

# Federal Approaches to the Regulation of Noncigarette Tobacco Products

Michael J.A. Freiberg, JD

---

**Context:** Under a grant funded by ClearWay Minnesota<sup>SM</sup> and in partnership with nationally recognized experts in tobacco product regulation, the Public Health Law Center investigated how laws at every level apply, or fail to apply, to noncigarette tobacco products—also called “other tobacco products.”

**Evidence acquisition:** During the years 2010–2011, standard legal research techniques were used to identify and compile relevant statutes, regulations, decisions, pleadings, proposals, and related materials. Sources included standard commercial legal databases such as LexisNexis and Westlaw, online sources for pending rules and legislation, and direct contact with courts for legal pleadings and unpublished decisions. These legal authorities related to many aspects of the regulation, including price, flavorants, youth access, marketing restrictions, and product design of other tobacco products. Five of these products were used as case studies: dissolvable tobacco products, electronic cigarettes, little cigars, snus, and water pipes.

**Evidence synthesis:** Research during the years 2010–2011 revealed that the federal regulation of other tobacco products lags behind the regulation of more “traditional” tobacco products, such as cigarettes and moist snuff. Federal regulatory options to expand regulation of these products were identified.

**Conclusions:** The article highlights several federal policy interventions that would address gaps in the regulation of other tobacco products. The FDA must determine whether these interventions will benefit public health and, if so, to what extent—the legal criteria for intervention under the federal Family Smoking Prevention and Tobacco Control Act.

(Am J Prev Med 2012;43(5S3):S249–S254) © 2012 American Journal of Preventive Medicine

---

## Context

In 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act<sup>1</sup> (TCA)—far-reaching legislation giving the Food and Drug Administration (FDA) the authority to regulate tobacco products. In his signing statement, the President stated that “the decades-long effort to protect our children from the harmful effects of tobacco has emerged victorious.”<sup>2</sup> Yet, despite this optimism, tobacco remains the leading cause of preventable death in the U.S.<sup>3</sup>

At least in part, tobacco remains a problem because the TCA left many gaps in regulation—gaps that may lead to increased tobacco initiation and use. One area in which these regulatory gaps are particularly apparent relates to noncigarette tobacco products, often called “other to-

bacco products”—such as cigars, electronic cigarettes, pipes, and certain kinds of novel smokeless tobacco products. So far, the bulk of the TCA has been applied to only four types of tobacco products: cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.<sup>4</sup> Similarly, the FDA’s 2010 youth-access regulation applies only to cigarettes and smokeless tobacco.<sup>5</sup> Further provisions of the law, such as the prohibition on characterizing flavors other than tobacco or menthol,<sup>6</sup> apply only to cigarettes. The failure of some provisions of the TCA to apply to some types of these other products represents a potential public health hazard.

Some of these gaps can be filled by state and local governments.<sup>7,8</sup> However, the TCA contemplated that many of these gaps would be filled by the FDA itself through regulation. Although there are many steps the FDA could take to regulate these other tobacco products more comprehensively, the FDA’s ability to issue regulations is limited by budgetary and statutory constraints.

This article will describe the criteria the FDA is required to use in evaluating regulatory options for other

---

From the Public Health Law Center, William Mitchell College of Law, St. Paul, Minnesota

Address correspondence to: Michael J. A. Freiberg, JD, Public Health Law Center, William Mitchell College of Law, 875 Summit Avenue, St. Paul MN 55105. E-mail: michael.freiberg@wmitchell.edu.

0749-3797/\$36.00

<http://dx.doi.org/10.1016/j.amepre.2012.07.036>

tobacco products. It will also point out some of the gaps in federal law relating to the regulation of these products, which at least arguably harm public health, and scientific reasons that these gaps might represent public health hazards. This is not intended to be an exhaustive list. Nor is the purpose of highlighting these gaps to recommend that the FDA address them all. Rather, it is intended to demonstrate that the FDA has many available regulatory options. Ultimately, it will be up to the FDA to determine which of these regulatory options will have the greatest positive impact on public health—the essential criterion for regulation under the TCA.

### **Evidence Acquisition**

During the years 2010–2011, standard legal research techniques were used to identify and compile relevant statutes, regulations, decisions, pleadings, proposals, and related materials. Sources included standard commercial legal databases such as LexisNexis and Westlaw, online sources for pending rules and legislation, and direct contact with courts for legal pleadings and unpublished decisions. These legal authorities related to many aspects of the regulation of other tobacco products, including price, flavorants, youth access, marketing, and product design. Five of these products were used as case studies: dissolvable tobacco products, electronic cigarettes, little cigars, snus, and water pipes.

### **Evidence Synthesis**

Research during the years 2010–2011 revealed that the federal regulation of these other products lags behind the regulation of more “traditional” tobacco products, such as cigarettes and moist snuff. Federal regulatory options to expand regulation of these products were identified.

### **Limitations on the U.S. Food and Drug Administration’s Authority**

Before highlighting some of the regulatory options available to the FDA, several limitations on the FDA’s authority must be acknowledged. First, it might be tempting to recommend that the FDA simply apply all cigarette regulations to the other products. Indeed, there are likely many instances where this would be appropriate from a public health perspective.

However, the TCA limits the FDA’s ability to impose requirements, or standards, on tobacco products. The FDA can issue new product standards only if “such regulation would be appropriate for the protection of the public health.”<sup>9</sup> The TCA charges the FDA with making this determination “with respect to the risks and benefits to the population as a whole,” taking into account the increased or decreased likelihood of tobacco cessation or initiation. These statutory requirements for product standards can be summarized as four criteria: public health

protection, population-level impact, cessation potential, and initiation potential.

Applying these four criteria to each kind of other tobacco product may yield results unique to each product type. For example, it may turn out that little cigars pose a greater risk than noncombustible tobacco products because of the appeal of flavored little cigars. Or, it may turn out that dissolvable tobacco products represent the greatest threat because of the possibility of the use of multiple kinds of tobacco products. In contrast, it is possible that some products have the potential to be used for cessation, or lead to substitution without initiation.

Determining the answer to these questions will likely be expensive, requiring market surveillance to determine whether a specific product makes tobacco initiation, continuation, or cessation more likely. The FDA has a limited budget, however, and must carefully prioritize which regulatory options it pursues.

However, these requirements do not present an insurmountable burden. The FDA is required to “consider” the risks and benefits to the population and the possibility of initiation or cessation, but the law does not require the FDA to find that all four criteria are met before issuing a new product standard. Presumably, if only one criterion is met, the FDA can adopt the regulation. So, for example, if the FDA determines that dissolvable tobacco products make tobacco initiation more likely but that the evidence is inconclusive regarding the likelihood of cessation or the population-level impact, it would have a sufficient basis to restrict access to the products. Further, the public health rationale applies only to tobacco product standards. It does not apply to other provisions of the law, such as the requirement that the FDA review new tobacco products before they become available on the market.<sup>10</sup>

The FDA will also need to take additional regulatory steps before regulating any product over which it has not yet declared jurisdiction (i.e., electronic cigarettes, little cigars, and water pipes). In the case of products already within the FDA’s jurisdiction (i.e., dissolvables and snus), it will be a more straightforward process. However, because the regulatory options are often the same, this article will discuss both groups of products.

Finally, this is a very dynamic regulatory field. The FDA has stated its intent to regulate some of these products but has not yet done so. Consequently, the FDA could adopt or decide not to adopt regulatory options highlighted in this article even before this article is published. Further, the tobacco industry has already challenged some FDA regulations in the courts, and will likely do so with any future meaningful regulation issued by the agency.

## Product Characteristics

The health risks and increasing popularity of the five studied product types (dissolvable tobacco products, electronic cigarettes, little cigars, snus, and water pipes) have been explored in other articles<sup>11–15</sup> and are beyond the scope of this article. However, this section will describe some characteristics unique to specific product types that lead to them not being regulated in the same manner as cigarettes or other noncigarette tobacco products.

In the case of some dissolvable tobacco products, there is some question regarding what kind of tobacco products they are. In January 2011, Star Scientific, the maker of Ariva and Stonewall brand dissolvable tobacco pellets, sought approval to sell a new line of products under these brand names<sup>16</sup> as “modified-risk tobacco products.”<sup>17</sup> In a puzzling decision a few months later, the FDA concluded that the products, known as Ariva-BDL and Stonewall-BDL, were not subject to regulation as tobacco products, presumably because they do not meet the definition of “smokeless tobacco.”<sup>18</sup> The rationale for this conclusion was redacted from a letter obtained through a Freedom of Information Act request. As a result of this decision, these products are not subject to any federal regulation.

In contrast, other forms of dissolvable tobacco likely meet the TCA’s definition of “smokeless tobacco,” which is defined as “any tobacco product that consists of cut, ground, powdered, or leaf tobacco . . . that is intended to be placed in the oral or nasal cavity.”<sup>19</sup> Snus would also meet this definition. As a result, the FDA currently has jurisdiction over these two categories of products, although not every regulation that applies to cigarettes also applies to them, as will be discussed.

In the case of electronic cigarettes, the FDA has announced its intent to regulate the products as tobacco products “unless they are marketed for therapeutic purposes, in which case they are regulated as drugs and/or devices.”<sup>20</sup>

## Available Federal Regulatory Options for Other Tobacco Products

### Category Prohibition

The first regulatory option available to the FDA is perhaps the most dramatic. The FDA has the authority to issue tobacco product standards which it determines would protect public health.<sup>21</sup> These standards could include the prohibition of entire classes of tobacco products with certain exceptions, including all cigarettes, all smokeless tobacco products, all little cigars, and all pipe tobacco.<sup>22</sup>

Moreover, the FDA has the authority to require premarket review for products that are not “substantially

equivalent” to those marketed in the U.S. prior to February 15, 2007.<sup>23</sup> New tobacco products that have different characteristics than products marketed before this date are not considered “substantially equivalent.”<sup>24</sup> “Characteristics” are defined broadly to include “the materials, ingredients, design, composition, heating source, or other features of a tobacco product.”<sup>25</sup> If any of these characteristics are different in a new tobacco product, it must go through the premarket review process. Further, this provision of the TCA does not require the FDA to meet the public health criteria required for tobacco product standards. If a product is a “new tobacco product,” it must not be sold until a premarket review is completed. It is therefore logical to place the burden on tobacco manufacturers to prove that a new tobacco product is “substantially equivalent” to previously existing products.

Among the five types of other tobacco products studied, there are two types of products that the FDA could prohibit because they would likely not meet the statutory definition of “substantially equivalent”: dissolvable tobacco products and electronic cigarettes.

In the case of dissolvable tobacco products, R.J. Reynolds began test marketing its Camel-brand line in 2009,<sup>26</sup> well after the February 2007 marketing deadline date. The products came in three varieties: “sticks” resembling toothpicks, “strips” resembling breath freshener strips, and pellet-shaped “orbs.” The design of Camel Strips and Camel Sticks is unlike anything available in the market prior to February 15, 2007, suggesting that they are not “substantially equivalent.” Although Camel Orbs may have a superficial resemblance to products such as Ariva and Stonewall, evidence suggests that the two types of products have different compositions. One study concluded that “levels of total nicotine per tablet in Camel Orbs were significantly lower than found in Ariva and Stonewall.”<sup>27</sup>

Even though the dissolvable brands Ariva and Stonewall were marketed before 2007, evidence suggests that the products have changed substantially. The manufacturer of the products stated in a comment to the FDA that it began “a program to update the Ariva and Stonewall products” in 2008.<sup>28</sup> Consequently, it seems unlikely that any of these brands of dissolvables meet the definition of “substantially equivalent,” and that the FDA could require their removal from the marketplace.

In the case of the new line of dissolvable products marketed as Ariva-BDL and Stonewall-BDL, it may be a moot point whether or not they are substantially equivalent, given that the FDA views them as not falling into the four categories over which it has declared jurisdiction. Although it could be credibly argued that the FDA should have a broader reach where new products are concerned, this does not appear to be the position that it has taken.

The argument that electronic cigarettes do not meet the definition of “substantially equivalent” relies on more indirect evidence, but it is no less compelling. A search of the LexisNexis database for news articles containing the phrase “electronic cigarettes” published prior to February 15, 2007, revealed only nine unique relevant articles. Four are from the years 2004–2006, and suggest that Ruyan-brand electronic cigarettes were being sold in China.<sup>29</sup> Four 2003 articles from Australian news sources discussed the future of smoking and mentioned “smokeless electronic cigarettes, asthma puffer-like nicotine inhalers” as one example of a product that might be sold in the future.<sup>30</sup> Finally, an article from November 1995 described a Chinese entrepreneur who invented a device which he initially named an electronic cigarette, but which contained “a concoction of Chinese herbs.”<sup>31</sup>

This review suggests that no electronic cigarettes were marketed in the U.S. prior to February 15, 2007. Given that the burden is on tobacco manufacturers to demonstrate substantial equivalence, the evidence seems sufficient for the FDA to remove electronic cigarettes from the marketplace and require the products to undergo a pre-market review process.

### Other Policy Options

There are additional regulatory options that the FDA could consider that are applied to cigarettes but not to other tobacco products. These options are presented mainly to highlight regulatory approaches that the FDA *could* take if it determines that doing so would benefit public health.

If the FDA chooses to implement these policy options, it would be consistent with the law to preserve to the maximum extent possible the authority of state and local governments to adopt more stringent measures to protect public health.<sup>32</sup> The TCA permits state and local governments to regulate “the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products.”<sup>33</sup> Further, current administration policy disfavors preemption.<sup>34</sup>

### Price-Related Options

Increasing the price of tobacco products has generally been recognized as sound public health strategy.<sup>35</sup> Although taxation is not part of the FDA’s standard regulatory arsenal,<sup>36</sup> the agency can consider several other regulations that would affect the price of the other products.

First, the FDA could prohibit the distribution of free samples of all tobacco products. Although the TCA required the FDA to issue a rule restricting the distribution of free samples of “cigarettes, smokeless tobacco, or other tobacco products,”<sup>37</sup> the FDA has determined that this provision applies only to cigarettes and smokeless to-

bacco.<sup>38</sup> Consequently, there is no federal prohibition on the distribution of free samples of electronic cigarettes, little cigars, or water pipe tobacco.

An exemption further expands the availability of free samples of tobacco products. Under the TCA and the FDA rule, a tobacco retailer may distribute free samples of up to 0.53 ounces of smokeless tobacco in a “qualified adult-only facility.”<sup>39</sup> This term includes facilities at events with a substantial youth audience, such as rodeos, car races, and concerts. Because of the extremely light weight of products such as dissolvables and snus, this represents a potentially serious loophole. By prohibiting the distribution of free samples of all tobacco products, the FDA would both expand the types of products covered and remove the exemption for qualified adult-only facilities.

Second, the FDA could prohibit the redemption of coupons. The TCA does not define the term “free samples,” and tobacco manufacturers have used deep discounts and coupons containing “buy one, get one free offers” to circumvent the limitations on free samples. Indeed, the tobacco industry has spent staggering sums on price-related strategies such as coupons and value-added discounts.<sup>40</sup> Restricting the redemption of coupons would help mitigate this loophole.

Finally, the FDA could create a minimum pack size for the other products. The federal tobacco marketing regulation prohibits the sale of cigarettes in packages containing fewer than 20 cigarettes,<sup>41</sup> but there is no comparable pack size limitation for the other products. Single cigarette sales have been shown to appeal to minors because of their low price, and have the potential to lead to tobacco initiation.<sup>42</sup> Creating a minimum pack size for other tobacco products would be one way to mitigate this possibility, although different systems would be needed for products sold in discrete units (i.e., dissolvables, little cigars, and snus) than for products sold en masse (i.e., water pipe tobacco).

### Flavors

The TCA prohibited the sale of cigarettes containing characterizing flavors such as fruit, candy, or alcohol, but excluding tobacco and menthol flavors.<sup>43</sup> In the context of cigarettes, documents uncovered in tobacco litigation demonstrate that tobacco manufacturers use flavors “as a way to target youth.”<sup>44</sup> Yet there is no comparable prohibition on flavoring in other tobacco products; prohibiting them from containing characterizing flavors would seem to be a promising way to reduce tobacco initiation.

### Warning Labels

The TCA required that as of September 2012, all cigarette packages sold in the U.S. must contain a color image

graphically depicting the health effects of smoking.<sup>45</sup> The law requires the warnings to occupy at least 50% of both sides of cigarette packages, as well as the top 20% of cigarette advertisements. Studies reveal that graphic warnings create an emotional response that leads to greater memory of the health risks associated with smoking.<sup>46</sup> Additionally, these graphics are better understood by individuals with poor reading comprehension skills. Federal courts have split on the constitutionality of graphic warning labels, increasing the possibility of review by the U.S. Supreme Court. In November 2011, a federal judge prevented these warning labels from taking effect.<sup>47</sup> In March 2012, in contrast, a federal appeals court upheld the constitutionality of graphic warning labels.<sup>48</sup>

Federally mandated warning labels for other tobacco products are likely not nearly as effective. The warning labels for smokeless tobacco are text-only and required to cover only 30% of the two principal display panels of a smokeless tobacco package.<sup>49</sup> Further, snus and some dissolvables are the only products highlighted in this article that clearly meet the TCA definition of “smokeless tobacco.” Consequently, the TCA requires no warning labels for Ariva-BDL dissolvables, electronic cigarettes, little cigars, and tobacco smoked in water pipes. If the U.S. Supreme Court were to uphold the constitutionality of graphic warning labels for cigarettes, the FDA may also want to consider graphic warning labels for other tobacco products.

### Health Claims

The TCA prohibits the sale of any tobacco product sold “for use to reduce harm or the risk of tobacco-related disease” unless the manufacturer has received permission to sell the product in such a manner.<sup>50</sup> This includes any product “the label, labeling, or advertising of which uses the descriptors ‘light’, ‘mild’, or ‘low’ or similar descriptors.”<sup>51</sup> By its terms, this provision applies to “any tobacco product.”<sup>52</sup> However, the FDA has interpreted this provision as applying to only the four categories of tobacco products over which the TCA grants authority to the agency.<sup>53</sup> Consequently, products such as little cigars are still being sold with descriptors such as “light.” The FDA could consider expanding the prohibition on health descriptors so that it covers these other tobacco products, unless the products have been shown to benefit public health.

### Youth Access and Marketing Restrictions

The FDA’s 2010 youth-access regulation applies only to cigarettes and smokeless tobacco, excluding products like Ariva-BDL, electronic cigarettes, little cigars, and water

pipe tobacco. Several provisions of this regulation may benefit public health if applied to these other products.

First, the regulation sets a nationwide standard for youth access. The minimum age to purchase cigarettes and smokeless tobacco is set at 18, and procedures are put in place to ensure compliance.<sup>54</sup> Second, the regulation prohibits the sale of cigarettes and smokeless tobacco by vending machines and by self-service methods in any facility that a minor can enter.<sup>55</sup> Finally, limitations are placed on the use of cigarette and smokeless tobacco brand names as well as the format, content, and location of those advertisements.<sup>56</sup> It might benefit public health if these requirements were applied to Ariva-BDL, electronic cigarettes, little cigars, and/or water pipe tobacco.

### Summary

Because many tobacco products are not currently regulated in the same manner as cigarettes, there is a need to consider new federal regulation of the products. This regulation could take many forms: prohibiting an entire category of tobacco products; price regulation, including regulations related to free samples, coupons, and minimum pack size; a prohibition on characterizing flavors; expanded warning labels, potentially including graphic warnings; a prohibition on health descriptors; and expanded youth access and marketing restrictions. However, it will be up to the FDA to determine which regulatory options advance its statutory goal of protecting the public health at a population level, and which options are feasible given budgetary constraints and the likelihood of litigation.

---

This article was written as part of a grant-funded research project. Any public dissemination of information relating to the grant was made possible by Grant Number RC-2009-0035 from ClearWay Minnesota<sup>SM</sup>. The contents of this paper are solely the responsibility of the author and do not necessarily represent the official views of ClearWay Minnesota.

The author wishes to thank the Senior Advisors on his research project, Dorothy K. Hatsukami, Ph.D., Forster Family Professor in Cancer Prevention, Professor of Psychiatry, University of Minnesota, and Mitch Zeller, J.D., Senior Vice President at Pinney Associates, for the valuable insight they offered.

Publication of this article was supported by ClearWay Minnesota<sup>SM</sup>.

No financial disclosures were reported by the author of this paper.

---

### References

1. Family Smoking Prevention and Tobacco Control Act, 21 U.S.C.A. §§ 387–387u (West 2009); Pub. L. No. 111-31, 123 Stat. 1776 (2009); 21

- C.F.R. §§ 1140.30, 1140.32 (2010). [www.govtrack.us/congress/bills/111/hr1256/text](http://www.govtrack.us/congress/bills/111/hr1256/text).
2. Remarks by the President at the Signing of the Family Smoking Prevention and Tobacco Control Act (June 22, 2009). [www.whitehouse.gov/the\\_press\\_office/Remarks-by-the-President-at-the-signing-of-the-family-smoking-prevention-and-tobacco-control-act/](http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-at-the-signing-of-the-family-smoking-prevention-and-tobacco-control-act/).
  3. CDC. Smoking-attributable mortality, years of potential life lost, and productivity losses—U.S., 2000–2004. *MMWR Morb Mortal Wkly Rep* 2008;57(45):1226–8.
  4. 21 U.S.C. § 387a(b) (2010).
  5. 21 C.F.R. § 1140 (2010).
  6. 21 U.S.C. § 387g(a)(1)(A) (2010).
  7. Zellers L, McLaughlin I. State and local policy as a tool to complement and supplement the FDA law. *Hastings Sci Technol Law J* 2010;2:117–30.
  8. Freiberg M. Options for state and local governments to regulate non-cigarette tobacco products. *Ann Health Law*, Vol. 21, Issue 2 (Winter 2012).
  9. 21 U.S.C. § 387f(d)(1) (2010).
  10. 21 U.S.C. § 387j (2010).
  11. Connolly GN, Richter P, Aleguas A Jr, Pechacek TF, Stanfill SB, Alpert HR. Unintentional child poisonings through ingestion of conventional and novel tobacco products. *Pediatrics* 2010;125(5):896–9.
  12. Trtchounian A, Talbot P. Electronic nicotine delivery systems: is there a need for regulation? *Tob Control* 2011;20(1):47–52.
  13. Delnevo CD, Hrywna M. “A whole ’nother smoke” or a cigarette in disguise: how RJ Reynolds reframed the image of little cigars. *Am J Public Health* 2007;97(8):1368–75.
  14. Mejia AB, Ling PM, Glantz SA. Quantifying the effects of promoting smokeless tobacco as a harm reduction strategy in the USA. *Tob Control* 2010;19(4):297–305.
  15. Martinasek MP, McDermott RJ, Martini L. Waterpipe (hookah) tobacco smoking among youth. *Curr Probl Pediatr Adolesc Health Care* 2011;41(2):34–57.
  16. Associated Press. Virginia tobacco maker seeks new FDA designation. *Fox News* 2011 January 4. [www.foxnews.com/health/2011/01/04/virginia-tobacco-maker-seeks-new-fda-designation/](http://www.foxnews.com/health/2011/01/04/virginia-tobacco-maker-seeks-new-fda-designation/).
  17. 21 U.S.C. § 387k (2010).
  18. Peterson M. Star Scientific’s tobacco lozenges get favorable FDA ruling. *Bloomberg* 2011 March 23. [www.bloomberg.com/news/2011-03-23/star-scientific-gets-favorable-fda-ruling-on-tobacco-lozenges.html](http://www.bloomberg.com/news/2011-03-23/star-scientific-gets-favorable-fda-ruling-on-tobacco-lozenges.html).
  19. 21 U.S.C. § 387(18) (2010).
  20. Deyton LR, Woodcock J. Regulation of e-cigarettes and other tobacco products, letter to stakeholders. 2011. [www.fda.gov/newsevents/publichealthfocus/ucm252360.htm](http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm).
  21. 21 U.S.C. § 387g(a)(3) (2010).
  22. 21 U.S.C. § 387g(d)(3)(A) (2010).
  23. 21 U.S.C. § 387j(a)(2)(A)(i) (2010).
  24. 21 U.S.C. § 387j(a)(3)(A)(i) (2010).
  25. 21 U.S.C. § 387j(a)(3)(B) (2010).
  26. Wilson D. Flavored tobacco pellets are denounced as a lure to young users. *New York Times* 2010, Apr 19. [www.nytimes.com/2010/04/19/business/19smoke.html?\\_r=1](http://www.nytimes.com/2010/04/19/business/19smoke.html?_r=1).
  27. Stanfill SB, Zhang L, Lawler TS, Watson CH, Ashley DL. Camel Orbs: nicotine, pH, tobacco-specific nitrosamines, and select flavor analysis. Comment submitted to FDA, 2009. [www.regulations.gov/#!documentDetail;D=FDA-2010-N-0123-0040](http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0123-0040).
  28. Star Scientific, Inc. Comment on FDA Docket No. FDA-2010-N-0123 (Impact of dissolvable tobacco use on public health), 2010. [www.regulations.gov/#!documentDetail;D=FDA-2010-N-0123-0024](http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0123-0024).
  29. Kurtenbach E. China probes safety of nicotine inhalers. *Associated Press Financial Wire* 2006, Dec 4.
  30. Skatssoon J. Running out of puff. *Townsville Bulletin/Townsville Sun* 2003, Apr 19.
  31. Landwehr A. “Healthy cigarette” inventor hopes device will make a killing. *The Patriot Ledger* 1995, Nov 13.
  32. Hobart R. Preemption: taking the local out of tobacco control. *American Medical Association*. 2003. [www.rwjf.org/newsroom/SLSPreemption2003.pdf](http://www.rwjf.org/newsroom/SLSPreemption2003.pdf).
  33. 21 U.S.C. § 387p(a)(2)(B) (2010).
  34. White House Office of the Press Secretary, Memorandum for the Heads of Executive Departments and Agencies. 2009. [www.whitehouse.gov/the\\_press\\_office/Presidential-Memorandum-Regarding-Preemption/](http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/).
  35. Chaloupka FJ, Straif K, Leon ME. Effectiveness of tax and price policies in tobacco control. *Tob Control* 2011;20(3):235–8.
  36. 21 U.S.C. § 387p(a)(1) (2010).
  37. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 102(a)(2)(G).
  38. FDA, Draft guidance for industry: compliance with regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents. 2011. [www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm252758.htm](http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm252758.htm).
  39. 21 C.F.R. § 1140.16(d)(2) (2010).
  40. Federal Trade Commission. Cigarette report for 2006. 2009. [www.ftc.gov/os/2009/08/090812cigarettereport.pdf](http://www.ftc.gov/os/2009/08/090812cigarettereport.pdf).
  41. 21 C.F.R. § 1140.16(b) (2010).
  42. Landrine H, Klonoff EA, Alcaraz R. Minors’ access to single cigarettes in California. *Prev Med* 1998;27(4):503–5.
  43. 21 U.S.C. § 387g(a)(1)(A) (2010).
  44. Dachille K. Pick your poison: responses to the marketing and sale of flavored tobacco products. 2009. [www.publichealthlawcenter.org/sites/default/files/resources/tclc-syn-flavored-2009.pdf](http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-syn-flavored-2009.pdf).
  45. Required warnings for cigarette packages and advertisements, 76 Fed. Reg. 36,628, 36,676 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).
  46. Hammond D, Fong GT, Borland R, Cummings KM, McNeill A, Driezen P. Text and graphic warnings on cigarette packages: findings from the international tobacco control four country study. *Am J Prev Med* 2007;32(3):202–9.
  47. Stein, R. Graphic cigarette warning labels blocked by judge. *Washington Post* 2011, Nov 7. [www.washingtonpost.com/national/health-science/graphic-cigarette-warning-labels-blocked-by-judge/2011/11/07/gIQAglidvM\\_story.html](http://www.washingtonpost.com/national/health-science/graphic-cigarette-warning-labels-blocked-by-judge/2011/11/07/gIQAglidvM_story.html).
  48. *Discount Tobacco City & Lottery, Inc. v. United States*, 2012 WL 899073 (6th Cir. March 19, 2012).
  49. 15 U.S.C. § 4402(a)(2)(A) (2010).
  50. 21 U.S.C. § 387k(a) (2010).
  51. 21 U.S.C. § 387k(b)(2)(A)(ii) (2010).
  52. 21 U.S.C. § 387k(b)(1) (2010).
  53. 21 U.S.C. § 387a(b) (2010).
  54. 21 C.F.R. § 1140.14 (2010).
  55. 21 C.F.R. § 1140.16(c) (2010).
  56. 21 C.F.R. §§ 1140.14(a), 1140.30, 1140.32, 1140.34 (2010).