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111TH CONGRESS, 1st Session | HOUSE OF REPRESENTATIVES | REPT. 111–58 Part 1

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

MARCH 26, 2009.—Ordered to be printed

Mr. WAXMAN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

DISSENTING AND ADDITIONAL DISSENTING VIEWS

[To accompany H.R. 1256]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1256) to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

The purpose of H.R. 1256, the "Family Smoking Prevention and Tobacco Control Act", is to amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to grant the Food and Drug Administration (FDA) the authority to regulate tobacco products.

H.R. 1256 allows the Secretary to restrict the sale and distribution of tobacco products, including advertising and promotion, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The legislation also allows the Secretary to take specified actions, including public notification and recall, against unreasonably harmful products.

H.R. 1256 requires the Secretary to establish tobacco product standards to protect the public health, but prohibits the Secretary from banning a class of tobacco products, such as all cigarettes, or reducing the nicotine level to zero. The legislation sets forth standards for the sale of modified-risk tobacco products and prohibits cigarettes from containing, as a characterizing flavor, any artificial or natural flavor (other than tobacco or menthol).

H.R. 1256 sets forth provisions regarding: (1) judicial review, (2) coordination with the Federal Trade Commission, (3) congressional review of regulations, and (4) state and local authority. The legislation also requires the Secretary to establish a Tobacco Products Scientific Advisory Committee.

H.R. 1256 amends the Federal Cigarette Labeling and Advertising Act to change cigarette warning label and advertising requirements. In addition, the legislation amends the Comprehensive Smokeless Tobacco Health Education Act of 1986 to change smokeless tobacco warning label and advertising requirements.

BACKGROUND AND NEED FOR LEGISLATION

The prevalence of tobacco use and its toll on human lives has long been a public health concern. The Centers for Disease Control and Prevention (CDC) estimates that 19.8% of U.S. adults (approximately 43 million people) are cigarette smokers. Current trends suggest that the annual rate of cessation among smokers remains fairly low, that the decline in the initiation rate may have slowed, and that overall adult prevalence may be flattening out at around 20%. In addition to the prevalence of tobacco use in the adult population, CDC estimates that 20% of U.S. high school students are cigarette smokers.

Cigarette smoking is the leading preventable cause of death in the United States. It is responsible for about 1 in 5 deaths annually, or more than 400,000 deaths per year according to CDC. According to the Institute of Medicine, smoking-related deaths account for more deaths than AIDS, alcohol, cocaine, heroin, homicide, suicide, motor vehicle crashes, and fires combined. Smoking harms nearly every organ of the body, causing many diseases and reducing the health of smokers in general. Cancer, the second leading cause of death, was among the first diseases causally linked to smoking. Approximately 8.6 million Americans suffer from chronic illnesses related to smoking. Smoking also increases the prevalence of cardiovascular and respiratory disease. Smokeless tobacco use

also has negatively affected the health of many Americans. According to the National Cancer Institute, smokeless tobacco contains 28 carcinogens and consumers of smokeless tobacco products increase their risk for certain cancers, including oral cancer.

In addition to the lives lost to tobacco, the financial losses amount to billions of dollars each year. CDC estimates that cigarette smoking costs more than $193 billion annually, based on lost productivity ($97 billion) and healthcare expenditures ($96 billion).

The Food and Drug Administration made its first attempt to address the harm caused by tobacco use in 1996. On August 28, 1996, FDA asserted jurisdiction over tobacco products under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA) and issued a final rule aimed at reducing underage smoking and use of smokeless tobacco products. The tobacco industry challenged this rule in court, claiming that FDA had exceeded its authority. A resulting Supreme Court decision in 2000, while acknowledging that tobacco use posed "perhaps the single most significant threat to public health in the United States," found that Congress had not given FDA authority over tobacco products as part of the FFDCA.

H.R. 1256 gives FDA explicit authority over tobacco products in a new chapter of the FFDCA relating solely to tobacco and authorizes FDA to regulate tobacco products "as appropriate for the protection of the public health." This new standard is more appropriate for inherently dangerous tobacco products than the standards of "safe" or "safe and effective," which apply to other FDA-regulated products.

Almost 80% of new users of tobacco products began when they were under the minimum legal age to purchase them. The use of tobacco products by the nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children. Every day, approximately 3,500 youth try a cigarette for the first time, and another 1,000 will become new, regular daily smokers. One-third of these youth will eventually die prematurely as a result. Tobacco advertising and marketing contribute significantly to the use of tobacco products by children and adolescents, who are more influenced by tobacco marketing than adults, and are exposed to substantial and unavoidable advertising that leads to favorable attitudes about tobacco use. Past efforts to restrict the advertising and marketing of tobacco products to youth have failed to adequately curb tobacco use by adolescents. H.R. 1256 provides FDA with the authority it needs to promulgate comprehensive restrictions on the sale, promotion, and distribution of tobacco products, actions that most public health experts agree can significantly reduce the number of people who start to use tobacco and significantly increase the number of people who quit using tobacco.

H.R. 1256 also grants FDA the authority to strictly regulate so-called "reduced harm" products and to prohibit unproven health claims by tobacco product manufacturers. This legislation prohibits the use of descriptors such as "light," "mild," and "low" to characterize the level of a substance in a product in labels or in advertising. As the National Cancer Institute found, these descriptors have led consumers to believe mistakenly that the products are less harmful than other tobacco products. The National Cancer Insti-

tute also found that these mistaken beliefs can reduce the motivation to quit smoking.

The current lack of government regulation has allowed the tobacco industry to design new products or modify existing ones in ways that increase their appeal to children and that contribute to the risk and incidence of disease. Flavors and product modification not only make the products more appealing to youth, but often result in exposure to additional carcinogens and other toxic constituents. The manipulation of nicotine and other chemical levels increases addictiveness and harm. H.R. 1256 grants FDA the authority to require product changes in current and future tobacco products, such as the reduction or elimination of ingredients, additives, and constituents (including smoke constituents). In addition, H.R. 1256 requires manufacturers to provide detailed disclosure of ingredients, nicotine levels, and harmful smoke constituents.

The current Surgeon General warnings on tobacco products are ineffective in providing adequate warnings about the dangers of tobacco products. This legislation requires stronger and more specific health warnings immediately upon enactment and gives FDA the authority to enlarge them further and to incorporate color graphics.

For too long, the tobacco industry in the United States has escaped the type of ordinary product regulation that applies to most other consumer products. This legislation levels the playing field with respect to tobacco products so that public health may be protected and improved.

HEARINGS

In the 110th Congress, the Subcommittee on Health held a legislative hearing on H.R. 1108, legislation similar to H.R. 1256, on October 3, 2007 (Printed Hearing 110–69). The Subcommittee heard from two panels of witnesses and experts. The first panel consisted of Fred Jacobs, M.D., J.D., Commissioner, New Jersey Department of Health and Senior Services; and Richard J. Bonnie, L.L.B., John S. Battle Professor of Law and Director, Institute of Law, Psychiatry and Public Policy, University of Virginia, Chair, Committee on Reducing Tobacco Use: Strategies, Barriers, and Consequences, Institute of Medicine. The second panel consisted of Risa Lavizzo-Mourey, M.D., M.B.A., President and CEO, Robert Wood Johnson Foundation; Scott Ballin, J.D., Steering Committee Member, Alliance for Health Economic and Agricultural Development; Mr. James Winkler, General Board of Church and Society, United Methodist Church; Mr. Henry Armour, President and CEO, National Association of Convenience Stores; Alan Blum, M.D., Professor, Wallace Endowed Chair, Director, Center for the Study of Tobacco and Society, College of Community Health Sciences, The University of Alabama; William Corr, Executive Director, Campaign for Tobacco Free Kids; and Jack E. Henningfield, Ph.D., Vice President, Research and Health Policy Pinney Associates. There were no legislative hearings held in the 111th Congress.

COMMITTEE CONSIDERATION

H.R. 1256 was introduced on March 3, 2009, by Rep. Henry A. Waxman (D–CA) along with 124 original cosponsors. The bill was referred to the Subcommittee on Health on March 3, 2009, but

later discharged by the full Committee. On Wednesday, March 4, 2009, the full Committee convened in open markup session and ordered H.R. 1256 favorably reported to the House by a record vote. Amendments offered during consideration of the bill were either defeated or withdrawn.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. A motion by Mr. Waxman to order H.R. 1256 favorably reported to the House was agreed to by a record vote of 39 yeas and 13 nays. The following are the recorded votes taken on the motion and amendments, including the names of those members voting for and against:

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 25

BILL: **H.R. 1256**, the "Family Smoking Prevention and Tobacco Control Act".

AMENDMENT: An amendment in the nature of a substitute by Mr. Buyer, No. 1, to strike all after the enacting clause of H.R. 1256 and insert the language of the "Youth Prevention and Tobacco Harm Reduction Act".

DISPOSITION: **NOT AGREED TO** by a roll call vote of 18 yeas to 34 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey				Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns			
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo				Mr. Shadegg			
Mr. Stupak		X		Mr. Blunt			
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack			
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan			
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 26

BILL: **H.R. 1256**, the "Family Smoking Prevention and Tobacco Control Act".

AMENDMENT: An amendment by Mr. Rogers, No.3, to exclude from funds authorized to the Food and Drug Administration in clause (ii) in order to use for certain food facilities inspections.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 15 yeas to 30 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall			
Mr. Markey				Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns			
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon				Mr. Whitfield	X		
Mr. Rush				Mr. Shimkus			
Ms. Eshoo				Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt			
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich			
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack			
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez				Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan			
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey			
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon							
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 27

BILL: **H.R. 1256**, the "Family Smoking Prevention and Tobacco Control Act".

AMENDMENT: An amendment by Mr. Rogers, No. 4, to insert a new section 6 on limitation on application of Act relating to approval or disapproval of heart disease drug applications by the FDA before the date of enactment of this Act.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 13 yeas to 28 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell				Mr. Hall	X		
Mr. Markey				Mr. Upton			
Mr. Boucher		X		Mr. Stearns			
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield			
Mr. Rush				Mr. Shimkus	X		
Ms. Eshoo				Mr. Shadegg			
Mr. Stupak		X		Mr. Blunt			
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle				Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez				Mrs. Myrick			
Mr. Inslee		X		Mr. Sullivan			
Ms. Baldwin		X		Mr. Murphy of PA			
Mr. Ross		X		Mr. Burgess			
Mr. Weiner		X		Ms. Blackburn			
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen							
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch							

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 28

BILL: **H.R. 1256**, the "Family Smoking Prevention and Tobacco Control Act".

AMENDMENT: An amendment by Mr. Burgess, No. 5, to strike subparagraph (B) as added by section 101(b)(3) of the bill to section 907(d)(3) of the Federal Food, Drug, and Cosmetic Act, and make such conforming amendments as may be necessary.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 14 yeas to 31 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey				Mr. Upton			
Mr. Boucher		X		Mr. Stearns			
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield			
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo				Mr. Shadegg			
Mr. Stupak		X		Mr. Blunt			
Mr. Engel		X		Mr. Buyer		X	
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle				Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez				Mrs. Myrick			
Mr. Inslee		X		Mr. Sullivan			
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn			
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon							
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch							

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 29

BILL: **H.R. 1256**, the "Family Smoking Prevention and Tobacco Control Act".

AMENDMENT: An amendment by Mr. Buyer, No. 7, making changers to certain findings in section 2, amending certain language in section 3, and amending section 101.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 17 yeas to 33 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey				Mr. Upton			
Mr. Boucher		X		Mr. Stearns			
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield			
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo				Mr. Shadegg			
Mr. Stupak		X		Mr. Blunt			
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle				Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick			
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 30

BILL: **H.R. 1256**, the "Family Smoking Prevention and Tobacco Control Act".

AMENDMENT: An amendment by Mr. Rogers, No. 10 en bloc, inserting a new section 6 limiting application of the Act unless the Health and Human Services Secretary certifies that FDA has approved or disapproved certain drug applications before the date of enactment of this Act.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 18 yeas to 33 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey				Mr. Upton			
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield			
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo				Mr. Shadegg			
Mr. Stupak		X		Mr. Blunt			
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle				Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick			
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

03/04/2009

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 31

BILL: **H.R. 1256**, the "Family Smoking Prevention and Tobacco Control Act".

AMENDMENT: An amendment by Mr. Rogers, No. 12, to subparagraph (B) of section 919(c)(2) as added by section 101(b)(3) of the bill.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 19 yeas to 33 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey				Mr. Upton			
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo				Mr. Shadegg			
Mr. Stupak		X		Mr. Blunt			
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle				Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick			
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

03/04/2009

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 32

BILL: **H.R. 1256**, the "Family Smoking Prevention and Tobacco Control Act".

MOTION: A motion by Mr. Waxman to order H.R. 1256 favorably reported to the House, without amendment Final Passage

DISPOSITION: **AGREED TO** by a roll call vote of 39 yeas to 13 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton		X	
Mr. Dingell	X			Mr. Hall	X		
Mr. Markey				Mr. Upton			
Mr. Boucher	X			Mr. Stearns		X	
Mr. Pallone	X			Mr. Deal		X	
Mr. Gordon	X			Mr. Whitfield		X	
Mr. Rush	X			Mr. Shimkus	X		
Ms. Eshoo				Mr. Shadegg			
Mr. Stupak	X			Mr. Blunt			
Mr. Engel	X			Mr. Buyer		X	
Mr. Green	X			Mr. Radanovich		X	
Ms. DeGette	X			Mr. Pitts		X	
Mrs. Capps	X			Ms. Bono Mack	X		
Mr. Doyle				Mr. Walden	X		
Ms. Harman	X			Mr. Terry	X		
Ms. Schakowsky	X			Mr. Rogers		X	
Mr. Gonzalez	X			Mrs. Myrick			
Mr. Inslee	X			Mr. Sullivan		X	
Ms. Baldwin	X			Mr. Murphy of PA	X		
Mr. Ross	X			Mr. Burgess		X	
Mr. Weiner	X			Ms. Blackburn		X	
Mr. Matheson	X			Mr. Gingrey		X	
Mr. Butterfield	X			Mr. Scalise		X	
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor	X						
Mr. Sarbanes	X						
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton	X						
Mr. Braley	X						
Mr. Welch	X						

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objectives of H.R. 1256 are to provide the Secretary with the proper authority over tobacco products in order to protect the public health and to reduce the number of individuals under 18 years of age who use tobacco products.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Subcommittee on Health held a hearing in the 110th Congress on H.R. 1108 (Serial No. 110–69), legislation similar to H.R. 1256, and the oversight findings of the Committee regarding the bill are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of budget authority and revenues regarding H.R. 1256 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. The Committee finds that H.R. 1256 would result in no new or increased entitlement authority or tax expenditures.

EARMARKS AND TAX AND TARIFF BENEFITS

Regarding compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 1256 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate on H.R. 1256 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate on H.R. 1256 provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 16, 2009.

Hon. HENRY A. WAXMAN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed estimate for H.R. 1256, the Family Smoking Prevention and Tobacco Control Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

DOUGLAS W. ELMENDORF,
Director.

Enclosure.

H.R. 1256—Family Smoking Prevention and Tobacco Control Act

Summary: H.R. 1256 would authorize the Food and Drug Administration (FDA) to regulate tobacco products, and would require the agency to assess fees on manufacturers and importers of tobacco products to cover the cost of FDA's new regulatory activities authorized by the bill. Such fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. The bill also contains provisions that affect direct spending and revenues associated with the retirement benefits of federal employees.

CBO estimates that:

• Implementing the bill would increase spending subject to appropriation, on net, by about $0.1 billion over the 2010–2014 period and by $0.8 billion over the 2010–2019 period, assuming annual appropriation actions consistent with the bill.

• Enacting H.R. 1256 would increase direct spending by $0.1 billion over the 2010–2014 period and by $0.5 billion over the 2010–2019 period.

• Federal revenues would increase by $0.3 billion over the 2010–2014 period and by $1.3 billion over the 2010–2019 period.

• Considering both the revenue and direct spending effects, enacting the bill would reduce budget deficits by a total of $0.2 billion over the 2010–2014 period and by $0.8 billion over the 2010–2019 period. (Those amounts exclude the effects that are subject to appropriation action.)

The legislation's effects on direct spending and revenues over the 2009–2013 and 2009–2018 periods are relevant for enforcing pay-as-you-go rules under the current budget resolution. CBO estimates that enacting H.R. 1256 would increase direct spending by $0.1 billion over the 2009–2013 period and by $0.4 billion over the 2009–2018 period. Enacting the bill also would increase revenues by $0.2 billion over the 2009–2013 period and by $1.0 billion over the 2009–2018 period. Together, those changes would yield net pay-as-you-go savings of $0.1 billion over five years and $0.6 billion over 10 years.

H.R. 1256 contains intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) because it would preempt certain state laws governing tobacco products and require tribal governments that manufacture or distribute tobacco products to comply with new federal regulations. CBO estimates that the costs to state, local, and tribal governments to comply with the mandates in the bill would not exceed the threshold established in UMRA ($69 million in 2009, adjusted annually for inflation).

CBO also expects that the federal regulations authorized by this bill would result in lower consumption of tobacco products and thus would reduce the amount of tax revenues and settlement funds collected by state and local governments. However, those declines in

revenues, estimated to total over $1 billion during the 2010–2014 period, would not result from intergovernmental mandates.

H.R 1256 would impose a number of mandates on private-sector entities. Among other things, the bill would assess a fee on companies that manufacture or import tobacco products, impose new restrictions on the sale, distribution and marketing of tobacco products, mandate disclosure of product information and grant FDA authority to regulate tobacco products. CBO estimates that the aggregate direct cost of complying with those mandates would exceed the threshold established by UMRA for private-sector mandates ($139 million in 2009, adjusted annually for inflation) in each year, beginning with 2010.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 1256 is shown in the following table. The costs of this legislation fall primarily within budget functions 550 (health) and 600 (income security).

	By fiscal year, in millions of dollars—											
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010–2014	2010–2019
CHANGES IN SPENDING SUBJECT TO APPROPRIATION												
Food and Drug Administration (FDA) Collection of New Tobacco Fees:												
Authorization Level	−235	−450	−477	−505	−534	−566	−599	−635	−672	−712	−2,201	−5,385
Estimated Outlays	−235	−450	−477	−505	−534	−566	−599	−635	−672	−712	−2,201	−5,385
Spending of Fees by FDA to Regulate Tobacco Products:												
Authorization Level	235	450	477	505	534	566	599	635	672	712	2,201	5,385
Estimated Outlays	50	275	498	610	619	627	629	631	668	708	2,052	5,315
Net Effect on FDA Spending:												
Authorization Level	0	0	0	0	0	0	0	0	0	0	0	0
Estimated Outlays	−185	−175	21	105	85	61	30	−4	−4	−4	−149	−70
Thrift Savings Plan Enhancement:												
Estimated Authorization Level	14	49	62	76	89	102	112	121	130	139	290	894
Estimated Outlays	13	47	62	75	88	101	111	121	130	139	285	887
Total Changes: [1]												
Estimated Authorization Level	14	49	62	76	89	102	112	121	130	139	290	894
Estimated Outlays	−172	−128	83	180	173	162	141	117	126	135	136	817
CHANGES IN DIRECT SPENDING												
Sick Leave Retirement Credit:												
Estimated Budget Authority	8	17	27	37	48	60	72	86	100	114	137	569
Estimated Outlays	8	17	27	37	48	60	72	86	100	114	137	569
Medicaid: Tobacco Provisions:												
Estimated Budget Authority	−1	−2	−4	−6	−9	−11	−13	−15	−18	−20	−22	−99
Estimated Outlays	−1	−2	−4	−6	−9	−11	−13	−15	−18	−20	−22	−99
Total Changes:												
Estimated Budget Authority	7	15	23	31	39	49	59	71	82	94	115	470
Estimated Outlays	7	15	23	31	39	49	59	71	82	94	115	470
CHANGES IN REVENUES												
Thrift Savings Plan Enhancement	50	79	98	122	155	198	255	330	426	550	504	2,263
Tobacco Excise Taxes and Fines	−13	−29	−40	−55	−73	−94	−117	−145	−177	−212	−210	−955
Total Changes in Revenues	37	50	58	67	82	107	138	185	249	338	294	1,308

	By fiscal year, in millions of dollars—											
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010–2014	2010–2019
NET IMPACT ON THE DEFICIT FROM CHANGES IN DIRECT SPENDING AND REVENUES												
Estimated Deficit Impact [2]	−30	−35	−35	−36	−43	−55	−79	−114	−167	−244	−179	−838

[1] In addition, H.R. 1256 would require the Government Accountability Office to conduct a study on cross-border trade in tobacco products. CBO estimates that study would cost about $1 million, assuming the availability of appropriated funds.

[2] Negative numbers indicate a reduction in the deficit.

Basis of estimate: For this estimate, CBO assumes that H.R. 1256 will be enacted near the start of fiscal year 2010, that the full amounts authorized will be collected (starting in fiscal year 2010) to fund FDA's regulatory activities authorized under the bill, and that outlays will follow historical patterns for similar activities.

H.R. 1256 would authorize FDA to regulate tobacco products. Such authority would include:

- Setting national standards for tobacco products, including a ban on cigarettes that contain certain additives or flavors (other than tobacco or menthol) that are a characterizing flavor of the tobacco product or tobacco smoke;
- Implementing new restrictions on the sale, distribution, and marketing of tobacco products;
- Requiring manufacturers of certain tobacco products to submit a marketing application to FDA and requiring manufacturers of certain products that are "substantially equivalent" to ones already on the market before a particular date to notify FDA by submitting a report with specified information before entering the market;
- Directing manufacturers and importers of tobacco products to adhere to new labeling requirements and to submit specific information, including health-related research, to the FDA about their products;
- Mandating the annual registration of all establishments that manufacturer, prepare, compound, or process tobacco products and specifying certain inspection, record-keeping and reporting requirements for manufacturers and importers; and
- Enforcing compliance with requirements specified in the bill.

H.R. 1256 would establish the Center for Tobacco Products within the FDA. It also would require FDA to reinstate certain regulations issued in 1996 intended to limit tobacco sales and marketing, especially to children. (The Supreme Court ruled in 2000 that the FDA did not have the authority to issue such regulations.) The bill explicitly would prohibit FDA from banning certain tobacco products or requiring the reduction of nicotine yields of tobacco products to zero. The legislation also would require FDA to issue new regulations relating to the testing and reporting of tobacco product information. (Such regulations could also include requirements for public disclosure of that information.) Among other things, H.R. 1256 would require the Secretary of Health and Human Services (HHS) to publish a list of the amounts of harmful and potentially harmful constituents of each tobacco product.

Use of tobacco products in the United States

At least partly as a result of efforts by the federal government, state governments, and the public health community, cigarette smoking has declined substantially over the past decade: in 2005, about 21 percent of adults in the United States were smokers, compared to about 25 percent in 1995. The recent increase in the federal excise tax on cigarettes as a result of the Children's Health Insurance Program Reauthorization Act (Public Law 111–3)—from $0.39 to $1.01 per pack—is likely to contribute to a continuing decline in smoking. CBO expects that consumption of tobacco prod-

ucts in the United States would further decline as a result of enacting H.R. 1256.

The effect of regulatory activities authorized under the bill on the use of tobacco products is uncertain because ongoing initiatives to reduce the use of tobacco products are expected to continue under current law. In particular, public heath efforts by federal, state, and local governments and by private entities have contributed to a substantial reduction in underage smoking in recent years. For example, the proportion of 17 year-olds who smoke declined from 19 percent in 1995 to 10 percent in 2005. Significant efforts to reduce underage smoking (the group most directly targeted by many of the interventions envisioned under the bill) have been taken as a result of the Master Settlement Agreement (MSA) in 1998 between major tobacco manufacturers and settling states. States and localities also continue to pursue public health initiatives independent of the MSA to reduce smoking and to limit health risks to the public associated with smoking. (However, funding for such activities is subject to the fiscal constraints of state and local budgets.) Public health efforts funded by federal programs and coverage of smoking cessation therapies (including those offered under certain public programs) also aim to reduce the use of tobacco under current law.

The expected impact of the legislation on the use of tobacco products stems from a combination of regulatory and economic factors. The regulatory changes with the largest potential to reduce smoking include: restricting access to tobacco by youths, requiring an increase in the size of warning labels on certain tobacco packaging (and authorizing the Secretary of HHS to mandate further changes to enhance warning labels), limiting certain marketing and advertising activities (especially those that target youths), and requiring FDA permission before manufacturers can market tobacco products that suggest reduced health risks or exposure to particular substances.[1] In addition, tobacco consumption would decline because the assessment of new fees on manufacturers and importers of tobacco products would probably result in higher prices of tobacco products.

Based on information from academic and other researchers, CBO estimates that H.R. 1256 would result in a further reduction in the number of underage tobacco users of 11 percent by 2019. CBO also estimates that implementing H.R. 1256 would lead to a further decline in smoking by adults by about 2 percent after 10 years. CBO has incorporated these projected changes in U.S. tobacco consumption into its estimates of the impact of the bill on Medicaid spending and on receipts from excise taxes on tobacco products.

Spending Subject to Appropriation

CBO estimates that implementing H.R. 1256 would increase spending subject to appropriation, on net, by $0.1 billion over the 2010–2014 period and by $0.8 billion over the 2010–2019 period, assuming the appropriation action consistent with the bill. The effect on discretionary spending by federal programs reflects the authorized funding relating to the federal regulation of tobacco prod-

[1] For example, pursuant to a timeline specified in the bill, descriptors on a tobacco product such as "low," "light," or "mild" would be prohibited and certain health-related claims not allowed unless manufacturers receive FDA's permission to market the product with that claim.

ucts and federal agency costs associated with changes to the Thrift Savings Plan (TSP) specified in the bill.

The costs for FDA to administer the new regulatory activities authorized under the legislation—$2.1 billion over the 2010–2014 period and $5.3 billion over the 2010–2019 period—would be covered by fees assessed on manufacturers and importers of tobacco products, resulting in a very small net impact on discretionary spending over the next 10 years (and no net impact over time). CBO estimates that automatic enrollment, under the bill, of new TSP participants would increase the cost for federal civilian agencies relating to their matching contributions for employees. The estimated TSP costs would sum to $0.9 billion over the 2010–2019 period, assuming the appropriation of the necessary amounts.

Collection of New Fees. H.R. 1256 would establish a program to assess fees to fund FDA's administrative costs for new regulatory activities relating to tobacco products authorized by the bill. The legislation would authorize the quarterly assessment of fees on manufacturers and importers of such products. It would authorize the appropriation of assessments equal to $85 million in 2009, $235 million in 2010, $450 million in 2011, $477 million in 2012, $505 million in 2013, $534 million in 2014, $566 million in 2015, $599 million in 2016, $635 million in 2017, $672 million in 2018, and $712 million in 2019 and each subsequent year.

Fees authorized by the bill would be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. As a result, those collections would be credited as an offset to discretionary spending.

Spending of Fees by FDA to Regulate Tobacco Products. Spending of the new fees assessed by FDA to regulate tobacco products also would be classified as discretionary spending because the authorized amounts would be available for obligation subject to appropriation action. Amounts collected would be available to cover FDA's administrative costs to regulate tobacco products at any point in the future.

Given the uncertainty surrounding how the FDA would implement such a large expansion of its regulatory activities, it is difficult to estimate the resources necessary—particularly in the early years—to implement the bill. We anticipate that, over the initial five-year period after enactment, FDA would actively develop the necessary infrastructure to operate the new tobacco program and that its ability to enter into obligations and disburse funds would grow rapidly. The legislation would limit the budget for the new program to the aggregate amount of fees collected for such purpose, and there would likely be some lag (at least initially) between when fees are collected and when they are spent.

Assuming appropriation action consistent with the bill, CBO estimates that implementing the program to assess fees to cover new FDA costs associated with regulating tobacco would reduce net discretionary outlays by $149 million over the 2010–2014 period and by $70 million over the 2010–2019 period, because the spending of fees would lag behind their collection.

Thrift Savings Plan. The bill would require that newly hired federal employees who are eligible for the TSP be automatically enrolled in that program. The automatic enrollment of participants in TSP would increase the matching contributions of the civilian

agencies that employ them (which are paid from personnel budgets and are usually considered spending subject to appropriation) by creating a greater and earlier participation rate of employees in the program. According to data from a 2006 survey conducted by the Federal Thrift Retirement Investment Board, 52 percent of employees enrolled in the Federal Employees Retirement System voluntarily contribute to the TSP in their first year of eligibility, but 86 percent contribute by their sixth year. (Although federal employees covered by the Civil Service Retirement System are also eligible to participate in the TSP, they would not be affected by automatic enrollment.) Using information from that survey, CBO expects that under automatic enrollment more than 90 percent of eligible new entrants would contribute to the TSP in their first year and that a similar proportion would continue to contribute by their 10th year (some would opt out in the beginning and others would likely change their status in the future).

For the uniformed services, the characteristics of potential participants differ. The current average rate for voluntary participation of new enlistees is approximately 25 percent, and unlike civilian employees, the uniformed services do not currently contribute on behalf of their members. Based on lower voluntary enrollment rates and the lack of agency contributions, CBO expects that under automatic enrollment more than 40 percent of eligible new entrants would contribute.

Assuming that the bill becomes effective in October 2009 and that civilian agencies would not begin matching contributions for an additional six months, participants would receive an increase in matching agency contributions of 3 percent of their basic pay for the third quarter of fiscal year 2010 and 3 percent per year thereafter. CBO estimates that enacting H.R. 1256 would increase agency contributions by nearly $0.9 billion over the 2010–2019 period.

Federal Trade Commission (FTC). The bill would authorize the FTC to enforce provisions in the bill relating to advertising that would be considered unfair or deceptive trade practices under the Federal Trade Commission Act. Currently, the FTC enforces certain laws governing warnings printed on labels of cigarettes and smokeless tobacco, among other things. Based on information from the FTC, CBO expects that the FTC's new enforcement activities under H.R. 1256 would replace some of its current enforcement activities that would be transferred to FDA under the bill. CBO estimates that any additional costs to the FTC would be insignificant.

Other Provisions. H.R. 1256 would require the Government Accountability Office to conduct a study on cross-border trade in tobacco products. CBO estimates that conducting such studies would cost about $1 million, assuming the availability of the necessary funds. CBO also anticipates that any additional costs for other federal agencies that might assist FDA with implementing certain requirements relating to the regulation of tobacco specified in the bill would not be significant.

Direct Spending

CBO estimates that enacting H.R. 1256 would increase direct spending, on net, by $0.1 billion over the 2010–2014 period and by $0.5 billion over the 2010–2019 period. That estimate reflects two effects of the bill:

- Authorizing FDA regulation of tobacco products and changes relating to such products required by the bill would lower consumption of tobacco and would generate savings to the Medicaid program, and
- Changing the calculation of federal retirement benefits under the Federal Employees Retirement System to reflect accrued sick leave hours would raise average retirement benefits paid to individuals.

Impact of FDA Regulation of Tobacco on Medicaid. CBO anticipates that FDA's regulation of tobacco products will lead to a decline in smoking among pregnant women. That decline will reduce health care spending on pregnancies because women who refrain from smoking during pregnancy are less likely to give birth to children with low birth weights—such children have relatively high costs both at birth and afterwards—or experience other complications during pregnancy. Part of the savings from reduced complications is offset by costs associated with the additional live births resulting from a decline in miscarriages. CBO estimates federal spending for Medicaid would decrease by $0.1 billion over the 2010–2019 period. (That savings is an estimated increment above savings previously estimated and credited to Public Law 111–3, which contains an increase in federal excise taxes on tobacco products.)

A decline in smoking could affect health care spending for many other medical conditions. An individual who stops smoking is less likely to suffer a heart attack or stroke over a given period of time compared to one who continues to smoke, so a potential reduction in utilization of acute care services for those or other conditions could lead to cost savings. The magnitude and timing of such savings are uncertain, however. Also, a reduction in smoking may add to costs in many cases by increasing the lifespans of persons who would incur health care costs over longer periods. In those cases, government spending for other benefits such as Social Security, Medicare, and from other retirement and mandatory spending programs would also increase. CBO continues to examine the impact of smoking related legislation on public and private payers. This cost estimate does not include potential effects on federal spending other than the estimated impact on Medicaid of reduced smoking levels on pregnancies.

Retirement Credit for Sick Leave. Currently, the retirement benefit calculation for federal employees in FERS does not incorporate any accrued sick leave hours. Under H.R. 1256, eligible federal employees who retire after enactment would add 100 percent of their remaining sick leave hours to their total years of service when calculating the retirement benefit owed. CBO estimates that an average of about three months would be added to employees' length of service as a result of including sick leave hours. That addition is estimated to boost the average retirement benefit by about $150 per year, increasing direct spending over the 2010–2019 period by $0.6 billion.

Other Effects on Direct Spending. Under H.R. 1256, FDA would have the discretion to impose criminal fines on entities convicted of violating certain new requirements established by the bill. Collections of criminal fines are recorded in the budget as revenues, deposited in the Crime Victims Fund, and later spent. Such ex-

penditures are classified as direct spending. CBO expects that relatively few cases would result in such criminal fines. Therefore, CBO estimates that enacting H.R. 1256 would not have a significant effect on revenues or direct spending from the collection of criminal fines over the 2010–2019 period.

Revenues

CBO estimates that enacting H.R. 1256 would increase federal revenues, on net, by $0.3 billion over the 2010–2014 period and by $1.3 billion over the 2010–2019 period. That estimate primarily reflects two effects of the bill:

- Authorizing FDA oversight of tobacco products and changes relating to such products required by the bill would lower consumption of tobacco and reduce receipts of federal excise taxes on those products, and
- Establishing a Roth contribution program would increase tax revenues because of the tax treatment of employee's contributions.

In addition, revenues may increase slightly from the collection of fines associated with violations of new requirements imposed by the bill.

Excise Taxes. As noted earlier, CBO expects that enacting H.R. 1256 would reduce the consumption of tobacco products in the United States, which in turn would reduce the collection of federal excise taxes. As a result, CBO estimates that the legislation would reduce federal revenues, by $0.2 billion over the 2010–2014 period and $1.0 billion over the 2010–2019 period, net of changes to income and payroll taxes. Over the 10–year period, the reduction in receipts would amount to less than 1 percent of receipts from excise taxes on tobacco expected under current law.

Effects of TSP Changes on Revenues. Enacting H.R. 1256 would increase revenues by an estimated $2.3 billion over the 2010–2019 period. Establishing a Roth contribution program (in which contributions to the retirement accounts would be made on an after-tax basis) would result in some TSP participants electing to contribute after-tax income to their retirement plan rather than contributing pre-tax amounts, thereby boosting income tax revenues by an estimated $3.3 billion over the 10–year period. However, because income taxes are deferred on regular TSP contributions, the anticipated increase in participants' contributions from automatic enrollment would offset part of the revenue increase, reducing receipts by $1.0 billion over the 2010–2019 period.

Collection of Fines. The effects on federal revenues also include relatively small effects from provisions that would allow the Secretary of HHS to levy fines against sponsors of misbranded and adulterated tobacco products, sellers of tobacco to underage individuals, and for other violations. The FTC would also be authorized to assess fines for certain violations of tobacco-related requirements enforced by the commission. We estimate that revenues associated with the collection of civil fines authorized under H.R. 1256 would be roughly $1 million annually.

Estimated impact on state, local, and tribal governments: H.R. 1256 contains intergovernmental mandates as defined in UMRA. CBO estimates that the costs of those mandates to state, local, and tribal governments would be small and would not exceed the

threshold established in UMRA ($69 million in 2009, adjusted annually for inflation).

The bill would preempt state laws governing tobacco products that are different from or in addition to the federal regulations authorized by the bill, including laws governing:

- Product standards
- Premarket review
- Adulteration
- Misbranding
- Labeling
- Registration
- Good manufacturing standards, or
- Modified-risk tobacco products.

That preemption would be an intergovernmental mandate as defined in UMRA. However, because the preemption would simply limit the application of state and local laws, CBO estimates that it would not impose significant costs on state or local governments.

H.R. 1256 would require tobacco manufacturers to register annually with the FDA and pay fees assessed by the agency. The bill would require both tobacco manufacturers and distributors of tobacco products to comply with federal regulations relating to the content, labeling, and marketing of tobacco products. CBO has identified two tribal governments that manufacture and distribute tobacco products. Because those governments would be required to comply with federal regulations authorized by the bill, they would face intergovernmental mandates as defined in UMRA. Based on information from tribal and federal officials, CBO estimates that the costs to tribal governments to comply with the bill would be small and would not exceed the UMRA threshold for intergovernmental mandates.

Other impacts

CBO also estimates that the amount of tax revenues and settlement funds collected by state and local governments would decline as a result of the federal regulations authorized by this bill because of lower consumption of tobacco products. However, those declines in revenues, estimated to total over $1 billion during the 2010–2014 period, would not result from intergovernmental mandates. Rather, the decline in revenues would be an indirect effect on state and local governments resulting from the new federal regulations imposed on companies that manufacture or import tobacco products.

In 2008, state and local governments collected about $19 billion in revenues from excise and general sales taxes levied on tobacco products. CBO estimates that this bill would lower consumption of those products and that excise taxes collected by state and local governments would fall by about $20 million in 2010, with that reduction growing to over $330 million in 2014. Similarly, CBO estimates that state and local governments would see a decline in sales-tax revenues of about $170 million over the 2010–2014 period.

Forty-six states, the District of Columbia, and five U.S. territories receive annual payments from tobacco manufacturers that are parties to the tobacco Master Settlement Agreement (MSA). In 2008, those payments totaled over $8 billion. Under the terms of

the MSA, those payments are adjusted annually to account for changes in the volume of cigarette sales in the United States of participating manufacturers. Because CBO estimates that enacting this legislation would result in lower consumption of tobacco products, CBO estimates that the annual payments to states under the MSA also would decline by over $160 million over the 2010–2014 period.

A decline in smoking among pregnant individuals is expected to result in a reduction of low-weight births. As a result, state spending for Medicaid would decrease by an estimated $17 million over the 2010–2014 period, with additional savings in subsequent years.

Estimated impact on the private sector: H.R. 1256 would impose a number of private-sector mandates, as defined in UMRA, on companies that manufacture or import tobacco products. CBO estimates that the total direct cost of these mandates would exceed the threshold established by UMRA ($139 million in 2009, adjusted annually for inflation) in each year, beginning with 2010. The bill would assess a fee on manufacturers and importers of tobacco products to cover the cost to FDA of regulating those products. The aggregate payments would sum to $235 million in 2010, and rise to more than $500 million a year by 2013.

The bill would impose new requirements related to the labeling and advertising of cigarette and smokeless tobacco products. New warnings on packaging and advertisements would have to be larger. The bill would also prohibit cigarettes or any of their component parts from containing certain additives or flavors (other than tobacco or menthol) that are a characterizing flavor of the tobacco product or tobacco smoke. CBO has not been able to determine whether the direct cost of these provisions would be significant.

The bill would require that FDA publish a final rule on tobacco products that would be similar to part 897 of the tobacco regulations promulgated by the Secretary of HHS in 1996 and subsequently invalidated by the Supreme Court. Certain restrictions that would be in that rule already exist under current federal and state law or are included in the 1998 Master Settlement Agreement between major tobacco manufacturers and settling states. As a result, and based on information from industry sources, CBO estimates that the incremental direct cost of these restrictions to manufacturers and importers of tobacco products would be small.

In addition, the bill would give FDA the authority to regulate the sale, distribution, advertising, promotion and use of tobacco products if such actions would be in the interest of the public health. FDA would also have the authority to set product standards that reduce quantities of nicotine and other harmful constituents allowed in tobacco products or otherwise alter the composition and testing of such products. CBO cannot estimate the potential cost of these provisions because the cost would depend on future actions by the Secretary of HHS.

Finally, the bill would require companies that manufacture or import tobacco products to disclose information about those products to the Secretary of HHS. That information, among other things, would include a listing of all ingredients and additives, a description of nicotine content, delivery, and form, and a listing of all potentially harmful constituents found in the tobacco product. At the discretion of the Secretary of HHS, those companies would

also be required to disclose any and all documents regarding research on risks to health of tobacco products, methods for reducing those risks, and the effectiveness of marketing practices used by companies that manufacture or distribute tobacco products. Such information would include both research activities and the findings associated with that research. CBO estimates that the direct cost of complying with these requirements would be small.

Estimate prepared by: Federal Spending: Food and Drug Administration—Julia Christensen, Medicaid—Ellen Werble and Colin Baker, Federal Retirement—Amber Marcellino, Thrift Savings Plan—Jared Brewster, Federal Trade Commission—Susan Willie; Federal Revenues: Grant Driessen and Barbara Edwards; Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum; Impact on the Private Sector: Patrick Bernhardt.

Estimate approved by: Peter H. Fontaine, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of federal mandates regarding H.R. 1256 prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

Regarding section 5(b) of the Federal Advisory Committee Act, H.R. 1256 requires the establishment of an advisory committee regarding tobacco products. See section 917 in the chapter IX that section 101(b) of the bill adds to the Federal Food, Drug, and Cosmetic Act. The Committee finds that establishing the advisory committee is the most efficient way of carrying out the policies involved.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the constitutional authority for H.R. 1256 is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several states, and with the Indian Tribes, in the provisions of Article I, section 8, clause 1, that relate to expending funds to provide for the general welfare of the United States, and in the provisions of Article I, section 8, clause 18, which grants Congress the power to make all laws necessary and proper to carry into execution the powers enumerated in section 8 and all other powers vested by the Constitution in the government of the United States.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that H.R. 1256 does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act of 1995.

EXCHANGE OF COMMITTEE LETTERS

CHARLES B. RANGEL, NEW YORK,
CHAIRMAN

FORTNEY PETE STARK, CALIFORNIA
SANDER M. LEVIN, MICHIGAN
JIM McDERMOTT, WASHINGTON
JOHN LEWIS, GEORGIA
RICHARD E. NEAL, MASSACHUSETTS
JOHN S. TANNER, TENNESSEE
XAVIER BECERRA, CALIFORNIA
LLOYD DOGGETT, TEXAS
EARL POMEROY, NORTH DAKOTA
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MINORITY STAFF DIRECTOR

March 16, 2009

The Honorable Henry Waxman
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Waxman:

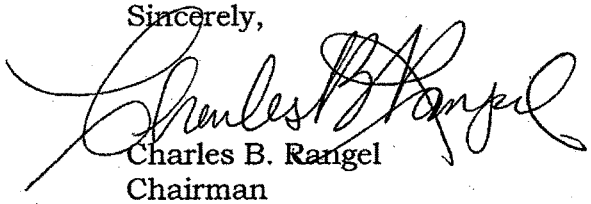
I am writing to confirm our understanding of H.R. 1256, the "Family Smoking Prevention and Tobacco Control Act."

The Committee has taken note that H.R. 1256 includes a prohibition against the use of clove to create a characterizing flavor in cigarettes. The Committee on Ways and Means believes this provision to be within its jurisdiction because most clove-flavored cigarettes currently sold in the United States are imported. I understand that you recognize our jurisdictional interest in this question, given its effects on trade and on customs revenues.

The Committee on Ways and Means has agreed to forego action on this bill and will not oppose its consideration, based on our understanding that you agree, as the bill moves through the legislative process, you will continue to discuss with the Committee on Ways and Means the concerns raised with respect to the clove provision. This is being done with the understanding that it does not in any way prejudice the Committee with respect to the appointment of conferees or the

full exercise of its jurisdictional prerogatives on this bill or similar legislation in the future.

Sincerely,



Charles B. Rangel
Chairman

cc: The Honorable Nancy Pelosi
The Honorable Steny Hoyer
The Honorable John Boehner
The Honorable Joe Barton
The Honorable Dave Camp
Mr. John Sullivan, Parliamentarian

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March 16, 2009

The Honorable Charles B. Rangel
Chairman,
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

Dear Chairman Rangel:

Thank you for your letter to me in which you expressed the jurisdictional interest of the Committee on Ways and Means in certain provisions of H.R. 1256, the "Family Smoking Prevention and Tobacco Control Act."

The bill provides for the regulation of tobacco products by the Food and Drug Administration (FDA). You have expressed concerns about the provision in the bill that prohibits the use of clove to create a characterizing flavor in cigarettes. I acknowledge your concerns and understand that the Committee on Ways and Means has jurisdiction over import bans because of the effects on import trade and on customs revenues. The Committee on Ways and Means did not seek a sequential referral of the bill on the basis of the clove provision. I appreciate your cooperation.

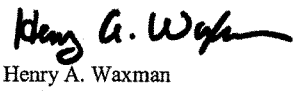
As the bill moves through the legislative process, we will continue to discuss with the Committee on Ways and Means the concerns raised with respect to the clove provision.

I agree that the decision not to seek a sequential referral to the Committee on Ways and Means in no way prejudices the Committee with respect to other jurisdictional questions or with respect to the appointment of conferees.

The Honorable Charles Rangel
March 16, 2009
Page 2

Per your request, I will include copies of our exchange of letters on these matters in the Congressional Record. I look forward to working with the Committee on Ways and Means as this bill moves forward to enactment.

Sincerely,



Henry A. Waxman
Chairman

cc: The Honorable Nancy Pelosi
The Honorable Steny Hoyer
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SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title; table of contents

The short title is designated as the "Family Smoking Prevention and Tobacco Control Act". This section also includes the Act's table of contents.

Section 2. Findings

Section 2 provides findings relating to tobacco use in the United States and the need for regulation.

A number of the findings included in the legislation address the constitutionality of the legislation. The Committee finds that the legislation is fully consistent with the First Amendment of the U.S. Constitution. Specifically, the reasonable restrictions on advertising and promotion of tobacco products are both necessary and narrowly tailored to protect a compelling federal interest.

In finding 31, Congress finds that the regulations promulgated by the Secretary of Health and Human Services in August 1996 and described in finding 30 will directly and materially advance the federal government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. This is based on the evidence cited by FDA in support of the 1996 regulation referenced in finding 30 and on numerous studies that have been conducted since 1996. For example, several studies have shown that exposure to tobacco advertising substantially increases the likelihood that children and adolescents will smoke. One such study, published in 2006 in the Archives of Pediatrics and Adolescent Medicine, found that tobacco marketing doubles the odds that children under 18 years of age will become tobacco users. Additionally, a 2002 study published in the Archives of Pediatrics and Adolescent Medicine and a 1998 study published in the Journal of the American Medical Association showed that the greatest impact was on influencing non-susceptible youth to become susceptible to smoking, though at least one study, published in 2006 in the Archives of Pediatrics and Adolescent Medicine, also showed that tobacco marketing leads children who already smoke to smoke more heavily. Even before some of the more recent studies were conducted, the National Cancer Institute found in 2001, based on a review of then existing research, that "the conclusion that there is a causal relationship between tobacco marketing and smoking initiation seems unassailable." More recently, in August 2008, the National Cancer Institute issued a peer reviewed monograph that examined evidence of the relationship between tobacco marketing and youth smoking. This monograph found that "the evidence base indicates a causal relationship between tobacco advertising and increased levels of tobacco initiation and continued consumption" and that even brief exposure to tobacco advertising influences adolescents' attitudes and perceptions about smoking as well as their intentions to smoke.

In finding 31, Congress also finds that less restrictive and less comprehensive approaches have not been and will not be effective in reducing the problems addressed by the regulations described in finding 30. For example, the Master Settlement Agreement (MSA) between the states and some of the major tobacco companies has

been in effect since 1998. Despite the MSA, prior federal legislation, and state efforts, CDC has found that the percentage of high school students who smoke increased from 21.9% in 2003 to 23% in 2005 and remains unacceptably high. The rates are particularly alarming given all the state excise tax increases, prevention and cessation programs, and smokefree air laws, which cumulatively should have forced youth smoking rates down below the current level. Major scientific reports issued after the MSA, such as the 2008 NCI Monograph on tobacco marketing, "The Role of the Media in Promoting and Reducing Tobacco Use," the 2007 Report of the President's Cancer Panel, "Promoting Healthy Lifestyles: Policy, Program and Personal Recommendations for Reducing Cancer Risk," and the 2007 Report of the Institute of Medicine on tobacco, "Ending the Tobacco Problem: A Blueprint for the Nation," all found a continuing serious problem despite prior efforts and concluded that additional restrictions on tobacco marketing are essential to reduce tobacco use, especially among youth.

In finding 31, Congress also finds that reasonable restrictions on the advertising and promotion of tobacco products contained in the 1996 regulation will lead to a significant decrease in the number of minors using and becoming addicted to those products. This too is based on the evidence cited by FDA in support of the 1996 regulation and on more recent studies and findings. For example, an article in the 2007 Archives of Pediatrics and Adolescent Medicine concluded that the more cigarette marketing teens are exposed to in retail stores, the more likely they are to smoke, and that restricting these retail marketing practices would reduce youth smoking. These conclusions were reaffirmed by the 2007 Report of the President's Cancer Panel and the 2007 Institute of Medicine Report.

In finding 32, Congress finds that the regulations described in paragraph 30 impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. The regulation is carefully tailored to focus on the types of advertising that will have the greatest impact on youth. The requirements are tailored to allow companies to advertise to adults in ways that provide information on what they are selling, for what reason, and for what price. There are no limits on print advertising in publications with adult readership and adult establishments, such as bars.

Section 3. Purpose

Section 3 provides the purpose of the bill, which is to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act. FDA would be given authority to set national product standards; ensure effective oversight; regulate the levels of tar, nicotine, and other components of tobacco products as appropriate for the protection of the public health; require tobacco product manufacturers to disclose research; continue to permit the sale of tobacco products to adults; promote cessation; and strengthen protections against illicit trade in tobacco products.

Section 4. Scope and effect

Section 4 states that nothing in this Act shall be construed to establish a precedent with regard to any other industry or affect any pending court action. This Act is also not intended to affect the authority of the Secretary of Agriculture regarding raw tobacco nor is it intended to affect any authority of the Secretary of the Treasury.

Section 5. Severability

Section 5 states that if any provision of this Act is held to be invalid, the remainder of this Act shall not be affected and shall continue to be enforced.

Title 1—Authority of the Food and Drug Administration

Section 101. Amendment of Federal Food, Drug, and Cosmetic Act

Chapter IX (in the FFDCA)—Tobacco products

The bill creates a new chapter within the FFDCA to regulate tobacco products.

Section 900. Definitions

Section 900 defines the following terms: additive; brand; cigarette; cigarette tobacco; commerce; counterfeit tobacco product; distributor; illicit trade; Indian tribe; Indian country; little cigar; nicotine; package; retailer; roll-your-own tobacco; small tobacco product manufacturer; smoke constituent; smokeless tobacco; state, territory; tobacco product manufacturer; tobacco warehouse; and United States.

The Committee notes. that "small tobacco product manufacturer" (STPM) is defined. The Committee believes that an entity that qualifies as an STPM has access to fewer economic resources and, therefore, needs the special considerations provided for STPMs in certain portions of the Act (e.g., Sec. 901(f) and Sec. 906(e)(1)(B)(v)). Accordingly, the term "employees" includes not only those persons considered employees under labor or tax laws, but also any other person working full-time for a manufacturer doing the work of a regular employee (e.g., under a services contract or consulting agreement). Without this understanding of the term "employee," some manufacturers would be able to qualify wrongfully as STPMs by replacing a number of their formal employees with consultants or contract workers or by changing their relationships with existing workers from a formal employer-employee relationship to an independent contractor relationship. The Food and Drug Administration should review annually the documentation of any company that qualifies as a small manufacturer to ensure that the number of its employees, taking into account employees of each entity it controls, is controlled by or is under common control, does not exceed 350. For purposes of determining the number of employees under the preceding sentence, the employees of a company that owns, has a substantial ownership interest in, or is owned by such manufacturer shall be included.

Section 901. FDA authority over tobacco products

Section 901(c) limits the scope of FDA's authority to regulate manufacturers of tobacco products, making clear that FDA does not have the authority to regulate tobacco growers. If a producer of tobacco leaf, however, is also a tobacco product manufacturer, the producer shall be subject to regulation in the producer's capacity as a manufacturer. The Committee notes that the phrase "in the producer's capacity as a manufacturer" refers to the actual process of manufacturing a tobacco product. While it covers a tobacco cooperative that operates as a tobacco product manufacturer, it does not refer to a tobacco producer who merely sells raw tobacco to a tobacco cooperative which operates a tobacco product manufacturing facility or to a tobacco producer who merely serves on the board of directors of such a cooperative.

In order to make clear the importance of tobacco regulation, as well as the Committee's intent not to have FDA regulation of tobacco detract from other responsibilities of the agency, Section 901(e) directs FDA to establish a separate Center for Tobacco Products.

Section 901(f) directs FDA to establish an Office to Assist Small Manufacturers of Tobacco Products to provide technical assistance to small manufacturers in complying with the requirements of this Act.

Section 902. Adulterated tobacco products

Section 902 lays out guidelines for determining whether tobacco products are adulterated. Filthy, decomposed, or otherwise contaminated substances in tobacco products, the preparation of such products, or the packaging of such products will cause them to be deemed adulterated. Tobacco products held under unsanitary conditions or manufactured, packed, or stored in violation of good manufacturing practices will likewise be deemed adulterated. A tobacco product will also be deemed adulterated if the manufacturer of it fails to pay required user fees, if it does not meet the product standards established for the product, or if the product is required to have premarket review and an order in effect under section 910 or to have an order in effect as a modified risk product under section 911 and does not have such an order in effect.

Section 903. Misbranded tobacco products

Section 903(a) states that tobacco products will be deemed misbranded if their label is false or misleading, if they are not correctly labeled (e.g., with the percentage of domestically grown versus foreign tobacco, proper warning labels, the name of the manufacturer, or in accordance with other requirements of the Secretary) or advertised, or if the manufacturing, distribution, or selling of the product does not comply with other parts of the Act.

Section 903(b) provides that the Secretary is specifically authorized to require prior approval of statements made on the label of a tobacco product.

Section 904. Submission of health information to the Secretary

Section 904(a) requires, within six months of passage, submission to the Secretary by brand and quantity of ingredients, compounds, substances, and additives that are added to the tobacco, paper, fil-

ter, or other part of the tobacco product. This section also requires a description of the content, delivery, and form of nicotine, as well as documents developed after enactment that relate to health, toxicological, behavioral, or physiologic effects of tobacco products. This information is required of all current tobacco products as well as any tobacco products introduced after enactment. Further, three years after enactment, a list of constituents, including smoke constituents, identified by the Secretary as harmful or potentially harmful, is required to be submitted to the Secretary.

Section 904(b) provides the Secretary with the authority to request documents and information on a broad range of issues, including, for example, documents and information relating to research activities and findings, scientific information on reduced-risk products and technology, the health effects of tobacco products and their components, and marketing research. This provision applies to both foreign and domestic manufacturers.

Section 904(c) requires a written notice to the Secretary at least 90 days prior to marketing if a tobacco manufacturer adds a new additive to their product or increases the amount of an additive. This section requires a written notice to the Secretary at least 60 days prior to marketing if a tobacco manufacturer eliminates or decreases an existing additive.

Section 904(d)(1) requires within three years of passage, and annually thereafter, the Secretary must publish in an easily available and understood format a list of harmful and potentially harmful constituents in each brand.

Section 904(d)(2) requires the Secretary also to conduct consumer research to ensure that publication of the list is not misleading to lay persons. After 5 years, the Secretary must report to Congress on the results of the consumer research, and provide a recommendation on whether or not publication of the list should continue or be modified.

Section 905. Annual registration

Section 905 requires registration of every entity that owns or operates in any state any establishment engaged in the manufacture, preparation, compounding, or processing of tobacco products. The same requirement extends to foreign establishments. At the time of this registration, a listing is required of all tobacco products, which are being manufactured, prepared, compounded, or processed. Once registered, every establishment is subject to an inspection once every two years.

Section 905(e) allows the Secretary to create a uniform system for identification of tobacco products.

Section 905(j) requires a report to the Secretary 90 days prior to the introduction of a new tobacco product demonstrating that the product is substantially equivalent to a tobacco product already on the market and therefore not subject to premarket review. If the new product is not substantially equivalent to a product already on the market, the new product must be reviewed pursuant to Section 910. Section 905(j) requires reports on products first marketed between February 16, 2007, and 21 months after enactment. Additionally, section 905(j) authorizes the Secretary to issue regulations creating exemptions from premarket notification for minor modifications of existing products or where otherwise appropriate.

Section 906. General provisions respecting control of tobacco products

Section 906(b) provides for notice and comment rulemaking.

Section 906(c) ensures limited confidentiality of certain information reported to the Secretary. Section 906(d) authorizes the Secretary to issue regulations restricting the sale and distribution of tobacco products, including access to, advertising, and promotion of tobacco products, if the Secretary determines that the regulations would be appropriate to protect the public health, taking into account factors specified in the provision.

Advertising and promotion restrictions are permitted to the full extent consistent with the First Amendment. The Committee notes that Section 906(d) authorizes the Secretary to impose restrictions on the advertising and promotion of tobacco products in any venue used to advertise and promote tobacco products, including retail establishments that limit admittance to persons over age 18, where the Secretary finds that such restrictions would be "appropriate for the protection of the public health," based on the factors laid out in Section 906(d)(1)(A) and (B), and where consistent with the First Amendment to the Constitution.

Section 906(d) does not permit the Secretary to prohibit the face-to-face sale of any tobacco product by a specific category of retail outlets, or to establish a national minimum age of greater than 18 years to purchase tobacco products. Section 906(d) requires the Secretary, however, to regulate the sale, distribution, promotion, and marketing of tobacco products that are sold through means other than a direct, face-to-face exchange. Section 906(d) permits advertising on conventional matchbooks to the extent permitted in adult publications, unless the Secretary determines that such treatment of matchbooks is not appropriate for the protection of the public health.

Section 906(e) allows for regulations requiring that tobacco products conform to specified good manufacturing practices or hazard analysis and critical control point methodology (with input from the public and interested parties, and from the Tobacco Products Scientific Advisory Committee). This section exempts small tobacco product manufacturers from the above requirements for at least four years following the effective date of the Secretary's regulation. Section 906(e)(2) provides for a petition process for a temporary or permanent exemption or variance from the regulation.

Section 907. Tobacco product standards

Consistent with the overall intent of the bill to protect the public health, including by reducing the number of children and adolescents who smoke cigarettes, section 907(a)(1) is intended to prohibit the manufacture and sale of cigarettes with certain "characterizing flavors" that appeal to youth. Examples of these products include, but are not limited to, those introduced in recent years such as "Mandalay Lime," "Warm Winter Toffee," "Mocha Taboo," and "Midnight Berry," which were the subject of an investigation and subsequent settlement agreement between one cigarette manufacturer and the attorneys general of 40 states in October 2006.

Accordingly, this section prohibits the use of any constituent or additive that causes a cigarette or its smoke to have a characterizing flavor other than menthol or tobacco. Section 907(a)(1) is not

intended to prohibit the use of specific ingredients, including those found in some American blend cigarettes, so long as those additives or constituents are not a characterizing flavor (other than tobacco or menthol) of the cigarette or its smoke. A cigarette (including any component of the cigarette) or its smoke should not be determined to have a prohibited characterizing flavor based solely on the presence of an ingredient in the product or its smoke.

The Committee has reviewed the products that will be banned after 90 days under this section and has concluded that the ban will not lead to negative public health effects, because of how the affected products generally are used and because of their low overall use by adult smokers. Specifically, none of the cigarettes covered by the ban—including those with the characterizing flavors of fruit, chocolate, and clove—is used regularly by a large number of addicted adult smokers. Instead, these cigarettes tend to be used only occasionally, either by regular users of other products, by individuals who are experimenting with tobacco use, or by those who smoke only in certain social settings. Given that few adult smokers ever use the flavored cigarettes that will be banned and that most adult smokers name other products as their regular brand, it is likely that regular use of these products by heavily addicted adult smokers is negligible.

All of these factors—irregular, experimental, and social setting use and low overall use within the U.S. population—support the Committee's conclusion that precipitous removal of these products from the market will not result in a large number of heavily addicted smokers facing the sudden withdrawal of the products to which they are addicted, with unknown consequences for the health of the individual users or the overall population. The Committee notes that prohibition of a product that is used regularly by a large number of heavily addicted adult users would pose different questions of public health than those posed by the ban in section 907(a)(1). For example, the health care system might not be capable of handling the sudden increased demand for cessation assistance in the case of a more broadly used product, leaving millions of smokers without medical support. In addition, the sudden removal of a legal source for such a product without the type of consideration and review that FDA will be able to conduct might unnecessarily increase the illegal black market risk, which could also pose a health hazard to users.

The Committee recognizes the unique issues surrounding menthol cigarettes and urges the Secretary to address these issues as quickly as practicable. The Committee is especially concerned about proportionately higher rates of menthol cigarette use among African American smokers, as well as the historic targeting of African Americans for menthol cigarette use by tobacco companies. While it is unclear what effect the presence of menthol in cigarettes may have on addictiveness, toxicity, or other qualities of cigarettes, the Committee recognizes that menthol cigarettes may pose unique health risks to those who smoke them. Given the high rates of use among African American smokers, including African American youth, as well as higher rates of lung cancer documented among African American smokers as compared to non-African American smokers, the Committee believes that it is critical for the Secretary

to move quickly to address the unique public health issues posed by menthol cigarettes.

Menthol cigarettes currently represent over one quarter of all cigarettes smoked in the United States, representing more than 12 million individual smokers. Additionally, nearly 7 in 10 African Americans who smoke choose to smoke menthol cigarettes. Given the number of open questions related to menthol cigarettes, the legislation authorizes the Secretary to ban or modify the use of menthol in cigarettes based on scientific evidence. Given the large number of Americans who smoke menthol, the disproportionate prevalence of menthol cigarettes among African Americans, the racial and ethnic differences in lung cancer incidence, and the uncertainty about the potentially negative consequences of an immediate menthol ban, the Committee believes that this approach ensures that FDA has the scientific evidence necessary to make the best decisions to protect the public health.

Section 907 allows the Secretary to adopt, through notice and comment rulemaking, a product standard for tobacco products if the Secretary determines that such standard is appropriate for the protection of the public health. "Appropriate for the protection of public health" is used because tobacco products are not "safe" or "safe and effective," the standards used by FDA for foods, drugs, and medical devices. The public health standard is intended to be a flexible standard that focuses on the overall goal of reducing the number of individuals who die or are harmed by tobacco products. Standard(s) could include provisions to alter nicotine yields, to reduce or eliminate other constituents, including smoke constituents, or components, or other aspects of the construction, constituents, properties, and labeling of the tobacco product.

J Section 907(a)(3) provides that the Secretary may adopt a tobacco product standard if the Secretary finds that it is appropriate for the protection of the public health. Section 907(a)(3)(B) sets forth certain considerations with respect to that finding and additional considerations with respect to a standard that would reduce or eliminate an additive, constituent (including a smoke constituent), or other component of a tobacco product. In the event that the Secretary has proposed the adoption of such a standard because the Secretary has found that the additive, constituent, or other component is or may be harmful, an objecting party may, in response to such finding, provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury. In issuing a final standard as with any rulemaking, the Secretary shall review and consider all information and scientific evidence and data, presented by any party that comments on the proposed standard, including any information, evidence, or other documentation that is submitted concerning the population impact or any other matter related to the proposed standard. The Committee intends the Secretary will base his or her determinations on sound information and scientific evidence and data when issuing the proposed standard that is appropriate for the protection of the public health.

The Committee also intends for the agency to have authority to establish product standards regarding the testing and measurement of products, nicotine yields, constituents, construction, components, ingredients, additives, and all other properties of the tobacco

product, including the form and content of the labeling. This authority is limited only by 907(d)(3), which prohibits FDA from banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars, all pipe tobacco, or all "roll your own" tobacco products, or requiring the reduction of nicotine levels to zero.

It is the Committee's intent that there be a level playing field between domestic tobacco growers and foreign tobacco growers with regard to the development and implementation of any tobacco product standard. Beginning two years after enactment, no tobacco product manufacturer shall use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under federal law to domestically grown tobacco.

The Secretary is required to review periodically the product standards, taking into consideration new medical, scientific, or other technological data. In creating rules, the Secretary is required to consult with other federal agencies and invite appropriate persons to provide their input before issuing a rule. The Secretary may also refer a proposed rule to the Tobacco Products Scientific Advisory Committee for collecting additional data and creating a report on the issue, which would then be made public.

Section 908. Notification and other remedies

Section 908(a) provides authority for the Secretary to give notice (e.g., through public service announcements) if a tobacco product presents an "unreasonable risk of substantial harm", and notification is necessary and the most practicable means available to eliminate the unreasonable risk.

Section 908(c) authorizes the Secretary to recall a tobacco product, after an opportunity for an informal hearing, if the product contains a manufacturing or other defect that would cause serious adverse health consequences or death and is not ordinarily contained in tobacco products on the market.

Section 909. Records and reports on tobacco products

Section 909(a) requires tobacco manufacturers and importers to establish and maintain records and submit them to the Secretary, if required by the Secretary by regulation, to ensure that tobacco products are not adulterated or misbranded and to otherwise protect the public health.

Section 909(a) allows the Secretary also to require manufacturers and importers to report serious unexpected adverse reactions caused by the use of a tobacco product. The Secretary also may require the reporting of other significant adverse reactions, if necessary, and of actions taken to correct or remove products from the market when undertaken to reduce a health risk.

Section 909(a) states that reports required under this section shall not be unduly burdensome, nor require the disclosure of the identity of patients or users unless required for reasons specified in the provision.

Section 910. Application for review of certain tobacco products

Section 910(a) requires premarket review for all new tobacco products entering the market, unless the Secretary determines that the product is substantially equivalent to an existing product. Sec-

tion 910(a) defines substantial equivalence to mean that the product has the same characteristics as a marketed product, or has different characteristics, but does not raise different public health questions. Section 910(a)(4) specifies information that must be provided under section 905(j) to establish substantial equivalence, including detailed information on adverse health effects, and provides that such information be made public within 30 days of a determination of substantial equivalence.

Section 910(b) requires an application for premarket review to contain all information published, known, or which should reasonably be known, to the applicant concerning studies on the health risks of the product. The application also must contain a listing of components, ingredients, and composition of products; how the product is operated or used; a description of the methods used to manufacture or produce the product; and samples of the product and the product's proposed labeling. The Secretary may refer the application to the Tobacco Products Advisory Committee.

Section 910(c) requires the Secretary, within 180 days after receipt of an application, to make a determination of whether to allow the new product to enter the market or deny the application. The Secretary may deny the application if the Secretary finds that the applicant has not shown that marketing of the product would be appropriate for the protection of the public health, or if the Secretary finds that the making and handling of the product do not conform to good manufacturing practices, the labeling is false or misleading, or the product fails to conform to an applicable product standard promulgated under section 907 without justification.

Section 910(d) provides the Secretary authority to withdraw or suspend an order pertaining to a new product for a number of reasons, including that continued marketing is no longer appropriate for the protection of public health; the application contained a materially false statement; the applicant has failed to maintain records or make reports; the labeling becomes false or misleading; or the product does not conform to a tobacco standard without appropriate justification. Section 910(f) authorizes the Secretary to require the maintenance of records and the making of reports as necessary to permit the Secretary to determine whether to withdraw or suspend the order pertaining to a new product.

Section 911. Modified risk tobacco products

Section 911 prohibits a person from selling or distributing a modified-risk tobacco product without having obtained an order pertaining to the product from FDA. Section 911(b) specifically limits the sale, distribution, and promotion of new or existing products for which the label, labeling, or advertising states or implies that the product presents a reduced risk of harm or of tobacco-related disease, or that there is reduced exposure to a substance, or that uses the words "light," "mild," or "low," or similar descriptors. This definition also includes any products with respect to which the manufacturer takes any action after passage of the legislation directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, which would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or lower exposure to a substance, or that it is less harmful.

Section 911(b)(2)(C) makes clear that the use of the following phrases on the label or advertising for a product do not constitute a reduced-harm claim: "smokeless tobacco"; "smokeless tobacco product"; "not consumed by smoking"; "does not produce smoke"; "smokefree"; "smoke-free"; "without smoke"; "no smoke"; or "not smoke". Products intended for use in the treatment of tobacco dependence are not modified-risk tobacco products and are subject to Chapter V of the FFDCA.

Section 911(d) also outlines the specific requirements that tobacco manufacturers must meet before receiving an order permitting the sale or distribution of modified-risk tobacco products. For example, an application for such an order must include a description of the product; the conditions for using the product with respect to the claim; formulation of the product; sample labels; all documents relating to research regarding the product (e.g., the effect on tobacco-related diseases and other health-related conditions); data on how consumers actually use the product; and any other information required by the Secretary. Section 911(e) requires the Secretary to make the application and all of its contents (except trade secrets and confidential commercial information) public and seek public comment. The application must be referred to the Tobacco Products Advisory Committee for its recommendations.

Section 911(g)(1) states that the Secretary shall issue an order that a product may be commercially marketed as a modified risk product only if the Secretary determines that the applicant has demonstrated that the product will significantly reduce harm and the risk of tobacco-related disease to individual users, and benefit the health of the population as a whole, taking into account the impact on both users and nonusers of tobacco products.

Section 911(g)(2) creates a special rule for allowing the sale and distribution of certain products, if the Secretary determines that (1) it would be appropriate for the protection of the public health; (2) the product's label, labeling, or advertising explicitly or implicitly claims only that the product contains a reduced level of a substance, or presents a reduced exposure to a substance; (3) scientific evidence of reduced harm is not, or cannot be made, available, using the best available scientific methods and cannot be made available without conducting long-term epidemiological studies; (4) such data as currently exists predicts substantially reduced morbidity or mortality among individual tobacco users; (5) the magnitude of the overall reductions in exposure to such substances is substantial and will not expose users to higher levels of other harmful substances; and (6) testing of actual consumer perceptions shows that consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents less of a risk than one or more other commercially marketed tobacco products. These products are limited to a distribution term of 5 years, but that term may be renewed.

Section 911(h) states that the Secretary may require a manufacturer of a modified-risk product subject to an order under this section to comply with requirements relating to labeling, advertising, and promotion of the tobacco product, and the Secretary must require postmarket surveillance.

Section 911(h) states that the Secretary has discretion to require that a modified-risk tobacco product making a comparative claim

compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (e.g., the average value of the top three brands). The Secretary also may require quantitative comparisons of the amount of the substance reduced. This information must be placed near the most prominent claim.

Section 911(j) states that the Secretary may withdraw the order pertaining to a modified risk product if: he or she can no longer make the findings on which the order was based; the application contained a material false statement; product representations about reduced risk or exposure are no longer valid; the applicant failed to conduct required postmarket studies and surveillance; or the applicant failed to meet any other condition of the order.

Section 911(l) requires the Secretary, within 2 years after enactment, to issue guidance or regulations on the scientific evidence required for assessment and ongoing review of modified-risk tobacco products. The regulations or guidance shall be developed by the Secretary in consultation with the Institute of Medicine (IOM).

Section 912. Judicial review

Section 912 states that any person adversely affected by an FDA regulation relating to performance standards or premarket review may, within 30 days, file a petition for judicial review of such regulation with a United States Court of Appeals. The remedies provided shall be in addition to, not in lieu of, any other remedies provided by law. Judgment by the appellate court shall be final, subject to review by the Supreme Court.

Section 913. Equal treatment of retail outlets

Section 913 seeks to ensure a level playing field among all retailers, and requires the Secretary to issue regulations requiring that retail establishments whose predominant business is the sale of tobacco products comply with any advertising restriction applicable to retail establishments accessible to individuals under the age of 18. This provision is necessary because the final rule promulgated by FDA on tobacco products, which is required to be reinstated under section 102 of the Committee's bill, exempted adult-only establishments from advertising restrictions applicable to retail outlets where persons younger than 18 years of age are allowed. This section is intended to level the playing field for all retailers, applying the restrictions on advertising equally across the board.

Section 914. Jurisdiction of and coordination with the Federal Trade Commission

Section 914(a) clarifies that the Federal Trade Commission's (FTC) authority regarding the advertising, sale, or distribution of tobacco products is not limited or diminished by the Act, and that violations of this Act related to advertising will also be considered unfair or deceptive practices under the Federal Trade Commission Act.

Section 914(b) states that the Secretary and the Chairman of the FTC are to coordinate enforcement of section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act.

Section 915. Regulation requirement

Section 915 requires the Secretary, within 36 months of enactment, to issue regulations that require the testing and reporting of tobacco product smoke constituents, ingredients, and additives that the Secretary determines should be tested in order to protect public health. Regulations may require disclosure of test results relating to tar and nicotine in labeling or advertising, and may require disclosure of test results relating to other constituents that the Secretary determines should be disclosed to the public, if such disclosures would be appropriate for the protection of the public health and would not mislead consumers.

Section 915(d) states that for small tobacco product manufacturers, the compliance times are delayed by at least 2 years and the testing and reporting requirements are delayed for 4 years. Additionally, two or more small tobacco product manufacturers may join together to purchase laboratory testing services. The Secretary also may delay the deadline for testing and reporting on a case-by-case basis.

Section 915(d)(2)(A) of the Act provides that testing regulations promulgated by FDA under Section 915 only shall provide an extended time period for small tobacco product manufacturers to complete product testing required by FDA. FDA regulations shall provide for such testing by small manufacturers to be conducted over a 4-year period, with each manufacturer testing 25% of its products per year. If, however, product testing is necessary due to the actions of a small manufacturer in seeking to market a new product within the definition of section 910(a)(1)(B), or modifying an existing product within the definition of section 910(a)(1)(B), that testing must be conducted within the same time frame applicable to non-small manufacturers under FDA rules. The Committee believes that commonly occurring natural variations in the tobacco leaf—meaning only those variations that result directly from geological, meteorological, or similar factors not under the control of and not the result of decisions by the tobacco grower, processor, or manufacturer—should not constitute a new product or a product modification for purposes of determining what time frames to apply for completion of testing.

Section 915(e) states that FDA regulations are required to provide an extension to a small tobacco product manufacturer for testing and reporting in the event that the manufacturer demonstrates an inability to gain access to an independent testing laboratory to conduct product testing in time to meet regulatory deadlines. This delay is conditioned, in part, on evidence provided to FDA that: (1) the products were submitted sufficiently in advance to meet regulatory deadlines; (2) the products are currently awaiting testing; and (3) neither that laboratory, nor any other laboratory, is able to complete testing by the deadline at customary, non-expedited testing fees.

The Committee believes that, in seeking an extension of time under this subsection, a small manufacturer should be required only to consult laboratories that are legitimate and that possess the expertise to produce meaningful and reliable testing reports. Therefore, we anticipate that FDA will assist small manufacturers in this regard through its Office to Assist Small Tobacco Product Manufacturers. The Committee expects that the Office will produce

a list of testing laboratories with which a small manufacturer can check for testing capacity and availability. The list should include a description of testing services, an address, and known contact information for each laboratory. While FDA's production of this list will not eliminate the duty of each small manufacturer to use its best efforts to identify such laboratories on its own, the list will provide great assistance to small manufacturers in fulfilling that duty.

As stated in this subsection, FDA's authority to extend deadlines based on a demonstrated lack of laboratory capacity extends only to testing and reporting required under Section 915.

Section 916. Preservation of state and local authority

Section 916(a) states that state authority is preserved, with no federal preemption, with regard to enacting, adopting, promulgating, and enforcing any law, rule, or regulation in critical areas with respect to tobacco products that is in addition to or more stringent than required under this Act, including measures relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising, and promotion of, or use of, tobacco products by individuals of any age, information reporting to the state, or measures relating to fire safety standards for cigarettes. State, tribal, and local taxation of tobacco products also is unaffected.

Section 916(a)(2)(A) states that states are generally preempted from establishing or continuing in effect any requirement that is different from or in addition to any FDA requirement relating to specified and limited areas, including tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, reporting, good anufacturing standards, and modified risk tobacco products.

Section 916(b) also states that product liability actions under state law are not modified or otherwise affected by this bill.

Section 917. Tobacco Products Scientific Advisory Committee

Section 917 establishes a 12-member advisory committee of relevant medical, scientific, and technological experts, with representatives of the public, tobacco growers, the health community, and tobacco manufacturers, as well, including one member solely and specifically representing the interests of small manufacturers of tobacco products. The small manufacturers' position may be filled by different persons, one at a time, based on different areas of expertise relevant to the topics being discussed. Representatives of the tobacco industry and growers will be on the Committee to provide technical input, but they will be non-voting.

Section 917(c) states that this Committee will provide advice and guidance to the Secretary on the effects of alteration of the nicotine yields from tobacco products; the threshold level at which nicotine becomes addictive; and any other health issues as requested by the Secretary.

Section 918. Drug products used to treat tobacco dependence

Section 918 requires the Secretary to consider designating nicotine replacement products, regulated under title V of the FFDCA, as fast-track research and approval products.

Section 918(a) requires the Commissioner of Food and Drugs to consider approving the extended use of over-the-counter nicotine replacement products, and to consider other issues relating to the approval of nicotine replacement therapies.

The Committee notes that the fees collected under section 919 of this Act shall not be used for the purposes of designating nicotine replacement products as fast-track research and approval products, or approving the extended use of over-the-counter nicotine replacement products, or to consider other issues relating to the approval of nicotine replacement therapies. The Committee notes that these activities are regulated under the authority of title V of the FFDCA.

The Committee has found that public health officials and other interested parties are not widely aware that FDA does not currently prohibit the sales of over-the-counter smoking cessation products—such as certain nicotine replacement products—in retail settings where age verification takes place. The Committee urges FDA to communicate its policy on such sales to the regulated community and public health officials through simple and effective means, such as through posting a statement of policy on the FDA's web site.

Section 918(b) requires the Secretary to report to Congress within 3 years on how best to regulate, promote, and encourage development of innovative products and treatments to promote abstinence from tobacco use, reductions in consumption, and reductions in the harm associated with tobacco use. Cessation assistance is a critical component of the fight against the tobacco epidemic. Accordingly, the Committee believes that it is important for health insurers—public and private—to cover effective cessation treatments for those addicted to tobacco, including both medications and counseling. While it is clear to the Committee that the benefits of such coverage greatly outweigh the costs both in terms of human health and in terms of financial savings, private and public insurer coverage of such services remains less than comprehensive. For example, as CDC reported in 2006, only 38 of 50 state Medicaid programs provided coverage for any cessation benefits to tobacco users, with only one state providing all benefits recommended under applicable Public Health Service treatment guidelines. In addition, it is unknown to what extent private insurers are choosing to cover such benefits.

In light of the critical importance of insurer coverage of cessation treatment for those suffering from nicotine addiction, the Committee urges the Secretary to examine this issue and to review the extent to which private insurers are covering effective cessation treatment for tobacco users. In conducting this examination, the Secretary should consider the potential cost savings of such coverage, taking into account not only the reduction of healthcare costs that would result, but also the gain in individual life years, improvements in quality of life, and increased productivity that would be achieved by such coverage.

Section 919. User fee

Section 919(a) requires the Secretary to assess a quarterly fee from tobacco product manufacturers and importers to cover the costs of the activities of the Food and Drug Administration related

to the regulation of tobacco products under the Act. Section 919(b)(4) makes clear that only the funds provided for in this chapter will be used to pay for FDA tobacco regulation. While section 919(c)(2)(B)(ii) allows for FDA to use other funds for startup costs during the first two quarters of the program only, any such funds must be repaid in full. In addition, none of the funds provided for in this chapter may be used to pay for activities not related to FDA's regulation of tobacco. The method of assessing fees shall be the same as that currently used by United States Department of Agriculture for all tobacco manufacturers and importers to fund the 2004 legislation providing transitional payments to tobacco grower quota holders.

Section 919(c)(3)(B) states that no manufacturer or importer shall be required to pay a user fee in excess of their percentage market share. Section 919(c)(2)(B) also limits the imposition of user fees to cigarettes, smokeless tobacco products, and roll-your-own tobacco until the Secretary exercises jurisdiction over other tobacco products.

Section 919(g) requires a report by the Government Accountability Office, within 3 years of enactment, that studies the prevalence of youth tobacco use and the brands that individuals under the age of 18 consume; the feasibility of structuring a user fee based on youth market share of a manufacturer; and the potential effects of tobacco marketing to youth if user fees were calculated based on youth market share.

Section 102. Final rule

Section 102 states that on the first day of publication of the Federal Register that is six months or more after the enactment of this Act, the Secretary shall publish a final rule on the advertising of, and access to, tobacco products, which shall become effective one year after passage of the bill.

The final rule is deemed to be in compliance with the Administrative Procedure Act. The final rule shall be identical in its provisions to the advertising and access regulations promulgated by FDA in 1996, except where specifically provided in this Act. Prior to making any future amendments to the published rule, the Secretary will be required to promulgate a proposed rule.

The final rule also includes a provision that allows the restricted distribution of smokeless tobacco products in qualified, adult-only facilities. In 1996, the Food and Drug Administration concluded that teens obtain free samples of tobacco products despite laws that prohibit the free distribution to minors. In the August 1996 rule, FDA wrote that "free samples represent a 'risk-free and cost-free' way for young people to obtain and possibly use cigarettes or smokeless tobacco and that, when free samples are distributed at cultural or social events, peer pressure may lead some young people to accept and to use the free samples." The Committee's intent in section 102 (a)(2) is to modify the final rule to allow free sampling of smokeless tobacco products only to adults in secured, enclosed, adult-only facilities or areas. The Committee expects FDA to monitor aggressively smokeless free-sampling facilities to assure that all requirements are being followed and that youth do not obtain the samples of smokeless tobacco that are being distributed. The Committee notes that this narrowly tailored sampling provi-

sion does not preclude the Secretary from taking further action related to the regulation or prohibition of free sampling of smokeless tobacco products.

The Secretary shall ensure that this Act, amendments made by the Act, and the implementing regulations, including such provisions, amendments, and regulations relating to the retail sale of tobacco products, are enforced with respect to the United States and Indian tribes.

Section 103. Conforming and other amendments to general provisions

Section 103 includes a number of export provisions and retailer/licensing provisions. Section 103 contains retailer procedural protections and requires FDA, to the extent feasible, to contract with the states for retailer enforcement.

As reflected in its findings, the Committee is concerned that, depending on the particular language, communications directed to consumers by tobacco manufacturers about the impact of the authority granted to FDA under this legislation could confuse or mislead consumers. The Committee recognizes that unlike most products regulated by FDA, tobacco products will remain harmful. Therefore, section 103(b)(13) of the bill, in a new subsection (tt) of Section 301 of the FFDCA, prohibits statements directed to consumers through the media or through the label, labeling, or advertising that would reasonably be expected to result in a consumer believing that the product is regulated, inspected, or approved by FDA, or that the product complies with requirements imposed by FDA, and that could result in consumers believing that the product is endorsed for use by FDA or that otherwise could result in consumers being misled about the harmfulness of the product because of the authority given to FDA by this legislation. The Committee did not attempt to identify every situation in which such specific statements would reasonably be expected to mislead consumers, instead giving FDA the authority to analyze any specific examples presented to it. This section was carefully written so that it involves only communications directed to consumers and does not therefore, for example, involve communications to government agencies, such as reports to the Securities and Exchange Commission, or as part of judicial or congressional proceedings, in formal documents that companies provide to shareholders in the ordinary course of business, or in scientific articles that appear in scientific journals.

Section 103(q)(2)(C) is designed to protect retailers against the imposition of double penalties based on a single violation of any restriction under section 906(d) by directing the Secretary to consider the amount of penalties paid to a state by a retailer for the same violation. This provision is not meant to change the system of setting penalties in any other area within the jurisdiction of the Food and Drug Administration.

Section 104. Study on raising the minimum age to purchase tobacco products

Section 104 requires the Secretary to submit to Congress, within 5 years after enactment of this Act, a report on the public health

implications of raising the minimum age to purchase tobacco products.

Section 105. Enforcement Action Plan for Advertising and Promotion Restrictions

Section 105(a) requires the Secretary, within six months of enactment, to develop, in consultation with public health organizations and others with expertise and experience in serving minority communities, and publish an action plan to enforce restrictions adopted pursuant to section 906 or pursuant to section 102(a) on the promotion and advertising of menthol and other cigarettes to youth. The action plan shall include provisions specifically designed to ensure enforcement of these restrictions in minority communities. Section 105(b)(2) directs the Secretary also to provide assistance to communities seeking to prevent underage tobacco use, including assistance with strategies to prevent underage tobacco use in communities with a disproportionate use of menthol cigarettes by minors.

Section 105(b) requires the Secretary, within three months of enactment, to inform state, local, and Tribal governments of the authority newly provided to such entities pursuant to section 203 of this Act or preserved under section 101(b) of this Act.

Title II. Tobacco Product Warnings; Constituent and Smoke Constituent Disclosure

Section 201. Cigarette label and advertising warnings

Section 201(a) amends section 4 of the Federal Cigarette Labeling and Advertising Act to specify nine new required warning labels, one of which must appear on cigarette packages and advertisements within 1 year of enactment of this Act. The warning must comprise at least the top 30% of the front and rear panels of the package, and at least 20% of the related advertisements. Retailers will not be held responsible for packages and advertisements bearing a warning label that they do not create or alter.

Section 201(c) requires that all warnings be displayed on all brands and be randomly distributed in all areas of the United States where the product is distributed and requires that a plan be submitted to the Secretary to ensure that the statements in product advertising are equally distributed and rotated quarterly and that all required label statements be displayed at the same time.

Section 202. Authority to revise cigarette warning label statements

Section 202 amends section 4 of the Federal Cigarette Labeling and Advertising Act to provide the Secretary with authority, by rulemaking, to adjust format, type size, and text of any label requirements, and to require that warning labels contain graphics, as well as to increase the required label area from 30% up to 50% of the front and rear panels.

Section 203. State regulation of cigarette advertising and promotion

Section 203 amends section 5 of the Federal Cigarette Labeling and Advertising Act to allow states or localities to enact statutes and promulgate regulations based on smoking and health, imposing specific bans or restrictions on the time, place, and manner of cigarette advertising or promotion. States or localities may not re-

strict the content of advertisements or promotions of any cigarettes based on smoking and health.

Section 204. Smokeless tobacco labels and advertising warnings

Section 204(a) amends section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 to specify the required warning labels that must appear on smokeless tobacco product labels and advertisements, and imposes minimum size and text requirements.

Section 204(b) requires that all warnings be displayed on all brands and be randomly distributed in all areas of the United States where the product is distributed and requires that a plan be submitted to the Secretary to ensure that the statements in product advertising are equally distributed and rotated quarterly, and that all required label statements are displayed at the same time.

Section 205. Authority to revise smokeless tobacco warning label statements

Section 205 amends section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 to provide the Secretary with authority, by rulemaking, to adjust format, type size, and text of any label requirements, and to require that warning labels contain graphics, as well as to increase the required label area from 30% up to 50% of the front and rear panels.

Section 206. Tar, nicotine, and other smoke constituent disclosure to the public

Section 206 amends section 4 of the Federal Cigarette Labeling and Advertising Act to require the Secretary to determine, using his or her sole discretion, whether cigarette and other tobacco product manufacturers should be required to include in each advertisement, package, label, or both, the tar and nicotine yields of a tobacco product, and whether the yields of other constituents will be required to be disclosed by appropriate means.

This section requires that any differences between the requirements established by the Secretary and tar and nicotine disclosure reporting requirements established by the Federal Trade Commission be resolved by a memorandum of understanding.

Title III.—Prevention of Illicit Trade in Tobacco Products

Section 301. Labeling, recordkeeping, records inspection

Section 301 further amends new title IX of the Federal Food, Drug, and Cosmetic Act by adding a new section 920.

Section 920(a) requires the label, packaging, and shipping containers of tobacco products to bear a statement "sale only allowed in the United States."

Section 920(b) directs the Secretary to issue regulations regarding the establishment and maintenance of records by any person who manufacturers, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products. These records will be used to track and assist in the investigation of illicit trade, smuggling, or counterfeiting of tobacco products. Retailers will not be required to maintain records of sales made to consumers.

Section 920(c) authorizes the Secretary to inspect and copy all records, including financial records, of each person who manufacturers, processes, transports, distributes, receives, holds, packages, exports, or imports a tobacco product that the Secretary has a reasonable belief is part of illicit trade, or smuggling, or is counterfeit.

Section 920(d) requires manufacturers and distributors to report to the Attorney General any knowledge that a tobacco product it manufactures or distributes has been imported, exported, distributed, or offered for sale (1) without payment of duties or taxes, or (2) for possible illicit marketing.

Section 302. Study and report

Section 302 requires the Comptroller General to conduct a study of cross-border trade in tobacco products, including illicit trade, cross-border advertising, and the health effects resulting from cross-border trade. This section also requires the Comptroller General to submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study described in this section no later than 18 months after enactment. Section 302(c) provides a definition for "cross-border trade," and states that the terms "Indian country," "state," and "territory" share the same definitions found in current law.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) * * *

* * * * * * *

(rr)(1) The term "tobacco product" means 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).

(2) The term "tobacco product" does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g).

(3) The products described in paragraph (2) shall be subject to chapter V of this Act.

(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, *tobacco product,* or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, *tobacco product,* or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, *tobacco product,* or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

* * * * * * *

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 417(g), 416, 504, 564, 703, 704(a), 760, or 761; or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 417, 416, 504, 505 (i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i)**[.]**, 515(f), 519, 564, 760, **[**or 761 or the refusal to permit access to**]** *761, 909, or 920 or the refusal to permit access to* or verification or copying of any such required record.

* * * * * * *

(g) The manufacture within any Territory of any food, drug, device, *tobacco product,* or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, *tobacco product,* or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

* * * * * * *

(j) The using by any person to his own advantage, 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 Act, any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573**[.]**, 704, **[**708, or 721**]** *708, 721, 904, 905, 906, 907, 908, 909, or 920(b)* concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) or any regulation issued under that section.. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, *tobacco product,* or cosmetic, if such act is done while such article is held for sale

(whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

* * * * * * *

[(p) The failure to register in accordance with section 510, the failure to provide any information required by section 510(j) or 510(k); or the failure to provide a notice required by section 510(j)(2).

[(q)(1) The failure or refusal to (A) comply with any requirement prescribed under section 518 or 520(g), (B) furnish any notification or other material or information required by or under section 519 or 520(g), or (C) comply with a requirement under section 522.]

(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(3).

(q)(1) The failure or refusal—

(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 916;

(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or 920; or

(C) to comply with a requirement under section 522 or 913.

(2) With respect to any [device,] *device or tobacco product,* the submission of any report that is required by or under this Act that is false or misleading in any material respect.

(r) The movement of a device *or tobacco product* in violation of an order under section 304(g) or the removal or alteration of any mark or label required by the order to identify the device *or tobacco product* as detained.

* * * * * * *

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) With respect to a tobacco product, any statement directed to consumers through the media or through the label, labeling, or advertising that would reasonably be expected to result in consumers believing that the product is regulated, inspected or approved by the Food and Drug Administration, or that the product complies with the requirements of the Food and Drug Administration, including a statement or implication in the label, labeling, or advertising of such product, and that could result in consumers believing that the product is endorsed for use by the Food and Drug Administration or in consumers being misled about the harmfulness of the product because of such regulation, inspection, or compliance.

* * * * * * *

PENALTIES

SEC. 303. (a) * * *

* * * * * * *

(f)(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this Act which relates to devices *or tobacco products* shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a person accredited under paragraph (2) of section 704(g) who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this Act that relates to devices *or tobacco products*.

* * * * * * *

(5)(A) A civil penalty under paragraph (1), (2), (3), or (4) shall be [assessed] *assessed, or a no-tobacco-sale order may be imposed,* by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil [penalty] *penalty, or upon whom a no-tobacco-sale order is to be imposed,* under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, *or the period to be covered by a no-tobacco-sale order,* the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. *A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of*

time, to request that the Secretary compromise, modify, or terminate the order.

* * * * * * *

(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.

(6) Any person who requested, in accordance with paragraph (5)(A), a hearing respecting the assessment of a civil penalty *or the imposition of a no-tobacco-sale order* and who is aggrieved by an order assessing a civil penalty *or the imposition of a no-tobacco-sale order* may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was [issued.] *issued, or on which the no-tobacco-sale order was imposed, as the case may be.*

* * * * * * *

(8) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone, or at the nearest regional or field office of the Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

* * * * * * *

SEIZURE

SEC. 304. (a)(1) * * *

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, [and] (D) Any adulterated or misbranded [device.] *device, and (E) Any adulterated or misbranded tobacco product.*

* * * * * * *

(d)(1) Any food, drug, device, *tobacco product,* or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold. After entry of the decree and upon the

payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 801(e) can and will be met. The provisions of this sentence shall not apply where condemnation is based upon violation of section 402(a) (1), (2), or (6), section 501(a)(3), section 502(j), or section 601 (a) or (d). Where such exportation is made to the original foreign supplier, then subparagraphs (A) and (B) of section 801(e)(1) and the preceding sentence shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 801(e) have been met. Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

* * * * * * *

(g)(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device *or tobacco product* which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device *or tobacco product* detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 302, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device *or tobacco product* may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device *or tobacco product* during the period of its detention for the purpose of identifying the device *or tobacco product* as detained. Any person who would be entitled to claim a device *or tobacco product* if it were seized under subsection (a) may appeal to the Secretary a detention of such device *or tobacco product* under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Sec-

retary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

(2)(A) Except as authorized by subparagraph (B), a device *or tobacco product* subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

(i) * * *

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

* * * * * * *

NEW DRUGS

SEC. 505. (a) * * *

* * * * * * *

(n)(1) * * *

(2) The Secretary may delegate the appointment and oversight authority granted under [section 904] *section 1004* to a director of a center or successor entity within the Food and Drug Administration.

* * * * * * *

SEC. 523. ACCREDITED PERSONS.

(a) * * *

(b) ACCREDITATION.—

(1) * * *

(2) ACCREDITATION.—

(A) * * *

* * * * * * *

(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under [section 903(g)] *section 1003(g)* the names of all accredited persons and the particular activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

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CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

* * * * * * *

EXAMINATIONS AND INVESTIGATIONS

SEC. 702. (a)(1)*(A)* The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

(B)(i) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this Act.

(ii) The Secretary shall not enter into any contract under clause (i) with the government of any of the several States to exercise enforcement authority under this Act on Indian country without the express written consent of the Indian tribe involved.

* * * * * * *

SEC. 703. RECORDS.

(a) IN GENERAL.—For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, *tobacco products,* or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, *tobacco product,* or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, *tobacco product,* or cosmetic to which such request relates, except that evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom obtained, and except that carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, *tobacco products,* or cosmetics in the usual course of business as carriers, except as provided in subsection (b).

* * * * * * *

FACTORY INSPECTION

SEC. 704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, *tobacco products,* or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, *tobacco products,* or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a

threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices *or tobacco products* are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices *or tobacco products* which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k) section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

* * * * * * *

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, *tobacco product,* or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

* * * * * * *

(g)(1) * * *

* * * * * * *

(13) The Secretary shall include in the annual report required under ⟦section 903(g)⟧ *section 1003(g)* the names of all accredited persons and the particular activities under this subsection for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

* * * * * * *

PUBLICITY

SEC. 705. (a) * * *

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, *tobacco products,* or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

* * * * * * *

PRESUMPTION

SEC. 709. In any action to enforce the requirements of this Act respecting a device, *tobacco product,* food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.

* * * * * * *

CHAPTER VIII—IMPORTS AND EXPORTS

IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, *tobacco products,* and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 *or section 905(h)* and shall request that if any [drugs or devices] *drugs, devices, or tobacco products* manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such [drugs or devices] *drugs, devices, or tobacco products* be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll), then such article shall be refused admission, except as provided in subsection (b) of this section. If such article is subject to a requirement under section 760 or 761 and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 760

or 761) has not complied with a requirement of such section 760 or 761 with respect to any such article, or has not allowed access to records described in such section 760 or 761, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.

* * * * * * *

(e)(1) A food, drug, device, *tobacco product,* or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it—

(A) * * *

* * * * * * *

(p)(1) Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—

(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;

(B) the public health implications of such exports, including any evidence of a negative public health impact; and

(C) recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.

(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.

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CHAPTER IX—TOBACCO PRODUCTS

SEC. 900. DEFINITIONS.

In this chapter:

(1) ADDITIVE.—The term "additive" means 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.

(2) BRAND.—The term "brand" means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, reg-

istered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

(3) CIGARETTE.—The term "cigarette"—

(A) means a product that—

(i) is a tobacco product; and

(ii) meets the definition of the term "cigarette" in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

(4) CIGARETTE TOBACCO.—The term "cigarette tobacco" means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter shall also apply to cigarette tobacco.

(5) COMMERCE.—The term "commerce" has the meaning given that term by section 3(2) of the Federal Cigarette Labeling and Advertising Act.

(6) COUNTERFEIT TOBACCO PRODUCT.—The term "counterfeit tobacco product" means 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).

(7) DISTRIBUTOR.—The term "distributor" as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this chapter.

(8) ILLICIT TRADE.—The term "illicit trade" means 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.

(9) INDIAN COUNTRY.—The term "Indian country" has the meaning given such term in section 1151 of title 18, United States Code.

(10) INDIAN TRIBE.—The term "Indian tribe" has the meaning given such term in section 4(e) of the Indian Self-Determination and Education Assistance Act.

(11) LITTLE CIGAR.—The term "little cigar" means a product that—

(A) is a tobacco product; and

(B) meets the definition of the term "little cigar" in section 3(7) of the Federal Cigarette Labeling and Advertising Act.

(12) NICOTINE.—The term "nicotine" means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

(13) PACKAGE.—The term "package" means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

(14) RETAILER.—The term "retailer" means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

(15) ROLL-YOUR-OWN TOBACCO.—The term "roll-your-own tobacco" means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

(16) SMALL TOBACCO PRODUCT MANUFACTURER.—The term "small tobacco product manufacturer" means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

(17) SMOKE CONSTITUENT.—The term "smoke constituent" means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

(18) SMOKELESS TOBACCO.—The term "smokeless tobacco" means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

(19) STATE; TERRITORY.—The terms "State" and "Territory" shall have the meanings given to such terms in section 201.

(20) TOBACCO PRODUCT MANUFACTURER.—The term "tobacco product manufacturer" means any person, including any repacker or relabeler, who—

(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(B) imports a finished tobacco product for sale or distribution in the United States.

(21) TOBACCO WAREHOUSE.—

(A) Subject to subparagraphs (B) and (C), the term "tobacco warehouse" includes any person—

(i) who—

(I) removes foreign material from tobacco leaf through nothing other than a mechanical process;

(II) humidifies tobacco leaf with nothing other than potable water in the form of steam or mist; or

(III) de-stems, dries, and packs tobacco leaf for storage and shipment;

(ii) who performs no other actions with respect to tobacco leaf; and

(iii) who provides to any manufacturer to whom the person sells tobacco all information related to the per-

son's actions described in clause (i) that is necessary for compliance with this Act.

(B) The term "tobacco warehouse" excludes any person who—

(i) reconstitutes tobacco leaf;

(ii) is a manufacturer, distributor, or retailer of a tobacco product; or

(iii) applies any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist.

(C) The definition of the term "tobacco warehouse" in subparagraph (A) shall not apply to the extent to which the Secretary determines, through rulemaking, that regulation under this chapter of the actions described in such subparagraph is appropriate for the protection of the public health.

(22) UNITED STATES.—The term "United States" means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.

(a) IN GENERAL.—Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 911, shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V.

(b) APPLICABILITY.—This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.

(c) SCOPE.—

(1) IN GENERAL.—Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter.

(2) LIMITATION OF AUTHORITY.—

(A) IN GENERAL.—The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(B) EXCEPTION.—Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who

grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(C) RULE OF CONSTRUCTION.—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

(d) RULEMAKING PROCEDURES.—Each rulemaking under this chapter shall be in accordance with chapter 5 of title 5, United States Code. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act.

(e) CENTER FOR TOBACCO PRODUCTS.—Not later than 90 days after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this chapter and related matters assigned by the Commissioner.

(f) OFFICE TO ASSIST SMALL TOBACCO PRODUCT MANUFACTURERS.—The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this Act.

(g) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating rules under this chapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

SEC. 902. ADULTERATED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be adulterated if—

(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 919 by the date specified in section 919 or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;

(5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907 unless such tobacco product is in all respects in conformity with such standard;

(6)(A) it is required by section 910(a) to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i); or

(B) it is in violation of an order under section 910(c)(1)(A);

(7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable condition prescribed by an order under section 906(e)(2); or

(8) it is in violation of section 911.

SEC. 903. MISBRANDED TOBACCO PRODUCTS.

(a) IN GENERAL.—A tobacco product shall be deemed to be misbranded—

(1) if its labeling is false or misleading in any particular;

(2) if in package form unless it bears a label containing—

(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and

(D) the statement required under section 920(a),

except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

(6) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;

(7) if, in the case of any tobacco product distributed or offered for sale in any State—

(A) its advertising is false or misleading in any particular; or

(B) it is sold or distributed in violation of regulations prescribed under section 906(d);

(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other de-

scriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and

(B) a brief statement of—

(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;

(9) if it is a tobacco product subject to a tobacco product standard established under section 907, unless it bears such labeling as may be prescribed in such tobacco product standard; or

(10) if there was a failure or refusal—

(A) to comply with any requirement prescribed under section 904 or 908; or

(B) to furnish any material or information required under section 909.

(b) PRIOR APPROVAL OF LABEL STATEMENTS.—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product. No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 911. No advertisement of a tobacco product published after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall, with respect to the language of label statements as prescribed under section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 or the regulations issued under such sections, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act.

SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

(a) REQUIREMENT.—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information:

(1) Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.

(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in

accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act.

(3) Beginning 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand. Effective beginning 3 years after such date of enactment, the manufacturer, importer, or agent shall comply with regulations promulgated under section 915 in reporting information under this paragraph, where applicable.

(4) Beginning 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, all documents developed after such date of enactment that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

(b) DATA SUBMISSION.—At the request of the Secretary, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

(3) Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

(c) TIME FOR SUBMISSION.—

(1) IN GENERAL.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the manufacturer of such product shall provide the information required under subsection (a).

(2) DISCLOSURE OF ADDITIVE.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the manufacturer shall, except as provided in paragraph (3), at least 90 days prior to such action so advise the Secretary in writing.

(3) DISCLOSURE OF OTHER ACTIONS.—If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing.

(d) DATA LIST.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list established under subsection (e).

(2) CONSUMER RESEARCH.—The Secretary shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

(e) DATA COLLECTION.—Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish, and periodically revise as appropriate, a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand. The Secretary shall publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

SEC. 905. ANNUAL REGISTRATION.

(a) DEFINITIONS.—In this section:

(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—The term "manufacture, preparation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

(2) NAME.—The term "name" shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person. If enactment of the Family Smoking Prevention and Tobacco Control Act occurs in the second half of the calendar year, the Secretary shall designate a date no later than 6 months into the subsequent calendar year by which registration pursuant to this subsection shall occur.

(c) REGISTRATION BY NEW OWNERS AND OPERATORS.—Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person's name, place of business, and such establishment.

(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons who are required to list such tobacco products under subsection (i) shall list such tobacco products in accordance with such system.

(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—Every establishment registered with the Secretary under this section shall be subject to inspection under section 704 or subsection (h), and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees duly designated by the Secretary at least once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

(h) REGISTRATION BY FOREIGN ESTABLISHMENTS.—Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (i) and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

(i) REGISTRATION INFORMATION.—

(1) PRODUCT LIST.—Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which have not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;

(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

(2) CONSULTATION WITH RESPECT TO FORMS.—The Secretary shall consult with the Secretary of the Treasury in developing the forms to be used for registration under this section to minimize the burden on those persons required to register with both the Secretary and the Tax and Trade Bureau of the Department of the Treasury.

(3) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.

(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO INTERSTATE COMMERCE.—

(1) IN GENERAL.—Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of February 15, 2007, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

(A) the basis for such person's determination that—

(i) the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to subsection (a)(3) of section 910, is substantially equivalent and that is in compliance with the requirements of this Act; or

(ii) the tobacco product is modified within the meaning of paragraph (3), the modifications are to a product that is commercially marketed and in compliance with the requirements of this Act, and all of the modifications are covered by exemptions granted by the Secretary pursuant to paragraph (3); and

(B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product.

(2) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007, PRODUCTS.—A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall be submitted to the Secretary not later than 21 months after such date of enactment.

(3) EXEMPTIONS.—

(A) IN GENERAL.—The Secretary may exempt from the requirements of this subsection relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 910, tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

(i) such modification would be a minor modification of a tobacco product that can be sold under this Act;

(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

(iii) an exemption is otherwise appropriate.

(B) REGULATIONS.—Not later than 15 months after the date of enactment of the Family Smoking Prevention and

Tobacco Control Act, the Secretary shall issue regulations to implement this paragraph.

SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

(a) IN GENERAL.—Any requirement established by or under section 902, 903, 905, or 909 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 907, section 910, section 911, or subsection (d) of this section, and any requirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, section 911, or subsection (d) of this section shall not apply to such tobacco product.

(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking or other notification under section 907, 908, 909, 910, or 911 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefore.

(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 903, 904, 907, 908, 909, 910, 911, or 704, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this chapter, or when relevant in any proceeding under this chapter.

(d) RESTRICTIONS.—

(1) IN GENERAL.—The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall 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—

(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.

No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

(3) LIMITATIONS.—

(A) IN GENERAL.—No restrictions under paragraph (1) may—

(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

(ii) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

(B) MATCHBOOKS.—For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of tobacco products, shall be considered as adult-written publications which shall be permitted to contain advertising. Notwithstanding the preceding sentence, if the Secretary finds that such treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult-written publications.

(4) REMOTE SALES.—

(A) IN GENERAL.—The Secretary shall—

(i) within 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, promulgate regulations regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of such products, including requirements for age verification; and

(ii) within 2 years after such date of enactment, issue regulations to address the promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and a consumer in order to protect individuals who have not attained the minimum age established by applicable law for the purchase of such products.

(B) RELATION TO OTHER AUTHORITY.—Nothing in this paragraph limits the authority of the Secretary to take additional actions under the other paragraphs of this subsection.

(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

(A) IN GENERAL.—In applying manufacturing restrictions to tobacco, the Secretary shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this chapter. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

(B) REQUIREMENTS.—The Secretary shall—

(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A);

(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices; and

(v) not require any small tobacco product manufacturer to comply with a regulation under subparagraph (A) for at least 4 years following the effective date established by the Secretary for such regulation.

(2) EXEMPTIONS; VARIANCES.—

(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this chapter;

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

(iii) contain such other information as the Secretary shall prescribe.

(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Secretary may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Secretary with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

(i) the date the petition was submitted to the Secretary under subparagraph (A); or

(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) APPROVAL.—The Secretary may approve—

(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this chapter; and

(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this chapter.

(D) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this chapter.

(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the end of the 3-year period following the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

(f) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

SEC. 907. TOBACCO PRODUCT STANDARDS.

(a) IN GENERAL.—

(1) SPECIAL RULES.—

(A) SPECIAL RULE FOR CIGARETTES.—Beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

(B) ADDITIONAL SPECIAL RULE.—Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

(2) REVISION OF TOBACCO PRODUCT STANDARDS.—The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

(3) TOBACCO PRODUCT STANDARDS.—

(A) IN GENERAL.—The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

(B) DETERMINATIONS.—

(i) CONSIDERATIONS.—In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(ii) ADDITIONAL CONSIDERATIONS.—In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, any party objecting to the

proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(4) CONTENT OF TOBACCO PRODUCT STANDARDS.—A tobacco product standard established under this section for a tobacco product—

(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

(i) for nicotine yields of the product;

(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

(iii) relating to any other requirement under subparagraph (B);

(B) shall, where appropriate for the protection of the public health, include—

(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d);

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

(5) PERIODIC REEVALUATION OF TOBACCO PRODUCT STANDARDS.—The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall endeavor to—

(A) use personnel, facilities, and other technical support available in other Federal agencies;

(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

(b) CONSIDERATIONS BY SECRETARY.—

(1) TECHNICAL ACHIEVABILITY.—The Secretary shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

(2) OTHER CONSIDERATIONS.—The Secretary shall consider all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand.

(c) PROPOSED STANDARDS.—

(1) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

(A) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard.

(3) FINDING.—A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a finding with supporting justification that the tobacco product standard is no longer appropriate for the protection of the public health.

(4) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

(d) PROMULGATION.—

(1) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco product standard and after consideration of comments submitted under subsections (b) and (c)

and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

(A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

(2) EFFECTIVE DATE.—A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Secretary shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard. If the Secretary determines, based on the Secretary's evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.

(3) LIMITATION ON POWER GRANTED TO THE FOOD AND DRUG ADMINISTRATION.—Because of the importance of a decision of the Secretary to issue a regulation—

(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

(B) requiring the reduction of nicotine yields of a tobacco product to zero,

the Secretary is prohibited from taking such actions under this Act.

(4) AMENDMENT; REVOCATION.—

(A) AUTHORITY.—The Secretary, upon the Secretary's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a tobacco product standard.

(B) EFFECTIVE DATE.—The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary determines that making it so effective is in the public interest.

(5) REFERRAL TO ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

(B) INITIATION OF REFERRAL.—The Secretary may make a referral under this paragraph—

(i) on the Secretary's own initiative; or

(ii) upon the request of an interested person that—

(I) demonstrates good cause for the referral; and

(II) is made before the expiration of the period for submission of comments on the proposed regulation.

(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

(E) PUBLIC AVAILABILITY.—The Secretary shall make a copy of each report and recommendation under subparagraph (D) publicly available.

(e) MENTHOL CIGARETTES.—

(1) REFERRAL; CONSIDERATIONS.—Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under section 917(a), the Secretary shall refer to the Committee for report and recommendation, under section 917(c)(4), the issue of the impact of the use of menthol in cigarettes on the public health, including such use among African Americans, Hispanics, and other racial and ethnic minorities. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsections (a)(3)(B)(i) and (b).

(2) REPORT AND RECOMMENDATION.—Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol.

SEC. 908. NOTIFICATION AND OTHER REMEDIES.

(a) NOTIFICATION.—If the Secretary determines that—

(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

(b) NO EXEMPTION FROM OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

(c) RECALL AUTHORITY.—

(1) IN GENERAL.—If the Secretary finds that 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, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

(B) NOTICE.—An amended order under subparagraph (A)—

(i) shall not include recall of a tobacco product from individuals; and

(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Secretary may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705(b).

(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a).

SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

(a) IN GENERAL.—Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded and to otherwise protect public health. Regulations prescribed under the preceding sentence—

(1) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience;

(2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported;

(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information; and

(6) may not require that the identity of any patient or user be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine risks to public health of a tobacco product, or to verify a record, report, or information submitted under this chapter.

In prescribing regulations under this subsection, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (6) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(b) REPORTS OF REMOVALS AND CORRECTIONS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall by regulation require a tobacco product manufacturer or importer of a tobacco product to report promptly to the Secretary any corrective action taken or removal from the market of a tobacco product undertaken by such manufacturer or importer if the removal or correction was undertaken—

(A) to reduce a risk to health posed by the tobacco product; or

(B) to remedy a violation of this chapter caused by the tobacco product which may present a risk to health.

A tobacco product manufacturer or importer of a tobacco product who undertakes a corrective action or removal from the market of a tobacco product which is not required to be reported under this subsection shall keep a record of such correction or removal.

(2) EXCEPTION.—No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.

(a) IN GENERAL.—

(1) NEW TOBACCO PRODUCT DEFINED.—For purposes of this section the term "new tobacco product" means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) PREMARKET REVIEW REQUIRED.—

(A) NEW PRODUCTS.—An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 905(j); and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this Act; or

(ii) the tobacco product is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3).

(B) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007, PRODUCTS.—Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after the date

of enactment of the Family Smoking Prevention and Tobacco Control Act; and

(ii) for which a report was submitted under section 905(j) within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

(A) IN GENERAL.—In this section and section 905(j), the term "substantially equivalent" or "substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

(i) has the same characteristics as the predicate tobacco product; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) CHARACTERISTICS.—In subparagraph (A), the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) LIMITATION.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(4) HEALTH INFORMATION.—

(A) SUMMARY.—As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

(b) APPLICATION.—

(1) CONTENTS.—An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may, on the Secretary's own initiative; or

(B) may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) ACTION ON APPLICATION.—

(1) DEADLINE.—

(A) IN GENERAL.—As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d).

(2) DENIAL OF APPLICATION.—The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the appli-

cation and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, and there is a lack of adequate information to justify the deviation from such standard.

(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall 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—

(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.

(5) BASIS FOR ACTION.—

(A) INVESTIGATIONS.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

(1) IN GENERAL.—The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for

which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909;

(ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or

(iii) has not complied with the requirements of section 905;

(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 912.

(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall

by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) SERVICE OF ORDER.—An order issued by the Secretary under this section shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

(f) RECORDS.—

(1) ADDITIONAL INFORMATION.—In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe.

SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.

(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) DEFINITIONS.—In this section:

(1) MODIFIED RISK TOBACCO PRODUCT.—The term "modified risk tobacco product" means 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.

(2) SOLD OR DISTRIBUTED.—

(A) IN GENERAL.—With respect to a tobacco product, the term "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" means a tobacco product—

(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance;

(ii) the label, labeling, or advertising of which uses the descriptors "light", "mild", or "low" or similar descriptors; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

(B) LIMITATION.—No tobacco product shall be considered to be "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products", except as described in subparagraph (A).

(C) SMOKELESS TOBACCO PRODUCT.—No smokeless tobacco product shall be considered to be "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: "smokeless tobacco", "smokeless tobacco product", "not consumed by smoking", "does not produce smoke", "smokefree", "smoke-free", "without smoke", "no smoke", or "not smoke".

(3) EFFECTIVE DATE.—The provisions of paragraph (2)(A)(ii) shall take effect 12 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act for those products whose label, labeling, or advertising contains the terms described in such paragraph on such date of enactment. The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with paragraph (2)(A)(ii).

(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the Food and Drug Administration and is subject to the requirements of chapter V.

(d) FILING.—Any person may file with the Secretary an application for a modified risk tobacco product. Such application shall include—

(1) a description of the proposed product and any proposed advertising and labeling;

(2) the conditions for using the product;

(3) the formulation of the product;

(4) sample product labels and labeling;

(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

(6) data and information on how consumers actually use the tobacco product; and

(7) such other information as the Secretary may require.

(e) PUBLIC AVAILABILITY.—The Secretary shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

(f) ADVISORY COMMITTEE.—

(1) IN GENERAL.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Secretary.

(g) MARKETING.—

(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph (2), the Secretary shall, with respect to an application submitted under this section, issue an order that a modified risk product may be commercially marketed only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

(A) IN GENERAL.—The Secretary may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

(i) such order would be appropriate to promote the public health;

(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product

to be a modified risk tobacco product under subsection (b) is limited to an explicit or implicit representation that such tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

(B) ADDITIONAL FINDINGS REQUIRED.—To issue an order under subparagraph (A) the Secretary must also find that the applicant has demonstrated that—

(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—

(I) is or has been demonstrated to be less harmful; or

(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and

(iv) issuance of an order with respect to the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

(C) CONDITIONS OF MARKETING.—

(i) IN GENERAL.—Applications subject to an order under this paragraph shall be limited to a term of not more than 5 years, but may be renewed upon a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.

(ii) AGREEMENTS BY APPLICANT.—An order under this paragraph shall be conditioned on the applicant's agreement to conduct postmarket surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the order on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations upon which the order was based in accordance with a protocol approved by the Secretary.

(iii) ANNUAL SUBMISSION.—The results of such postmarket surveillance and studies described in clause (ii) shall be submitted annually.

(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

(A) the scientific evidence submitted by the applicant; and

(B) scientific evidence and other information that is made available to the Secretary.

(4) BENEFIT TO HEALTH OF INDIVIDUALS AND OF POPULATION AS A WHOLE.—In making the determinations under paragraphs (1) and (2), the Secretary shall take into account—

(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence; and

(E) comments, data, and information submitted by interested persons.

(h) ADDITIONAL CONDITIONS FOR MARKETING.—

(1) MODIFIED RISK PRODUCTS.—The Secretary shall require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information 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.

(2) COMPARATIVE CLAIMS.—

(A) IN GENERAL.—The Secretary may require for the marketing of a product under this subsection that a claim comparing a tobacco product to 1 or more other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3 brands of an established regular tobacco product).

(B) QUANTITATIVE COMPARISONS.—The Secretary may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

(3) LABEL DISCLOSURE.—

(A) IN GENERAL.—The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.

(B) CONDITIONS OF USE.—If the conditions of use of the tobacco product may affect the risk of the product to human health, the Secretary may require the labeling of conditions of use.

(4) TIME.—An order issued under subsection (g)(1) shall be effective for a specified period of time.

(5) ADVERTISING.—The Secretary may require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the product comply with requirements relating to advertising and promotion of the tobacco product.

(i) POSTMARKET SURVEILLANCE AND STUDIES.—

(1) IN GENERAL.—The Secretary shall require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the applicant conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of postmarket surveillance and studies shall be submitted to the Secretary on an annual basis.

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

(j) WITHDRAWAL OF AUTHORIZATION.—The Secretary, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Secretary determines that—

(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Secretary can no longer make the determinations required under subsection (g);

(2) the application failed to include material information or included any untrue statement of material fact;

(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

(A) a tobacco product standard is established pursuant to section 907;

(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

(5) the applicant failed to meet a condition imposed under subsection (h).

(k) CHAPTER IV OR V.—A product for which the Secretary has issued an order pursuant to subsection (g) shall not be subject to chapter IV or V.

(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

(C) establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception;

(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product; and

(F) establish a reasonable timetable for the Secretary to review an application under this section.

(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate

scientific and medical experts, on the design and conduct of such studies and surveillance.

(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 910 and which the applicant seeks to commercially market under this section.

(m) DISTRIBUTORS.—Except as provided in this section, no distributor may take any action, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, with respect to a tobacco product that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

SEC. 912. JUDICIAL REVIEW.

(a) RIGHT TO REVIEW.—

(1) IN GENERAL.—Not later than 30 days after—

(A) the promulgation of a regulation under section 907 establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 910(c), any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

(2) REQUIREMENTS.—

(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Secretary.

(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Secretary shall file in the court in which such petition was filed—

(i) the record of the proceedings on which the regulation or order was based; and

(ii) a statement of the reasons for the issuance of such a regulation or order.

(C) DEFINITION OF RECORD.—In this section, the term "record" means—

(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

(ii) all information submitted to the Secretary with respect to such regulation or order;

(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

(iv) any hearing held with respect to such regulation or order; and

(v) any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

(c) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review, a regulation or order issued under section 906, 907, 908, 909, 910, or 916 shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.

The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

SEC. 914. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

(a) JURISDICTION.—

(1) IN GENERAL.—Except where expressly provided in this chapter, nothing in this chapter shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

(2) ENFORCEMENT.—Any advertising that violates this chapter or a provision of the regulations referred to in section 102 of the Family Smoking Prevention and Tobacco Control Act, is an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act and shall be considered a violation of a rule promulgated under section 18 of that Act.

(b) COORDINATION.—With respect to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986—

(1) the Chairman of the Federal Trade Commission shall coordinate with the Secretary concerning the enforcement of such Act as such enforcement relates to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco; and

(2) the Secretary shall consult with the Chairman of such Commission in revising the label statements and requirements under such sections.

SEC. 915. REGULATION REQUIREMENT.

(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall promulgate regulations under this Act that meet the requirements of subsection (b).

(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a)—

(1) shall require testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand and subbrand that the Secretary determines should be tested to protect the public health, provided that, for purposes of the testing requirements of this paragraph, tobacco products manufactured and sold by a single tobacco product manufacturer that are identical in all respects except the labels, packaging design, logo, trade dress, trademark, brand name, or any combination thereof, shall be considered as a single brand; and

(2) may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, ingredients, or additives, that the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco-related disease.

(c) AUTHORITY.—The Secretary shall have the authority under this chapter to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

(d) SMALL TOBACCO PRODUCT MANUFACTURERS.—

(1) FIRST COMPLIANCE DATE.—The initial regulations promulgated under subsection (a) shall not impose requirements on small tobacco product manufacturers before the later of—

(A) the end of the 2-year period following the final promulgation of such regulations; and

(B) the initial date set by the Secretary for compliance with such regulations by manufacturers that are not small tobacco product manufacturers.

(2) TESTING AND REPORTING INITIAL COMPLIANCE PERIOD.—

(A) 4-YEAR PERIOD.—The initial regulations promulgated under subsection (a) shall give each small tobacco product manufacturer a 4-year period over which to conduct testing and reporting for all of its tobacco products. Subject to paragraph (1), the end of the first year of such 4-year period shall coincide with the initial date of compliance under this section set by the Secretary with respect to manufacturers that are not small tobacco product manufacturers or the end of the 2-year period following the final promulgation of such regulations, as described in paragraph (1)(A). A small tobacco product manufacturer shall be required—

(i) to conduct such testing and reporting for 25 percent of its tobacco products during each year of such 4-year period; and

(ii) to conduct such testing and reporting for its largest-selling tobacco products (as determined by the Secretary) before its other tobacco products, or in such other order of priority as determined by the Secretary.

(B) CASE-BY-CASE DELAY.—Notwithstanding subparagraph (A), the Secretary may, on a case-by-case basis, delay the date by which an individual small tobacco product manufacturer must conduct testing and reporting for its tobacco products under this section based upon a showing of undue hardship to such manufacturer. Notwithstanding the preceding sentence, the Secretary shall not extend the deadline for a small tobacco product manufacturer to conduct testing and reporting for all of its tobacco products beyond a total of 5 years after the initial date of compliance under this section set by the Secretary with respect to manufacturers that are not small tobacco product manufacturers.

(3) SUBSEQUENT AND ADDITIONAL TESTING AND REPORTING.—The regulations promulgated under subsection (a) shall provide that, with respect to any subsequent or additional testing and reporting of tobacco products required under this section, such testing and reporting by a small tobacco product manufacturer shall be conducted in accordance with the timeframes described in paragraph (2)(A), except that, in the case of a new product, or if there has been a modification described in section 910(a)(1)(B) of any product of a small tobacco product manufacturer since the last testing and reporting required under this section, the Secretary shall require that any subsequent or additional testing and reporting be conducted in accordance with the same timeframe applicable to manufacturers that are not small tobacco product manufacturers.

(4) JOINT LABORATORY TESTING SERVICES.—The Secretary shall allow any 2 or more small tobacco product manufacturers to join together to purchase laboratory testing services required by this section on a group basis in order to ensure that such manufacturers receive access to, and fair pricing of, such testing services.

(e) EXTENSIONS FOR LIMITED LABORATORY CAPACITY.—

(1) IN GENERAL.—The regulations promulgated under subsection (a) shall provide that a small tobacco product manufacturer shall not be considered to be in violation of this section before the deadline applicable under paragraphs (3) and (4), if—

(A) the tobacco products of such manufacturer are in compliance with all other requirements of this chapter; and

(B) the conditions described in paragraph (2) are met.

(2) CONDITIONS.—Notwithstanding the requirements of this section, the Secretary may delay the date by which a small tobacco product manufacturer must be in compliance with the testing and reporting required by this section until such time as the testing is reported if, not later than 90 days before the deadline for reporting in accordance with this section, a small to-

bacco product manufacturer provides evidence to the Secretary demonstrating that—

(A) the manufacturer has submitted the required products for testing to a laboratory and has done so sufficiently in advance of the deadline to create a reasonable expectation of completion by the deadline;

(B) the products currently are awaiting testing by the laboratory; and

(C) neither that laboratory nor any other laboratory is able to complete testing by the deadline at customary, nonexpedited testing fees.

(3) EXTENSION.—The Secretary, taking into account the laboratory testing capacity that is available to tobacco product manufacturers, shall review and verify the evidence submitted by a small tobacco product manufacturer in accordance with paragraph (2). If the Secretary finds that the conditions described in such paragraph are met, the Secretary shall notify the small tobacco product manufacturer that the manufacturer shall not be considered to be in violation of the testing and reporting requirements of this section until the testing is reported or until 1 year after the reporting deadline has passed, whichever occurs sooner. If, however, the Secretary has not made a finding before the reporting deadline, the manufacturer shall not be considered to be in violation of such requirements until the Secretary finds that the conditions described in paragraph (2) have not been met, or until 1 year after the reporting deadline, whichever occurs sooner.

(4) ADDITIONAL EXTENSION.—In addition to the time that may be provided under paragraph (3), the Secretary may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Secretary determines, based on evidence properly and timely submitted by a small tobacco product manufacturer in accordance with paragraph (2), that a lack of available laboratory capacity prevents the manufacturer from completing the required testing during the period described in paragraph (3).

(f) RULE OF CONSTRUCTION.—Nothing in subsection (d) or (e) shall be construed to authorize the extension of any deadline, or to otherwise affect any timeframe, under any provision of this Act or the Family Smoking Prevention and Tobacco Control Act other than this section.

SEC. 916. PRESERVATION OF STATE AND LOCAL AUTHORITY.

(a) IN GENERAL.—

(1) PRESERVATION.—Except as provided in paragraph (2)(A), nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting

to the State, or measures relating to fire safety standards for tobacco products. No provision of this chapter shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

SEC. 917. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish a 12-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee (in this section referred to as the "Advisory Committee").

(b) MEMBERSHIP.—

(1) IN GENERAL.—

(A) MEMBERS.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

(ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

(iii) 1 individual as a representative of the general public;

(iv) 1 individual as a representative of the interests of the tobacco manufacturing industry;

(v) 1 individual as a representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee; and

(vi) 1 individual as a representative of the interests of the tobacco growers.

(B) NONVOTING MEMBERS.—The members of the committee appointed under clauses (iv), (v), and (vi) of subparagraph (A) shall serve as consultants to those described in clauses (i) through (iii) of subparagraph (A) and shall be nonvoting representatives.

(C) CONFLICTS OF INTEREST.—No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products.

(2) LIMITATION.—The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Food and Drug Administration or any agency responsible for the enforcement of this Act. The Secretary may appoint Federal officials as ex officio members.

(3) CHAIRPERSON.—The Secretary shall designate 1 of the members appointed under clauses (i), (ii), and (iii) of paragraph (1)(A) to serve as chairperson.

(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Secretary—

(1) as provided in this chapter;

(2) on the effects of the alteration of the nicotine yields from tobacco products;

(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and

(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

(d) COMPENSATION; SUPPORT; FACA.—

(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish the Advisory Committee clerical and other assistance.

(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act does not apply to the Advisory Committee.

(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

SEC. 918. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.

(a) IN GENERAL.—The Secretary shall—

(1) at the request of the applicant, consider designating products for smoking cessation, including nicotine replacement products as fast track research and approval products within the meaning of section 506;

(2) consider approving the extended use of nicotine replacement products (such as nicotine patches, nicotine gum, and nicotine lozenges) for the treatment of tobacco dependence; and

(3) review and consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention.

(b) REPORT ON INNOVATIVE PRODUCTS.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary, after consultation with recognized scientific, medical, and public health experts (including both Federal agencies and nongovernmental entities, the Institute of Medicine of the National Academy of Sciences, and the Society for Research on Nicotine and Tobacco), shall submit to the Congress a report that examines how best to regulate, promote, and encourage the development of innovative products and treatments (including nicotine-based and non-nicotine-based products and treatments) to better achieve, in a manner that best protects and promotes the public health—

(A) total abstinence from tobacco use;

(B) reductions in consumption of tobacco; and

(C) reductions in the harm associated with continued tobacco use.

(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Secretary on how the Food and Drug Administration should coordinate and facilitate the exchange of information on such innovative products and treatments among relevant offices and centers within the Administration and within the National Institutes of Health, the Centers for Disease Control and Prevention, and other relevant agencies.

SEC. 919. USER FEES.

(a) ESTABLISHMENT OF QUARTERLY FEE.—Beginning on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to this chapter. The fees shall be assessed and collected with respect to each quarter of each fiscal

year, and the total amount assessed and collected for a fiscal year shall be the amount specified in subsection (b)(1) for such year, subject to subsection (c).

(b) ASSESSMENT OF USER FEE.—

(1) AMOUNT OF ASSESSMENT.—The total amount of user fees authorized to be assessed and collected under subsection (a) for a fiscal year is the following, as applicable to the fiscal year involved:

(A) For fiscal year 2009, $85,000,000 (subject to subsection (e)).

(B) For fiscal year 2010, $235,000,000.

(C) For fiscal year 2011, $450,000,000.

(D) For fiscal year 2012, $477,000,000.

(E) For fiscal year 2013, $505,000,000.

(F) For fiscal year 2014, $534,000,000.

(G) For fiscal year 2015, $566,000,000.

(H) For fiscal year 2016, $599,000,000.

(I) For fiscal year 2017, $635,000,000.

(J) For fiscal year 2018, $672,000,000.

(K) For fiscal year 2019 and each subsequent fiscal year, $712,000,000.

(2) ALLOCATIONS OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—

(A) IN GENERAL.—The total user fees assessed and collected under subsection (a) each fiscal year with respect to each class of tobacco products shall be an amount that is equal to the applicable percentage of each class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

(B) APPLICABLE PERCENTAGE.—

(i) IN GENERAL.—For purposes of subparagraph (A), the applicable percentage for a fiscal year for each of the following classes of tobacco products shall be determined in accordance with clause (ii):

(I) Cigarettes.

(II) Cigars, including small cigars and cigars other than small cigars.

(III) Snuff.

(IV) Chewing tobacco.

(V) Pipe tobacco.

(VI) Roll-your-own tobacco.

(ii) ALLOCATIONS.—The applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under section 625(c) of Public Law 108–357 for each such class of product for such fiscal year.

(iii) REQUIREMENT OF REGULATIONS.—Notwithstanding clause (ii), no user fees shall be assessed on a class of tobacco products unless such class of tobacco products is listed in section 901(b) or is deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter.

(iv) REALLOCATIONS.—In the case of a class of tobacco products that is not listed in section 901(b) or deemed by the Secretary in a regulation under section

901(b) to be subject to this chapter, the amount of user fees that would otherwise be assessed to such class of tobacco products shall be reallocated to the classes of tobacco products that are subject to this chapter in the same manner and based on the same relative percentages otherwise determined under clause (ii).

(3) DETERMINATION OF USER FEE BY COMPANY.—

(A) IN GENERAL.—The total user fee to be paid by each manufacturer or importer of a particular class of tobacco products shall be determined for each quarter by multiplying—

(i) such manufacturer's or importer's percentage share as determined under paragraph (4); by

(ii) the portion of the user fee amount for the current quarter to be assessed on all manufacturers and importers of such class of tobacco products as determined under paragraph (2).

(B) NO FEE IN EXCESS OF PERCENTAGE SHARE.—No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the percentage share of such manufacturer or importer.

(4) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF TOBACCO PRODUCT.—The percentage share of each manufacturer or importer of a particular class of tobacco products of the total user fee to be paid by all manufacturers or importers of that class of tobacco products shall be the percentage determined for purposes of allocations under subsections (e) through (h) of section 625 of Public Law 108–357.

(5) ALLOCATION FOR CIGARS.—Notwithstanding paragraph (4), if a user fee assessment is imposed on cigars, the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by such manufacturer or importer during the prior fiscal year.

(6) TIMING OF ASSESSMENT.—The Secretary shall notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment imposed on such manufacturer or importer under this subsection for each quarter of each fiscal year. Such notifications shall occur not later than 30 days prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made by the last day of the quarter involved.

(7) MEMORANDUM OF UNDERSTANDING.—

(A) IN GENERAL.—The Secretary shall request the appropriate Federal agency to enter into a memorandum of understanding that provides for the regular and timely transfer from the head of such agency to the Secretary of the information described in paragraphs (2)(B)(ii) and (4) and all necessary information regarding all tobacco product manufacturers and importers required to pay user fees. The Secretary shall maintain all disclosure restrictions established by the head of such agency regarding the information provided under the memorandum of understanding.

(B) ASSURANCES.—Beginning not later than fiscal year 2015, and for each subsequent fiscal year, the Secretary shall ensure that the Food and Drug Administration is able

to determine the applicable percentages described in paragraph (2) and the percentage shares described in paragraph (4). The Secretary may carry out this subparagraph by entering into a contract with the head of the Federal agency referred to in subparagraph (A) to continue to provide the necessary information.

(c) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(2) AVAILABILITY.—

(A) IN GENERAL.—Fees appropriated under paragraph (3) are available only for the purpose of paying the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under this chapter and the Family Smoking Prevention and Tobacco Control Act. No fees collected under subsection (a) may be used for any other costs.

(B) PROHIBITION AGAINST USE OF OTHER FUNDS.—

(i) IN GENERAL.—Except as provided in clause (ii), fees collected under subsection (a) are the only funds authorized to be made available for the purpose described in subparagraph (A).

(ii) STARTUP COSTS.—Clause (i) does not apply until the date on which the Secretary has collected fees under subsection (a) for 2 fiscal year quarters. Until such date, other amounts available to the Food and Drug Administration (excluding fees collected under subsection (a)) are authorized to be made available to pay the costs described in subparagraph (A), provided that such amounts are reimbursed through fees collected under subsection (a).

(3) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2009 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equal to the amount specified in subsection (b)(1) for the fiscal year.

(d) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(e) APPLICABILITY TO FISCAL YEAR 2009.—If the date of enactment of the Family Smoking Prevention and Tobacco Control Act occurs during fiscal year 2009, the following applies, subject to subsection (c):

(1) The Secretary shall determine the fees that would apply for a single quarter of such fiscal year according to the application of subsection (b) to the amount specified in paragraph

(1)(A) of such subsection (referred to in this subsection as the "quarterly fee amounts").

(2) For the quarter in which such date of enactment occurs, the amount of fees assessed shall be a pro rata amount, determined according to the number of days remaining in the quarter (including such date of enactment) and according to the daily equivalent of the quarterly fee amounts. Fees assessed under the preceding sentence shall not be collected until the next quarter.

(3) For the quarter following the quarter to which paragraph (2) applies, the full quarterly fee amounts shall be assessed and collected, in addition to collection of the pro rata fees assessed under paragraph (2).

SEC. 920. LABELING, RECORDKEEPING, RECORDS INSPECTION.

(a) ORIGIN LABELING.—

(1) REQUIREMENT.—Beginning 1 year after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the label, packaging, and shipping containers of tobacco products for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement "sale only allowed in the United States".

(2) EFFECTIVE DATE.—The effective date specified in paragraph (1) shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with such paragraph.

(b) REGULATIONS CONCERNING RECORDKEEPING FOR TRACKING AND TRACING.—

(1) IN GENERAL.—The Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.

(2) INSPECTION.—In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

(3) CODES.—The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system.

(4) SIZE OF BUSINESS.—The Secretary shall take into account the size of a business in promulgating regulations under this section.

(5) RECORDKEEPING BY RETAILERS.—The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.

(c) RECORDS INSPECTION.—If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee duly

designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, upon the presentation of appropriate credentials and a written notice to such person, to have access to and copy all records (including financial records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products. The Secretary shall not authorize an officer or employee of the government of any of the several States to exercise authority under the preceding sentence on Indian country without the express written consent of the Indian tribe involved.

(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

(1) NOTIFICATION.—If the manufacturer or distributor of a tobacco product has knowledge which reasonably supports the conclusion that a tobacco product manufactured or distributed by such manufacturer or distributor that has left the control of such person may be or has been—

(A) imported, exported, distributed, or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or

(B) imported, exported, distributed, or diverted for possible illicit marketing,

the manufacturer or distributor shall promptly notify the Attorney General and the Secretary of the Treasury of such knowledge.

(2) KNOWLEDGE DEFINED.—For purposes of this subsection, the term "knowledge" as applied to a manufacturer or distributor means—

(A) the actual knowledge that the manufacturer or distributor had; or

(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

Chapter [IX] *X*—MISCELLANEOUS

SEPARABILITY CLAUSE

SEC. [901.] *1001.* If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATE AND REPEALS

SEC. [902.] *1002.* (a) * * *

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SEC. [903.] *1003.* FOOD AND DRUG ADMINISTRATION.

(a) * * *

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(d) COMMISSIONER.—

(1) * * *

(2) GENERAL POWERS.—The Secretary, through the Commissioner, shall be responsible for executing this Act and for—

(A) * * *

* * * * * * *

(C) research relating to foods, drugs, cosmetics, [and] devices*, and tobacco products* in carrying out this Act;

* * * * * * *

SEC. [904.] *1004.* SCIENTIFIC REVIEW GROUPS.

Without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Commissioner of Food and Drugs may—

(1) * * *

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SEC. [905.] *1005.* LOAN REPAYMENT PROGRAM.

(a) * * *

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SEC. [906.] *1006.* PRACTICE OF MEDICINE.

Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

SEC. [907.] *1007.* CONTRACTS FOR EXPERT REVIEW.

(a) * * *

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SEC. [908.] *1008.* NOTICES TO STATES REGARDING IMPORTED FOOD.

(a) * * *

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SEC. [909.] *1009.* GRANTS TO STATES FOR INSPECTIONS.

(a) * * *

(b) NOTICES REGARDING ADULTERATED IMPORTED FOOD.—The Secretary may make grants to the States for the purpose of assisting the States with the costs of taking appropriate action to protect the public health in response to notification under [section 908] *section 1008*, including planning and otherwise preparing to take such action.

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SEC. [910.] *1010.* OFFICE OF THE CHIEF SCIENTIST.

(a) * * *

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FEDERAL MEAT INSPECTION ACT

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TITLE IV—AUXILIARY PROVISIONS

* * * * * * *

SEC. 409.(a) Notwithstanding any other provisions of law, including [section 902(b)] *section 1002(b)* of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 392(a)), the provisions of this Act shall not derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act prior to enactment of the Wholesome Meat Act.

* * * * * * *

FEDERAL CIGARETTE LABELING AND ADVERTISING ACT

* * * * * * *

[LABELING

[SEC. 4. (a)(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

[SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

[SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

[SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

[SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

[(2) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised (other than through the use of outdoor billboards) within the United States any cigarette unless the advertising bears, in accordance with the requirements of this section, one of the following labels:

[SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

[SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

[SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

[SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

[(3) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised within the United States through the use of outdoor billboards any cigarette unless the advertising bears, in accordance with the requirements of this section, one of the following labels:

[SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, And Emphysema.

[SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Health Risks.

[SURGEON GENERAL'S WARNING: Pregnant Women Who Smoke Risk Fetal Injury, And Premature Birth.

[SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

[(b)(1) Each label statement required by paragraph (1) of subsection (a) shall be located in the place label statements were placed on cigarete packages as of the date of the enactment of this subsection. The phrase "Surgeon General's Warning" shall appear in capital letters and the size of all other lettes in the label shall be the same as the size of such letters as of such date of enactment. All the letters in the label shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package.

[(2) The format of each label statement required by paragaph (2) of subsection (a) shall be the format required for label statements in cigarette advertising as of the date of the enactment of this subsection, except that the phrase "Surgeon General's Warning" shall appear in capital letters, the area of the rectangle enclosing the label shall be 50 per centum larger in size with a corresponding increase in the size of the type in the label, the width of the rule forming the border around the label shall be twice that in effect on such date, and the label may be placed at a distance from the other edge of the advertisement which is one-half the distance permitted on such date. Each label statement shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material in the advertisement.

[(3) The format and type style of each label statement required by paragraph (3) of subsection (a) shall be the format and type style required in outdoor billboard advertising as of the date of the enactment of this subsection. Each such label statement shall be printed in capital letters of the height of the tallest letter in a label statement on outdoor advertising of the same dimension on such date of enactment. Each such label statement shall be enclosed by a black border which is located within the perimeter of the format required in outdoor billboard advertising of the same dimension on such date of enactment and the width of which is twice the width of the vertical element of any letter in the label statement within the border.

[(c)(1) Except as provided in paragraph (2), the label statements specified in paragraphs (1), (2), and (3) of subsection (a) shall be rotated by each manufacturer or importer of cigarettes quarterly in alternating sequence on packages of each brand of cigarettes manufactured by the manufacturer or importer and in the advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer or importer and approved by the Federal Trade Commission. The Federal Trade Commission shall approve a plan submitted by a manufacturer or importer of cigarettes which will provide the rotation required by this subsection and which assures that all of the labels required by paragraphs (1), (2), and (3) will be displayed by the manufacturer or importer at the same time.

[(2)(A) A manufacturer or importer of cigarettes may apply to the Federal Trade Commission to have the label rotation described

in subparagraph (C) apply with respect to a brand style of cigarettes manufactured or imported by such manufacturer or importer if—

[(i) the number of cigarettes of such brand style sold in the fiscal year of the manufacturer or importer preceding the submission of the application is less than one-fourth of 1 percent of all the cigarettes sold in the United States in such year, and

[(ii) more than one-half of the cigarettes manufactured or imported by such manufacturer or importer for sale in the United States are packaged into brand styles which meet the requirements of clause (i).

If an application is approved by the Commission, the label rotation described in subparagraph (C) shall apply with respect to the applicant during the one-year period beginning on the date of the application approval.

[(B) An applicant under subparagraph (A) shall include in its application a plan under which the label statements specified in paragraph (1) of subsection (a) will be rotated by the applicant manufacturer or importer in accordance with the label rotation described in subparagraph (C).

[(C) Under the label rotation which the manufacturer or importer with an approved application may put into effect each of the labels specified in paragraph (1) of subsection (a) shall appear on the packages of each brand style of cigarettes with respect to which the application was approved an equal number of times within the twelve-month period beginning on the date of the approval by the Commission of the application.

[(d) Subsection (a) does not apply to a distributor a retailer of cigarettes who does not manufacture, package, or import cigarettes for sale or distribution within the United States.]

SEC. 4. LABELING.

(a) LABEL REQUIREMENTS.—

(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

WARNING: Cigarettes are addictive.

WARNING: Tobacco smoke can harm your children.

WARNING: Cigarettes cause fatal lung disease.

WARNING: Cigarettes cause cancer.

WARNING: Cigarettes cause strokes and heart disease.

WARNING: Smoking during pregnancy can harm your baby.

WARNING: Smoking can kill you.

WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

WARNING: Quitting smoking now greatly reduces serious risks to your health.

(2) PLACEMENT; TYPOGRAPHY; ETC.—Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise at least the top 30 percent of the front and rear panels of the package. The word "WARNING" shall appear in capital letters and all text shall be in con-

spicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c).

(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that—

(A) contains a warning label;

(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

(b) ADVERTISING REQUIREMENTS.—

(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word "WARNING" shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital "W" of the word "WARNING" in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-

point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

(4) ADJUSTMENT BY SECRETARY.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

(c) MARKETING REQUIREMENTS.—

(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

(3) REVIEW.—The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(B) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an ad-

vertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).

(d) CHANGE IN REQUIRED STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

(e) TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE.—

(1) IN GENERAL.—The Secretary shall, by a rulemaking conducted under section 553 of title 5, United States Code, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

(2) RESOLUTION OF DIFFERENCES.—Any differences between the requirements established by the Secretary under paragraph (1) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

(3) CIGARETTE AND OTHER TOBACCO PRODUCT CONSTITUENTS.—In addition to the disclosures required by paragraph (1), the Secretary may, under a rulemaking conducted under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act.

(4) RETAILERS.—This subsection applies to a retailer only if that retailer is responsible for or directs the label statements required under this section.

PREEMPTION

SEC. 5. (a) **[**No**]** *Except to the extent the Secretary requires additional or different statements on any cigarette package by a regula-*

tion, by an order, by a standard, by an authorization to market a product, or by a condition of marketing a product, pursuant to the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), or as required under section 903(a)(2) or section 920(a) of the Federal Food, Drug, and Cosmetic Act, no statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.

* * * * * * *

(c) EXCEPTION.—Notwithstanding subsection (b), a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the Family Smoking Prevention and Tobacco Control Act, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.

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COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT OF 1986

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[SEC. 3. SMOKELESS TOBACCO WARNING.

[(a) GENERAL RULE.—

[(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCERWARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSSWARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES'.

[(2) It shall be unlawful for any manufacturer, packager, or importer of smokeless tobacco products to advertise or cause to be advertised (other than through the use of outdoor billboard advertising) within the United States any smokeless tobacco product unless the advertising bears, in accordance with the requirements of this Act, one of the labels required by paragraph (1).

[(b) LABEL FORMAT.—The Federal Trade Commission shall issue regulations requiring the label statement required by subsection (a) to appear—

[(1) in the case of the smokeless tobacco product package—

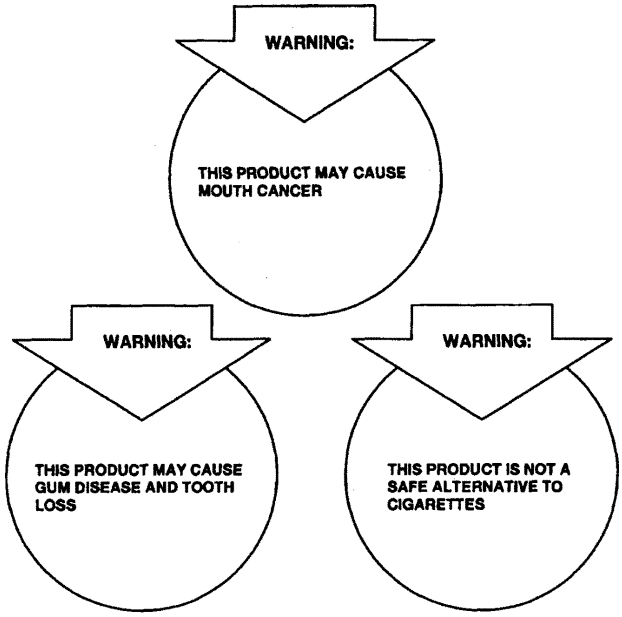
[(A) in a conspicuous and prominent place on the package, and

[(B) in a conspicuous format and in conspicuous and legible type in contrast with all other printed material on the package, and

[(2) in the case of advertising subject to subsection (a)(2)—

[(A) in a conspicuous and prominent location in the advertisement and in conspicuous and legible type in contrast with all other printed material in the advertisement,

[(B) in the following format:



[(C) the label statement shall appear in capital letters and the area of the circle and arrow shall be determined by the Federal Trade Commission.

[(c) LABEL DISPLAY.—The Federal Trade Commission shall issue regulations requiring each label statement required by subsection (a) to—

[(1) in the case of a smokeless tobacco product package, be randomly displayed by each manufacturer, packager, or importer of a smokeless tobacco product in each 12-month period in as equal a number of times as is possible on each brand of the product and be randomly distributed in all parts of the United States in which such product is marketed, and

[(2) in the case of any advertisement of a smokeless tobacco product, be rotated every 4 months by each manufacturer, packager, or importer of a smokeless tobacco product in an alternating sequence in the advertisement for each brand of the product.

[(d) PLAN.—(1) Each manufacturer, packager, or importer of a smokeless tobacco product shall submit a plan to the Federal Trade Commission which specifies the method such manufacturer, packager, or importer will use to rotate, display, and distribute the statements required by subsection (a) in accordance with the requirements of subsections (b) and (c).

[(2) The Federal Trade Commission shall approve a plan submitted by a manufacturer, packager, or importer of a smokeless tobacco product under paragraph (1) if such plan provides for the rotation, display, and distribution on smokeless tobacco product packages and advertisements of the statements required by subsection (a) in a manner which complies with this section and the regulations promulgated pursuant to this section.

[(e) APPLICATION.—This section does not apply to a distributor or a retailer of any smokeless tobacco product which does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

[(f) TELEVISION AND RADIO ADVERTISING.—Effective 6 months after the date of the enactment of this Act, it shall be unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.]

SEC. 3. SMOKELESS TOBACCO WARNING.

(a) GENERAL RULE.—

(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

WARNING: This product can cause mouth cancer.

WARNING: This product can cause gum disease and tooth loss.

WARNING: This product is not a safe alternative to cigarettes.

WARNING: Smokeless tobacco is addictive.

(2) Each label statement required by paragraph (1) shall be—

(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 30 percent of each such display panel; and

(B) in 17-point conspicuous and legible type and in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

(5) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that—

(A) contains a warning label;

(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

(b) REQUIRED LABELS.—

(1) It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

(2)(A) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

(B) For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement.

(C) The word "WARNING" shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

(D) The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

(E) The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital "W" of the word "WARNING" in the label statements.

(F) The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement.

(G) The label statements shall be in English, except that—

(i) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

(ii) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

(C) The Secretary shall review each plan submitted under subparagraphs (A) and (B) and approve it if the plan—

(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection.

(4) The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

* * * * * * *

SEC. 7. PREEMPTION.

(a) FEDERAL ACTION.—[No] *Except as provided in the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), no* statement relating to the use of smokeless tobacco products and health, other than the statements required by section 3, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

* * * * * * *

TITLE 5, UNITED STATES CODE

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PART III—EMPLOYEES

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SUBPART G—INSURANCE AND ANNUITIES

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CHAPTER 84—FEDERAL EMPLOYEES' RETIREMENT SYSTEM

Sec
8401. Definitions.

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SUBCHAPTER III—THRIFT SAVINGS PLAN

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8432d. Qualified Roth contribution program.

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SUBCHAPTER II—BASIC ANNUITY

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§ 8415. Computation of basic annuity

(a) * * *

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[(k)**]** *(l)(1)* In computing an annuity under this subchapter, the total service of an employee who retires from the position of a registered nurse with the Veterans Health Administration on an immediate annuity, or dies while employed in that position leaving any survivor entitled to an annuity, includes the days of unused sick leave to the credit of that employee under a formal leave system, except that such days shall not be counted in determining average pay or annuity eligibility under this subchapter.

(2) Except as provided in paragraph (1), in computing an annuity under this subchapter, the total service of an employee who retires on an immediate annuity or who dies leaving a survivor or survivors entitled to annuity includes the days of unused sick leave to his credit under a formal leave system, except that these days will not be counted in determining average pay or annuity eligibility under this subchapter. For purposes of this subsection, in the case of any such employee who is excepted from subchapter I of chapter 63 under section 6301(2)(x)-(xiii), the days of unused sick leave to his credit include any unused sick leave standing to his credit when he was excepted from such subchapter.

[(l)**]** *(m)* In the case of any annuity computation under this section that includes, in the aggregate, at least 2 months of credit under section 8411(d) for any period while receiving benefits under subchapter I of chapter 81, the percentage otherwise applicable under this section for that period so credited shall be increased by 1 percentage point.

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§ 8422. Deductions from pay; contributions for other service

(a) * * *

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(d)(1) * * *

(2) Deposit may not be required for days of unused sick leave credited under [section 8415(k)] *paragraph (1) or (2) of section 8415(l)*.

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SUBCHAPTER III—THRIFT SAVINGS PLAN

* * * * * * *

§ 8432. Contributions

(a) * * *

(b)(1)(A) * * *

(B) The amount to be contributed pursuant to an election under subparagraph (A) [(or any election allowable by virtue of paragraph (4))] shall be the percentage of basic pay or amount designated by the employee or Member.

[(2) Under the regulations—

[(A) an employee or Member who has not previously been eligible to make an election under this subsection shall not become so eligible until the date (described in paragraph (1)) beginning after the date of commencing service as an employee or Member;

[(B) an employee or Member whose appointment or election to a position or office in the Federal Government follows a previous period of service during which that individual met the requirements of subparagraph (A) shall be eligible to make an election under this subsection notwithstanding any period of separation;

[(C) an employee or Member who elects under subparagraph (D) to terminate contributions shall not again become eligible to make an election under this subsection until the date (described in paragraph (1)) commencing after the election to terminate; and

[(D) an election to terminate may be made under this subparagraph at any time as provided under paragraph (1).

[(3) An employee or Member who elects to become subject to this chapter under section 301 of the Federal Employees' Retirement System Act of 1986 may make the first election for the purpose of subsection (a) during the period prescribed for such purpose by the Executive Director. The period prescribed by the Executive Director shall commence on the date on which the employee or Member makes the election to become subject to this chapter.

[(4) The Executive Director shall prescribe such regulations as may be necessary to carry out the following:

[(A) Notwithstanding subparagraph (A) of paragraph (2), an employee or Member described in such subparagraph shall be afforded a reasonable opportunity to first make an election under this subsection beginning on the date of commencing service or, if that is not administratively feasible, beginning on the earliest date thereafter that such an election becomes ad-

ministratively feasible, as determined by the Executive Director.

[(B) An employee or Member described in subparagraph (B) of paragraph (2) shall be afforded a reasonable opportunity to first make an election under this subsection (based on the appointment or election described in such subparagraph) beginning on the date of commencing service pursuant to such appointment or election or, if that is not administratively feasible, beginning on the earliest date thereafter that such an election becomes administratively feasible, as determined by the Executive Director.

[(C)(i) Notwithstanding the preceding provisions of this paragraph, contributions under paragraphs (1) and (2) of subsection (c) shall not be payable with respect to any pay period before the earliest pay period for which such contributions would otherwise be allowable under this subsection if this paragraph had not been enacted.

[(ii) Notwithstanding subparagraph (A) or (B), contributions under paragraphs (1) and (2) of subsection (c) shall not begin to be made with respect to an employee or Member described under paragraph (2)(A) or (B) until the date that such contributions would have begun to be made in accordance with this paragraph as administered on the date preceding the date of enactment of the Thrift Savings Plan Open Elections Act of 2004.

[(D) Sections 8351(a)(2), 8440a(a)(2), 8440b(a)(2), 8440c(a)(2), and 8440d(a)(2) shall be applied in a manner consistent with the purposes of subparagraphs (A) and (B), to the extent those subparagraphs can be applied with respect thereto.

[(E) Nothing in this paragraph shall affect paragraph (3).]

(2)(A) The Board shall by regulation provide for an eligible individual to be automatically enrolled to make contributions under subsection (a) at the default percentage of basic pay.

(B) For purposes of this paragraph, the default percentage shall be equal to 3 percent or such other percentage, not less than 2 percent nor more than 5 percent, as the Board may by regulation prescribe.

(C) The regulations shall include provisions under which any individual who would otherwise be automatically enrolled in accordance with subparagraph (A) may—

(i) modify the percentage or amount to be contributed pursuant to automatic enrollment, effective from the start of such enrollment; or

(ii) decline automatic enrollment altogether.

(D) For purposes of this paragraph, the term "eligible individual" means any individual who, after any regulations under subparagraph (A) first take effect, is appointed, transferred, or reappointed to a position in which that individual is eligible to contribute to the Thrift Savings Fund.

(E) Sections 8351(a)(1), 8440a(a)(1), 8440b(a)(1), 8440c(a)(1), 8440d(a)(1), and 8440e(a)(1) shall be applied in a manner consistent with the purposes of this paragraph.

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§ 8432d. Qualified Roth contribution program

(a) DEFINITIONS.—For purposes of this section—

(1) the term "qualified Roth contribution program" means a program described in paragraph (1) of section 402A(b) of the Internal Revenue Code of 1986 which meets the requirements of paragraph (2) of such section; and

(2) the terms "designated Roth contribution" and "elective deferral" have the meanings given such terms in section 402A of the Internal Revenue Code of 1986.

(b) AUTHORITY TO ESTABLISH.—The Board shall by regulation provide for the inclusion in the Thrift Savings Plan of a qualified Roth contribution program, under such terms and conditions as the Board may prescribe.

(c) REQUIRED PROVISIONS.—The regulations under subsection (b) shall include—

(1) provisions under which an election to make designated Roth contributions may be made—

(A) by any individual who is eligible to make contributions under section 8351, 8432(a), 8440a, 8440b, 8440c, 8440d, or 8440e; and

(B) by any individual, not described in subparagraph (A), who is otherwise eligible to make elective deferrals under the Thrift Savings Plan;

(2) any provisions which may, as a result of enactment of this section, be necessary in order to clarify the meaning of any reference to an "account" made in section 8432(f), 8433, 8434(d), 8435, 8437, or any other provision of law; and

(3) any other provisions which may be necessary to carry out this section.

* * * * * * *

§ 8438. Investment of Thrift Savings Fund

(a) * * *

(b)(1) The Board shall establish—

(A) * * *

* * * * * * *

(D) a Small Capitalization Stock Index Investment Fund as provided in paragraph (3); **[**and**]**

(E) an International Stock Index Investment Fund as provided in paragraph (4)**[**.**]***; and*

(F) a self-directed investment window, if the Board authorizes such window under paragraph (5).

* * * * * * *

(5)(A) The Board may authorize the addition of a self-directed investment window under the Thrift Savings Plan if the Board determines that such addition would be in the best interests of participants.

(B) The self-directed investment window shall be limited to—

(i) low-cost, passively-managed index funds that offer diversification benefits; and

(ii) other investment options, if the Board determines the options to be appropriate retirement investment vehicles for participants.

(C) The Board shall ensure that any administrative expenses related to use of the self-directed investment window are borne solely by the participants who use such window.

(D) The Board may establish such other terms and conditions for the self-directed investment window as the Board considers appropriate to protect the interests of participants, including requirements relating to risk disclosure.

(E) The Board shall consult with the Employee Thrift Advisory Council (established under section 8473) before establishing any self-directed investment window.

* * * * * * *

§ 8439. Accounting and information

(a) * * *

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[(d)**]** *(d)(1)* Each employee, Member, former employee, or former Member who elects to invest in **[**the Common Stock Index Investment Fund, the Fixed Income Investment Fund, the International Stock Index Investment Fund, or the Small Capitalization Stock Index Investment Fund, defined in paragraphs (1), (3), (5), and (10), respectively, of section 8438(a) of this title**]** *any investment fund or option under this chapter, other than the Government Securities Investment Fund,* shall sign an acknowledgement prescribed by the Executive Director which states that the employee, Member, former employee, or former Member understands that an investment in **[**either such Fund**]** *any such fund or option* is made at the employee's, Member's, former employee's, or former Member's risk, that the employee, Member, former employee, or former Member is not protected by the Government against any loss on such investment, and that a return on such investment is not guaranteed by the Government.

(2)(A) In the case of an investment made under section 8438(c)(2) in any fund or option to which paragraph (1) would otherwise apply, the participant involved shall, for purposes of this subsection, be deemed—

(i) to have elected to invest in such fund or option; and

(ii) to have executed the acknowledgement required under paragraph (1).

(B)(i) The Executive Director shall prescribe regulations under which written notice shall be provided to a participant whenever an investment is made under section 8438(c)(2)(B) on behalf of such participant in the absence of an affirmative election described in section 8438(c)(1).

(ii) The regulations shall ensure that any such notice shall be provided to the participant within 7 calendar days after the effective date of the default election.

(C) For purposes of this paragraph, the term "participant" has the meaning given such term by section 8471(3).

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SUBCHAPTER VII—FEDERAL RETIREMENT THRIFT INVESTMENT MANAGEMENT SYSTEM

* * * * * * *

§ 8477. Fiduciary responsibilities; liability and penalties

(a) * * *

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(e)(1)(A) * * *

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(C)*(i)* A fiduciary shall not be liable under subparagraph (A) with respect to a breach of fiduciary duty under subsection (b) committed before becoming a fiduciary or after ceasing to be a fiduciary.

(ii) A fiduciary shall not be liable under subparagraph (A), and no civil action may be brought against a fiduciary—

(I) for providing for the automatic enrollment of a participant in accordance with section 8432(b)(2)(A);

(II) for enrolling a participant in a default investment fund in accordance with section 8438(c)(2)(B); or

(III) for allowing a participant to invest through the self-directed investment window or for establishing restrictions applicable to participants' ability to invest through the self-directed investment window.

* * * * * * *

DISSENTING VIEWS

Forcing the Food and Drug Administration (FDA) to regulate tobacco products—products that will never qualify as "safe and effective"—could have significant negative impacts on all Americans. This Committee has spent a great deal of time investigating the ways in which the FDA has been unable to fulfill its core mission. Therefore, we are concerned that burdening the FDA with added responsibilities outside of the agency's expertise and core missions at this time will have dire consequences for the American people and the FDA's ability to ensure the safety and efficacy of our nation's food, drugs, and medical devices. We are also concerned that effectively giving the FDA stamp of approval on cigarettes will improperly lead people to believe these products are safer than they truly are.

H.R. 1256 also allows the use of FDA general funds for "startup costs" associated with the bill's new tobacco regulation activities. The bill allows the FDA to divert resources from its core mission, including funds from food safety inspections and drug and device approvals. While the bill specifies these funds must be reimbursed by manufacturer user fees, it does not provide a timeline for reimbursement, further straining FDA's limited resources. Regardless of how quickly FDA is able to collect manufacturer user fees, the bill requires use of general funds for tobacco startup costs for at least six months. Depending on the timing of user fee collection, additional resources would have to be diverted from FDA general funds as the agency awaits annual appropriations. At a time when FDA is struggling to perform many of its core functions, diversion of its limited resources will negatively impact the safety of the American public.

In order to rectify the concerns about H.R. 1256 outlined below, the Committee considered a substitute amendment offered by Congressman Steve Buyer to establish the Tobacco Harm Reduction Center under the Department of Health and Human Services (HHS). The substitute would have protected the already overburdened FDA from carrying out significant new tobacco regulations. The substitute was based on public health policies that acknowledge a continuum of risk among all tobacco products and referenced scientific literature which shows that smokeless tobacco products are 90–99% less hazardous than cigarettes in their risk of causing tobacco-related illness and death. The substitute would have ensured adult tobacco users are given complete, accurate and truthful information about the risks and relative risks of all tobacco products so that they can make informed health decisions. The substitute incentivized the development of reduced-risk tobacco products. Additionally, the substitute expressly prohibited regulations affecting tobacco growers, strengthened preventions against minors' tobacco use, was funded through the normal appropriations

process instead of new user fees, and protected American jobs. All Republican members present at the markup voted in favor of this substitute.

H.R. 1256 purports to utilize a science-based approach to the regulation of tobacco products but ignores accepted scientific evidence that harm reduction strategies for moving people to less dangerous tobacco products will in fact lead to lower incidences of smoking-related illnesses. This is especially troublesome given the legislation's lack of incentives for States to use Master Settlement funds for smoking cessation and other public health programs.

If enacted, this legislation significantly curtails, if not entirely eliminates, incentives to develop and market products that reduce exposure to tobacco toxicants. In order to obtain approval of a modified-risk product, an applicant must demonstrate that the marketing and labeling of the product will not mislead consumers into believing that the product is or has been demonstrated to be less harmful. Further, it has to be demonstrated that the product reduces risk for both the individual and for the population as a whole. It is unlikely that such a standard could ever be proven. The legislation provides no incentives to manufacturers to research and develop reduced-risk products, and the requirement forcing companies to turn over all research to the FDA—whether used in reduced-risk product development or not—is a significant hindrance to the development of modified-risk products.

The standard for approval of modified-risk products is unclear in H.R. 1256, which will create, at best, ambiguities for applicants in the standards that must be met or, at worst, product standards that can never be achieved, thus eliminating modified-risk products coming to market. We are concerned that such disincentives will effectively freeze the current tobacco market and prevent innovation which could lead to significantly less harmful tobacco products and improve our nation's health.

It is important to note that in 2001 the Institute of Medicine noted, "The potential for reduction in morbidity and mortality that could result from the use of less toxic products by those who do not stop using tobacco justifies inclusion of harm reduction as a component in a broad program of tobacco control."

Additionally, the Royal College of Physicians has stated, "The fundamental argument of this report is that this current situation is perverse, unjust, and acts against the rights and best interests of smokers and the public health. Harm reduction has the potential to play a major part in preventing death and disability in the millions of people who currently smoke and who, in the context of exposure to currently available drivers and supports to cessation, either cannot or will not otherwise quit smoking. These smokers have a right to be able to obtain and choose from a range of safer nicotine products, and they have a right to accurate and unbiased information to guide that choice."

The American Association of Public Health Physicians wrote on March 3, 2009, in regard to H.R. 1256, "the current bill [H.R. 1256], in its current form, would assure current levels of tobacco-related deaths while doing nothing of significance to reduce the number of teens who would initiate tobacco use with no bill at all."

We are also opposed to the annual tax assessments placed on manufacturers. If Congress deems this regulation necessary for the protection of the public health then it should be important enough to appropriate funds for these activities. Manufacturers will be assessed $712 million by 2018. Claiming that a tax is a user fee does not change the fact that it is a tax. This is a dangerous precedent that grows the size of government and taxes the American people through secrecy and synonyms.

H.R. 1256 will limit competition and provide essentially a monopoly to the largest companies operating today. In doing so, smaller companies will be denied competitive opportunities within the market because the barriers to entry are just too high. This legislation has the unintended consequence of creating monopolies within the market. Section 906 could allow the FDA to create a virtual monopoly in the tobacco market by creating tobacco product standards that only a few of the well-capitalized companies have the resources to achieve. The regressive nature of excise taxes, as well as the price increases that accompany monopolistic behavior, will impact low-income Americans the hardest.

If the FDA is forced to regulate tobacco products, this legislation calls for the immediate codification of regulations that were drafted over twelve years ago. The regulations issued in 1996 were promulgated under the premise that cigarettes were medical devices. H.R. 1256 would not regulate cigarettes as medical devices but rather creates a new category of tobacco products with separate regulatory requirements. Since 1996, the Master Settlement Agreement has been executed and various other State regulations have been enacted with respect to marketing, advertising, and tobacco use. We believe that it is poor public policy to not revisit the regulations and take the time to better understand the current regulations those manufacturers are operating under and then update the language as necessary.

We also believe that the marketing provisions of H.R. 1256 are violative of the First Amendment. Section 102 of the bill directs the Secretary of Health and Human Services to publish an interim final rule that is "identical in its provisions" to the proposed rule promulgated by the FDA in 1996. Numerous legal experts have stated that the broad restrictions in that proposal are in effect a de facto ban on tobacco advertising, and violate the First Amendment. In fact, the U.S. Supreme Court held in *Lorillard Tobacco Co.* v. *Thomas Reilly, Attorney General of Massachusetts,* 533 U.S. 525 (2001) that a Massachusetts tobacco regulation that was virtually identical to one part of the FDA 1996 proposal was unconstitutional.

The effect of the various provisions in H.R. 1256 is a suspension of the ability to advertise tobacco products to adults, violating the First Amendment protections for commercial speech. The U.S. Supreme Court has emphasized repeatedly, including the landmark Central Hudson case, *Central Hudson Gas & Electric* v. *Public Service Commission*, 447 U.S. 557 (1980) that truthful, nondeceptive commercial speech cannot be banned or restricted unless the restriction "directly and materially advances" a "substantial governmental interest" and is "narrowly tailored" to "reasonably fit" that interest.

Finding 30 in the legislation states that the final regulations issued on August 20, 1996, are consistent with the First Amendment. Finding 31 states the regulations described in Finding 30 "will directly and materially advance the federal government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use."

These findings attempt to address the Constitutional test of the Supreme Court for determining if restrictions on commercial speech violate the First Amendment. One prong of the test is the restriction must be to advance a compelling government interest. The test also has a prong that states the restrictions be "narrowly tailored" to "reasonably fit" that interest. Finding 31 states that "less restricting and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations." Again, the authors of the bill try to preempt Constitutional questions regarding the legislation by reciting findings designed to answer the Constitutional test for restricting free speech. However, Finding 31 is not based in fact and clearly ignores the fact that youth smoking has declined dramatically since the Master Settlement Agreement. A 2006 University of Michigan study has shown youth smoking rates have declined from over 28% in 1997 to less than 15% in 2006. Additionally, the rate of youths able to purchase cigarettes in stores has dropped dramatically since the imposition of the Synar Amendment in 1996.

It is important to note that aside from the bill's findings, H.R. 1256 does not include any other provisions designed to protect minors from tobacco use. Many members of the Committee would have supported further steps to require States to use more of their Master Settlement Agreement funds to combat underage smoking and promote smoking cessation while also strengthening the Synar Amendment on the underage purchasing of cigarettes. Such steps would have been narrowly tailored to achieve the government interest without imposing clearly unconstitutional restrictions of First Amendment rights. In addition to these provisions being narrowly tailored, they would have also proved much more effective in addressing youth smoking rates and helping people to quit smoking. Unfortunately, H.R. 1256 was drafted in a manner that would have made such amendments non-germane during Committee consideration of the legislation.

The Majority understands the violative nature of many of the provisions in the legislation and thus included a severability clause to allow some parts of the bill to stand with the presumption that others would be struck down by the courts. In fact, in the Lorillard case, the Supreme Court struck down a regulation promulgated by the Attorney General of Massachusetts that was similar in many respects to the FDA's proposed rule. The Massachusetts regulation banned outdoor ads within 1,000 feet of schools, parks and playgrounds and also restricted point-of-sale advertising for tobacco products.

In finding that the Massachusetts regulation was not narrowly tailored, Justice Sandra Day O'Connor actually noted a similar problem with the FDA regulation:

> First, the Attorney General did not seem to consider the impact of the 1,000-foot restriction on commercial speech in major metropolitan areas. The Attorney General apparently selected the 1,000-foot distance based on the FDA's decision to impose an identical 1,000-foot restriction when it attempted to regulate cigarette and smokeless tobacco advertising. The FDA's regulations would have had widely disparate effects nationwide. Even in Massachusetts, the effect of the Attorney General's speech regulations will vary based on whether a locale is rural, suburban, or urban. The uniformly broad sweep of the geographical limitation demonstrates a lack of tailoring.

In more recent commercial speech cases, the Supreme Court has substantially raised the bar government regulators need to hurdle to impose restrictions on advertising. Justice O'Connor, speaking for the majority of the Court, for example, in *Thompson* v. *Western States Medical Center*, 535 U.S. 357 (2002), stated, "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort."

The government has a legitimate interest in protecting minors from the use of tobacco products. The proposed advertising regulations in H.R. 1256, however, are overbroad and impermissibly restrictive. They are clearly unconstitutional.

Additionally, we remain concerned about provisions in H.R. 1256 which will affect our nation's tobacco growers. While the bill purports to have no effect on tobacco growers, regulation regarding leaf cultivation and curing are inevitable under the bill and might lead the FDA to require tobacco manufacturers to buy only certain types of tobacco which are grown or cured in specific ways. Pesticide provisions in H.R. 1256 could also increase farmers' fixed costs and increase liability exposure. FDA and EPA will impose regulations on what pesticides can be used, how much can be used, and when they can be applied. This will be true of imported and domestic leaf, and the requirements can be initiated at the FDA's discretion. The bill leaves significant uncertainty concerning future pesticide requirements to which tobacco growers will be subject. H.R. 1256 also gives FDA the authority to regulate product blends and product design which will indirectly affect growers by requiring tobacco manufacturers to regulate all aspects of the growing and curing of tobacco in order to produce ingredients that are satisfactory to FDA.

H.R. 1256 also includes significant inconsistencies with regard to the treatment of tobacco exports. In Section 103, the bill amends Section 801(e)(1) of the Food, Drug and Cosmetic Act (FDCA) by adding the words "tobacco product" and in doing so exempts tobacco products from the requirements of H.R. 1256. However, Section 103 contains a handful of other amendments to Section 301 of the FDCA that could bring exports back within the jurisdiction of the FDA for violating certain sections of the bill. For example, in Section 103(a)(10), the bill states that it would be a violation of H.R. 1256 if a manufacturer did not comply with tobacco product standards set forth in Section 907 of the FDCA. This provision arguably puts exports under the same product standards applicable to domestic and imported tobacco products. Additionally, the fol-

lowing sections may also be applicable to tobacco exports: use of tobacco product warnings; ingredient, nicotine, and constituent reporting; general provisions respecting control of tobacco products; notification and other remedies; records and reports on tobacco products; modified-risk products; preservation of State and local authority; and tracking and tracing regulations.

In the absence of proper Committee evaluation of H.R. 1256 and without the stated concerns addressed, we oppose the legislation.

Sincerely,

JOE BARTON,
Ranking Member, Committee on Energy and Commerce.
NATHAN DEAL,
Ranking Member, Subcommittee on Health.
STEVE BUYER.
JOSEPH R. PITTS.
MIKE ROGERS.
JOHN SULLIVAN.
MICHAEL C. BURGESS.
MARSHA BLACKBURN.
STEVE SCALISE.

ADDITIONAL DISSENTING VIEWS

The incapacity of the FDA to fully implement their current responsibilities is without question. Over 16 hearings on FDA related matters alone came before this committee's Oversight and Investigations Subcommittee on the 110th Congress, and already in the 111th we have held a hearing on the ineffectiveness of CFSAN and their roles in food safety outbreaks. Now, we as a Committee are proposing to advance a bill to give to the FDA one of the largest increases in regulatory power by allowing their control over an inherently dangerous product like tobacco.

In should be intuitively obvious to the casual observer this action would be both illogical and harmful. The FDA's resources are already strained given the agency's current mission intersecting with the rapid changes in the global marketplace. More and more supervision is required of the drugs and medical device departments simply by the sheer increase in volume—as opposed to deleterious actions by individual bad actors—not to mention the need for FDA to have more supervision in their other departments as well.

Furthermore, even if we were to concede that the FDA should regulate tobacco—which we clearly do not—it is extremely hypocritical to allow a science-based agency like the FDA to regulate this inherently dangerous drug without giving to them the power and ability to take nicotine levels down to zero milligrams. Under the bill language as it currently stands, the FDA could take nicotine levels down to 0.00000001—or any number just short of absolutely zero milligrams of nicotine—but the FDA can not take the level of nicotine all the way to zero. This is hypocritical. If we are truly concerned with the marketing and manufacturing of the safety and efficacy of this inherently dangerous drug is scientifically measured, then we should allow the FDA's evidence-based review to determine whether science requires a mandate of zero milligrams of nicotine in cigarettes. Any handicapping of scientific review by a body who is not inherently scientific—such as Congress—makes no sense.

Sincerely,

MICHAEL C. BURGESS.

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