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

### Key Conservative Concerns

#### *Take-Away Points*

- The bill limits freedom of speech.
- The bill severely weakens the core health-promoting function of the FDA.
- The bill increases taxes on tobacco companies by \$5.4 billion over 10 years on top of the \$72.1 billion tobacco tax over 10 years scheduled to take effect April 1, 2009 in order to fund the expansion of SCHIP.
- The bill imposes numerous mandates on states and on private businesses.
- Many conservatives may question the motivations behind loopholes created for Menthol and Indians.

*For more details on these concerns, see below.*

### H.R. 1256 — Family Smoking Prevention and Tobacco Control Act (*Waxman, D-CA*)

**Order of Business:** The bill is expected to be considered under a closed rule to concur in the Senate Amendment to H.R. 1256, the Family Smoking Prevention and Tobacco Control Act on Friday, June 12, 2009. H.R. 1256 passed the House on April 2, 2009, by a vote of 298-112.

**Major Changes Since the Last Time This Legislation Was Before the House:** The Senate Amendments to H.R. 1256 make several minor changes to the tobacco portion of bill including:

- Adds a provision that requires the new Tobacco Product Scientific Advisory Committee, within two years of its establishment, to report to the Secretary on the public health impact of dissolvable tobacco products, including their use

among children.

- Allows the Secretary to modify the ban on outdoor advertising within 1,000 feet of schools and playgrounds in order to address First Amendment case law, including *Lorillard Tobacco Co. v. Reilly*.
- Specifies that after October 1, 2009 user fees will be the only authorized funds for tobacco regulation activities and general FDA funds can no longer be used for start up costs. Previously, the bill allowed borrowing of general FDA funds until user fees had been collected for two fiscal year quarters. The Senate Amendments require the Secretary to determine appropriate startup cost reimbursement policy to ensure that there is no net change in the amount of funds otherwise available for other FDA
- Establishes stronger language that prohibits any express or implied claim through media, labeling, or advertising that would mislead consumers into believing that the product is approved, deemed safe, endorsed or the somehow less harmful by virtue of its regulation or inspection by FDA, or its compliance with FDA regulatory requirements.
- Creates additional civil monetary penalties up to \$15,000 per violation, not to exceed \$1,000,000 per proceeding, on any person who “intentionally” violates a requirement within the bill with additional enhanced penalties.
- Requires new studies from the GAO and FDA on the progress and effectiveness of implementing provisions under the bill that will be made publicly available. Three years after enactment, and every two years thereafter, the FDA must report to Congress on performance, impediments, finances and data on new product applications. Five years after enactment, the GAO must also submit a report evaluating the program and any recommendations.
- Requires the warning labels to occupy the top 50% (up from 30% in the House passed version) of the front and rear panels of the package. Further instructs the Secretary, within 24 months of enactment, to issue a rule requiring color graphics depicting the negative health effects of smoking to accompany the label requirements. Allows the Secretary to revise the format, type size, color graphics, and text of the label requirements so that labels and graphics are clear, legible and in the appropriate area.

**Summary:** H.R. 1256 would amend the Federal Cigarette Labeling and Advertising Act and the Federal Food, Drug, and Cosmetic Act to grant broad new authority to the Food and Drug Administration (FDA) to regulate and impose new restrictions on the manufacture, distribution, advertising, labeling, disclosure, promotion, sale and use of tobacco (cigarettes and smokeless) Specific bill provisions include the following:

### **Division A—Family Smoking Prevention and Tobacco Control Act**

*Findings and Purpose.* The bill contains 13 pages of findings purporting the need to regulate tobacco products to protect the public health, and language designed to ensure that the bill does not affect the authorities of the Secretaries of Agriculture or Treasury. The bill also includes severability language providing that judicial invalidation of one or

more sections of the legislation will not result in the nullification of the entire regulatory regime proposed by the bill.

*Regulatory Authority.* H.R. 1256 gives FDA the authority to regulate tobacco products, which are defined as “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product”, and establishes a new Center for Tobacco Products within the FDA to exercise regulatory authority. The bill states that tobacco does not qualify as a drug or medical device for purposes of FDA regulation, and limits the FDA’s regulatory authority to tobacco leaf in the possession of tobacco manufacturers (thus excluding tobacco growers).

*Adulterated and Misbranded Products.* The bill defines adulterated and misbranded tobacco products, defining the former to include products that “consists in whole or in part of any filthy, putrid, or decomposed substance,” and defining misbranded products to include those that are “false or misleading,” as well as those which do not adhere to the registration, labeling, and other regulatory regimes established under the bill. The bill grants the FDA, through the Secretary of Health and Human Services, the right to pre-approve statements made on tobacco product labels.

*Information Disclosure.* The bill requires all tobacco manufacturers, not later than 6 months after the date of enactment, to disclose to the Secretary the names and descriptions of all ingredients and additives added to the tobacco product as well as content, delivery, and form of nicotine in each. The bill grants authority to the Secretary to obtain information from tobacco companies on the health effects of smoking and requires the Secretary to publish “a list of harmful and potentially harmful constituents” in tobacco products by brand. The bill further requires manufacturers, upon the Secretary’s request, to release all documents related to current and future products.

*Registration and Inspection.* H.R. 1256 requires all tobacco manufacturers to register their names and places of business with the Secretary and requires the Secretary to make such information public. The bill also requires inspection of every domestic tobacco manufacturing establishment at least once every two years, and a requirement that overseas tobacco manufacturing establishments have “adequate and effective means” for the Secretary to ensure that tobacco products manufactured overseas should be refused entry into the United States. While the Secretary is required to contract with states to enforce the FDA-promulgated regulations, the Secretary is prohibited from contracting with states to enforce the tobacco regulations on Indian tribal lands—or directly engage in enforcement activity on tribal lands—without the express written consent of the tribe involved.

*General Authority.* The bill would permit the Secretary to restrict by regulation the sale, distribution, and advertising of tobacco products “if the secretary determines that such regulation would be appropriate for the protection of the public health.” In exercising this authority, the Secretary may not 1) “prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets;” 2) set an age limit on the sale of tobacco products higher than 18 years of age; or 3) require use of a physician’s

prescription in order to obtain tobacco products. However, the bill does require the Secretary to promulgate regulations addressing the sale, distribution, and marketing of tobacco products remotely so as to discourage the purchase of tobacco products by underage individuals.

*Product Standards.* H.R. 1256 would ban all “artificial or natural flavors” **except for menthol**, and requires all tobacco products to meet domestic standards with respect to pesticide use. The bill permits the Secretary to impose further restrictions should the regulations be in the interest of the public health. However, “because of the importance of a decision of the Secretary to issue a regulation” banning all cigarettes or reducing the level of nicotine permitted in tobacco products to zero, the bill explicitly prohibits the Secretary from taking either action.

*Notification and Recalls.* The bill grants the Secretary the authority to order notification to the public, through public service announcements or other means, of tobacco products that “present an unreasonable risk of substantial harm to the public health...and no more practicable means is available...to eliminate such risk.” The bill also authorizes the Secretary to order recalls in the event that “there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in other tobacco products on the market that would cause serious, adverse health consequences or death.”

*Record-Keeping.* H.R. 1256 requires tobacco companies to create and preserve records, as established by regulation, designed to determine that tobacco products are not adulterated or misbranded and to protect the public health, and to provide reports of any corrective action taken by tobacco manufacturers to remove products from the market for health reasons. The bill language states that identities of any patients discussed in applicable records should remain confidential, unless disclosure is necessary “to determine risks to public health of a tobacco product.”

*Review of New Tobacco Products.* The bill requires pre-market review for all new tobacco products introduced after February 15, 2007, unless the product is “substantially equivalent” to existing products. The application for pre-market review requires full disclosure of the products’ components, and research of the health effects of same. The bill would require the Secretary to reject such new tobacco products if “there is a lack of a showing that permitting such tobacco products to be marketed would be appropriate for the protection of the public health,” among other conditions necessary for approval. The bill also permits the Secretary to withdraw premarket approval, due to a company’s non-compliance with regulations or new information on the public health effects of a product, effectively removing the product from the marketplace.

*Modified Risk Tobacco Products.* H.R. 1256 places restrictions on the introduction or marketing of modified risk tobacco products. Specifically, the bill requires that any product marketed as modified risk must “significantly reduce harm and the risk of tobacco-related disease to individual tobacco users” and “benefit the health of the population as a whole,” including both tobacco users and non-users. In the event that the

Secretary cannot make such a determination without long-term epidemiological data that is not available, the Secretary may issue a temporary approval of not more than five years for the marketing of modified risk products, provided that “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,” and the product is subject to annual post-market surveillance review. The bill also places additional restrictions on the marketing, advertising, and comparative claims presented by modified risk tobacco products.

*Judicial Review.* The bill provides a process for individuals adversely affected by regulations issued pursuant to the bill, or whose application for pre-market approval was denied, to seek judicial review with the U.S. Court of Appeals for the circuit in which the party resides or has a principal place of business, subject to review by the Supreme Court.

*Regulatory Requirements.* H.R. 1256 requires the Secretary to issue regulations within three years of enactment regarding tobacco product testing and disclosure of product constituents, and permits the Secretary to require label or advertising disclosure of tobacco product constituents. The bill provides for delays of regulatory and testing requirements for “small tobacco product manufacturers,” defined as those employing fewer than 350 individuals. The bill also clarifies that none of its provisions prohibit the Federal Trade Commission (FTC) from regulating tobacco advertising or sales.

*Limited Pre-Emption.* H.R. 1256 pre-empts state laws relating to tobacco product standards, mis-labeling, adulteration, labeling, and related product standards; according to the Congressional Budget Office (CBO), this pre-emption language constitutes an intergovernmental mandate as defined in the Unfunded Mandates Reform Act. However, the bill retains states’ ability to enact more stringent standards with respect to tobacco advertising and promotion.

*Scientific Advisory Committee.* The bill establishes the Tobacco Products Scientific Advisory Committee to provide technical expertise and recommendations to the Secretary regarding the regulation of tobacco products.

*Smoking Cessation.* The bill requires the Secretary to consider approving the extended use of nicotine replacement products “for the treatment of tobacco dependence.”

*User Fee.* The bill assesses user fees on tobacco companies and funds FDA regulation of tobacco activities in the amount of \$85 million in Fiscal Year 2009, increasing each year until reaching \$712 million in Fiscal Year 2019 and each subsequent year. The bill assesses user fees by class of tobacco products (e.g. cigarettes, cigars, etc.), and allocates them to companies within a class of tobacco products, based on the percentages outlined in tobacco buyout legislation (P.L. 108-357) passed in October 2004.

*Restores 1996 Rule on Tobacco Advertising.* The bill requires the Secretary to publish within 180 days of the bill’s enactment a final rule on regulation of tobacco identical to regulations published on October 28, 1996, with an effective date of one year following the bill’s enactment. The original regulations would restrict tobacco advertising by,

among other things, prohibiting billboards within 1,000 feet of schools and permitting only black-and-white advertising. The bill would modify the original regulation to permit the free distribution of smokeless tobacco only, and only in quantities of fewer than 15 grams (0.53 ounces) in certain “qualified adult-only facilities.” The bill exempts the final rule, as modified, from review under the Congressional Review Act.

*Nullifies Earlier Documents.* H.R. 1256 would nullify the precedent of certain documents issued by FDA during 1995-96 as they relate to a prior attempt to classify nicotine in tobacco products as a drug for purposes of FDA regulation. (H.R. 1256 would make tobacco subject to FDA regulation, but as a “tobacco product,” not a drug or medical device.)

*New Penalties.* The bill would add failure to comply with the bill’s requirements as grounds for imposition of fines, civil and/or criminal penalties, along with other offenses relating to counterfeiting tobacco products or “the charitable distribution of tobacco products.” The bill also gives the Secretary the authority to impose a “no-tobacco sale order” against retail outlets and establishes a new system of federal fines against retail establishments selling tobacco products improperly, authorizing fines of up to \$10,000 for establishments with six or more violations within a four year period.

*Studies.* The bill would require a study on cross-border trade and counterfeiting in tobacco products, and require a specific study by HHS on raising the minimum age to purchase tobacco products. The bill also requires, no later than one year after its establishment, the Tobacco Product Scientific Advisory Committee to submit to the Secretary a report and recommendations on 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.

*Labeling Requirements.* The bill requires all cigarettes and smokeless tobacco sold in the United States to bear clear warnings about the risks associated with tobacco use and prescribes the wording, typeface, and font size associated with such warnings. (Tobacco products manufactured domestically for international use are exempt from this requirement.) H.R. 1256 further requires that all advertising, including matchbooks, contain language from the warning labels, and prescribes the proportions by which such label warning must relate to the overall size of the advertisement. The bill gives the Secretary of HHS the authority to alter or increase the size of the labeling requirements, permits states to further regulate the type and manner, but not the content, of cigarette advertising, and extends a prohibition on television and radio advertising to smokeless tobacco products subject to the jurisdiction of the Federal Communications Commission.

*Tar and Nicotine Disclosure.* The bill gives the Secretary the authority to conduct a rulemaking process to determine whether to require the disclosure of tar, nicotine, and other constituent levels in tobacco advertising, subject to a memorandum of understanding with the Federal Trade Commission.

*Shipping Requirements.* H.R. 1256 requires that all packaging and shipping containers shall bear statements stating “sale only allowed in the United States” and requires the

Secretary to issue regulations regarding the maintenance of records by entities manufacturing, transporting, or distributing tobacco products. The bill also requires tobacco manufacturers and distributors to notify the Attorney General and the Secretary of the Treasury upon obtaining information “which reasonably supports the conclusion” that tobacco products formerly held by the entity have circumvented payment of applicable taxes or “diverted for possible illicit marketing.”

### ***Division B—Federal Retirement Reform Act***

**Summary:** The bill would require the automatic enrollment of newly-hired eligible federal employees and members of the uniformed services in the Thrift Savings Plan (TSP). The bill also would authorize the Federal Thrift Retirement Investment Board (FTRIB) to establish a Roth IRA contribution plan and self-directed investment options within the TSP.

The bill makes changes to the TSP for federal workers to require auto-enrollment of workers. According to CBO, the House-passed version would reduce revenues by \$290 million over five years, and \$892 million over ten, due to revenue loss associated with additional employees making pre-tax TSP contributions. However, due to an additional provision establishing an after-tax savings component (similar to the Roth IRA or Roth 401(k) options) in the TSP, resulting from employees substituting pre-tax TSP contributions with after-tax ones, the CBO estimates this would generate \$504 million in revenue over five years, and \$2.26 billion over ten. In addition to acting as an offset for the tobacco bill, some of the funds will be used to help fund the Survivor Benefits Program (SBP) and Dependency and Indemnity Compensation (DIC).

Notable provisions of pensions portion of the House version include:

- Requires the Federal Retirement Thrift Investment Board to automatically enroll newly hired federal and military employees in the Thrift Savings Plan (TSP).
- Establishes a qualified Roth IRA contribution option for the TSP, allowing a taxable contribution to their TSP account and tax-free withdrawals upon retirement.

**Cost to Taxpayers:** According to the Congressional Budget Office (CBO), H.R. 1256 would result in \$2.2 billion in mandatory spending over five years, and \$5.4 billion over ten, related to the Food and Drug Administration’s regulation of tobacco. The bill would offset these costs by imposing a “fee” on tobacco companies to finance the FDA regulation. CBO also estimates a decline in revenues of \$210 million over five years, and \$955 million over ten, related to a 2% reduction in overall smoking levels due to tobacco regulation, and loss of commensurate tobacco tax revenue. In order to pay for this reduced revenue, the rule incorporated provisions in H.R. 1804, relating to the federal Thrift Savings Plan (TSP). The bill would establish a system of auto-enrollment in TSP for all federal employees, causing a minor revenue loss. The bill would also generate additional tax revenue by establishing a new plan to permit after-tax TSP contributions,

similar to a Roth IRA or the recently-established Roth 401(k) option. Finally, CBO estimates a five-year increase in spending subject to appropriation of \$.1 billion over 5 years and \$.08 billion over 10 years as a result of H.R. 1256's enactment.

**Committee Action:** The bill was introduced on March 3, 2009, and referred to the Energy and Commerce. On March 4, 2009, a mark-up was held in Committee and the bill was reported by a 39-13 vote.

**Possible Conservative Concerns:** Numerous aspects of H.R. 1256 may raise concerns for conservatives, including, but not necessarily limited to, the following:

**Process:** Some conservatives may be concerned that the non-tobacco portions were removed from the bill by the rule in order to deny Republicans options for a Motion to Recommit.

**User Fee as Tax Increase:** Some conservatives may be concerned that on the same day that one of the most regressive taxes in US history goes into affect, congressional Democrats are planning yet another tax masked as a "user fee" on tobacco products. The bill includes \$5.4 billion in assessments on tobacco companies, to finance the FDA's work regulating tobacco products.

**Restricts Free Speech Rights:** In addition to codifying federal restrictions, which tobacco companies agreed to in their 1998 settlement with state Attorneys General, H.R. 1256 places additional federal restrictions on tobacco advertising. Some of the federal restrictions on advertising content in H.R. 1256 include the following specifications for the size of warning labels on tobacco products:

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.

Some conservatives may be concerned that the highly prescriptive, constitutionally questionable restrictions described above, and elsewhere in H.R. 1256, constitute an undue intrusion on companies' constitutional free speech rights to advertise a product that most Americans already know is unhealthy.

**Hinders Introduction of Reduced Risk Tobacco Products:** H.R. 1256 places stringent restrictions on the introduction and marketing of new products that would reduce or modify the inherent risks associated with the consumption of tobacco. The bill states that a reduced risk product may be marketed only if the product will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users" and also will "benefit the population as a whole," including persons who do not consume tobacco products. Some conservatives may be concerned that such onerous restrictions on the introduction of reduced risk tobacco products could have the effect of inhibiting the use

of products that could reduce the risks associated with tobacco consumption while potentially serving as a barrier to entry for new market competitors.

**FDA Improper Agency to Regulate Tobacco:** As FDA Commissioner Andrew von Eschenbach testified before the House Energy and Commerce Committee in October 2007, the FDA has heretofore been structured as an agency to promote and protect the public health. In the Commissioner's opinion, requiring FDA to "approve" tobacco products as a result of H.R. 1256 would dramatically change the agency's focus: *"Associating any agency whose mission is to promote public health with the approval of inherently dangerous products would undermine its mission and likely have perverse incentive effects."*

**Other Important Priorities for FDA:** Energy and Commerce Oversight Subcommittee Chairman Bart Stupak (D-MI), in holding a hearing on FDA's decision to approve an antibiotic despite receiving false clinical trial data, called the incident "a microcosm of the failure by all FDA stakeholders—FDA, pharmaceutical sponsors, and third-party monitors—to ensure the integrity of clinical trials used to support the safety and approval of new drug applications." On top of questions which Democrats themselves have raised regarding FDA's competence, some conservatives may question whether the food safety concerns that have arisen in recent months make an appropriate time to significantly expand the agency's regulatory mission.

**Multiple Layers of Regulation:** While establishing FDA authority to regulate tobacco products, H.R. 1256 would also retain the FTC's authority to regulate tobacco advertising and distribution on the federal level, and would provide only limited pre-emption of state laws, allowing more stringent state restrictions on tobacco advertising and promotion. Some conservatives may be concerned that these multiple layers of regulation will impose undue bureaucratic and logistical difficulties on tobacco manufacturers—even though H.R. 1256 would explicitly retain tobacco as a lawful product.

**Little Impact on Tobacco Use:** The CBO estimate of H.R. 1256 notes that under its budgetary model, smoking by adults would decline by only 2% after 10 years. Some conservatives may question whether this marginal reduction in smoking levels warrants the significant intrusion on free speech rights and government-run regulatory bureaucracy that would be created under the legislation.

**Billions in Unfunded Mandates:** The Congressional Budget Office, in its score of H.R. 1256, calculates that the fee imposed in the bill would constitute an unfunded mandate on tobacco companies of \$235 million in Fiscal Year 2009, and more than \$2.2 billion over five years, greatly exceeding the threshold established in the Unfunded Mandates Reform Act (\$139 million in 2009, adjusted annually for inflation). CBO also notes that the bill includes several unfunded mandates that would both pre-empt existing state tobacco regulations and require tribal governments manufacturing or distributing tobacco products to comply with the new federal regulatory regime.

**Violates Trade Agreements:** Former HHS Secretary Leavitt, writing to Energy and

Commerce Committee Ranking Member Barton on last year's FDA tobacco bill, noted that the legislation could be viewed by foreign governments as a hostile trade action. Because the bill bans clove and other flavored cigarettes—many of which are manufactured in foreign countries—while expressly permitting production of menthol cigarettes, Indonesia or other foreign governments could file complaints at the World Trade Organization claiming discrimination against their products. Some conservatives may be concerned that passage of H.R. 1256 could ultimately result in retaliatory measures being taken against American-made products—and could lead to trade disputes with a negative effect on economic growth.

**Menthol Loophole.** As noted above, H.R. 1256 would prohibit the use of all “artificial or natural” cigarette flavorings—with the exception of menthol, which is permitted under the bill. Because data from the Centers for Disease Control indicate that 75% of African-American smokers consume menthol cigarettes, seven former Secretaries of Health and Human Services, representing both political parties, wrote to Congress to criticize a menthol “loophole” that “caves to the financial interests of tobacco companies” by “send[ing] a message that African-American youngsters are valued less than white youngsters.” Some conservatives may note the hypocrisy in this loophole.

**Administration Position:** A formal Statement of Administration Policy (SAP) is unavailable at press time.

**Does the Bill Expand the Size and Scope of the Federal Government?:** Yes, the bill would grant new authority to the Food and Drug Administration to regulate tobacco products.

**Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?:** Yes, the bill imposes new fees on tobacco companies, which CBO estimates would total \$235 million in Fiscal Year 2009, \$2.2 billion over five years, and nearly \$5.4 billion over ten years, all greatly exceeding the thresholds established in the Unfunded Mandates Reform Act (\$139 million in 2009, adjusted annually for inflation). Also, the bill imposes a variety of in-depth mandates on private-sector manufacturing, labeling, marketing, packaging, shipping, and other aspects of private business.

**Does the Bill Comply with House Rules Regarding Earmarks/Limited Tax Benefits/Limited Tariff Benefits?:** The Committee on Energy and Commerce, in House Report 111-058 - Part 1, reports that “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..”

**Constitutional Authority:** The Committee on Energy and Commerce, in House Report 110-762, cites constitutional authority under Article I, Section 8, Clause 3 (relating to the regulation of interstate commerce) and Article I, Section 8, Clause 1 (relating to legislation promoting the general welfare of the United States).

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