



U. S. S E N A T E R E P U B L I C A N P O L I C Y C O M M I T T E E

Legislative Notice

No. 14

June 1, 2009

**S. 982—The Family Smoking Prevention and Tobacco Control Act**

*Reported from the Committee on Health, Education, Labor and Pensions with amendments on May 20, 2009 by a vote of 15-8; no written report.*

**Noteworthy**

- On Thursday, May 21, cloture was filed on the motion to proceed to H.R. 1256, the House-passed FDA tobacco legislation.
- S. 982, the Family Smoking Prevention and Tobacco Control Act, would amend the Federal Food, Drug and Cosmetic Act to give the Food and Drug Administration (FDA) new powers to regulate the manufacture and marketing of tobacco products.
- The Senate Committee on Health, Education, Labor and Pensions favorably reported S. 982 on May 20, 2009, on a 15-8 vote. Senators Gregg, Murkowski and McCain supported the legislation, while Senator Hagan opposed it.
- It creates a new Center for Tobacco Products within the FDA to establish tobacco product standards. However, the Secretary of Health and Human Services will not be allowed to ban existing tobacco products or reduce nicotine levels to zero.
- It creates a new standard, applicable only to tobacco products, that allows the FDA to regulate those products “as appropriate for the protection of the public health.” All other products regulated by the FDA must be determined to be “safe” or “safe and effective.”
- Andrew von Eschenbach, M.D., the former head of the FDA, has argued that associating the FDA with the approval of an inherently dangerous product would undermine the agency’s mission and give people the false impression that tobacco products approved by the FDA are safe and effective.
- The bill has the support of many anti-smoking groups and the American Cancer Society, but also of Philip Morris, the nation’s largest cigarette manufacturer. Many argue that Philip Morris has supported the legislation, particularly the restrictions on marketing, as a way to cement its dominance in the tobacco market.
- The Congressional Budget Office estimates that the legislation would reduce the number of underage tobacco smokers by 11 percent by 2019, but would reduce the number of smoking adults by only two percent over the same time period.

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## Summary

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S. 982, the Family Smoking Prevention and Tobacco Control Act, would amend the Federal Food, Drug and Cosmetic Act (FFDCA) to give the Food and Drug Administration (FDA) new powers to regulate the manufacture and marketing of tobacco products. A new Center for Tobacco Products is created within the FDA to establish tobacco product standards. The standards must be sufficient to protect the public health, but the Secretary of Health and Human Services (HHS) cannot ban existing tobacco products or reduce nicotine levels to zero. The legislation permits most existing products to remain on the market and reserve to Congress the power to ban tobacco products.<sup>1</sup> The FDA also gets authority to issue regulations governing the sale, promotion and distribution of tobacco products.

The Senate Committee on Health, Education, Labor and Pensions favorably reported S. 982 on May 20, 2009, on a 15-8 vote. Senators Gregg, Murkowski and McCain supported the legislation, while Senator Hagan opposed it. The House passed companion legislation (H.R. 1256) by a vote of 298-112 on April 2, 2009 (Vote No. 187). Related legislation passed the Senate in 1994 by a vote of 78-15 (Vote No. 157, July 15, 1994).<sup>2</sup>

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## Background

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According to the CDC, the adverse health effects from cigarette smoking account for nearly 1 of every 5 deaths each year in the United States.<sup>3</sup> More deaths are caused each year by tobacco use than by all deaths from human immunodeficiency virus (HIV), illegal drug use, alcohol use, motor vehicle accidents, suicides and murders combined.<sup>4</sup> The FDA attempted to regulate tobacco in a 1996 rule by asserting that cigarettes and tobacco were delivery devices for nicotine. The rule was struck down by the Supreme Court in 2000 in *FDA v. Brown and Williamson Tobacco Corp.* The Court based its ruling in part on the fact that tobacco products are manifestly unsafe. Therefore, if the FDA wanted to regulate tobacco products, it would have no choice but to prohibit the marketing of tobacco products.<sup>5</sup>

Following the Court's ruling in *FDA v. Brown and Williamson*, in order for the FDA to regulate tobacco products, Congress has to grant the FDA additional statutory authority. The legislation does this by establishing a new Chapter IX of the FFDCA solely for the purpose of regulating

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<sup>1</sup> In fact, the purpose section lists as one of the intents of the legislation "to continue to permit the sale of tobacco products to adults..."

<sup>2</sup> Vote available at:

[http://www.senate.gov/legislative/LIS/roll\\_call\\_lists/roll\\_call\\_vote\\_cfm.cfm?congress=108&session=2&vote=00157](http://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=108&session=2&vote=00157)

<sup>3</sup> CDC, Fact Sheet: Health Effects of Cigarette Smoking. Available at:

[http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/health\\_effects/health\\_effects.htm](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/health_effects.htm).

<sup>4</sup> CDC, Fact Sheet: Health Effects of Cigarette Smoking.

<sup>5</sup> Congressional Research Service, "FDA Tobacco Regulation: The Family Smoking Prevention and Tobacco Control Act of 2009," April 7, 2009, R40475.

tobacco products. Importantly, the section establishes a new standard for FDA regulation, applicable only to tobacco products, that allows the FDA to regulate tobacco products “as appropriate for the protection of the public health.” All other FDA-regulated products must be determined to be “safe” or “safe and effective.” Andrew von Eschenbach, M.D., the former head of the FDA, argued that associating the FDA with the approval of an inherently dangerous product would undermine the agency’s mission and also give people the impression that tobacco products approved by the FDA were safe and effective.<sup>6</sup> Moreover, von Eschenbach expressed concern that the legislation would divert attention and resources from the FDA’s primary responsibility for food and drug safety at a time when the agency already faces significant challenges.

The tobacco bill has the support of many anti-smoking groups and the American Cancer Society, but also Philip Morris, the nation’s largest cigarette manufacturer. Many argue that Philip Morris has supported the legislation, and particularly the restrictions on marketing, as a way to cement its dominance in the tobacco market.<sup>7</sup> Other major cigarette companies, including R.J. Reynolds and Lorillard, oppose the bill.

The Congressional Budget Office (CBO) estimates that the legislation would reduce the number of underage tobacco smokers by 11 percent by 2019, but would reduce the number of smoking adults by only two percent over the same time period.

Among other provisions, the bill would:

- Create the Center for Tobacco Products within the FDA and give the FDA the authority to regulate the sale, distribution and advertisement of tobacco products in order to protect the public health.
- Require manufacturers of tobacco products to register with the FDA and meet new regulatory requirements, including submitting a list of all product ingredients.
- Prohibit the use of any natural or artificial flavor, including candy, spice, herb or fruit flavors, *other than* tobacco or menthol.
- Prevent the secretary from banning tobacco products or requiring the reduction of nicotine yields to zero.
- Require new tobacco products (defined as products commercially marketed after February 15, 2007, or not “substantially equivalent to existing tobacco products”) to seek marketing approval from the FDA.
- Establish regulations related to the approval and marketing of reduced-risk tobacco products.
- Establish user fees on tobacco manufacturers to pay for the new regulations.
- Direct the FDA to reissue its 1996 rule related to the sale, distribution and use of cigarettes and tobacco products, which was struck down by the Supreme Court in *FDA v. Brown and Williamson*.

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<sup>6</sup> Statement of Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs before the Subcommittee on Health Committee on Energy and Commerce United States House of Representatives, H.R. 1108, Family Smoking Prevention and Tobacco Control Act, October 3, 2007. Available at: <http://www.fda.gov/ola/2007/tobacco100307.html>.

<sup>7</sup> See *New York Times*, “Philip Morris’s Support Casts Shadow Over a Bill to Limit Tobacco,” March 31, 2009. Available at: <http://www.nytimes.com/2009/04/01/business/01tobacco.html>.

- Enhance warning labels applicable to tobacco products and require the inclusion of color graphic labels.

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## **Major Bill Provisions**

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*Center for Tobacco Products:* Within 90 days of enactment of the legislation, the secretary is required to establish within the FDA a Center for Tobacco Products. The secretary is also required to establish an office to assist small tobacco product manufacturers in complying with the requirements of the legislation.

*Submission of Health Information:* Within six months of enactment, each tobacco manufacturer is required to submit to the FDA a listing of all ingredients, compounds and additives in all of its tobacco products. Companies are also required to submit all documents developed after the date of enactment that relate to health, toxicological, behavioral or physiological effects of current or future tobacco products. The secretary can also require manufacturers to submit a variety of other research and data, including marketing research on tobacco products. The bill provides that the information obtained shall be considered confidential and should not be disclosed.

*Registration and Inspection:* Each manufacturer is required to register every year with the FDA, and each establishment registered with the FDA is required to be inspected at least once every two years.<sup>8</sup> Foreign companies are also required to register.

*Authority to Regulate Tobacco Products:* The secretary may, by regulation, require restrictions on the sale and distribution of tobacco products, including restrictions on advertising, if the secretary determines that such regulation “would be appropriate for the protection of the public health.” Such a determination should be made with consideration of the risks and benefits to the population as a whole, including users and nonusers of tobacco products. This authority is limited by requirements that no restriction may: 1) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or 2) establish a minimum age requirement higher than 18 years old. Restrictions on advertising may be imposed “consistent with and to [the] full extent permitted by the first amendment to the Constitution.” S. 982 also requires the secretary to promulgate regulations related to the sale and distribution of products over the internet.

*Manufacturing Practices:* S. 982 creates standards for good manufacturing practices, which can include testing for pesticide residues.

*Tobacco Product Standards and Menthol Exception:* The bill establishes new standards for tobacco products that restrict the additives that can be included in cigarettes. Beginning three months after the date of enactment, cigarettes cannot include characterizing flavors except menthol. This is an important exception because menthol is the most widely used flavoring in cigarettes (accounting for more than one-quarter of the market) and menthol-flavored cigarettes are the most popular product for African-Americans.<sup>9</sup> Seven former secretaries of HHS, from

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<sup>8</sup> It should be noted that a recurring problem uncovered in previous incidents involving Heparin and peanut butter was that the FDA does not meet its current inspection obligations.

<sup>9</sup> Congressional Research Service, “FDA Tobacco Regulation: The Family Smoking Prevention and Tobacco Control Act of 2009,” April 7, 2009, R40475.

Democratic and Republican administrations, sent a letter to members of the Senate and House of Representatives demanding that menthol-flavored cigarettes be banned just like other cigarette flavorings the legislation would outlaw.<sup>10</sup> The bill does provide that the Tobacco Products Scientific Advisory Committee should within one year provide a report and recommendation on the public health impacts of menthol—including on children and ethnic minorities. The secretary can also adopt additional tobacco product standards if appropriate to the protection of the public health, which could include standards on nicotine yields. However, the secretary is prohibited from banning all cigarettes or smokeless tobacco products, or requiring the reduction of nicotine yields to zero.

*Notification and Recalls:* The bill provides procedures for notice and an order for recall if a product “presents an unreasonable risk of substantial harm to the public health,” or if there is a manufacturing defect in the product, although there is no process for the secretary to immediately remove dangerous products. Tobacco product manufacturers would be required to maintain records to assure that products are not adulterated or misbranded.

*Standards Applicable to New Tobacco Products:* Marketing of all new products, defined as those marketed after February 15, 2007, must be approved by the FDA unless the product is “substantially equivalent” to an existing product. An exception is provided for products introduced within 21 months of the date of enactment of the bill and for which a substantial equivalence claim is made—even if the FDA does not approve the claim. This provision has received criticism from public health officials.<sup>11</sup> The bill provides that an application to market a new product should be denied by the secretary if there is “a lack of showing that permitting such tobacco product to be marketed would be appropriate for protection of the public health.”

*Modified Risk Tobacco Products:* The legislation would require FDA approval before a manufacturer could market any reduced risk tobacco products. Modified risk tobacco products include any products labeled as “light,” “mild” or “low,” or where the marketing implies that the product is less harmful than other tobacco products. Products intended to be used for smoking cessation or the treatment of tobacco dependence are exempted if they have been approved as a drug or device by the FDA. In order to market a modified risk product, the secretary must determine that the product—as it is actually used by consumers<sup>12</sup>—will: 1) significantly reduce harm and the risk of tobacco-related disease to individual users, and 2) benefit the health of the population as a whole, taking into account both users and non-users of tobacco products. The secretary shall require post-market surveillance and studies of the modified-risk product to review the accuracy of the claims on which the approval was based.

*Testing and Reporting:* Within three years of enactment, the secretary shall promulgate rules requiring the testing and reporting of tobacco product constituents, ingredients and additives by brand and sub-brand. The secretary may require tobacco products to disclose the results of tar and nicotine tests on labels or advertising.

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<sup>10</sup> *New York Times*, “Opposition to Menthol Cigarettes Grows,” June 5, 2008.

<sup>11</sup> Congressional Research Service, “FDA Tobacco Regulation: The Family Smoking Prevention and Tobacco Control Act of 2009,” April 7, 2009, R40475.

<sup>12</sup> Smokers may alter their use of tobacco products to satisfy their nicotine addiction by, for example, increasing their puff volume or frequency. See Congressional Research Service, “FDA Tobacco Regulation: The Family Smoking Prevention and Tobacco Control Act of 2009,” April 7, 2009.

*Preemption:* The legislation preempts state and local requirements related to tobacco product standards, pre-market review, adulteration, misbranding, labeling, registration, manufacturing standards and modified risk tobacco products. State or local regulations related to prohibiting the sale or advertising of products to individuals of any age are specifically not preempted.

*Tobacco Products Scientific Advisory Committee:* The legislation creates a 12-member advisory committee that shall advise the secretary on: 1) the effects of altering nicotine yields from tobacco products, 2) on whether there is a threshold level below which nicotine does not produce dependence on tobacco products and 3) other safety, dependence or health issues related to tobacco products.

*Products Used to Treat Tobacco Dependence:* The secretary would have authority to consider granting fast-track approval to smoking cessation products. A report would be required within three years on how best to regulate, promote and encourage the development of innovative products and treatments to reduce or eliminate tobacco consumption and reduce the harm caused by tobacco products.

*User Fees:* User fees would be established for each manufacturer and importer of tobacco products and collected quarterly. The fees begin in 2009 at \$85 million and increase to \$712 million by 2019 and each subsequent year. The program is flat-funded at that point, so some may question whether the agency will fall behind on funding. The legislation provides that these are the only fees to be used in relation to the purposes in the legislation, except that start-up costs during the first six months will be reimbursed.

*Reinstating 1996 Tobacco Rule:* The legislation requires that the 1996 tobacco rule (with some modifications) be published as a final rule within 180 days, without opportunity for notice and comment. The rule was struck down by the Supreme Court in 2000 in *FDA v. Brown and Williamson Tobacco Corp.* because the FDA did not have authority to regulate tobacco. The rule includes a number of restrictions on advertising, including a prohibition on promotional items like hats and T-shirts, and a ban on all outdoor advertising for tobacco products within 1,000 feet of any elementary or secondary school or playground. A similar school-related advertising ban in Massachusetts was found unconstitutional by the Supreme Court in *Lorillard Tobacco Company v. Thomas Reilly, Attorney General of Massachusetts*. CRS said that this ban in the 1996 rule would likely be found unconstitutional as well.<sup>13</sup> A number of groups, including the ACLU and the Association of National Advertisers, have objected to this provision and requested that the rule be open to notice and comment to address the legal developments since the 1996 tobacco rule was developed. Additionally, since the rule was written in 1996, the tobacco Master Settlement Agreement was enacted and other state regulations have been passed with respect to the marketing and advertising of tobacco.

*Penalties:* Civil penalties are established for retailers with a training program as follows: a warning letter for the first violation; \$250 for the second violation within 12 months; \$500 for the third violation within 12 months; \$2,000 for the fourth violation within 12 months; \$5,000

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<sup>13</sup> CRS wrote that, “it does not appear that the 1996 rule’s restriction on advertisement within 1,000 feet of a school or playground would survive” the First Amendment test established by the Supreme Court. Congressional Research Service, “FDA Tobacco Regulation: The Family Smoking Prevention and Tobacco Control Act of 2009,” April 7, 2009, R40475.

for the fifth violation within 36 months; and \$10,000 for the sixth and subsequent violations within 48 months. Some may question whether these penalties are relatively low if the goal is deterrence. Penalties for tobacco companies are up to \$15,000 for a single violation and up to \$1 million for violations adjudicated in a single proceeding.

*Tobacco Product Warnings:* Cigarette packages would be required to include one of a number of new warnings, which must be rotated regularly, including: “Warning: Cigarettes are addictive”; “Warning: Cigarettes cause cancer”; “Warning: Smoking can kill you.” The warnings must be in large type and comprise the top 50 percent of the front and rear panels of the package. Within 24 months of enactment, the secretary must promulgate regulations that require color graphic labels depicting the negative health consequences of smoking. Smokeless tobacco products have separate warning requirements, including labels like, “Warning: This product can cause mouth cancer”; Warning: This product can cause gum disease and tooth loss”; or Warning: This product is not a safe alternative to cigarettes.”

*Disclosure of Tar, Nicotine and Other Ingredients:* The secretary would be required to conduct a rulemaking to determine if cigarette and other tobacco products should be required to include disclosure of the tar and/or nicotine yields of the product on packaging or advertisements. The secretary may also prescribe disclosure requirements for other constituent elements, but these disclosures would not be included on the face of any cigarette package or advertisement.

*Prevention of Illicit Trade in Tobacco Products:* The legislation also requires new regulations regarding the keeping and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, export, or imports tobacco products. It also requires a study of the cross-border trade in tobacco products, including illicit trade.

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## **Budget Estimate**

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CBO estimates that S. 982 will result in \$2.1 billion in mandatory spending over five years and that it will cost \$5.3 billion over the 2009-2019 period to administer the new regulatory activities authorized by the legislation.

Because the bill is expected to reduce tobacco use, and therefore tobacco excise tax revenues, the bill requires an additional offset to meet pay-go requirements. The House included a controversial provision that requires the mandatory enrollment of all federal government employees, including members of our armed forces, in the Federal Thrift Savings Plan (TSP). This provision is expected to be included in the Senate bill. Additionally, the House included language that would establish a Roth IRA within an employee’s TSP account. The addition of a Roth-like option within TSP can be expected to generate tax revenue within the budget window. Contributions to regular 401(k) plans, IRAs and the current TSP can be deducted immediately from one’s income tax, but withdrawals are taxed at normal income tax rates when the money is withdrawn, with a 10 percent penalty if it is withdrawn before age 59½. For Roth-like vehicles, income taxes are paid on the contributions but the accrual within the retirement fund is not taxed. Allowing TSP participants to put some of their money into a Roth IRA will generate immediate tax revenue as a portion of regular TSP contributions will be diverted into the Roth IRA.

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## **Anticipated Amendments**

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- Senator Burr Alternative: Senator Burr will offer a comprehensive alternative, the “Preventing Death and Disease from Tobacco Use Act,” that will also regulate tobacco by creating a Tobacco Harm Reduction Center within HHS but outside the over-burdened FDA. The amendment would recognize the “continuum of risk” among tobacco products, increase cessation and prevention funding, and encourage current smokers to migrate to less harmful, smokeless tobacco products. The bill would also virtually ban all print advertising by tobacco companies and fund the Tobacco Harm Reduction Center with industry paid user fees.
- Findings and First Amendment: Senator Enzi will file an amendment to strike the findings in the legislation. The findings are superfluous to the impact of the legislation, and they are meant to try to shield the legislation from First Amendment scrutiny.
- Imminent Hazard: Senator Enzi will file an amendment to provide the FDA the authority to remove products from the market if they present an imminent hazard to public health.