The Family Smoking Prevention and Tobacco Control Act: An Overview

Ricardo Carvajal
David Clissold
Jeffrey Shapiro
The Family Smoking Prevention and Tobacco Control Act:
An Overview

RICARDO CARVAJAL*
DAVID CLISSOLD**
JEFFREY SHAPIRO***

Signed into law on June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (FSPTCA)\(^1\) provides the Food and Drug Administration (FDA) with regulatory authority over virtually every aspect of the design, production, marketing and advertising of tobacco products. Although the FSPTCA has its detractors,\(^2\) there is little question that the law’s enactment marks a dramatic shift in the relationship between the federal government and the tobacco industry.

This article summarizes the new law’s major provisions and highlights some of the legal issues that implementation of the law is likely to raise. Early indications suggest that FDA will move expeditiously to implement the FSPTCA. FDA has already announced the launch of its new Center for Tobacco Products (CTP) and the appointment of CTP’s first director, Dr. Lawrence Deyton. Dr. Deyton was a clinical professor of medicine and health policy at the George Washington University School of Medicine and Health Sciences, and also served as Chief Public Health and Environmental Hazards Officer for the U.S. Department of Veterans Affairs (VA), where he gained substantial experience with the administration of tobacco cessation programs.\(^3\) FDA has also established the Tobacco Products Scientific Advisory Committee (TPSAC), which will be involved in many aspects of FDA’s regulation of tobacco products, and has begun hiring additional staff and reassigning existing staff to work on the new law’s implementation.

The first lawsuit challenging the constitutionality of several key provisions of the FSPTCA has already been filed.\(^4\) As our review of the FSPTCA will make clear, that lawsuit will be but one of many challenges presented to FDA as it implements the new law.

Findings, Purposes and Scope

Many of the issues of greatest importance in the regulation of tobacco products are addressed in section 2 of the FSPTCA, which sets out the findings of Congress—all 49 of them. It appears that Congress intended to provide as strong

---

\(^*\) Mr. Carvajal is Of Counsel with the law firm of Hyman, Phelps & McNamara, PC, Washington, DC.

\(^**\) Mr. Clissold is a Director of the law firm of Hyman, Phelps & McNamara, PC, Washington, DC.

\(^***\) Mr. Shapiro is a Director with the law firm of Hyman, Phelps & McNamara, PC, Washington, DC.


\(^3\) The establishment of a CTP Products is required under FSPTCA section 901(e).

\(^4\) Commonwealth Brands, Inc., et al. v. FDA, C.A. No.: 1:09-CV-0117-JHM-ERG (W.D. KY filed (Aug. 31, 2009)).
a rationale as possible for some of the law’s more controversial provisions, particularly those that sanction the imposition of restrictions on commercial speech. The Congressional findings discuss the many harms associated with tobacco use, including the effect of tobacco use on children, the addictive power of nicotine, the impact of tobacco use on healthcare costs, the risks posed by products marketed as modified risk products, and past efforts of industry to target youth and maximize cigarettes’ addictive power.

Section 3 sets out the purposes of the FSPTCA. These state that the central purpose of the FSPTCA is to ensure that FDA has adequate authority to regulate tobacco products. As section 4 makes clear, however, the FSPTCA is not intended to affect the growing, cultivation or curing of raw tobacco. In case any provisions of the FSPTCA exceed constitutional limitations, section 5 provides for severability of those provisions.

As noted, FDA has already begun to implement the FSPTCA, which requires FDA to issue a number of regulations and take other actions in the next few years. In an acknowledgment of the burdens imposed on the agency, section 6 delays implementation of provisions that imposed fixed deadlines on agency actions. The statutory deadlines for actions that FDA must complete by a specified date are to be determined by reference to the date on which FDA begins to collect user fees, and the law allows for an additional 90-day delay at FDA’s discretion. These modified deadlines do not apply to FDA’s reissuance of its final rule restricting tobacco advertising and availability, or to the revision of cigarette labeling and advertising warnings (discussed further below). They also do not apply to actions required of industry.

**Federal Food, Drug, and Cosmetic Act (FDCA)**

The principal amendments to the FDCA are set forth in sections 101, 103, and 301 of the FSPTCA. In general, the law is based on the structure of the FDCA. First, it provides essential definitions, such as the definition of “tobacco product.” Next, it provides a comprehensive statutory framework for FDA’s regulatory oversight of tobacco products. Finally, it describes the conditions that would cause a tobacco product to be adulterated or misbranded, thus subjecting the manufacturer and/or the product to enforcement actions.

FSPTCA section 101 adds a new Chapter IX to the FDCA and reassigns the provisions previously found in Chapter IX to new Chapter X. For purposes of this article, the authors refer to Chapter IX of the FDCA as amended by the FSPTCA simply as “Chapter IX.” FSPTCA section 103 contains conforming amendments to sections of the FDCA that address seizure, injunction, and import detention, among other enforcement authorities. Finally, FSPTCA section 301 adds provisions to FDCA Chapter IX intended to prevent illicit trade in tobacco products.

**Definitions are Key**

FDCA section 101(rr)(1) broadly defines “tobacco product” as “any product made or derived from tobacco that is intended for human consumption, including any component, part or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).” Explicitly excluded from this definition are drugs, devices and
combination products, which are subject to regulation under FDCA Chapter V. Thus, some products derived from tobacco and intended for human consumption might nonetheless fall outside the scope of the FSPTCA if they are intended for use as a drug or device. Also, section 101(a) prohibits the marketing of a tobacco product “in combination” with other articles subject to regulation under the FDCA (e.g., the joint marketing of a cigarette and a tobacco cessation drug).

FDCA section 900 sets forth numerous additional definitions. A cursory glance at the definitions provided in section 900 reveals the extent to which Chapter IX borrows from terms and concepts in other chapters of the FDCA. For example, section 900(1) defines “additive” to mean:

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

This definition borrows heavily from the definition of “food additive” in section 201(s). Thus, FDA can be expected to consider prior administrative and judicial interpretations of “food additive” in determining how to apply the definition of a tobacco product “additive.”

Some of the definitions in section 900 are relevant to determining the applicability and scope of Chapter IX. For example, FDCA section 901 contains several provisions that address FDA’s authority over tobacco products. That section provides that Chapter IX currently applies only to certain forms of tobacco, namely cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, all of which are defined in section 900. FDA can render Chapter IX applicable to other forms of tobacco by issuing a regulation to that effect under the authority of section 901. Section 901 also provides that Chapter IX does not apply to producers of tobacco leaf, including “tobacco warehouses” as defined in section 900.

**Adulteration and Misbranding**

As with other FDA-regulated products, there are a series of adulteration and misbranding provisions set out in section 902. A tobacco product is adulterated if: it bears or contains any filthy, putrid, or decomposed substance, or any added poisonous or deleterious substance; it was prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health; the methods, facilities or controls used for its manufacture do not conform to good manufacturing practices (GMPs); it does not comply with an applicable product standard; it is marketed without an order where such an order is required; or there has been a failure to pay a user fee.\(^5\)

\(^5\) FDA is granted authority under section 906(e) to establish by regulation GMP requirements that address methods, facilities and controls.

\(^6\) Section 919 authorizes FDA to assess and collect quarterly fees from each manufacturer and importer of tobacco products to which Chapter IX applies. FDA is authorized to collect $85 million in the first fiscal year and more thereafter, increasing to $712 million by fiscal year 2019. All fees are required to be used for the regulation of tobacco products.
In addition to having authority to seize tobacco products that are adulterated, FDA has authority under section 908 to issue order public notification to eliminate “an unreasonable risk of substantial harm to the public health.”\(^7\) FDA, however, must first determine that notification is necessary to eliminate the risk, and that no more practical means of doing so are available. If there is a “reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death,” then FDA must issue an order immediately stopping distribution.\(^8\) FDA can subsequently amend the order to require a recall.

A number of new misbranding provisions are in section 903(a). A tobacco product is misbranded if its labeling: is false or misleading in any particular; fails to include specified information (e.g., name and place of business, and percent of tobacco used in the product that is domestic versus foreign grown); fails to conspicuously bear required statements or any directions for use or warnings required by regulation; or does not comply with an applicable product standard. A product is also misbranded if: its advertising is false or misleading; it is sold or distributed in violation of advertising restrictions imposed by FDA; or its advertising or printed matter fails to include the product’s established name, a brief statement of warnings, or a description of the product’s components or formula as required by FDA. In addition, a product is misbranded if it is from an unregistered establishment or otherwise does not comply with the requirements of section 905 (discussed further below), or if there has been a failure to comply with requirements pertaining to the submission of health information, notification and recall activities, or reporting.

FDA’s misbranding authorities are not limited to the postmarket context. Section 903(b) grants FDA premarket approval authority over labeling to ensure compliance with applicable requirements. It also grants FDA authority to subject advertising for modified risk products to premarket approval. As discussed further below, these provisions are already the subject of a judicial challenge based on the First Amendment. If the provisions survive the challenge, they can be expected to have a chilling effect on the communication of information to consumers via tobacco product labeling and advertising. Manufacturers will have to carefully weigh their desire to communicate as much information as possible in labeling and advertising against the risk that FDA will object, and thereby delay marketing of a product.

As with other adulterated or misbranded products subject to FDA jurisdiction, adulterated or misbranded tobacco products are subject to the enforcement provisions of the FDCA. Such products are subject to seizure under section 304, or if offered for import, are subject to detention under section 801(a). Manufacturers and distributors of such products are subject to injunction under section 302, and to civil and criminal liability under section 303.

**FDA’s Access to Information**

Chapter IX contains a number of provisions that are designed to keep FDA informed of which manufacturers and importers are in operation, and of which products are on the market and what their attributes are. FDA also has authority to require the submission of information on the health effects of tobacco products

---

\(^7\) FDCA § 908(a)(1).
\(^8\) Id. § 908(c).
Section 905 imposes an annual registration requirement on any owner or operator of a domestic establishment engaged in the manufacture, preparation, compounding or processing of tobacco products. This requirement is separate from the registration requirement imposed by the Alcohol and Tobacco Tax and Trade Bureau. All existing domestic owners and operators must register by December 31, 2009, and any new owner or operator must register immediately upon beginning operations. Any establishment added by an owner or operator must also be registered immediately upon beginning operations. Foreign establishments will be required to register in accordance with regulations that FDA will issue. FDA is required to inspect registered establishments at least once every two years. This directive regarding frequency of inspection is meant to prevent the types of gaps in FDA’s oversight of industry that have been evident with respect to other FDA-regulated products, most notably foods.9

In addition to providing the name and place of business of each establishment, owners and operators must also provide a list of all products manufactured, prepared, compounded or processed for commercial distribution. For each product that is subject to a standard or to premarket approval, information on the authority for marketing and a copy of labeling must be provided. For other products, a copy of labeling and a “representative sample of advertisements” must be provided. If there are any changes to a product list, those changes must be included in a report that is to be submitted biannually.

Leaving aside registration information, manufacturers and importers must submit to FDA what section 904 refers to as “health information,” including: a list of all ingredients added to any part of a product; the form, content, and delivery of nicotine in the product; a list of constituents in the product and its smoke that are identified by FDA as harmful10 or that are required under section 915 (discussed further below); and all documents relating to health, toxicology or behavioral or physiologic effects of a manufacturer’s current or future tobacco products. Manufacturers also must disclose to FDA an increase in the quantity of an existing additive or the addition of a new additive 90 days prior to marketing, and must disclose within 60 days of marketing the elimination or decrease of an existing additive or the addition or increase of an additive that FDA has deemed not to be harmful.

In addition, in keeping with the Congressional purpose of ensuring that consumers are better informed about the health effects of tobacco products, manufacturers and distributors must at FDA’s request submit documents relating to research conducted, supported, or possessed by the manufacturer or its agents that relate to the health effects of tobacco products and their constituents (including smoke constituents), or to whether use in tobacco products of a technology known to the manufacturer could result in a reduction of risk to health.

Chapter IX also authorizes FDA to impose on manufacturers and importers such record keeping and reporting requirements as FDA deems reasonable to assure that tobacco products are not adulterated or misbranded and to “otherwise protect public health”—in other words, records and reports relating to adverse

---

9 Food legislation under consideration would impose a similar frequency-of-inspection requirement for food facilities.
10 Under section 904(d), FDA is required to publish a list of harmful and potentially harmful constituents in a tobacco product and its smoke, by brand.
events, corrective actions, and removals. Under section 909, FDA may issue a regulation that requires a manufacturer or importer to report to FDA when a tobacco product causes or contributes to a “serious unexpected adverse experience” or “any significant increase in the frequency of a serious, expected adverse product experience.” FDA must by regulation require manufacturers and importers to report a corrective action or removal if it is undertaken to reduce a risk to health or to remedy a violation that may present a risk to health. In the absence of a risk to health, a manufacturer or importer must keep a record of the corrective action or removal. These provisions parallel similar provisions imposed on medical device manufacturers.

Finally, under section 915, FDA has authority to determine which tobacco product constituents, ingredients, and additives must be tested by manufacturers “to protect the public health,” and to then issue a regulation that requires testing and reporting of those substances by brand and subbrand. The regulation may also require that manufacturers, packagers, or importers disclose through labels or advertising the results of testing for tar and nicotine, and for other constituents, ingredients, or additives as determined by FDA to be necessary to protect the public health.

Establishment of Standards

FDCA section 907 establishes a standard for cigarettes that prohibits the addition of characterizing artificial or natural flavors, herbs or spices, with an exception for menthol. Congress deferred action on menthol pending further study by the TPSAC on the potential effects of prohibiting menthol-flavored cigarettes on children and racial and ethnic minorities. The prohibition on other characterizing flavors is already in effect, and has reportedly prompted at least one manufacturer to reengineer its clove cigarette as a cigar so as to work around the prohibition. Section 907 also authorizes FDA to modify the standard for cigarettes and to establish standards for other tobacco products as “appropriate for the protection of the public health.” The question of whether a standard is appropriate “for the protection of the public health” must be determined by reference to scientific evidence concerning the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard; the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products.

11 FDCA § 909(a).
12 Id. § 909(a)(1).
13 Id. § 915(b)(1).
14 Id. § 907(e).
15 See Clove Cigars Avoid Ban on Flavored Cigarettes, WALL STREET JOURNAL (Sept. 7, 2009). The prohibition went into effect three months after the date of enactment. In addition, beginning two years after enactment, cigarette manufacturers may not use tobacco that contains a pesticide chemical residue in excess of any tolerance applicable under federal law.
16 FDCA § 907(a)(3)(A). FDA, however, cannot ban cigarettes, nor can it require nicotine levels to be zero. See id. § 900.
17 Id. § 907(a)(3)(B)(i).
If a standard requires the reduction or elimination of an additive, constituent or other component on the ground that it may be harmful, then anyone objecting to the proposed standard can submit evidence demonstrating that the proposed standard does not “reduce or eliminate risk of illness or injury.” As a practical matter, this procedural safeguard could have the effect of curtailing FDA’s use of standards to reduce or eliminate potentially harmful substances in tobacco products because of the resources that the agency would have to expend to evaluate and appropriately respond to evidence submitted by objectors.

A standard must include provisions that are “appropriate for the protection of the public health,” including provisions for nicotine yield and reduction of other constituents or harmful components. A standard may also include provisions regarding: the product’s construction, substances and properties; testing and test results that demonstrate compliance with the standard; measurement of the product’s characteristics; restrictions on sale and distribution; and labeling for proper use of the product. Any provisions of a standard are subject to periodic reevaluation by FDA in light of new scientific information or technological data, and FDA has authority to amend or revoke a standard. Revocation of a standard, however, requires a finding that the standard no longer protects the public health, and FDA must allow at least 60 days for comment. FDA is explicitly prohibited from banning cigarettes, smokeless tobacco products, cigars, pipe tobacco or roll-your-own tobacco.

In setting a standard, FDA must consider whether compliance with the standard is technically achievable. FDA also must consider whether the standard could have “countervailing effects” on tobacco users (both adults and adolescents) and non-users. As an example of a countervailing effect, the statute cites the “creation of a significant demand for contraband” or other noncompliant tobacco products.

FDA may refer a standard-related regulation to TPSAC on its own initiative or at the request of an interested person for good cause shown. As noted earlier, FDA has already established the TPSAC, which consists of 12 members: nine voting members (seven scientists, one government official and one representative of the public) and three non-voting members (one manufacturing industry representative, one small manufacturer representative and one growers’ representative). The setting of standards is just one of the many regulatory activities in which the TPSAC is expected to be involved.

Two types of tobacco products were singled out by Congress for special consideration. FDA must refer to the TPSAC immediately on its establishment “the issue of the impact of the use of menthol in cigarettes on the public health,” including the impact on children and racial and ethnic minorities. The TPSAC must report back with its recommendations within one year. FDA also must refer to the TPSAC “the issue of the nature and impact of dissolvable tobacco products on the public health,” including their use by children. The TPSAC must report back within two years.

---

18 Id. § 907(a)(3)(B)(ii).
19 Id. § 907(a)(4)(A).
20 Id. § 907(b)(2).
21 Id.
22 FDCA § 907(c).
23 Id. § 907(f).
Getting to Market

Under Chapter IX, tobacco products already on the market as of February 15, 2007 (grandfathered products) have a distinct advantage over products marketed after that date, (new tobacco products). FDCA § 910(a) defines a “new tobacco product” as any product not commercially marketed in the United States as of February 15, 2007, including any previously marketed products to which “any” modification is made. Although all tobacco products are subject to the requirements discussed thus far, a new tobacco product is also required to be the subject of either an approved premarket application submitted under section 910 (discussed further below) or a 90-day premarket notification (PMN) submitted under section 905(j).24 These provisions governing premarket review of tobacco products essentially track provisions governing premarket review of medical devices that were added to the FDCA by the Medical Device Amendments of 1976.25

A PMN must provide a basis for the manufacturer’s determination that the product is either substantially equivalent to a previously marketed (or predicate) product, or that the product has been permissibly modified.26 The product cannot be lawfully marketed until FDA issues an order that the product meets the requirement of substantial equivalence and is in compliance with the requirements of the FDCA. For a product to be deemed substantially equivalent, FDA must by order find that the product has the same characteristics as the predicate, meaning that the materials, ingredients, design, composition, heating source or other features of the product are the same as those of the predicate. If the product has different characteristics, then FDA must find that the information submitted (including clinical data, if required) demonstrates that the product does not raise different questions of public health than does the predicate.27 A product cannot be determined to be substantially equivalent if it has been removed from the market at FDA’s initiative or if it has been determined by a court to be misbranded or adulterated.

In addition to providing a basis for the determination of substantial equivalence, a PMN must include a summary of “any health information”28 related to the product, including detailed information on adverse health effects. In the alternative, the PMN must state that such health information is available at anyone’s request. If a summary is included in the PMN, then FDA must make the summary available to the public within 30 days of the issuance of an order determining that the product is substantially equivalent.

If a new product is not substantially equivalent to a predicate, then that product must be the subject of an application for premarket review (PMA). A PMA must contain: reports of all information “which should reasonably be known” to the applicant concerning investigations made to show the product’s health risks and whether the product presents less risk than other products; a statement of the

24 If a new product is marketed between Feb. 15, 2007 and Mar. 22, 2011, a PMN need not be submitted until the latter date. In addition, FDA may by regulation exempt tobacco products for investigational use from premarket approval requirements. Id. § 910(g).

25 See id. §§ 515, 510(k).

26 Id. § 905(j). Under section 905(j)(3), a permissible modification consists of adding or deleting an additive (or increasing or decreasing its quantity) if FDA determines that such a modification is minor and that a premarket notification is not necessary to ensure that marketing of the product “would be appropriate for protection of the public health.” FDA is required to issue a regulation that implements section 905(j)(3).

27 Id. § 910(a)(3).

28 Id. § 910(a)(4)(A).
product’s ingredients, components, principles of operation; a description of the facilities and controls used in manufacture; a demonstration of compliance with any applicable standard; samples of the product and its components as required by FDA; and labeling specimens. FDA may refer a PMA to the TPSAC for a report and recommendation.

Within 180 days of a PMA submission, FDA must issue an order allowing or prohibiting marketing of the product. FDA must deny a PMA if the applicant fails to show that permitting marketing of the product would be “appropriate for the protection of the public health.” As with the establishment of tobacco product standards, the question of whether marketing of a product would be appropriate for the protection of the public health is to be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account… the increased or decreased likelihood that existing users of tobacco products will stop using such products; and… the increased or decreased likelihood that those who do not use tobacco products will start using such products.

In making this complex determination, FDA is encouraged (but not required) to rely on well-controlled investigations.

FDA must also deny a PMA if: there is nonconformance with GMP requirement; the product’s proposed labeling is false or misleading in any particular; or the product is not shown to conform to an applicable standard. If FDA denies a PMA, the agency can inform the applicant of how to cure deficiencies in the PMA. If FDA approves a PMA, the agency can include in its approval order restrictions on sale and distribution of the product under section 906(d) (discussed further below).

Once FDA approves a PMA, the agency can withdraw or temporarily suspend that approval. The circumstances, under which FDA can do so are limited, and FDA must first consult with the TPSAC and provide notice and the opportunity for an informal hearing. FDA must withdraw an approval if the agency finds that continued marketing of a product “no longer is appropriate for the protection of the public health.” Similar actions with respect to other FDA-regulated product categories suggest that this endeavor would be time and resource intensive; the agency most likely would not undertake it lightly. A similar provision in the Medical Device Amendments has rarely been used in the many years since it took effect. FDA also must withdraw an approval if: there is an untrue statement of material fact in the PMA; the applicant is in flagrant violation of recordkeeping and reporting requirements or has unlawfully refused access to records; the applicant is in violation of registration requirements; or new information shows a continuing violation of GMPs, a continuing use of false or misleading labeling, or a lack of compliance with a standard on which the PMA approval was conditioned. An applicant whose PMA is denied can file a petition for judicial review within 30 days.

In addition to its authority to withdraw approval of a PMA, FDA also has authority to temporarily suspend marketing of a product. FDA must do so if, after

29 Id. § 910(b)(1).
30 Id. § 910(c)(2)(A).
31 Id. § 910(c)(4).
32 Id. § 910(d)(1)(A).
33 See id. § 515(e).
providing an opportunity for an informal hearing, FDA determines that there is a reasonable probability that continued marketing of the product “would cause serious, adverse health consequences or death, which is greater than ordinarily caused by tobacco products on the market.”\footnote{Id. \S 910(d)(3).} If FDA orders a temporary suspension, it must then proceed to withdraw its approval of the PMA. To facilitate its activities relating to withdrawal of approval and temporary suspension, FDA can by regulation or order require applicants to keep such records and make such reports as FDA needs to determine if there are grounds for a withdrawal or suspension. FDA must be allowed access to these records.

**A Special Category: Modified Risk Tobacco Products**

Historically, some tobacco products have been marketed as being less harmful than others, either because they had less of a substance believed to be harmful (e.g., tar) or because they incorporated some technological innovation that was believed to reduce the harms associated with smoking (e.g., a filter).\footnote{See Brandt, Allan M., *The Cigarette Century*, BASIC BOOKS, New York, N.Y. (2007).} Some products, marketed in this manner did not meaningfully reduce risk to individual users, and are believed by some to have increased harm to the population as a whole by convincing some users that they need not quit to reduce their health risk, and by enticing some non-users into the fold. The FSPTCA tackles this problem by immediately\footnote{As of the date of enactment, a distributor may not take any action reasonably expected to result in consumers believing that a tobacco product or its smoke may present a lower disease risk or is less harmful than other products, or that it presents a reduced exposure to a substance. FDCA \S 911(m).} and severely restricting the marketing of “modified risk tobacco products.”\footnote{FDA, however, cannot subject modified risk tobacco products to regulation as drugs. See id. FDCA \S 900.}

FDCA Section 911 prohibits the marketing of a modified risk tobacco product without an approval order from FDA. A modified risk product is defined as “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.”\footnote{Under FDCA \S 911(b)(1), a tobacco dependence product is not subject to regulation as a modified risk tobacco product if it is approved as a drug or device.} This definition is satisfied when the product’s labeling or advertising represents explicitly or implicitly that: the product presents a lower risk of tobacco-related disease; the product is less harmful than other products; the product or its smoke contains a reduced level or presents a reduced exposure to a substance; or the product or its smoke does not contain a substance. The definition is also satisfied when the product’s labeling or advertising uses descriptors such as “light,” “mild,” or “low;” however, it is still permissible to use certain phrases (e.g., “smoke-free”) to describe smokeless tobacco. Finally, the definition is satisfied when the manufacturer takes “any action directed to consumers through the media or otherwise, other than by means of the tobacco product’s label, labeling, or advertising … that would reasonably be expected to result in consumers believing” that the product presents a reduced risk.\footnote{Id. \S 911(b)(2)(A)(iii).}

An application seeking FDA approval to market a modified risk product must include a description of the product’s advertising and labeling, the formulation and conditions of use, sample labeling, data on actual use by consumers, and “all documents … relating to research findings conducted, supported, or possessed”\footnote{Id. \S 910(d)(3).}
by the manufacturer that relate to “the effect of the product on tobacco-related diseases and health-related conditions.” FDA must make an application available to the public and request comment on the information it contains, as well as on the product’s proposed labeling and advertising. FDA also must refer an application to the TPSAC, which must report back within 60 days.

FDA can issue an order approving marketing of a modified risk product only for a specified period of time, and only if an applicant demonstrates that the product as actually used will “significantly reduce harm and the risk of tobacco-related disease to individual tobacco users,” and “benefit the health of the population as a whole” (taking into account both users and nonusers). This standard requires FDA to take into account: the relative health risks that the product poses to individuals; whether tobacco users that would otherwise quit would instead switch to the product; the possibility that non-users of tobacco would start using the product; the product’s risks and benefits compared to those of smoking cessation drugs approved to treat nicotine dependence; and information submitted by third parties.

As a condition of approval, FDA must require that the labeling and advertising for a modified risk product enable the public to comprehend the relative significance of the information regarding modified risk “in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.” In addition, FDA can impose conditions on the use of claims that compare the modified risk product to other products, and can impose labeling disclosure requirements regarding substances in or produced by the tobacco product, as well as conditions of use where those may affect risk to human health. Furthermore, the conditions of approval imposed by FDA do not end with labeling and advertising. FDA also must condition its approval on the applicant’s agreement to annually submit the results of postmarket studies based on an FDA-approved protocol to determine the approval order’s impact on “consumer perception, behavior, and health.”

If a modified risk product does not meet the standard of significantly reducing harm to individual users and benefiting the health of the population as a whole, it may nonetheless reach the market if it is approved by FDA under a “special rule” in section 911(g)(2). Under the special rule, FDA may issue an order approving the marketing of a modified risk product if the applicant demonstrates that all four of the following conditions have been met: the order would be “appropriate to promote the public health;” any labeling and advertising claims that would cause the product to meet the definition of a modified risk product are limited to claims that the product presents less exposure to a substance; long term epidemiological studies would be required to meet the standard described in the preceding paragraph; and the available scientific evidence demonstrates that subsequent studies are reasonably likely to show a reduction in morbidity or mortality to individual users.

To issue an order under the special rule, FDA must also find that: the overall reduction of exposure to a harmful substance is substantial and verifiable under actual use; actual use will not result in comparatively higher levels of exposure to

40 Id. § 911(d).
41 Id. § 911(g)(1).
42 FDA is required to issue a regulation or guidance within two years of enactment that establishes standards for studies needed to support issuance of an approval order, and for postmarket studies (discussed further below). The regulation or guidance must also establish a “reasonable” timetable for the review of applications.
43 Id. § 911(h)(1).
44 Id. § 911(i).
other harmful substances; consumer perception testing shows that the product as labeled and marketed will not be perceived as being less harmful or presenting a lower risk of disease than other products; and issuing an order is expected to benefit the health of the population as a whole (taking into account users and nonusers). In addition, an order issued under the special rule is subject to renewal every five years.45

In specified circumstances, FDA must withdraw an approval for a modified risk product. After providing an opportunity for an informal hearing, FDA must withdraw its approval if, based on new information, the applicant cannot make demonstrations or FDA cannot make determinations that were required for the product’s approval. FDA must also withdraw its approval if: the application omitted material information or made an untrue statement of material fact; any representation of reduced risk or exposure is no longer valid; the applicant fails to submit required postmarket studies; or the applicant fails to meet conditions imposed on labeling or advertising.

While the FSPTCA severely restricts the marketing of modified risk products, it encourages the development smoking cessation drug products. FDCA section 918 requires FDA to consider designating such drug products as fast track research and approval products under FDCA section 506. FDA must also consider approving the extended use of nicotine-replacement products that are intended to treat tobacco dependence. Finally, section 918(b) requires FDA to report to Congress on the development of “innovative products” to better achieve not just abstinence from tobacco or reduced use thereof, but also to reduce the harms that stem from continued use of tobacco.

Restrictions on Promotion and Distribution

The most contentious provisions of the FSPTCA are those that require or authorize restrictions on labeling, advertising, and other promotional activities. Truthful commercial speech is entitled to protection under the First Amendment of the United States Constitution. As discussed further below, certain provisions in the FSPTCA and in FDCA Chapter IX are already the subject of litigation challenging their constitutionality.

The FSPTCA directs FDA to reissue its 1996 final rule that imposes requirements and restrictions on labeling, advertising and distribution of cigarettes and smokeless tobacco that contain nicotine.46 Although Congress struck some minor provisions from the rule regarding the use of established names and statements of intended use in labeling and advertising, the essential elements of the rule remain unchanged.47

The most controversial aspects of the rule are those that restrict advertising and labeling. The rule permits advertising in newspapers, magazines, periodicals or other publications; on billboards, posters and placards; on non-point-of-sale promotional material, such as direct mail; and in audio or video at the point-of-sale. Any other type of advertising, however, must be submitted to FDA 30 days prior to its use.48 With certain exceptions, advertisements and labeling must be only black text on

45 Id. § 911(g)(2)(C).
47 See FSPTCA § 102(a)(2).
a white background, and no music or sound effects are allowed in audio or video format advertising—only the spoken word is permitted.49 The rule prohibits a range of other promotional activities by manufacturers and distributors. For example, the rule prohibits the distribution of free samples, although this provision is modified by the FSPTCA to permit the distribution of free samples of smokeless tobacco in limited circumstances, such as in adult-only facilities. The rule also prohibits the sale or distribution of non-tobacco items and services, the award of gifts, and the sponsorship of events, if the public can easily identify the promotional activity as that of a tobacco manufacturer or distributor.50

Although the rule as issued in 1996 prohibited outdoor advertising within 1000 feet of the perimeter of any public playground or playground area in a public park, elementary school, or secondary school, the FSPTCA requires FDA to amend this section to conform with First Amendment case law. Most notably, in Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001), the Supreme Court held in part that similar restrictions imposed by the Attorney General of Massachusetts violated the First Amendment, in that the Attorney General failed to show that they were “not more extensive than necessary to advance the State's substantial interest in preventing underage tobacco use.”51 FDA will have the delicate task of interpreting the Lorillard decision and determining what types of restrictions will pass constitutional muster.

In addition to limiting promotional activity, the rule imposes upon retailers the obligation to ensure that all sales of cigarettes and smokeless tobacco are to persons 18 years of age or older, as confirmed by a photo identification (ID) for anyone under 26 years of age. Also, under the FSPTCA, FDA must issue regulations addressing non-face-to-face sale and distribution to prevent underage sale, and must issue regulations addressing non-face-to-face promotion and marketing to protect underage consumers.52

The FSPTCA’s impact on promotional activity is not limited to directing FDA to reissue its final rule. The FSPTCA also directs FDA to develop an enforcement action plan to enforce restrictions on promotion and advertising of cigarettes to youth within six months of enactment, with an emphasis on enforcement in minority communities.53 Within three months of enactment, FDA must inform state and local governments about their authority to curtail promotion and distribution tobacco products.54 FDA is also directed to help communities that seek help to curb underage tobacco use.

More importantly, Chapter IX grants FDA broad authority to restrict the sale, distribution, advertising, and promotion of tobacco products consistent with the First Amendment and if “appropriate for the protection of the public health.”55 Whether a proposed restriction meets this standard is “to be determined with

49 Id. § 897.32.
50 Id. § 897.34.
51 Lorillard Tobacco Co., 533 U.S. at 565.
52 FDCA § 906(d)(4)(A).
53 FSPTCA § 105(a).
54 Id. § 105(b). Under FDCA section 916, states and federal agencies retain authority to impose requirements in addition to or more stringent than those in Chapter IX, except insofar as they relate to standards, premarket review, adulteration, misbranding, labeling, registration, GMPs or modified risk tobacco products. With respect to advertising and promotion, FSPTCA § 203 amends the FCLAA to allow states or localities to impose bans or restrictions on the time, place, and manner of such activity, but not on content. In making statutory amendments that address state authority, Congress made clear that there is no intent to preempt state product liability laws.
55 FDCA § 906(d).
respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.\textsuperscript{56} FDA’s exercise of this authority is almost certain to be challenged through litigation.

Lastly, the FSPTCA amends the Federal Cigarette Labeling and Advertising Act (FCLAA) and the Comprehensive Smokeless Tobacco Health and Education Act (CSTHEA) to strengthen the warnings required on cigarette and smokeless tobacco labeling and advertising.\textsuperscript{57} Both laws are amended to specify new required warning labels, one of which must appear on all packages and advertisements. For cigarettes, the warning must cover at least the top 50 percent of the front and rear panels of packaging and at least 20 percent of advertisements. For smokeless tobacco, the warning must cover at least 20 percent of the two principal display panels of a package and at least 20 percent of advertisements. All warnings must be displayed on all brands and be randomly distributed throughout the United States, and a plan must be submitted by a product’s manufacturer, importer, distributor or retailer for approval by FDA to ensure equal distribution and quarterly rotation of all required messages. For cigarettes, FDA is directed to issue a regulation requiring the use of color graphics in labeling that depict the negative health consequences of smoking. Looking forward, FDA is directed to determine whether tobacco product manufacturers should be required to include tar and nicotine yields in labeling and advertising, and whether the yield of other constituents should be disclosed by appropriate means.\textsuperscript{58}

**Getting a Handle on Illicit Trade**

The advent of burdensome regulatory requirements and restrictions, coupled with the status of tobacco products as a source of revenue for federal and state governments, led Congress to address in some detail the need to prevent illicit trade\textsuperscript{59} in tobacco products. Thus Chapter IX imposes numerous requirements designed to help FDA track the movement of tobacco products in the marketplace.

FDCA section 920(b) directs FDA to issue regulations requiring the establishment and maintenance of records that are necessary to help it investigate illicit trade. The records are to be established and maintained by “any person who manufactures, processes, transports, distributes, receives, packages, holds, exports or imports” a tobacco product. FDA can gain access to all records relating to that product at any point in its distribution upon a “reasonable belief that a tobacco product is

\textsuperscript{56} Id. \textsuperscript{906}(d)(i).

\textsuperscript{57} Under the FSPTCA, the Federal Trade Commission (FTC) retains jurisdiction over the advertising, sale, and distribution of tobacco products unless otherwise provided under the FSPTCA. An advertising violation of Chapter IX or FDA’s reissued regulation is an unfair or deceptive act or practice that violates section 5(a) of the FTC Act. FDA is directed to coordinate with the FTC with respect to relevant provisions of the FCLAA and CSTHEA.

\textsuperscript{58} There are some significant limitations on FDA’s authority to restrict the distribution of tobacco products. For example, FDA cannot prohibit face-to-face sales by specific categories of retail outlets, nor can FDA raise the minimum age for purchase above eighteen. Under FSPTCA § 104, FDA is directed to conduct a study on the public health implications of raising the minimum age and report back to Congress within five years.

\textsuperscript{59} Section 900(8) defines “illicit trade” as “any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale or purchase of tobacco products including any practice or conduct intended to facilitate such activity.”
part of an illicit trade or smuggling or is a counterfeit product."  

60 "FDA can also require the use of codes or other devices to track products. FDA, however, cannot require retailers to keep records of individual purchasers.

A manufacturer or distributor’s obligations with respect to stanching illicit trade are not limited to keeping records. If a manufacturer or distributor "has knowledge which reasonably supports the conclusion" that a tobacco product may be or has been marketed without paying taxes or diverted for possible illicit marketing, the manufacturer or distributor must so notify the Attorney General and the Department of the Treasury. "Knowledge" is defined broadly to require the exercise of due care.

Finally, within one year of enactment, the labels, packaging, and shipping containers of tobacco products other than cigarettes must state “sale only allowed in the United States.” The date on which that requirement applies to cigarettes hinges on FDA's issuance of the regulation requiring the use of color graphics in labeling that depict the negative health consequences of smoking. It remains to be seen whether these provisions will prevent or significantly curtail a black market in unregulated cigarettes.

Already Under Challenge

The statutory restrictions described above so impinge upon a manufacturer’s ability to market and promote new tobacco products, and especially modified risk products, that they have prompted litigation challenging their constitutionality. In Commonwealth Brands, Inc., et al., v. FDA, 61 five tobacco manufacturers (including R.J. Reynolds Tobacco Company, Lorillard Tobacco Company and Commonwealth Brands, Inc.) and a retailer of tobacco products sued FDA alleging that certain provisions of the FSPTCA violate their First Amendment right to engage in commercial speech, among other constitutional violations. 62 The plaintiffs have asked the court to enjoin FDA from enforcing the challenged provisions of the FSPTCA.

The plaintiffs in Commonwealth Brands allege that the FSPTCA essentially eliminates the few remaining avenues for communication with their adult customers. In the absence of that communication, plaintiffs are unable to increase market share by convincing customers to switch from competing brands to plaintiffs’ brands (in the case of manufacturers) and hampering their ability to use tobacco advertising to generate sales of tobacco and other products (in the case of retailers). The plaintiffs contend that the FSPTCA’s numerous restrictions on labeling, advertising, and promotion are not warranted by a compelling governmental interest, that they do not directly advance the government’s interest, and that they are more extensive than is necessary. The challenged provisions thus fail to pass constitutional muster under the test for government regulation of commercial speech that was announced by the Supreme Court in Central Hudson Gas & Electric Corp. v. Public Serv. Comm’n, 447 U.S. 557 (1980).

60 Section 900(6) defines “counterfeit tobacco product” as “a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a tobacco product listed in a registration under section 905(i)(1).”

61 C.A. No.: 1:09-CV-0117-JHM-ERG (W.D. KY filed (Aug. 31, 2009)).

62 The filing of this suit was predicted during Congressional deliberations on H.R. 1256 (which subsequently became the FSPTCA).
Notably, two of the plaintiffs in Commonwealth Brands (Lorillard and R.J. Reynolds) were also involved as plaintiffs in Lorillard Tobacco. Doubtless, FDA will have Lorillard Tobacco very much in mind as the agency prepares to reissue its final rule and implement the other challenged provisions of the FSPTCA—assuming those efforts are not derailed by an adverse decision in Commonwealth Brands.

Further Down the Road

If the history of FDA's regulation of other product categories is any guide, the passage of the FSPTCA is but the opening volley in what is certain to be a long and contentious evolutionary process in which the benefits and shortcomings of the law will be made evident, debated strenuously, and addressed in future amendments that expand or trim FDA's authority. Perhaps in anticipation of that eventuality, the FSPTCA requires FDA to periodically submit reports on the agency's progress and any impediments toward implementation of the law. Not content to receive reports only from FDA, Congress also directed the Government Accountability Office (GAO) to submit a report five years after the date of enactment on the adequacy of FDA's authority and resources under the law, together with any recommendations to strengthen FDA's authority to more effectively protect public health. FDA's and GAO's reports should make for interesting reading.