe tobacco were also defined as "tobacco products." *Id.* Unlike the other bills discussed above, Senate Bill 1638 did not separately define "tobacco product manufacturers." *Id.*

64. *See id.* § 575(a).

65. *See id.* § 575(b).

66. *Id.* § 575(c).

67. *See id.* § 203(a)(3).

68. *Id.* § 573(a). Moreover, the performance standard provisions also explicitly authorized the Secretary to "require that a manufacturer test, report and disclose tobacco and tobacco smoke constituents, including labeling and advertising disclosures related to such constituents, including, but not limited to, tar and nicotine." *Id.* § 573(b).

69. *See id.* § 576. Warning labels on packages are the only notable exception to Senate Bill 1638's express preservation of state and local authority in this area. *Id.* § 575(e).

70. *See H.R. 1244*, 105th Cong. § 3(11) (1997). *See also S. 527*, 105th Cong. § 3(11) (1997).

structive.⁷¹ For example, a highly restrictive advertising bill, which would have virtually prohibited tobacco advertising and placed severe limits on tobacco promotional activities, applied to cigars and little cigars as well as cigarettes and smokeless tobacco.⁷² Moreover, at least one proposed federal youth access bill, which would have prohibited tobacco vending machines (except in adult-only facilities), defined tobacco products to encompass cigars and little cigars.⁷³ However, Congress did not pass any of these bills, including the ingredients disclosure/warning bill.

Interestingly, nearly ten years ago, Congress had before it a relatively comprehensive tobacco bill covering cigars that would have, *inter alia*, expanded federal ingredients reporting and disclosure requirements.⁷⁴ Specifically, the bill would have required tobacco manufacturers, importers, and packagers to provide the Secretary of Health and Human Services with a complete list of:

(A) each tobacco additive used in the manufacture of each tobacco product brand name that such person manufactures, imports, or packages; and

(B) for each such additive, the range of the quantities of such additive used by such person in all tobacco product brand names manufactured, imported, or packaged by such person.⁷⁵

While neither the proposed brand nor the quantity reporting requirements appear to be as stringent as some of the recently enacted state ingredients reporting statutes,⁷⁶ passage of the bill might have been a step forward. For example, under the bill the Secretary would have been authorized to request information “regarding the impact of such additives on health” from the manufacturer, importer, or purchaser.⁷⁷ The Secretary also would have been required to issue regulations setting forth “requirements for manufacturers to place information on packages of tobacco products or in package inserts . . . so that the public will be adequately informed of the tobacco additives contained in any brand or variety of tobacco products”⁷⁸

71. See, e.g., H.R. 3298, 105th Cong. (1998); H.R. 1244, 105th Cong. (1997); S. 527, 105th Cong. (1997); H.R. 762, 105th Cong. (1997); S. 2795, 101st Cong. (1990).

72. See H.R. 762, 105th Cong. (1997). Section 3 of the bill sets forth advertising and promotion restrictions applicable to tobacco products and Sections 5(1)(a) and (b) define tobacco products to expressly include, *inter alia*, cigars and little cigars. *Id.* §§ 3, 5(1)(A) & (B).

73. See H.R. 3298, 105th Cong. § 4 (1997).

74. See S. 2795, 101st Cong. (1993), which was originally numbered S. 1883 (136 Cong. Rec. D396-02; 1990 WL 46785). See also S. REP. NO. 101-338 (1990).

75. S. 2795, 101st Cong. § 1551(a)(1) (1993) (emphasis added).

76. See, e.g., MASS. GEN. LAWS ch. 94, § 307B (1997); MINN. STAT. § 461.17 (1999); TEX. HEALTH & SAFETY CODE § 161.251-255 (1991). See discussion *infra* Part II.

77. S. 2795, 101st Cong. § 1551(b).

78. *Id.* § 1551 (c)(1). However, spices, flavorings, and colorings need only be listed as such, without specific names. See *id.*

Finally, the Secretary would have been empowered to prohibit the use of particular additives, or require reductions in additive levels, if the Secretary determined "that any tobacco additive in a tobacco product, either by itself or in conjunction with any other additive, significantly increases the risk of the product to human health"⁷⁹

These requirements, among others, would have applied to the manufacturers, importers, and packagers of cigars and little cigars, as well as cigarettes, smokeless tobacco, snuff pipe tobacco, "and any other product that contains tobacco and is intended for human use"⁸⁰ under a remarkably broad definition of tobacco products. Notably, neither the bill, nor the accompanying Senate bill report, provide any clues about the overall rationale for including all forms of tobacco, including cigars, in the proposed regulatory scheme. However, the President of the Cigar Association testified in opposition to the bill's inclusion of cigars.⁸¹ Noting that the purpose of the bill "is 'to encourage cessation of tobacco use' among young people and to strengthen laws limiting sales of tobacco products to minors,"⁸² the cigar industry representative asserted "cigars are not youth-oriented products."⁸³ In a statement reminiscent of declarations made for decades by cigarette and smokeless tobacco manufacturers, he added, "the cigar industry disapproves of advertising designed to encourage cigar smoking by those under 21 years of age."⁸⁴

Furthermore, the cigar industry representative specifically objected to requiring cigar manufacturers to report quantities of constituents to the federal government.⁸⁵ The cigar spokesman based this objection on the alleged lack of "recognized testing methodology for measuring the constituents of cigars or their smoke (as distinguished from other tobacco products)."⁸⁶ These two themes, a denial of youth cigar use and complaints about the lack of a uniform protocol for testing cigar constituents, were echoed in the cigar industry's testimony opposing inclusion of ci-

79. *Id.* § 1551 (c)(2). The risk determination would have been made pursuant to regulation as well. *See Id.*

80. S. 2795, 101st Cong. § 1561(10) (1990).

81. *See Tobacco Product Education & Health Protection Act of 1990: Hearing on S. 1883 Before the Senate Committee on Labor and Human Resources*, 101st Cong. (1990) (statement of the Cigar Association of America). The testimony refers to S. 1883, an apparently re-numbered version of the original bill. The bill was also re-filed in 1991 with some amendments. Amendments related to ingredient-reporting and disclosure are discussed *infra* note 94.

82. *Tobacco Product Education & Health Protection Act of 1990: Hearing on S. 1883 Before the Senate Committee on Labor and Human Resources*, 101st Cong. (1990) (statement of the Cigar Association of America).

83. *Id.*

84. *Id.*

85. *See id.*

86. *Id.*

gars in the FDA rule and under comprehensive tobacco settlement legislation.⁸⁷

The Senate Report addressed the cigar industry's concerns by acknowledging that there are differences among the various tobacco products, and that cigar and pipe tobacco manufacturers may find it more difficult to comply with the bill.⁸⁸ In fact, the Committee Report suggested that cigar and pipe tobacco manufacturers might need additional time to satisfy the new reporting and disclosure requirements.⁸⁹ Nonetheless, the Report concluded that all tobacco products should be subject to the reporting and disclosure requirements contained in the bill.⁹⁰

With regard to ingredients reporting and disclosure, the Senate Report also sheds some light on the Committee's view of the competing interests of informing the public of the health risks of tobacco product additives and the industry's concern with protection of trade secrets. First, the Committee acknowledged that the legislation attempted to strike a balance. The Committee asserted "disclosure of additives to the public and to the Secretary is required in a manner that does not disclose specific quantities of additives to specific brands. Rather disclosure of a range of quantities for each company is required."⁹¹

Moreover, the Committee Report concluded that the current additive reporting system provides no useful information from which the Secretary of Health and Human Services can assess health risks.⁹² It asserted that:

[I]t was the intent of Congress in 1984, when P.L. 98-474 was signed into law, to provide the Secretary with useful information for which to make the kind of judgment it requested. Clearly that objective was not achieved by the reporting requirement that was established. The Committee believes that it is time to follow through on the intent of

87. See *supra* note 55.

88. See EDWARD KENNEDY, THE TOBACCO PRODUCT EDUCATION AND HEALTH PROTECTION ACT: COMMITTEE VIEWS, S. REP. NO. 101-338, at 35 (1990).

89. See *id.*

90. See *id.*

91. *Id.* Apparently the committee believed that reporting quantity ranges would protect information that might reveal the exact formulation of a particular product, while permitting the Secretary of Health and Human Services to gather data for an initial assessment of health risks. *Id.* at 34. Notably, the bill itself prohibited, *inter alia*,

[t]he using by any person to the advantage of such person, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this title, any information acquired under authority of this title concerning any method or process that as a trade secret is entitled to protection. This paragraph shall not be construed to prohibit disclosure of information to Congress.

S. 2795, 101st Cong. § 2741(a)(5) (1991). However, this prohibition is significantly less protective than the current law governing reporting and disclosure of additive lists for cigarettes and smokeless tobacco. See *In re R.J. Reynolds Tobacco Co.*, No. 992-3025 (1999) (showing R.J. Reynolds' willingness to enter into an agreement containing a consent order by the Federal Trade Commission). See also *supra* note 2.

92. See S. REP. NO. 101-338, at 34-35 (1990). The lack of information about quantity, brand, and company were specifically cited as problematic. *Id.* at 34.

Congress as indicated by the passage of the earlier legislation. The reporting requirement contained in this bill should result in useful information so that judgments about the risk of individual additives or combinations of additives will be technically feasible.⁹³

Neither this bill, nor an amended version filed the following year,⁹⁴ were enacted however. Even if the legislation had been adopted, it is not clear that the reportable information—ranges of additive quantities—would have been sufficient to permit the Secretary to conduct health assessments, or to exercise his authority to prohibit the use (or to reduce quantities) of additives.

Quite recently, and apparently in response to the dramatic new health warning label and tougher tobacco ingredients and smoke constituent reporting laws being considered in Canada⁹⁵ Senator Lautenberg and others filed federal legislation to replace and strengthen existing U.S. warning and reporting laws. The bill, S. 2125, would cover cigars and pipe tobacco, along with cigarettes and smokeless tobacco.⁹⁶

While the warning requirements are stronger than the current U.S. provisions, they are not nearly as bold as the Canadian plan.⁹⁷ Furthermore, it is not clear that S. 2125's reporting provisions would yield new health information⁹⁸ or whether such information would be disclosed to the public.⁹⁹ Notably, the bill, which repeals FCLAA and CSTHEA one year after enactment, does not expressly preempt state and local laws or address preemption of liability claims.¹⁰⁰

93. *Id.* at 35.

94. The second bill, S. 1088, amended, *inter alia*, the additive reporting requirements to include "the levels of tar, nicotine, and carbon monoxide for each brand." S. 1088, 102d Cong. § 2751(a)(1)(A) (1991). Thus, it would have added smoke constituent reporting to the federal statute. The public disclosure provisions were also amended to add information about tar, nicotine, and carbon monoxide to the mandatory packaging regulations. *Id.* § 2751(c)(1).

95. S. 2125, "Smoker's Right to Know and Truth in Tobacco Labeling Act," 106th Cong., 2d Sess. (2000); *see also* "Lautenberg & Lugar Propose Bipartisan Tobacco Labeling Bill," Government Press Releases by Federal Document Clearing House, Jan. 19, 2000.

96. *See id.*

97. *See* 134 (14) C. Gaz. 961-988 (2000).

98. *See* S. 2125, sec. 6(a) which states in part, "Each person that manufactures, packages, or imports into the United States any tobacco product shall annually report in a form and at a time specified by the Secretary by regulation—(1) the identity of an *added ingredient or constituent* of the product other than tobacco, water, or reconstructed tobacco sheet made wholly from tobacco; and (2) the nicotine, tar, and carbon monoxide intake from such product for average consumers based on standards established by the Secretary by regulation; *if such information is not information which the Secretary determines to be trade secret or confidential information subject to Section 552(b)(4) of title 5, United States Code, and Section 1905 of title 18, United States Code . . .*" (emphasis added).

99. *See* S. 2125, sec. 6(b). "The Secretary shall review the information contained in each report submitted under subsection (a) and if the Secretary determines that such information directly affects the public health, the Secretary shall require that such information be included in a label under Sections 3 and 4."

100. *See id.* sec. 9.

Hiding tobacco-ingredient information and other data concerning the health risks of its products is a longstanding tobacco industry practice. Such allegations of industry fraud were at the heart of the recently settled Attorney Generals Medicaid reimbursement cases.¹⁰¹ It is possible, if more of those cases had gone to trial, that secret tobacco ingredients might have been disclosed.¹⁰²

II. STATE LAWS

At the present juncture, it appears that a couple of states are likely to obtain more information about tobacco additives and smoke constituents—including cigars—under their own laws than Congress will demand. As discussed below, to date the states of Massachusetts, Minnesota, and Texas have taken action to fill the void, with varying, and at this stage, uncertain results.¹⁰³ Particularly in the absence of federal action, the outcome of industry challenges to these state laws is critical to the development of momentum for accessing tobacco product ingredients and smoke emissions data in the United States. Even a trickle of information about a limited set of ingredients or emissions from one jurisdiction could open the door for more aggressive regulation requiring disclosure of health-related information. In turn, such a development could lead to increased product regulation and public education campaigns in a number of jurisdictions.

A. *The Massachusetts Ingredients Reporting and Disclosure Law*

Massachusetts was the first state to adopt its own tobacco ingredient reporting-and-disclosure law.¹⁰⁴ With the notable exceptions of limiting

101. See, e.g., Edward Correia & Patricia Davidson, *The State Attorney Generals' Tobacco Suits: Equitable Remedies*, 7 CORNELL J. L. & PUB. POL'Y 843, 853 (1998).

102. See 12.3 Tobacco Products Liability Reporter 3.278 (1997) (discussing *Massachusetts v. Philip Morris Inc.*, No. 95-7378, (Mass. Super. 1998) and *R.J. Reynolds Tobacco Co. v. Humphrey* (D. Minn. 1997)) [hereinafter TPLR].

103. In Massachusetts, the industry has pursued an aggressive, and to date, relatively successful, litigation strategy to block enforcement of the state ingredients law. See *infra* notes 110-112 and accompanying text; See also *Philip Morris Inc. v. Harshbarger*, 159 F.3d 670 (1st Cir. 1998). In Minnesota and Texas the tobacco industry, including cigar manufacturers, has besieged the state public health agencies (charged with implementing the laws) with critical comments and proposed amendments to reporting forms and (in Texas) regulations. While a lawsuit by the tobacco industry, facially challenging the Minnesota statute, was dismissed shortly before the state's successful Medicaid suit went to trial, the industry has not been fully cooperative about providing the information specifically called for by the reporting forms issued pursuant to the statute. See *infra* discussion accompanying notes 146-58. The state of Utah recently enacted an unusual law requiring its health department to "obtain annually publicly available information regarding cigarettes and tobacco products from other states and sources" regarding the list of substances reportable under the Minnesota statute (in burned and unburned states) and nicotine yield ratings. UTAH CODE § 26-43-102 (1999).

104. See MASS. GEN. LAWS, ch. 94, § 307B (1996). The state of New Hampshire passed a similar law in 1998, requiring the New Hampshire department of health to "obtain annually from the Commonwealth of Massachusetts Department of Public Health, or other sources if they become

its scope to unburned ingredients¹⁰⁵ and particular classes of tobacco products (cigarettes and smokeless tobacco),¹⁰⁶ the Commonwealth adopted an extensive reporting and disclosure system. Specifically, the Massachusetts statute requires cigarette and smokeless tobacco manufacturers to report "[t]he identity of any added constituent other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco, to be listed in descending order according to weight, measure or numerical count" for each brand sold in the state to the Massachusetts Department of Public Health.¹⁰⁷ This brand specific reporting of specific quantities of non-tobacco ingredients is a significant departure from existing federal law.¹⁰⁸

Moreover, the reported ingredients and nicotine-yield information is subject to public disclosure. Specifically, if the state public health department determines that there is "a reasonable scientific basis for concluding that the availability of such information could reduce risks to public health," and the state attorney general advises that such a disclosure would not constitute a taking, the reported information is a public record.¹⁰⁹

However, the tobacco industry has succeeded in thwarting implementation of the Massachusetts ingredient reporting-and-disclosure pro-

available, a public report containing the list of additives for each brand of tobacco products sold." N.H. REV. STAT. § 78:12-e (1998).

105. See *infra* discussion accompanying notes 113-119 on cigarette smoke constituent reporting regulations proposed by the Massachusetts Department of Public Health.

106. However, in 1998, more than a year after the Massachusetts Cigarette and Smokeless Tobacco Ingredient Statute was enacted, cigar ingredients/warning regulations were proposed by the Massachusetts Department of Public Health (proposed Amendments: 105 CMR 650.000). The state Department of Public Health regulations would have imposed a limited testing and reporting obligation on certain cigar manufacturers as part of a warning label system. Specifically, cigar manufacturers with more than 2% of the national market would be required to test for and report nicotine, carbon monoxide, and tar level yields under a specified testing protocol. See 105 CMR 650.106. The reported information would be featured on a new cigar warning label comparing cigar yields for these substances to cigarette yields. See *id.* However, this proposal was apparently dropped in favor of a set of cigar regulations, recently promulgated by the Massachusetts Attorney General's Office. See 940 CMR 22. The new state regulations feature warning label requirements for cigar packages and advertisements, some youth-access retail restrictions, and outdoor advertising limits. See *id.* However, they do not include any cigar testing or ingredient reporting requirements. See *id.* Similar companion regulations pertaining to cigarettes and smokeless tobacco were simultaneously adopted. See 940 CMR 21. The regulations, which were to take effect August 1, 1999, were promulgated pursuant to the Attorney General's authority to define and halt unfair or deceptive marketing practices. The regulations were challenged by a number of cigarette, smokeless, and cigar manufacturers, along with a cigar retailer. The consolidated cases are currently before the 1st Circuit Court of Appeals. Consolidated Cigar Corp., et al. v. Thomas Reily, No. 00-1107, U.S. Court of Appeals (1st Cir.); Lorrillard Tobacco Co. v. Reilly, No. 00-1117, U.S. Court of Appeals (1st Cir.); U.S. Tobacco Co. v. Thomas Reilly, No. 00-1118, U.S. Court of Appeals (1st Cir.).

107. See MASS. GEN. LAWS ch. 94, § 307B (1996).

108. See *supra* Part I(B) for a discussion of the FCLAA and CSTHE ingredients reporting requirements.

109. See MASS. GEN. LAWS ch. 94, § 307B (1996).

visions of the statute, claiming that enforcement would destroy trade secrets in violation of the U.S. Constitution.¹¹⁰ On appeal, the court refused to vacate or modify the preliminary injunction, agreeing that the plaintiff tobacco companies were likely to succeed on the merits of their takings claim, and that they faced irreparable harm if the statute became operational before their challenge was fully heard.¹¹¹ Shortly before this article went to press the federal district court issued a permanent injunction prohibiting enforcement of the ingredients provisions of the Massachusetts statute.¹¹²

The Commonwealth of Massachusetts statute, and the state's ability to defend it in court when faced with a trade secrets challenge, might have been improved by including smoke-emission testing, reporting, and disclosure provisions. The Massachusetts Department of Public Health ("D.P.H.") has proposed such regulations, independent of the ingredients statute.¹¹³ Specifically, the regulations would require testing and reporting of numerous, specified cigarette smoke constituents.¹¹⁴ Both mainstream and side stream smoke would be covered.¹¹⁵

110. See *Philip Morris, Inc. v. Harshbarger*, 159 F.3d 670 (1st Cir. 1998). The First Circuit refused to vacate or modify the preliminary injunction granted by the lower court, based on the industry's argument that the statute's ingredient reporting and disclosure provisions violate constitutional prohibitions on government takings without compensation under the Takings Clause. *Id.* at 680. The nicotine yield reporting requirements of the statute, however, were not challenged and therefore are in effect. *Id.* at 673 n.3. Earlier the First Circuit affirmed a lower court ruling rejecting the industry's federal preemption challenge to the Massachusetts statute. *Philip Morris Inc. v. Harshbarger*, 122 F.3d 58, 87 (1st Cir. 1997).

111. See *Harshbarger*, 159 F.3d at 673.

112. See *Philip Morris, Inc. v. Reilly*, 2000 U.S. Dist. LEXIS 12947 (D. Mass. Sept. 7, 2000).

113. See 105 CMR 665.000 ("Testing and Reporting of Constituents of Cigarette Smoke"). At the industry's initiative, the Massachusetts Department of Public Health ("DPH") negotiated with cigarette manufacturers in an effort to commence a voluntary smoke constituent testing and reporting program, which would (at least initially) encompass only a limited number of cigarette brands. Telephone interview with Howard Saxner, Gen. Counsel, Mass. DPH (Mar. 18, 1999). As of March 22, 1999, the DPH agreed to defer further action on the proposed regulations until the cigarette manufacturers complete a six to eight month benchmarking study of a sample of cigarette brands. The industry study will examine smoke constituent levels for selected brands and the functional relationship between smoke constituent and tar levels. Reportedly, 25 cigarette brand styles will be studied for mainstream smoke yields, and 12 brand styles will be studied for side-stream smoke yields. The new Massachusetts smoke-yield testing parameters (45 ml. puff of two seconds duration every 30 seconds) will be used, and raw data will be shared with the DPH when the industry study is completed.

Cigarette manufacturers proposed to conduct the benchmark study to create a mechanism for predicting smoke-constituent yields of brands sold in Massachusetts, without having to individually measure smoke yields of each brand on the market. Reportedly, the companies objected to the regulatory plan to annually test each individual brand claiming, *inter alia*, that the testing plan was unwieldy because of the number of brands involved. They also cited anticipated methodological differences between the various company laboratories as an obstacle to testing. Telephone interview with Howard Saxner, Gen. Counsel, Mass. DPH (June 18, 1999).

114. See 105 DMR 664.000.

115. See *id.* at 665.003, 665.200, 665.201.

Under the Massachusetts proposed regulations, the specified smoke constituents¹¹⁶ must be reported "on the basis of the average yield per cigarette for each brand, sub-brand and non-branded generic product."¹¹⁷ Moreover, the regulations contain a fairly broad disclosure provision, apparently permitting the Massachusetts D.P.H. to release or distribute a smoke constituent report (or information contained in such a report) "[i]f the Department determines it is in the public interest to do so"¹¹⁸

Ironically, shortly before the recent settlement of the Massachusetts Medicaid reimbursement case a Massachusetts judge hearing pre-trial arguments ordered the defendant tobacco companies to disclose ingredients to counsel and experts for the Commonwealth.¹¹⁹ The settlement apparently foreclosed another opportunity for disclosure of tobacco ingredients.

B. The Texas Tobacco Product Ingredient Reporting and Disclosure Law

The Texas and Minnesota laws, which both cover cigars by virtue of their definitions of tobacco products, may fare better than the Massachusetts statute.¹²⁰ On its face, the Texas statute's reporting requirements are quite similar to the Massachusetts law. The Texas statute requires each cigarette and tobacco product manufacturer¹²¹ to file an annual report with

116. *See id.* at 665.200, 665.201. Constituents of mainstream smoke to be tested include ammonia, aromatic amines, benzoapyrene, volatile carbonyls, hydrogen cyanide, mercury, toxic trace metals, nitric oxide, tobacco specific nitrosamines, selected basic semi-volatiles, phenolic compounds, tar, and carbon monoxide. *See id.* at 665.200. Side-stream smoke constituents to be tested under the regulations include ammonia, aromatic amines, benzoapyrene, selected volatile carbonyls, hydrogen cyanide, mercury, toxic trace metals, nitric oxide, tobacco specific nitrosamines, selected basic semi-volatiles, phenolic compounds, tar, selected volatiles, and carbon monoxide. *See Id.* at 665.201.

117. *Id.* at 665.100(B).

118. *Id.* at 665.102.

119. *See Commonwealth v. Philip Morris, Inc.*, No. 95-07378, 1998 Mass. Super. LEXIS 438 (Mass. Super. Ct. Oct. 29, 1998). Reportedly, Superior Court Justice Martha B. Sosman "rejected defense attempts to keep the lists away from the commonwealth's Department of Health, which is appealing a federal court injunction preventing enforcement of a recently enacted disclosure law." *Mass. Lawyers Can Get Cigarette Ingredients If Case Goes Ahead*, 12 No. 14 MEALEY'S LITIGATION REPORT: TOBACCO 6 (1998) (citation omitted).

120. *See* 25 TEX. ADMIN. CODE § 101.3 (1999), *amended by* 24 Tex. Reg. 3509, 3511 (May 7, 1999); MINN. STAT. § 461.17 (1999); MINN. STAT. § 609.685 (1987 & 1999) (defining tobacco to include cigars); MASS. GEN. LAWS ch. 94, § 307B (1996 & 1999). The Texas law has been challenged and reshaped at the agency level though tobacco industry comments objecting to reporting forms and the proposed regulations. As a result, implementation of the laws has been repeatedly delayed. In Texas the effective date for reporting has now been pushed back to December 1999. *See* 25 TEX. ADMIN. CODE § 101.3 (1999), *amended by* 24 Tex. Reg. 3509, 3511 (May 7, 1999). The prior amendment called for reporting to commence "on or before March 1, 1999." 25 TEX. ADMIN. CODE § 101.3.

121. The statute provides that the term "tobacco product" has the meaning assigned by TEX. TAX CODE § 155.001 (1998) which in turn defines "tobacco product" to include cigars. TEX. HEALTH & SAFETY CODE § 161.251 (1999); TEX. TAX CODE §§ 155.001(9), 155.001(14)(A) (1999).

the department of health for the cigarette and tobacco products it distributes in the state, stating:

(1) the identity of each ingredient¹²² in the cigarette or tobacco product, listed in descending order according to weight, measure or numerical count,¹²³ other than:

(A) tobacco;

(B) water; or

(C) a reconstituted tobacco sheet made wholly from tobacco;

and

(2) a nicotine yield rating for the cigarette or tobacco product established under 161.253.¹²⁴

The language of the Texas statute appears to subject cigarettes and all tobacco products, including cigars, to identical requirements. However, the implementing regulations exempt cigars from the nicotine yield reporting requirements and create a separate section delineating the ingredients reporting standards for cigars.¹²⁵

The Texas regulations also set forth detailed disclosure criteria and elaborate procedures for making and challenging disclosure decisions.

122. The Texas statute "does not require a manufacturer to disclose the specific amount of any ingredient in a cigarette or tobacco product if that ingredient has been approved as safe when burned and inhaled by the United States Food and Drug Administration or a successor entity." TEX. HEALTH & SAFETY CODE § 161.252(b) (1999).

123. The reporting forms require tobacco manufacturers to submit this information by chemical name and number, for each brand and sub-brand. 25 TEX. ADMIN. CODE § 101.4(1) (1998).

124. Under this Section the state health department must adopt standards for nicotine yield rating which must reflect "as accurately as possible, nicotine intake for an average consumer of the cigarette or tobacco product." TEX. HEALTH & SAFETY CODE § 161.253 (1999). In October 1999 the Texas Health Department repealed its proposed rule for nicotine reporting and substituted standards modeled on the Massachusetts nicotine yield reporting system. *See* 24 Tex. Reg. 8705 (1999); 105 CMR 660.004. The industry petitioned for this change, arguing that following the Massachusetts model would save the industry "more than \$1500 annually for each brand style exempted from the new rule. 24 Tex. Reg. 8706 (1999). The new Texas rule is more flexible than the original, with testing and reporting requirements varying based on brand market shares. Reportedly, the Texas Department of Health agreed to alter the rule in exchange for the industry's withdrawal of its petition to modify the regulatory definition of the term "ingredient." Telephone Interview with Dr. Phillip Huang, Texas Department of Health (November 1, 1999).

125. *See* 25 TEX. ADMIN. CODE § 101.3(a) (1999) (exempting cigars from nicotine yield reporting); § 101.4 (delineating reporting requirements for cigars). Although neither the published comments nor the agency response to those comments explains the rationale for excluding cigars from the nicotine reporting requirements, it is clear that the cigar industry lobbied aggressively for special treatment and exemptions. *See* 23 Tex. Reg. 5687, 5688, 5691 (1998). Indeed, although the Health Department declined to grant the cigar industry's request to exempt or reduce small manufacturers or "small sales" from the ingredients reporting requirements at this time (citing a lack of market share data), it explicitly expressed sympathy for the industry and invited it to suggest changes in the rule which would allow for verification of market share in Texas. 23 Tex. Reg. 5691 (1998).

These provisions appear to be significantly more protective of tobacco manufacturers and "trade secret" information than the statutory language requires. For example, the statute essentially provides that reported information is available to the public unless one of the three following exceptions applies. First, reported information is protected as confidential if the Texas "attorney general determines that the disclosure of particular information would constitute a taking of property"¹²⁶ Second, reported information is deemed confidential "if the department determines that there is no reasonable scientific basis for concluding that the availability of the information could reduce risks to public health."¹²⁷ These two criteria are similar to the provisions of the Massachusetts statute.

The third Texas exception, however, could conceivably swallow the disclosure rule. Under the statute, reported information "is confidential under Chapter 552, Government Code, if the information would be excepted from public disclosure as a trade secret under state or federal law."¹²⁸ The Chapter 552 or Texas Open Record Law exception could prove to be quite wide. First, the substantive scope of the exception is generous." A trade secret or commercial or financial information obtained from a person and privileged or confidential by statute or judicial decision is excepted from the requirements of Section 552.021"¹²⁹ Second, the multi-layered procedures set forth under the Texas Open Records Law provide ample opportunity for the tobacco industry to challenge and at a minimum delay any disclosure.¹³⁰

126. TEX. HEALTH & SAFETY CODE § 161.254(b) (1999).

127. *Id.* § 161.254(c).

128. *Id.* § 161.254(d).

129. TEX. GOV'T CODE § 552.110 (1994). According to open records decisions issued by the Texas Attorney General, the state of Texas follows the Restatement of Torts definition of "trade secret." See 1988 Op. Tex. Att'y Gen. 494 (1988); 1990 Op. Tex. Att'y Gen. 554 (1990). Under this definition a six factor test is used to determine whether information qualifies as a trade secret:

(1) the extent to which the information is known outside of the company's business; (2) the extent to which it is known by employees and others involved in the company's business; (3) the extent of measures taken by the company to guard the secrecy of its information; (4) the value of the information to the company and to its competitors; (5) the amount of effort or money expended by the company in developing [the] information (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

1988 Op. Tex. Att'y Gen. 494 (1988) (citing RESTATEMENT OF TORTS § 757, cmt. b (1939)). See also 1999 Op. Tex. Att'y Gen. 661 (noting that the broad Restatement definition of trade secret "would also be the principal test applied in a determination by this office under subsection (b) of Section 161.254 as to whether disclosure of ingredient information reported to the department would be an 'unconstitutional taking.'").

Section 552.110 of the Texas Open Record Law also excepts certain types of "commercial or financial information" that may not qualify as a trade secret. TEX. GOV'T CODE § 552.110.

130. See 25 TEX. ADMIN. CODE § 101.10 (1998). See TEX. GOV'T CODE § 552.306 (1992 & Supp. 1999) (delineating procedures to be followed by the Attorney General); *id.* § 552.304 (regarding public comments); *id.* § 552.305 (allowing those whose property interests are at stake have a special statutory right to participate in the process).

Furthermore, the Texas regulations require the department of public health to take a number of steps before releasing reported information. In practice these requirements shift the burden of proving whether reported information may be disclosed to the public health department and state attorney general instead of requiring the industry to dispel the statutory presumption of disclosure.

Specifically, in response to tobacco industry criticism and comments regarding confidentiality protections¹³¹ the following new section was added to the Texas regulations:¹³²

(e) Before releasing any information, the department shall:

(1) submit the information to the attorney general with a request that he/she make the determinations called for under subsection (b)¹³³ and (d)¹³⁴ of this section and Government Code sec. 552.110;

(2) submit the information to the attorney general in accordance with procedures set out in the Government Code, Chapter 552, and the attorney general's *Open Records Handbook*;

(3) contemporaneous with each submission under this subsection, notify the person who submitted the information, so they may exercise their rights under Government Code sec. 552.110; and

(4) following an opinion from the attorney general under this subsection which would allow the release of any information, the submitter shall be immediately notified and the department shall delay release for 30 days to allow:

(A) the department to make the determination called for in subsection (c)¹³⁵ of this section; and

(B) the submitter of the information opportunity to obtain judicial review of the attorney general's opinion.¹³⁶

131. See 23 Tex. Reg. 5687, 5690-5691 (1998).

132. See 25 TEX. ADMIN. CODE § 101.10 (1998).

133. Subsection (b) provides:

The department may not disclose information . . . until the department has obtained the advice of the attorney general under this section with respect to the particular information disclosed. If the attorney general determines that the disclosure of particular information would constitute an unconstitutional taking of property, the information is confidential and the department shall exclude that information from disclosure.

25 TEX. ADMIN. CODE § 101.10(b) (1998).

134. Subsection (d) provides: "Information included in a report filed under this subchapter is confidential under Government Code, Chapter 552, if the information would be excepted from public disclosure as a trade secret under state or federal law." *Id.* § 101.10(d).

135. Subsection (c) provides: "Information included in a report filed under this subchapter is confidential if the department determines that there is no reasonable scientific basis for concluding that the availability of the information could reduce risks to public health." *Id.* § 101.10(c).

136. 25 TEX. ADMIN. CODE § 101.10(e) (1998). Under Section 552.303 of the Texas Government Code the government agency holding the disputed information may not disclose the

Moreover, the industry sought and obtained an Open Records Decision from the Texas Attorney General that narrows the scope of required tobacco ingredients disclosure.¹³⁷ The decision clarifies a number of issues pertaining to the disclosure process and to standards for confidentiality. The clarifications primarily benefit the industry. While it acknowledges that generally the Attorney General must examine a particular report or document in order to determine whether disclosure would constitute a taking, the decision also provides a safe harbor for all ingredients information submitted under the Texas statute which would be considered confidential under the two relevant federal statutes, FCLAA and CSTHEA.

However, because the definition of the term "ingredients" set forth in the Texas regulations¹³⁸ differs from the definitions contained in FCLAA and CSTHEA, (which refer to ingredients "added to" tobacco in the manufacturing process),¹³⁹ certain information not covered under the federal laws may well be discloseable in Texas. For example, under the Texas definition of ingredients, information about pesticide residue present in tobacco products may be disclosed.

Furthermore, because neither of the federal laws providing confidentiality protections to ingredients information applies to cigars, none of the ingredients data reported by cigar manufacturers will be automatically deemed confidential.

C. Minnesota's Tobacco and Smoke Constituent Reporting and Disclosure Law

The Minnesota ingredients reporting statute, in contrast to the Massachusetts and Texas laws, covers a relatively short list of constituents in both a burned (emissions) and unburned state. Specifically it requires:

Each manufacturer of tobacco products¹⁴⁰ sold in Minnesota shall provide the commissioner of health with an annual report . . . for each brand of such product, [if] any of the following substances [is] pres-

information "until the attorney general makes a final determination or, if suit is filed under this chapter, until a final determination that the information is public has been made by the court with jurisdiction over the suit . . .," unless a protective order is obtained under Section 552.322 of the Texas Government Code. TEX. GOV'T CODE § 552.303(a) (1999).

137. See 1999 Op. Tex. Att'y Gen. 662 (1999).

138. See 25 TEX. ADMIN. CODE § 101.2(7) (1999). The Texas regulation defines "ingredient" as "[a]ny ingredient, substance, chemical or compound other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco, which all is *present in the product* including but not limited to, flavorants, processing aides, casing sauces, contaminants, combustion modifiers, and packing materials, to the full extent the manufacturer is aware of the presence of any such ingredient." *Id.* (emphasis added).

139. See 15 U.S.C. 1335a(a); 15 U.S.C. 4403(a)(1)(A).

140. Minnesota law defines tobacco products to include cigars. See MINN. STAT. § 609.685(1)(a) (1987 & 1999).

ent in detectable levels in the product in its unburned state and if the product is typically burned when consumed, in its burned state:

- (1) ammonia or any compound of ammonia;
- (2) arsenic;
- (3) cadmium;
- (4) formaldehyde; and
- (5) lead.¹⁴¹

The reporting forms issued by the Minnesota Department of Public Health require testing and reporting of particular quantities of the five specified substances¹⁴² in mainstream smoke, side-stream smoke and in unburned states for cigarettes, smokeless tobacco, cigars and pipe (or "roll your own") tobacco.¹⁴³ Moreover, the disclosure provision of the Minnesota law is quite broad and general: "Reports under this section are public data."¹⁴⁴ According to the statute, the Minnesota Health Commissioner is also required to share copies of tobacco industry reports with local governments if the locality requests the report "to assist in the enforcement of local ordinances."¹⁴⁵

R.J. Reynolds Co. ("RJR") filed suit to enjoin enforcement of the Minnesota statute immediately after it was enacted, claiming, *inter alia*, that it was preempted by FCLAA and that it violated the takings clause of the U.S. Constitution by forcing disclosure of trade secrets.¹⁴⁶ In contrast to the aggressively litigated, multi-company Massachusetts lawsuit,

141. MINN. STAT. § 461.17(1) (1999).

142. These five substances are particularly harmful:

Doug Blanke, consumer policy director for the Minnesota attorney general's office, said the five substances were included in the disclosure law partly because they are known for "being bad for you."

They also play well-researched roles in smoking, Blanke said. Tobacco industry documents released in the Minnesota trial revealed that ammonia may increase the "kick" of nicotine, much the way that "freebasing" cocaine increases its potency, he said.

Leslie Brooks Suzukamo, *Marketing of 'Pure' Cigarettes May Face Obstacles: State's Disclosure Law Could Undercut Firms' Promotional Strategy* (visited Nov. 24, 1998) <http://www.pioneerplanet.com/news/mtc_docs/013626.htm>.

143. The reporting form sparked a variety of industry complaints, including objections to testing requirements and the inclusion of cigars. With regard to testing, some tobacco manufacturers apparently claim that the Commissioner has exceeded her statutory authority by mandating testing and reporting of specific quantities of the listed substances (in their burned and unburned state). Instead, the industry argues that under the statute it need only indicate whether the five substances are present in a particular tobacco product. Telephone Interviews with Richard A. Wexler, Minnesota Assistant Attorney General, Manager, Health Division, State of Minnesota, Office of the Attorney General (December 16, 1998).

144. MINN. STAT. § 461.17(3) (1999).

145. *Id.* § 461.17(2).

146. See R.J. Reynolds Tobacco Co. v. Humphrey, 12.3 TPLR 3.278, paras. 1, 3-4, 23-24, 29-30 (D. Minn. 1997).

the Minnesota case was filed by, and ultimately dismissed,¹⁴⁷ at the request of a single cigarette manufacturer plaintiff.¹⁴⁸ This single company strategy is curious considering that the Minnesota law encompasses virtually all tobacco products, including cigars.¹⁴⁹

Notably, as part of the ensuing settlement of the state of Minnesota's Medicaid reimbursement suit (which was the most favorable state settlement from a public health perspective), the defendant companies promised not to "facially challenge the enforceability or constitutionality of existing Minnesota laws or rules relating to tobacco control, including, but not limited to Minnesota Statutes Section 461.17 regarding the disclosure of certain ingredients in cigarettes."¹⁵⁰ However, this settlement-induced promise does not cover cigar manufacturers, who were not parties to the Medicaid suit.¹⁵¹ It also may not protect the state of Minnesota from a variety of other industry challenges to the letter and spirit of the ingredients reporting statute, including, for example, suits claiming that it is unenforceable or unconstitutional as applied.

147. The court granted RJR's motion to dismiss without prejudice under the condition that it pay the state of Minnesota \$10,000 in attorneys' fees if the company "commence[s] a subsequent action in state or federal court asserting claims substantially similar to those in this action." Plaintiff's Motion to Dismiss, *R.J. Reynolds v. Humphrey* (D.Minn. 1997) (No. 97-1317). In proceedings leading up to the dismissal the state of Minnesota sought unconditioned attorneys' fees in excess of \$40,000 and argued that RJR was required to provide specific reasons for moving to dismiss the case under Rule 7(b)(1) of the Federal Rules of Civil Procedure. Defendants' Response to Plaintiff's Motion for Dismissal, *R.J. Reynolds Tobacco Co. v. Humphrey* (D.Minn. 1997) (No. 97-1317).

Although the court did not apparently order RJR to specify its reason for seeking dismissal, the company filed a responsive pleading objecting to an award of attorneys' fees and asserting that it wished to suspend its lawsuit against the Minnesota ingredients law "due to two significant developments which occurred *after* the complaint was filed." *Id.* (emphasis supplied). First, RJR cited the state announced delay in requiring tobacco companies to file ingredients reports until at least the spring of 1998. *See id.* Second, the company acknowledged that potential congressional action on the June 20, 1997 Proposed Settlement, which authorized the FDA to expand ingredients reporting, militated in favor of delaying the lawsuit. *See id.* "The possibility that Congress may act in an area addressed by the State law challenged in this case, before the reports required by the State law would have been filed, argues in favor of suspending the instant litigation at this time." *Id.*

148. Defendants' Response to Plaintiff's Motion for Dismissal, *R.J. Reynolds Tobacco Co. v. Humphrey* (D.Minn. 1997) (No. 97-1317). The state of Minnesota raised this point in seeking attorneys' fees as a condition of dismissal, noting that RJR could easily avoid paying fees conditioned on a future lawsuit challenging the statute "by having one of the other tobacco companies be named the plaintiff." *Id.*

149. *See supra* note 140.

150. *Minnesota v. Philip Morris, Inc.*, No. C1-94-8565, Settlement Agreement and Stipulation for Entry of Consent Judgment, Section IV.A.2, p. 15 (2d Dist. Ct. Minn. County, May 8, 1998). Arguably the industry did not promise to forgo other types of challenges to the ingredients disclosure law, including, for example claims that the law is unconstitutional or should not be enforced as applied to the industry. As part of the settlement the industry also made other limited promises not to challenge certain types of tobacco control laws, including at least one pertaining to cigars.

151. *See Philip Morris*, C1-94-8565, Settlement Agreement, at Section I.C.4.

As part of the Medicaid reimbursement settlement the tobacco industry also made other limited promises not to oppose passage of certain types of laws in Minnesota, "intended by their terms to reduce tobacco use by children"¹⁵² including, for example, "[l]egislation to expand the self-service-sale restrictions of the youth access to tobacco law and to remove the current exception for sales of cigars."¹⁵³ Notably the industry carved out a wide exception that may swallow the rule." The foregoing does not prohibit Settling Defendants from resisting enforcement of, or suing for declaratory or injunctive relief with respect to any such legislation or rule on any grounds."¹⁵⁴ Analogous qualifying language may severely limit the value of similar promises the industry made to the remaining states pursuant to the Master Settlement Agreement.¹⁵⁵

At this writing the Minnesota ingredients reporting and disclosure law has yielded some limited data. As of March 9, 1999 the State Department of Public Health had received thirty reporting forms from tobacco manufacturers, including cigar manufacturers.¹⁵⁶ According to a department spokesperson the returned forms vary considerably in their degree of completion. As anticipated, many of the larger cigarette manufacturers responded with only a "yes" or "no" to questions on the form about the five specified ingredients, indicating only whether or not the substance is present in a tobacco product.¹⁵⁷ These companies did not report any information about quantities of the specified substances. They

152. *Id.* at Section IV.A.2.

153. *Id.* at Schedule B. State and local laws limiting the use of vending machines dispensing tobacco products have been deployed nationwide in an effort to block youth access. PETER D. JACOBSON & JEFFREY WASSERMAN, *TOBACCO CONTROL LAWS: IMPLEMENTATION AND ENFORCEMENT* 15 (1997). The recent rise in cigar smoking among youth, along with the glamorization of cigars in a variety of media has been well documented. Most recently reports of increased production and placement of cigar vending machines have emerged. PRNewswire, *International Industries to Double Number of Company-Owned Cigar Vending Machines* (visited Sept. 3, 1998) <<http://www.SureTrade.com>>. Reportedly the cigar vending machines will dispense the lower-priced mass marketed cigars (\$2.00), more likely to be purchased by youth, as well as expensive premium cigars (\$35). *Id.*

154. *Philip Morris, Inc.*, C1-94-8565, Settlement Agreement at Section IV.A.1.

155. See Master Settlement Agreement at Section II.F. (listing eight categories of state and local legislation the industry pledged not to oppose, including bills or rules encompassing cigars in the definition of tobacco products). *Id.* at Section III(m) (attaching qualifying language and four express exceptions to the no lobbying pledge). Furthermore, cigar manufacturers are not parties to either settlement and therefore are not subject to their terms. The Master Settlement Agreement can be viewed in its entirety on the Internet. *Master Settlement Agreement* (visited Oct. 10, 1999) <<http://www.naa.org/settle.htm>>.

156. Telephone Interview with Janet Olstad, Office of the Commissioner, Minnesota Department of Health (March 9, 1999). The state of Minnesota distributed reporting forms to 636 tobacco manufacturers but it is not clear how many of the manufacturers on the list actually sell tobacco products in Minnesota and therefore are subject to the state law. In an effort to improve its list and manufacturer accountability the state is sending out a second series of letters asking the 636 manufacturers to clarify whether they sell tobacco products in Minnesota or not. *Id.*

157. See e.g., Brown & Williamson Corporation, Minnesota Tobacco Substance Report: Cigarettes, February 1999 (visited March 24, 2000) <<http://www.health.state.mn.us>>.

also failed to provide any information about the quantities or properties of the five poisons when burned.

Moreover, some tobacco manufacturers added gratuitous language indicating that the ingredients are present in food, air, water, etc.¹⁵⁸ A complete set of returned forms have been posted on the Minnesota Department of Public Health's web site: <http://www.health.state.mn.us>.

III. CANADIAN INGREDIENTS AND SMOKE CONSTITUENTS REPORTING AND DISCLOSURE

The government of Canada has adopted a significantly more expansive set of tobacco constituent and smoke emissions reporting regulations than has been contemplated to date in the United States, or anywhere else in the world.¹⁵⁹ On June 10, 1998, Health Canada issued an Information

158. For example, reports for a number of cigar brands, including *inter alia*, Dunhill and Montecruz, simply state:

The five substances (amonia or any compound of amonia, arsenic, cadmium, formaldehyde and lead) named in Minnesota Statutes (sic) § 461.17, Subdivision 1, are prevalent in nature, and scientific literature is replete with studies indicating the presence of these substances in air, food, water and, indeed, in many everyday consumer products, including tobacco products.

Therefore, trace amounts . . . may be present in either the unburned state or the burned state, or both, of the subject brand, but tests have not been conducted to make that determination.

Minnesota Tobacco Substance Reporting Form, Cigars, Brand: Dunhill; Sub-Brand: European—Slim Panatellas (visited March 24, 2000) <www.health.state.mn.us>.

159. The nationwide Canadian regulations were proposed shortly before the Province of British Columbia adopted a stringent Tobacco Testing and Disclosure Regulation. <<http://www.cctc.ca/bcreports>> (visited September 15, 1999). The British Columbia regulations "require tobacco companies to both reveal the additives and ingredients in each brand of cigarettes, and to provide a detailed chemical analysis of the smoke of each brand of cigarettes." *Id.* Recently the British Columbia Ministry of Health released brand (but not quantity) specific information reported by tobacco companies to the public through its homepage web site, announcing:

[t]his marks the first time brand-specific information on the additives and ingredients of cigarettes sold in a jurisdiction has been released publicly by a government. It is also the first time such detailed information on the toxicity of cigarette smoke has been released by a government to the public anywhere in the world.

Id. While some manufacturers, including Imperial Tobacco and Benson & Hedges have agreed to comply with regulations, RJR Macdonald filed suit against the government of British Columbia in October 1998 challenging the constitutionality of the regulations. <[http://www.newswire.ca/releases/October 1998/30](http://www.newswire.ca/releases/October%201998/30)> (visited Dec. 29, 1998). One news report indicated that the company claimed that smoke constituent information is protected as a trade secret."The RJR-Macdonald writ claimed the province exceeded constitutional authority by requiring tobacco companies to reveal trade secrets, such as the chemical ingredients in cigarette smoke." *Id.*"Canada: RJR-Macdonald Sues British Columbia Government, Tobacco Reporter 1998." *Id.* However, the writ itself distinguishes between additives and ingredients reporting and smoke constituent reporting. *RJR-Macdonald, Inc. v. Attorney General of British Columbia, Writ of Summons and Statement of Claim, Supreme Court of British Columbia, Oct. 1998.* A trade secret claim is asserted with regard to reporting of additives and ingredients information, but is not raised with regard to smoke constituent reporting. *Id.* at 8. Rather, objections to the smoke constituent regulations are primarily based on an argument that such mandatory, and costly, analysis and testing by a single province is "ultra vires" as a barrier to inter-provincial trade. *Id.* at 15. Notably, RJR-Macdonald alleged, *inter alia*:

[m]aking public information about the presence of such constituents and the yield ratings thereof in cigarette smoke is misleading without making public the presence of the same

Letter outlining proposed tobacco reporting regulations and soliciting comments (hereinafter I.L. No. 819).¹⁶⁰ Specifically, Health Canada proposed to expand reporting requirements to collect information about an extensive list of ingredients and emissions for many classes of tobacco products.¹⁶¹

Reporting requirements for ingredients and emissions under the proposed regulations would cover “over 50 chemical compounds, including those found in whole tobacco (unburned),¹⁶² mainstream smoke (inhaled by the smoker)¹⁶³ and side-stream smoke (inhaled by non-smokers).”¹⁶⁴ Total smoke emissions for the same categories of chemicals must also be reported.¹⁶⁵

Furthermore, emissions data would be collected under two distinct methodologies: “1) the existing standard smoking machine method; and 2) a ‘maximum’ emission method, designed to provide data that reflects the emissions that are actually available to the consumer.”¹⁶⁶ An analysis of data reported under each of these proposed testing parameters could

constituents and the yield ratings thereof in the food we eat, the water we drink and the air we breathe, as well as in a host of other consumer and industrial products to which the public is exposed

Id. at 11. Similar language appears in some of the ingredients and smoke constituent reports submitted by tobacco manufacturers in the State of Minnesota. *See supra* note 159.

160. HEALTH PROTECTION BRANCH, HEALTH CANADA, INFORMATION LETTER NO. 819, PROPOSED TOBACCO (REPORTING) REGULATIONS (June 10, 1998) [hereinafter I.L.No. 819].

161. *See id.* at 2-3.

162. *See id.* at 3. The following classes of tobacco constituents must be reported for all tobacco products, including cigars: nicotine alkaloids, ammonia, pH, nitrosamines, toxic trace metals, nitrates humectants, plasticizers and preservatives. *Id.* at Table A. The I.L. explains that under the current law cigarette manufacturers only report “the ingredients they added” while the new regulations cover many components of the tobacco itself, as well as papers, filters, tubes, etc. *Id.* at 3-4. *See also* Proposed Tobacco Reporting Regulations, 134(14) C. Gaz. 1006-1007 (April 1, 2000) (providing a list of data collection methods for tobacco constituents). A discussion of the chemistry and toxicology of tobacco products is beyond the scope of this Article. For a discussion of cigar chemistry and toxicology, see U.S. DEP’T OF HEALTH AND HUM. SERVS., CIGARS: HEALTH EFFECTS AND TRENDS 55-97 (1998).

163. Under the proposed regulations Canadian cigar manufacturers must report mainstream smoke emissions for the following categories: tar, nicotine, carbon monoxide, polynuclear aromatic hydrocarbons, carbonyls, phenolics, ammonia, hydrogen cyanide, basic, semivolatiles, pH, toxic trace metals, nitrosamines, aromatic amines, Nox, eugenol, and miscellaneous organics. *See* I.L. No. 819, *supra* note 160, at Table B. However, quite recently Health Canada amended its proposed regulations to exempt pipe tobacco and cigars—other than small cigars—from the emissions reporting requirements. *See* Proposed Tobacco Reporting Regulations, Sections 1 and 14, *id.* at 989, 997-1000.

164. *Id.* at 3. The same categories of side-stream smoke emissions must be reported. *Id.* at Table C.

165. *See id.* at Table D.

166. *Id.* at 3. Additional information about the proposed methods is available from Office of Tobacco Control, Environmental Health Directorate, Health Protection Branch, 7th Floor, Brooke Claxton Building, Address locator 0907D1, Tunney’s Pasture, Ottawa, Ontario, K1A 0K9. Tel. (613)941-2423. *Id.* at 8. *See also* Proposed Tobacco Reporting Regulations, Schedules 1, 2, and 3, 134(14) C. Gaz. 10006-1010 (April 1, 2000).

prove to be very useful to scientists studying tobacco emissions and policy-makers concerned about health effects.

The proposed Canadian regulations would also require manufacturers of all tobacco products, including cigars, to annually provide "lists of studies on the toxicity and on the health effects of tobacco products; lists of studies on the tastes and flavor of tobacco products; lists of studies relating to the modification of tobacco products; and, lists of studies on ingredients of tobacco products."¹⁶⁷ Moreover, the regulations propose new requirements for reporting promotional and sponsorship activities, as well as information about certain advertising expenditures (e.g., the cost to manufacturers of point-of-sale product displays and the amount of display fees paid to retailers) and sales.¹⁶⁸

However, details about the scope of public disclosure of information reported by tobacco manufacturers under the new regulations are not articulated in the I.L. No. 819, which simply states:

It is the intention of Health Canada to release selected items of reported data in the form of an annual report. The data to be released will include the currently released sales data and emission data. Proprietary information, such as ingredient lists and other trade secret information will not be released.¹⁶⁹

It is not yet clear how proprietary information will be defined under the Canadian regulations. However, the distinction between ingredients information and emissions data is worth noting. While unburned constituent or ingredients data is likely to be protected (or at least claimed to be so by the tobacco industry), emissions data is apparently not considered proprietary by Health Canada. American jurisdictions faced with industry "trade secret" challenges may wish to consider adopting a similar model, thereby ensuring (or at least increasing the likelihood of) public release of brand specific emissions data.

VI. CONCLUSION

The United States has a woefully inadequate tobacco ingredients reporting legal policy, requiring only cigarette and smokeless tobacco manufacturers to submit aggregated lists of ingredients in their unburned state. Several states have stepped forward in an attempt to require reporting relating to other tobacco products, such as cigars, and to obtain quantity and brand specific ingredients, and in one state: Minnesota, emissions information. These states have faced multi-faceted industry challenges to their laws. To date the industry's trade secrets arguments,

167. *Id.* at 4.

168. *See id.* at 4-6.

169. *Id.* at 6-7.

made in both judicial and regulatory forums, have effectively delayed or weakened implementation of the laws.

The results of state experimentation with ingredients reporting/disclosure laws, which has been the model for development of tobacco regulations in a variety of spheres (i.e., youth access prohibitions, advertising restrictions), could influence tobacco policy in the United States for the foreseeable future.¹⁷⁰ Particularly during this experimental phase, American jurisdictions attempting to enforce tobacco ingredients or emissions reporting laws, as well as those contemplating adopting them, could find it useful to look to leadership from our Canadian neighbors. Consistent with the Canadian model, it is possible that adopting regulations requiring testing, reporting, and disclosure of smoke constituents, at least as a preliminary step, will shore up legal defenses to industry challenges to such laws.¹⁷¹ Legally defensible releases of information about toxic smoke constituents produced by tobacco products, including cigars, coupled with reporting requirements for (unburned) ingredients could pave the way for more comprehensive tobacco products ingredients reporting and disclosure laws and policies.¹⁷²

Of course a focus on emissions will bring testing issues and debate about testing methodology to the forefront. Cigarette testing for tar, nicotine and carbon monoxide, the only tobacco emissions ever seriously examined by the U.S. government, has a long and controversial history.¹⁷³ Although a discussion of the Federal Trade Commission's ("FTC") cigarette testing is beyond the scope of this Article, it is worth noting that at a 1994 national conference convened to examine the validity of the existing and highly criticized protocol, a National Cancer Institute Expert Committee (hereinafter Committee) explicitly considered whether constituents other than tar, nicotine, and carbon monoxide should be added to the protocol.¹⁷⁴ The Committee concluded that "to avoid confusing smokers, no smoke constituents other than tar, nicotine and carbon mon-

170. At this writing, the emergence of a comprehensive national ingredients reporting and disclosure law, particularly one that covers cigars, does not seem likely. See *supra* discussion of S. 2125 in Part I.B.3.

171. In the U.S. the tobacco industry has aggressively protected tobacco ingredients information as a trade secret. See, e.g., *Philip Morris, Inc. v. Harshbarger*, 159 F.3d 670, 673 (1st Cir. 1998). However, reporting of smoke emissions data was not in issue in that case and may be harder for the industry to win. *Philip Morris*, 159 F.3d at 672. Reportedly in Minnesota the industry has claimed that the emissions reporting (testing) requirements exceed statutory authority. See *supra* discussion accompanying note 146.

172. Alternatively, severability provisions could protect emissions requirements if provisions related to unburned ingredients are struck or stayed.

173. For a detailed description of some of the testing and the issues involved see NATIONAL INST. OF HEALTH, THE FTC CIGARETTE TEST METHOD FOR DETERMINING TAR, NICOTINE, AND CARBON MONOXIDE YIELDS OF U.S. CIGARETTES (1996) [hereinafter FTC CIGARETTE TEST]. See also John Slade & Jack E. Henningfield, *Tobacco Product Regulation: Contest and Issues*, 53 FOOD & DRUG L.J. 43 (1998); Jeffrey S. Wigand, *Cigarette Testing Methods, Product Design, and Labeling: Time to Clean Up the Negative Baggage*, 7 TOBACCO CONTROL 336-337 (1998).

174. See FTC CIGARETTE TEST *supra* note 173, at vi.

oxide be measured and published at the present time. Smokers should be informed of the presence of other hazardous smoke constituents with each package and with all advertisements. These constituents should be classified by toxic effects."¹⁷⁵ However, portions of a report of Committee deliberations about smoke constituents and possible changes to warning labels suggest the reverse.

The concept of full disclosure of cigarette characteristics is entirely consistent with the current Federal Trade Commission (FTC) method. . . . One might object that such detailed disclosure of cigarette characteristics will confuse the smoker. Such an assertion is unscientific and unfair. To publish a label that discloses, for example, the tobacco-specific nitrosamine contents of a particular brand of cigarettes is no more confusing or complicated than printing a label that discloses the riboflavin and potassium yields of a particular brand of breakfast cereal. It would be remarkable to discover cereal manufacturers or consumer advocates arguing that the vitamin contents or trace metal levels of cereals should be withheld from consumers because vitamin E and zinc levels might correlate—at least roughly—with dietary fiber contents.¹⁷⁶

The Committee went on to acknowledge that there is no data, "at least in the public domain," on the impact of providing smokers or would be smokers with additional information about cigarette contents.¹⁷⁷ However, it added that while the effect on the demand side of the equation is unknown, it seems likely that such disclosure would have a salutary effect on the supply side." Enhanced and complete disclosure of cigarette characteristics by a standardized label would create a basis for more effective competition among manufacturers."¹⁷⁸

Apparently the 1994 U.S. testing methodology conference sparked research in Canada leading up to the development of a new testing protocol which is being implemented under a British of Columbia cigarette law designed regulate what smokers actually draw into their lungs.¹⁷⁹ This new methodology, developed at the Labstat International laboratory in

175. *Id.* at vii.

176. *Id.* at 68.

177. *Id.*

178. *Id.* at 70. In a question and answer section of the report, one committee member opined that even if a consumer does not choose among tobacco products based on the level of a particular chemical, "the disclosure of such contents provides an incentive for manufacturer to try to reduce that component." *Id.* at 72.

179. See Jane Armstrong, *Research Burns Light Cigarettes: New Testing Methods Account for Low-nicotine Smokers Puffing Harder and More Often*, THE GLOBE AND MAIL, Dec. 28, 1998, at A3.

Kitchner, Ontario under the direction of Dr. William Rickert,¹⁸⁰ will also be relied on under the broader tobacco products ingredients and emissions regulations proposed for the entire nation by Health Canada.¹⁸¹

Fully engaging and resolving the testing controversy,¹⁸² however, may be necessary to the development of coherent national and perhaps ultimately international tobacco products regulation of ingredients and smoke emissions. Furthermore, the recent proliferation of ETS restrictions in the United States, which are concerned with side-stream smoke, may provide a useful context in which to build broad-based public support for such a policy.

180. *Id.*

181. See 134(14) C. Gaz. Tobacco Reporting Regulations Schedules 2 and 3 (April 1, 2000).

182. One of the testing issues which arose in the course of negotiations to defer implementation of cigarette smoke constituent testing regulations in favor a benchmarking study between the Mass. Department of Public Health and cigarette manufacturers is the reported lack of sufficient testing facilities needed to produce contemporaneous data for all 600 cigarette brands which would be subject to the proposed testing regulations. Telephone conversation with Howard Saxner, General Counsel, Massachusetts Department of Public Health (March 18, 1999).

