# CONGRESSIONAL BUDGET OFFICE
# COST ESTIMATE

January 30, 2008

# S. 625
## Family Smoking Prevention and Tobacco Control Act

*As ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on August 1, 2007*

## SUMMARY

S. 625 would authorize the Food and Drug Administration (FDA) to regulate tobacco products, and would require FDA to assess fees on manufacturers and importers of tobacco products primarily to cover the cost of FDA's new regulatory activities authorized under the bill. CBO estimates that:

- Enacting S. 625 would increase federal revenues, on net, by $2.2 billion over the 2009-2013 period and by $5.2 billion over the 2009-2018 period. (We expect that it would have no budgetary effect in fiscal year 2008, assuming enactment on or about October 1, 2008.)

- Direct spending also would increase, on net, by $2.0 billion over the 2009-2013 period and by $5.2 billion over the 2009-2018 period.

- Considering both the revenue and direct spending effects, enacting the bill would have no net budgetary effect over the 2009-2018 period. It would reduce budget deficits (or increase surpluses) by a total of $0.3 billion over the 2009-2013 period. (Over the 2008-2017 period, we estimate that enacting the bill would reduce budget deficits, or increase surpluses, by about $23 million.) In addition, CBO estimates that implementing the bill would have no significant effect on spending subject to appropriation.

Pursuant to section 203 of S. Con. Res. 21, the Concurrent Resolution on the Budget for Fiscal Year 2008, CBO estimates that changes in direct spending and revenues from enacting the bill would not cause an increase in the on-budget deficit greater than $5 billion in any of the 10-year periods between 2018 and 2057.

S. 625 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, however, that the costs to state, local, and tribal governments to comply with the mandates in the bill would be small and would not exceed the threshold established in UMRA ($68 million in 2008, adjusted annually for inflation).

CBO also estimates 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 more than $1.3 billion during the 2009-2013 period, would not result from intergovernmental mandates.

A decline in smoking among pregnant individuals is expected to result in healthier birth outcomes. CBO therefore estimates that state spending for Medicaid would decrease by about $14 million over the 2009-2013 period.

S. 625 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 ($136 million in 2008, adjusted annually for inflation) in fiscal year 2009 and in each subsequent year.

## ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 625 is shown in the following table. The costs of this legislation fall primarily within budget functions 370 (commerce and housing credit) and 550 (health).

| | By Fiscal Year, in Millions of Dollars | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2008-2013 | 2008-2018 |
| **CHANGES IN REVENUES** | | | | | | | | | | | | | |
| Collections of Fees[a] | 0 | 251 | 480 | 508 | 537 | 568 | 601 | 636 | 673 | 712 | 753 | 2,344 | 5,719 |
| Excise Taxes and Fines | 0 | -8 | -18 | -27 | -36 | -45 | -56 | -65 | -75 | -84 | -93 | -134 | -507 |
| Total Changes in Revenues | 0 | 243 | 462 | 481 | 501 | 523 | 545 | 571 | 598 | 628 | 660 | 2,210 | 5,212 |
| **CHANGES IN DIRECT SPENDING** | | | | | | | | | | | | | |
| Spending of Fees by FDA to Regulate Tobacco Products[b] | | | | | | | | | | | | | |
| Estimated Budget Authority | 0 | 235 | 450 | 476 | 504 | 533 | 564 | 597 | 631 | 668 | 701 | 2,198 | 5,359 |
| Estimated Outlays | 0 | 50 | 275 | 497 | 609 | 618 | 625 | 626 | 628 | 664 | 698 | 2,049 | 5,290 |
| Medicaid | | | | | | | | | | | | | |
| Estimated Budget Authority | 0 | -1 | -2 | -4 | -5 | -7 | -9 | -10 | -12 | -13 | -15 | -19 | -78 |
| Estimated Outlays | 0 | -1 | -2 | -4 | -5 | -7 | -9 | -10 | -12 | -13 | -15 | -19 | -78 |
| Total Changes | | | | | | | | | | | | | |
| Estimated Budget Authority | 0 | 234 | 448 | 472 | 499 | 526 | 555 | 587 | 619 | 655 | 686 | 2,179 | 5,281 |
| Estimated Outlays | 0 | 49 | 273 | 493 | 604 | 611 | 616 | 616 | 616 | 651 | 686 | 2,030 | 5,212 |
| **NET IMPACT ON THE FEDERAL BUDGET** | | | | | | | | | | | | | |
| Estimated Net Effect[c] | 0 | -194 | -189 | 12 | 103 | 88 | 71 | 45 | 18 | 23 | 23 | -268 | 0 |

Note: FDA = Food and Drug Administration.

a. CBO estimates that the assessments in S. 625 would reduce income and payroll taxes by an estimated 25 percent of the gross assessments because assessments on firms are indirect business charges that reduce the tax base of income and payroll taxes. Numbers reported here reflect net receipts to the Treasury. For the purpose of this estimate, we assume that S. 625 will be enacted on October 1, 2008; as a result, we estimate that no fees would be collected for fiscal year 2008.

b. Reflects funding generated by the assessment of fees on manufacturers and importers of tobacco products. Authorized amounts would be deposited in the Tobacco Product User Fee Fund established under the bill and available to FDA for obligation without further appropriation action. Fees collected in excess of the levels authorized to pay for FDA's administrative costs would be deposited in the general fund of the Treasury.

c. Negative numbers indicate a reduction in the deficit (or an increase in the surplus); positive numbers indicate the opposite.

## BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 625 will be enacted on October 1, 2008, that the full amounts authorized will be collected (starting in fiscal year 2009) to fund FDA's regulatory activities authorized under the bill, and that outlays will follow historical patterns for similar activities.

S. 625 would authorize FDA to regulate tobacco products. Such authority would include:

- Setting national standards for tobacco products;
- 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 tobacco manufacturers and importers 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.

S. 625 would establish the Center for Tobacco Products within the FDA. It would also 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 reserve to the Congress the authority to ban tobacco products. The legislation also would mandate that FDA issue new regulations relating to the testing and reporting of tobacco product information. Such regulations may also include public disclosure requirements. Among other things, S. 625 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.

**Revenues**

CBO estimates that enacting S. 625 would increase federal revenues, on net, by $2.2 billion over the 2009-2013 period and by $5.2 billion over the 2009-2018 period. The legislation would affect revenues in three ways:

- Requiring FDA to assess fees on tobacco manufacturers and importers primarily to cover the cost of FDA's new activities related to regulating tobacco products would increase governmental receipts (assuming that the fees would be recorded as revenues in the federal budget),

- 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

- Collecting fines associated with violations of certain new requirements imposed by the bill would be recorded as federal revenues.

**Collections of Fees**. To fund FDA's administrative expenses for new regulatory activities relating to tobacco products authorized by the bill, S. 625 would require the quarterly assessment of fees on manufacturers and importers of such products equal to $85 million in 2008, $235 million in 2009, and $450 million in 2010. In later years, total assessments charged to cover FDA's regulatory costs would be capped at the aggregate fees charged for previous fiscal year, increased by a formula specified in the bill. (In accordance with the formula specified in the bill, CBO estimates that assessments beyond 2010 would grow annually by almost 6 percent, reflecting the past changes in per capita personnel costs at FDA.) For the purpose of this estimate, we assume that S. 625 will be enacted on or about October 1, 2008; as a result, we estimate that no fees would be collected for fiscal year 2008.

Although FDA has not completed its analysis of the annual costs necessary to implement the bill, CBO expects that starting in fiscal year 2009 the maximum fee levels authorized each year would be assessed. Given the comprehensive nature of the new regulatory authority granted under the bill, CBO expects that the tobacco program at FDA created under such new authority would be developed within the constraints of funding generated by such assessments.

S. 625 also would require that FDA further increase aggregate assessments authorized under the bill by 42.174 percent each year. Additional collections generated by the adjustment would be deposited in the general fund of the Treasury. In total, we estimate that implementing the bill would increase federal revenues from assessments on manufacturers

and importers of tobacco products by $3.1 billion over the 2009-2013 period and by $7.6 billion over the 2009-2018 period.

Excise taxes and other indirect business charges reduce the tax base of income and payroll taxes. CBO estimates that the assessments in S. 625 would reduce income and payroll taxes by an estimated 25 percent of the gross assessments. Hence, overall federal revenues would increase, on net, by $2.3 billion over the 2009-2013 period and by $5.7 billion over the 2009-2018 period as a result of these assessments.

**Impact of FDA Regulation of Tobacco on Revenues**. CBO estimates that consumption of tobacco products would decline as a result of enactment of S. 625, which in turn would reduce the collection of federal excise taxes. The expected effect of the legislation on tobacco consumption results 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 certain tobacco packaging to contain larger and pictorial 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 to those regulatory actions, tobacco consumption would decline because the assessment of new fees on manufacturers and importers of tobacco products required by the bill likely would result in higher prices of tobacco products.

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. Public heath efforts by federal, state, and local governments and 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 expanding coverage of smoking cessation therapies under certain public programs also aim to reduce the use of tobacco under current law.

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1. For example, pursuant to a timeline specified under 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. Sponsors of the so-called "modified risk products" would have to prove to FDA's satisfaction that they would reduce harm to individuals and produce certain benefits to the public health, and comply with other requirements in the bill.

Based on information from academic and other researchers, CBO estimates that S. 625 would result in a further reduction in the number of underage tobacco users of roughly 10 percent. Some of those effects would persist into adulthood as children age, but some children would only delay beginning to smoke rather than permanently remaining nonsmokers. CBO also estimates that, as a consequence of this legislation, smoking by adults overall would decline by amounts reaching about 2 percent after ten years. As a result of those reductions in rates of smoking, CBO estimates that the legislation would reduce federal revenues by $517 million over the 2009-2018 period, net of increases to income and payroll taxes. Over the 10-year period, the reduction in receipts would amount to less than one percent of excise tax receipts from tobacco expected under current law.

The effects on 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 Federal Trade Commission (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 fines authorized under S. 625 would be roughly $1 million annually.

## Direct Spending

S. 625 would affect direct spending in two main ways. First, spending by FDA to regulate tobacco products as authorized by the bill would be classified as direct spending. Second, CBO also expects that any reduction in smoking rates resulting from the bill's new requirements and FDA's regulatory activities would generate savings to the Medicaid program. CBO estimates that enacting the legislation would increase direct spending, on net, by $2.0 billion over the 2008-2013 period and by $5.2 billion over the 2008-2018 period.

**Spending of Fees by FDA to Regulate Tobacco Products**. To fund FDA's costs associated with regulating tobacco products, S. 625 would require the assessment of fees on manufacturers and importers of tobacco products. Authorized amounts collected for such purpose would be deposited into the Tobacco Product User Fee Fund established under the bill. Spending of the fees by FDA would be classified as direct spending because deposited amounts would be available for obligation without further appropriation action. (CBO anticipates that the assessments would be classified as revenues; they are discussed in the revenue section of this estimate.)

Given the uncertainty surrounding how the FDA would design 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. The bill would set the total aggregate assessments to be

collected for FDA's administration costs in 2009 and 2010 equal to $685 million. (We expect that FDA would not assess fees for 2008 because we assume that enactment of S. 625 will occur on or about October 1, 2008.) Such amounts would be available for obligation to cover FDA's administrative costs to regulate tobacco at any point in the future. We anticipate that over the initial five-year period after enactment, FDA would be actively developing the necessary infrastructure to operate the new tobacco program and that its ability to enter into obligations and disburse funds would grow rapidly. CBO expects that the budget for the new program would be limited by fees collected for such purpose.

CBO estimates that implementing FDA's activities required by the bill would increase direct spending by $2.0 billion over the 2009-2013 period and by $5.3 billion over the 2009-2018 period.

**Impact of FDA Regulation of Tobacco on Medicaid**. CBO anticipates that the decline in smoking due to FDA's regulation of tobacco products also would reduce the number of women on Medicaid who smoke during pregnancy. This reduction would lead to lower spending by the Medicaid program—which covers about 40 percent of all pregnancies in the United States—because women who do not smoke are less likely to have miscarriages, experience complications during pregnancy, and give birth to children with low birth weights.

A variety of research indicates that children with low birth weights have higher medical costs, particularly at birth, but also later in life. Savings of some such costs would be partly offset by higher costs for additional live births because of the decline in miscarriages. On net, CBO estimates that FDA's regulation of tobacco products would reduce federal Medicaid spending by $78 million over the 2009-2018 period. Reduced smoking levels may have additional effects on other federal health care programs. However, CBO did not estimate any additional effects, because the magnitude and direction of those effects is less certain than the impact of reduced smoking levels on pregnancies covered by Medicaid.

**Other Effects on Direct Spending**. Under S. 625, 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 expenditures are classified as direct spending. CBO expects that relatively few cases would result in such criminal fines. Therefore, CBO estimates that enacting S. 625 would not have a significant effect on direct spending from the collection of criminal fines over the 2009-2018 period.

### Spending Subject to Appropriation

CBO estimates that implementing S. 625 would not have a significant effect on spending by other federal programs affected by the bill whose funding is subject to appropriation. The costs for FDA to administer the new regulatory activities authorized under S. 625 would be covered by fees assessed on manufacturers and importers of tobacco products, would not be subject to appropriation, and therefore are classified as direct spending.

**Regulatory Activities of the Federal Trade Commission**. 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. S. 625 would transfer some of that regulatory authority to FDA. Based on information from the FTC, CBO expects that any additional costs incurred by the FTC to enforce the new requirements would be offset by savings that result from transferring some of FTC's current authority to FDA. Therefore, CBO estimates that implementing S. 625 would not have a significant effect on spending by the commission.

**Other Provisions**. S. 625 would require the Comptroller General of the United States to conduct a study of cross-border trade in tobacco products. CBO estimates the study would cost less than $500,000, assuming the availability of appropriated funds. CBO also anticipates that any additional costs for other federal agencies that might assist FDA with implementing certain requirements under the bill would not be significant.

## ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 625 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 ($68 million in 2008, 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 approval
- 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.

S. 625 would require manufacturers of tobacco products to register annually with FDA and pay fees assessed by the agency. The bill would require both manufacturers and distributors of tobacco products to comply with federal regulations relating to the content, labeling, and marketing of those 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 threshold for intergovernmental mandates ($68 million in 2008, adjusted annually for inflation).

**Other Impacts**

CBO also estimates 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 more than $1.3 billion during the 2009-2013 period, would not result from intergovernmental mandates.

In 2006, state and local governments collected about $20 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 $25 million in 2009, with that reduction growing to almost $400 million in 2013. Similarly, CBO estimates that state and local governments would see a decline in sales-tax revenues of about $230 million over the 2009-2013 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. In 2006, those payments totaled over $7 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 $180 million over the 2009-2013 period.

A decline in smoking among pregnant individuals is expected to result in healthier birth outcomes under the bill. CBO therefore estimates that state spending for Medicaid would decrease by about $14 million over the 2009-2013 period.

## ESTIMATED IMPACT ON THE PRIVATE SECTOR

S. 625 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 ($136 million in 2008, adjusted annually for inflation) in fiscal year 2009 and in each subsequent year.

The bill would assess a fee on manufacturers and importers of tobacco products to cover the cost to FDA of regulating those products. CBO estimates that the aggregate payments would be $334 million in fiscal year 2009, $640 million in fiscal year 2010, $677 million in fiscal year 2011, $716 million in fiscal year 2012, and $758 million in fiscal year 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 and, in the case of cigarette warning labels, include pictorial graphics. The bill would also prohibit cigarettes or any of their component parts from containing certain additives or artificial or natural 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 nearly identical to part 897 of the tobacco regulations promulgated by the Secretary of HHS in 1996 and subsequently invalidated by the Supreme Court. Many restrictions in the 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 or otherwise alter the composition and

testing of tobacco products. CBO is not able to 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 that companies that manufacture or import tobacco products disclose information to the Secretary of HHS about those products. 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. Required information would also include 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.

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