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H.R.1256

Title: To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.

Sponsor: [Rep Waxman, Henry A.](#) [CA-30] (introduced 3/3/2009) [Cosponsors](#) (178)

Related Bills: [H.RES.307](#), [H.RES.532](#), [S.982](#)

Latest Major Action: Became Public Law No: 111-31 [GPO: [Text](#), [PDF](#)]

House Reports: [111-58](#) Part 1, [111-58](#) Part 2

SUMMARY AS OF:

6/11/2009--Passed Senate amended. (There are 4 [other summaries](#))

Division A: Family Smoking Prevention and Tobacco Control Act - Family Smoking Prevention and Tobacco Control Act - **Title I: Authority of the Food and Drug Administration** - (Sec. 101) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to provide for the regulation of tobacco products by the Secretary of Health and Human Services through the Food and Drug Administration (FDA).

Defines a tobacco product as any product made or derived from tobacco that is intended for human consumption. Prohibits a tobacco product from being marketed in combination with any other article or product regulated under FFDCA. Requires the Secretary to regulate tobacco products. Excludes from FDA authority: (1) the tobacco leaf that is not in the possession of a tobacco product manufacturer; (2) the producers of the tobacco leaf, unless the producer is also a manufacturer; and (3) tobacco farms.

Directs the Secretary to establish within FDA: (1) the Center for Tobacco Products to implement this Act; and (2) an identifiable office to provide technical and other nonfinancial assistance to assist small tobacco product manufacturers in complying with this Act.

Deems a tobacco product to be adulterated if: (1) it contains any filthy, putrid, or decomposed substance or is contaminated by any added poisonous or deleterious substance that may render the product injurious to health; (2) it has been prepared, packed, or held under unsanitary conditions; (3) its package is composed of any poisonous or deleterious substance; (4) the manufacturer or importer of the product fails to pay the assessed user fee; (5) it fails to meet specified tobacco product standards; (6) it does not have required premarket review; (7) it fails to meet applicable requirements or conditions on manufacturing, packing, or storage; or (8) it fails to conform to requirements for modified risk tobacco products.

Deems a tobacco product to be misbranded if: (1) its labeling, packaging, or advertising contains any false or misleading information; (2) its label or advertising

fails to contain all required information displayed prominently and conspicuously, including its established name, manufacturer, and contents and adequate directions and warnings; (3) it was manufactured, prepared, or processed in an establishment not registered with the Secretary; or (4) there is any failure to submit the required information or notices to the Secretary. Allows the Secretary to require prior approval of all label statements on tobacco products to ensure that such statements: (1) do not violate misbranding provisions; and (2) comply with other provisions of this Act.

Requires tobacco product manufacturers or importers to submit to the Secretary: (1) a listing of all ingredients, including ingredients added by the manufacturer to the tobacco, paper, or filter, by brand and quantity; (2) a description of the content, delivery, and form of nicotine in each tobacco product; (3) a listing of all constituents, including smoke constituents, identified by the Secretary as harmful or potentially harmful to health in each tobacco product; and (4) all documents developed that relate to the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents, ingredients, components, and additives.

Allows the Secretary to request additional information from a tobacco product manufacturer or importer relating to: (1) research activities or findings on the effects of tobacco products and their constituents and on whether the health risk can be reduced if the manufacturer employs known or available technology; and (2) marketing research or practices used by manufacturers or distributors.

Sets forth notifications that manufacturers must make to the Secretary regarding any change in a tobacco product.

Requires the Secretary to publicly display and annually publish a list (that is understandable and not misleading to a lay person) of harmful or potentially harmful constituents in each tobacco product by brand and quantity.

Requires owners and operators of establishments in the United States engaged in the manufacture, preparation, compounding, or processing of a tobacco product to register annually with the Secretary. Allows the Secretary to prescribe a uniform system for the identification of tobacco products, which registrants must use. Requires the Secretary to make such registration information available to the public and to inspect registered establishments every two years.

Requires foreign establishments to register and ensure that adequate and effective means are available to determine whether their tobacco products conform with FFDC requirements.

Prohibits the disclosure of privileged or confidential trade secrets and commercial financial information that is obtained by the Secretary.

Allows the Secretary to restrict: (1) the sale or distribution of tobacco products if appropriate for the protection of the public health; and (2) the advertising and promotion of tobacco products consistent with, and to the full extent permitted by,

the First Amendment. Prohibits restrictions that: (1) limit the sale or distribution of a tobacco product to written or oral authorization by a practitioner licensed to prescribe medicine; (2) prohibit the sale of a tobacco product in face-to-face transactions by a specific category of retail outlets; or (3) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

Requires the Secretary to promulgate regulations to prevent the sale and distribution of tobacco products to minors through means other than a direct, face-to-face exchange between a retailer and a consumer.

Directs the Secretary to prescribe regulations to protect the public health and assure that tobacco products are in compliance with this Act by requiring good manufacturing practices or hazard analysis and critical control point methodology. Requires the Secretary to: (1) provide a reasonable period for manufacturers to conform to good manufacturing practices; and (2) not require any small tobacco product manufacturer to comply with such regulations for at least four years. Allows the Secretary to grant exemptions and variances from such regulations under certain circumstances.

Allows the Secretary to enter into contracts for research, testing, and demonstrations respecting tobacco products and to obtain tobacco products for such purposes.

Prohibits a cigarette or any of its components from containing as a constituent or additive any artificial or natural flavor (other than tobacco or menthol) or any herb or spice (including strawberry, grape, orange, clove, cinnamon, and vanilla) that is a characterizing flavor of the tobacco product or tobacco smoke. Prohibits a tobacco product manufacturer from using tobacco, including foreign grown tobacco, that contains a pesticide chemical residue at a level greater than any tolerance applicable to domestically grown tobacco. Allows the Secretary to adopt additional tobacco product standards as appropriate to protect the public health, which may include standards for: (1) reducing nicotine yields; (2) reducing or eliminating other constituents or harmful components; and (3) product testing. Allows the Secretary to amend or revoke a tobacco product standard.

Prohibits the Secretary from: (1) 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 (2) requiring the reduction of nicotine yields of a tobacco product to zero.

Requires the Secretary to refer to the Tobacco Products Scientific Advisory Committee for report and recommendation the issues of: (1) the impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics, and other racial and ethnic minorities; and (2) the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children.

Allows the Secretary to notify the public if a tobacco product poses an unreasonable risk of substantial harm to the public health. Requires the Secretary to order a cease in distribution and a recall (after a hearing) of a tobacco product if there is a reasonable probability that it contains a defect not ordinarily contained in tobacco products that would cause serious, adverse health consequences or death.

Requires manufacturers and importers to comply with record keeping and reporting requirements established by the Secretary, such as informing the Secretary of any information that reasonably suggests that a marketed tobacco product may have caused or contributed to a serious unexpected adverse experience. Prohibits the Secretary from: (1) imposing unduly burdensome requirements; or (2) requiring that the identity of any patient or user be disclosed unless required for the medical welfare of an individual, to determine risks to the public health, or to verify information. Requires the Secretary to have due regard for the ethics of the medical profession.

Directs the Secretary to require prompt notification by manufacturers and importers of any corrective action taken or any removal from the market of a tobacco product to reduce a health risk posed by the product or to remedy a violation of this Act that may present such a risk.

Requires premarket approval of all new tobacco products (products not substantially equivalent to an existing tobacco product) commercially marketed after February 15, 2007. Defines "substantially equivalent" as having the same characteristics or having different characteristics but not raising different questions of public health.

Sets forth an application process for premarket approval of a new tobacco product, including health information that must be included. Authorizes the Secretary to: (1) allow, prohibit, or restrict distribution of such a tobacco product; and (2) temporarily suspend an application if the probability that continued distribution would cause serious, adverse health consequences or death is greater than that for tobacco products on the market.

Prohibits the sale of any modified risk tobacco product unless an order is issued by the Secretary. Defines a "modified risk tobacco product" as any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related diseases associated with commercially marketed tobacco products, specifically products where: (1) the labeling or advertising represents that the product presents a lower risk of tobacco-related disease or is less harmful than other tobacco products, contains a reduced level of or presents a reduced exposure to a substance, or is free of a substance; (2) the labeling or advertising uses descriptors such as "light," "mild," or "low"; or (3) the product manufacturer has taken action reasonably expected to result in consumers believing that the product or its smoke presents a lower risk of disease, is less harmful, presents a reduced exposure, or is free of a substance.

Sets forth requirements for filing with the Secretary an application for a modified risk tobacco product.

Directs the Secretary to issue an order that a modified risk tobacco product may be commercially marketed only if the Secretary determines that an applicant has demonstrated that such product, as it is actually used by consumers, will: (1) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (2) benefit the health of the population as a whole including users and nonusers of tobacco.

Allows the Secretary to issue an order allowing the sale of a tobacco product that may not be commercially marketed as a modified risk tobacco product for five years if certain requirements are met, including that: (1) such order would be appropriate to promote the public health; and (2) issuing such an order is expected to benefit the health of the population as a whole.

Requires the Secretary to require that advertising and labeling concerning modified risk tobacco products enable the public to understand the information and its significance 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.

Directs the Secretary to require that the results of postmarket surveillance and studies on modified risk tobacco products be submitted annually.

Sets forth procedures for the withdrawal of an order allowing commercial distribution of a modified risk tobacco product.

Prohibits distributors from taking any action that would reasonably be expected to result in consumers believing that a tobacco product or its smoke may present a lower risk of disease or is less harmful than other tobacco products.

Sets forth provisions regarding the judicial review of regulations and denied applications for new tobacco products.

Requires the Secretary to require retail establishments for which the predominant business is the sale of tobacco products to comply with advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

Deems any violation of this Act pertaining to advertising to be an unfair or deceptive act or practice under the Federal Trade Commission (FTC) Act. Requires the Chairman of FTC to coordinate with the Secretary concerning enforcement of the FTC Act for the advertisement of cigarettes or smokeless tobacco. Requires the Secretary to consult with the Chairman in revising the label statements and requirements for tobacco products under the FTC Act.

Requires the Secretary, acting through the Commissioner of FDA, to promulgate regulations under this Act within two years that require the testing and reporting of

tobacco product constituents, ingredients, and additives that the Secretary determines should be tested to protect the public health. Gives the Secretary the authority to conduct or require the testing, reporting, or disclosure of tobacco product constituents.

Delays the imposition of such testing regulations on small tobacco product manufacturers. Allows additional such delays under certain circumstances. Sets forth provisions governing testing by such manufacturers.

Declares that this Act does not: (1) prohibit federal agencies, states, political subdivisions, or Indian tribes from enacting additional or more stringent measures, except requirements relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products; (2) prohibit state, tribal, or local taxation of tobacco products; and (3) modify or affect the liability of any person under the product liability laws of any state.

Requires the Secretary to establish a Tobacco Products Scientific Advisory Committee to provide advice, information, and recommendations to the Secretary, including on the effects of altering nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved.

Requires the Secretary to consider: (1) designating products for smoking cessation, including nicotine replacement products, as fast track research and approval products; (2) approving the extended use of nicotine replacement products for the treatment of tobacco dependence; and (3) evidence for additional indications for such products.

Directs the Secretary to report to Congress on how best to regulate, promote, and encourage the development of innovative products and treatments to better achieve, in a manner that best protects and promotes the public health: (1) total abstinence from tobacco use; (2) reductions in consumption of tobacco; and (3) reductions in the harm associated with continued tobacco use.

Requires the Secretary to assess a quarterly user fee on manufacturers and importers of tobacco products based on the class of tobacco product and the company market share to pay for the costs of tobacco regulation activities. Requires that FDA funds (excluding user fees) used before October 1, 2009, on such activities be reimbursed.

(Sec. 102) Requires the Secretary to publish a final rule regarding cigarettes and smokeless tobacco that is identical to regulations promulgated by the Secretary on August 28, 1996, that set out restrictions under FFDCA on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine, except for labeling requirements. Sets forth provisions governing the distribution of free samples of cigarettes, smokeless tobacco, or other tobacco products. Limits the

effect of specified advisory opinions and prohibits the Secretary and FDA from citing them as binding precedent.

(Sec. 103) Adds tobacco related violations to the list of prohibited acts under FFDCA. Prohibits the charitable distribution of tobacco products. Prohibits making any statement or representation directed to consumers in a label or labeling or through the media or advertising of a tobacco product that either conveys, or misleads or would mislead consumers into believing, that: (1) the product is approved by FDA; (2) FDA deems the product to be safe for use by consumers; (3) the product is endorsed by FDA for use by consumers; or (4) the product is safe or less harmful by virtue of its regulation or inspection by FDA or its compliance with regulatory requirements set by FDA.

Allows the Secretary to impose a no-tobacco-sale order at retail outlets for repeated violations of restrictions on the sale of tobacco products. Sets forth civil monetary penalties for violations of FFDCA related to tobacco products

Requires the Secretary to submit a report to the relevant committees on: (1) the nature, extent, and destination of U.S. tobacco product exports that do not conform to tobacco product standards established under this Act; (2) the public health implications of such exports; and (3) recommendations or assessments of policy alternatives available to reduce any negative public health impact.

Sets forth provisions providing for notice of violations to retailers.

(Sec. 104) Directs the Secretary to convene an expert panel to study the public health implications of raising the minimum age to purchase tobacco products.

(Sec. 105) Requires the Secretary to develop an action plan to enforce restrictions on the promotion and advertising of menthol and other cigarettes to youth.

(Sec. 106) Directs the Secretary to report to specified congressional committees on FDA's progress in implementing this Act.

Directs the Comptroller General to study and report to such committees on: (1) the adequacy of the authority and resources provided to the Secretary to carry out the goals and purposes of this Act; and (2) any recommendations for strengthening that authority to more effectively protect the public health with respect to the manufacture, marketing, and distribution of tobacco products.

Title II: Tobacco Product Warnings; Constituent and Smoke Constituent Disclosure - (Sec. 201) Amends the Federal Cigarette Labeling and Advertising Act to prohibit any person from manufacturing, packaging, selling, offering to sell, distributing, or importing for sale or distribution within the United States any cigarettes the packages of which fail to bear specified warning labels. Specifies the location, size, type size, and color of such labeling.

Prohibits tobacco product manufacturers, importers, distributors, or retailers to advertise cigarettes within the United States without specified labeling. Specifies the location, size, type size, color, and border of warning labels for different types of advertisements.

Directs the Secretary to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany cigarette label statements.

(Sec. 202) Allows the Secretary to alter label requirements to promote greater public understanding of the risks associated with the use of tobacco products.

(Sec. 203) Allows states or localities to impose specific bans or restrictions on the time, place, and manner, but not the content, of the advertising or promotion of any cigarettes.

(Sec. 204) Amends the Comprehensive Smokeless Tobacco Health Education Act of 1986 to apply the same restrictions on labeling and advertising to smokeless tobacco products.

(Sec. 206) Requires the Secretary to determine whether manufacturers should be required to include on the label and advertisements the tar and nicotine yields of the product. Allows the Secretary to require disclosure of the level of constituents in a tobacco product if such disclosures would benefit the public health or increase consumer awareness of the health consequences of the use of tobacco products.

Title III: Prevention of Illicit Trade in Tobacco Products - (Sec. 301) Sets forth labeling, inspection, and record keeping requirements to prevent the illicit trade, smuggling, or counterfeiting of tobacco products.

Requires a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury promptly of any knowledge that reasonably supports the conclusion that a tobacco product manufactured or distributed has left its control and may be or has been: (1) imported, exported, distributed, or sold without paying duties or taxes; or (2) diverted for possible illicit marketing.

(Sec. 302) Requires the Comptroller General to conduct a study to collect data on cross-border trades and advertising in tobacco products and the health effects resulting from such trades and to make recommendations on monitoring such trades and preventing or eliminating such advertising.

Division B: Federal Retirement Reform Act - Federal Retirement Reform Act of 2009 - **Title I: Provisions Relating to Federal Employees Retirement** - (Sec. 101) Thrift Savings Plan Enhancement Act of 2009 - Requires the Executive Director of the Federal Retirement Thrift Investment Board to provide for: (1) automatic enrollment in the Thrift Savings Plan (TSP) at a specified default percentage (between 2% and 5%) of basic pay of anyone appointed, transferred, or reappointed to a position in which that individual is eligible to contribute to TSP; and (2) the inclusion in TSP of a qualified Roth contribution program.

(Sec. 104) Authorizes the Board to include a mutual fund window under TSP, if such window would be in the best interest of participants.

(Sec. 105) Sets forth reporting requirements related to the operation of TSP.

(Sec. 106) Requires any participant who elects to invest in any investment fund or option other than the G Fund to sign an acknowledgment that the participant is not protected by the government against any loss on such investments and that a return on such investment is not guaranteed by the government.

Provides that a fiduciary shall not be liable and no civil action may be brought against a fiduciary for: (1) providing for the automatic enrollment of a participant; (2) enrolling a participant in a default investment fund; or (3) allowing a participant to invest through the mutual fund window or establishing restrictions applicable to a participant's ability to invest through such a window.

(Sec. 107) Gives the Executive Director authority to issue subpoenas to obtain materials.

(Sec. 108) Revises provisions regarding the legal proceedings to which TSP funds are subject.

(Sec. 109) Sets forth terms under which a surviving spouse may maintain the portion of a TSP account to which he or she is entitled.

(Sec. 110) Directs the Secretary of Defense to report to Congress on the cost, and the effect on recruitment and retention, of providing a matching payment for TSP contributions by members of the Armed Forces.

Title II: Special Survivor Indemnity Allowance for Surviving Spouses of Armed Forces Members - (Sec. 201) Increases the monthly special survivor indemnity allowance paid to surviving spouses of members of the uniformed services who have had their survivor benefit plan annuity reduced due to dependency and indemnity compensation payments.

MAJOR ACTIONS:

3/3/2009 Introduced in House

3/26/2009 Reported by the Committee on Energy and Commerce. H. Rept. [111-58](#), Part I.

3/26/2009 Reported (Amended) by the Committee on Oversight and Government. H. Rept. [111-58](#), Part II.

4/2/2009 Passed/agreed to in House: On passage Passed by recorded vote: 298 - 112 ([Roll no. 187](#)).

6/11/2009 Passed/agreed to in Senate: Passed Senate with an amendment by Yea-Nay Vote. 79 - 17. [Record Vote Number: 207](#).

6/12/2009 Resolving differences -- House actions: On motion that the House agree to the Senate amendment Agreed to by the Yeas and Nays: 307 - 97 ([Roll no. 335](#)).

6/12/2009 Cleared for White House.

6/16/2009 Presented to President.

6/22/2009 Signed by President.

6/22/2009 Became Public Law No: 111-031 [[Text](#), [PDF](#)]