CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

March 24, 2009

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

As ordered reported by the Committee on Oversight and Government Reform on March 18, 2009

SUMMARY

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

CBO estimates that:

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

- Enacting H.R. 1256 would increase direct spending by $0.2 billion over the 2010-2014 period and by $0.6 billion over the 2010-2019 period;

- Federal revenues would increase by $0.3 billion over the 2010-2014 period and by $1.3 billion over the 2010-2019 period; and

- Considering both the revenue and direct spending effects, enacting the bill would reduce budget deficits by a total of $0.1 billion over the 2010-2014 period and by $0.7 billion over the 2010-2019 period. (Those amounts exclude the effects that are subject to appropriation action.)

The legislation's effects on direct spending and revenues over the 2009-2013 and 2009-2018 periods are relevant for enforcing pay-as-you-go rules under the current budget resolution. CBO estimates that enacting H.R. 1256 would increase direct spending by $0.1 billion over the 2009-2013 period and by $0.5 billion over the 2009-2018 period. Enacting the bill also would increase revenues by $0.2 billion over the 2009-2013 period and by $1.0 billion over the 2009-2018 period. Together, those changes would yield net pay-as-you-go savings of $0.1 billion over five years and $0.5 billion over 10 years.

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

CBO also expects that the federal regulations authorized by this bill would result in lower consumption of tobacco products and thus would reduce the amount of tax revenues and settlement funds collected by state and local governments. However, those declines in revenues, estimated to total over $1 billion during the 2010-2014 period, would not result from intergovernmental mandates.

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

ESTIMATED COST TO THE FEDERAL GOVERNMENT

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

	By Fiscal Year, in Millions of Dollars											
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010-2014	2010-2019
CHANGES IN SPENDING SUBJECT TO APPROPRIATION												
Food and Drug Administration (FDA)												
Collection of New Tobacco Fees												
Authorization Level	-235	-450	-477	-505	-534	-566	-599	-635	-672	-712	-2,201	-5,385
Estimated Outlays	-235	-450	-477	-505	-534	-566	-599	-635	-672	-712	-2,201	-5,385
Spending of Fees by FDA to Regulate Tobacco Products												
Authorization Level	235	450	477	505	534	566	599	635	672	712	2,201	5,385
Estimated Outlays	50	275	498	610	619	627	629	631	668	708	2,052	5,315
Net Effect on FDA Spending												
Authorization Level	0	0	0	0	0	0	0	0	0	0	0	0
Estimated Outlays	-185	-175	21	105	85	61	30	-4	-4	-4	-149	-70
Thrift Savings Plan Enhancement												
Estimated Authorization Level	14	49	62	76	89	102	112	121	130	139	290	894
Estimated Outlays	13	47	62	75	88	101	111	121	130	139	285	887
Total Changes[a]												
Estimated Authorization Level	14	49	62	76	89	102	112	121	130	139	290	894
Estimated Outlays	-172	-128	83	180	173	162	141	117	126	135	136	817
CHANGES IN DIRECT SPENDING												
Sick Leave Retirement Credit												
Estimated Budget Authority	8	17	27	37	48	60	72	86	100	114	137	569
Estimated Outlays	8	17	27	37	48	60	72	86	100	114	137	569
Other Retirement Provisions												
Estimated Budget Authority	8	6	7	10	11	12	12	13	13	14	42	106
Estimated Outlays	8	6	7	10	11	12	12	13	13	14	42	106
Medicaid: Tobacco Provisions												
Estimated Budget Authority	-1	-2	-4	-6	-9	-11	-13	-15	-18	-20	-22	-99
Estimated Outlays	-1	-2	-4	-6	-9	-11	-13	-15	-18	-20	-22	-99
Total Changes												
Estimated Budget Authority	15	21	30	41	50	61	71	84	95	108	157	576
Estimated Outlays	15	21	30	41	50	61	71	84	95	108	157	576

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	By Fiscal Year, in Millions of Dollars											
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010-2014	2010-2019
CHANGES IN REVENUES												
Thrift Savings Plan Enhancement	50	79	98	122	155	198	255	330	426	550	504	2,263
Tobacco Excise Taxes and Fines	-13	-29	-40	-55	-73	-94	-117	-145	-177	-212	-210	-955
Total Changes in Revenues	37	50	58	67	82	107	138	185	249	338	294	1,308
NET IMPACT ON THE DEFICIT FROM CHANGES IN DIRECT SPENDING AND REVENUES												
Estimated Deficit Impact[b]	-22	-29	-28	-26	-32	-43	-67	-101	-154	-230	-137	-732

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

b. Negative numbers indicate a reduction in the deficit.

BASIS OF ESTIMATE

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

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

- Setting national standards for tobacco products, including a ban on cigarettes that contain certain additives or flavors (other than tobacco or menthol) that are a characterizing flavor of the tobacco product or tobacco smoke;

- Implementing new restrictions on the sale, distribution, and marketing of tobacco products;

- Requiring manufacturers of certain tobacco products to submit a marketing application to FDA and requiring manufacturers of certain products that are "substantially equivalent" to ones already on the market before a particular date to notify FDA by submitting a report with specified information before entering the market;

- Directing manufacturers and importers of tobacco products to adhere to new labeling requirements and to submit specific information, including health-related research, to the FDA about their products;

- Mandating the annual registration of all establishments that manufacturer, prepare, compound, or process tobacco products and specifying certain inspection, record-keeping and reporting requirement for manufacturers and importers; and

- Enforcing compliance with requirements specified in the bill.

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

Use of Tobacco Products in the United States

At least partly as a result of efforts by the federal government, state governments, and the public health community, cigarette smoking has declined substantially over the past decade: in 2005, about 21 percent of adults in the United States were smokers, compared to about 25 percent in 1995. The recent increase in the federal excise tax on cigarettes as a result of the Children's Health Insurance Program Reauthorization Act (Public Law 111-3)─from $0.39 to $1.01 per pack─is likely to contribute to a continuing decline in smoking. CBO expects that consumption of tobacco products in the United States would further decline as a result of enacting H.R. 1256.

The effect of regulatory activities authorized under the bill on the use of tobacco products is uncertain because ongoing initiatives to reduce the use of tobacco products are

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

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

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

Spending Subject to Appropriation

CBO estimates that implementing H.R. 1256 would increase spending subject to appropriation, on net, by $0.1 billion over the 2010-2014 period and by $0.8 billion over the 2010-2019 period, assuming the appropriation action consistent with the bill. The

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

effect on discretionary spending by federal programs reflects the authorized funding relating to the federal regulation of tobacco products and federal agency costs associated with changes to the Thrift Savings Plan (TSP) specified in the bill.

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

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

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

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

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

and there would likely be some lag (at least initially) between when fees are collected and when they are spent.

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

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

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

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

Federal Trade Commission (FTC). The bill would authorize the FTC to enforce provisions in the bill relating to advertising that would be considered unfair or deceptive

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

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

Direct Spending

CBO estimates that enacting H.R. 1256 would increase direct spending, on net, by $0.2 billion over the 2010-2014 period and by $0.6 billion over the 2010-2019 period. That estimate primarily reflects two effects of the bill:

- Authorizing FDA regulation of tobacco products and changes relating to such products required by the bill would lower consumption of tobacco and would generate savings to the Medicaid program; and

- Changing the calculation of federal retirement benefits under the Federal Employees Retirement System to reflect accrued sick leave hours would raise average retirement benefits paid to individuals.

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

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

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

H.R. 1256 contains several other provisions that would affect federal retirement benefits for certain employees. Such provisions include: allowing FERS employees who reenter government service after an absence to "buy back" the credit towards federal retirement benefits for their prior government service (for those employees who had received a refund of their employee contributions toward retirement when they left government service); altering the formula for calculating retirement benefits for CSRS employees with part-time service; adjusting retirement eligibility calculations for certain FERS employees with qualifying pre-1997 service in the District of Columbia; and exempting certain CSRS employees from paying interest on repaid contributions towards retirement benefits. In total, CBO estimates those provisions would increase direct spending by $0.1 billion over the 2010-2019 period.

Other Effects on Direct Spending. Under H.R. 1256, FDA would have the discretion to impose criminal fines on entities convicted of violating certain new requirements established by the bill. Collections of criminal fines are recorded in the budget as revenues, deposited in the Crime Victims Fund, and later spent. Such expenditures are classified as direct spending. CBO expects that relatively few cases would result in such

criminal fines. Therefore, CBO estimates that enacting H.R. 1256 would not have a significant effect on revenues or direct spending from the collection of criminal fines over the 2010-2019 period.

Revenues

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

- Authorizing FDA oversight of tobacco products and changes relating to such products required by the bill would lower consumption of tobacco and reduce receipts of federal excise taxes on those products, and

- Establishing a Roth contribution program would increase tax revenues because of the tax treatment of employee's contributions.

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

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

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

Collection of Fines. The effects on federal revenues also include relatively small effects from provisions that would allow the Secretary of HHS to levy fines against sponsors of misbranded and adulterated tobacco products, sellers of tobacco to underage individuals,

and for other violations. The FTC would also be authorized to assess fines for certain violations of tobacco-related requirements enforced by the commission. We estimate that revenues associated with the collection of civil fines authorized under H.R. 1256 would be roughly $1 million annually.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 1256 contains intergovernmental mandates as defined in UMRA. CBO estimates that the costs of those mandates to state, local, and tribal governments would be small and would not exceed the threshold established in UMRA ($69 million in 2009, adjusted annually for inflation).

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

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

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

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

Other Impacts

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

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

Forty-six states, the District of Columbia, and five U.S. territories receive annual payments from tobacco manufacturers that are parties to the tobacco Master Settlement Agreement (MSA). In 2008, those payments totaled over $8 billion. Under the terms of the MSA, those payments are adjusted annually to account for changes in the volume of cigarette sales in the United States of participating manufacturers. Because CBO estimates that enacting this legislation would result in lower consumption of tobacco products, CBO estimates that the annual payments to states under the MSA also would decline by over $160 million over the 2010-2014 period.

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

ESTIMATED IMPACT ON THE PRIVATE SECTOR

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

the cost to FDA of regulating those products. The aggregate payments would sum to $235 million in 2010, and rise to more than $500 million a year by 2013.

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

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

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

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

PREVIOUS CBO ESTIMATE

On March 16, 2009, CBO transmitted a cost estimate for H.R. 1256 as ordered reported by the House Committee on Energy and Commerce on March 4, 2009. This version is nearly identical to the earlier legislation, except for the addition of provisions that affect retirement benefits for certain employees of the federal government. The version of H.R. 1256 approved by the Committee on Oversight and Government Reform reflects changes that would add $106 million in estimated direct spending over the 2010-2019 period, as compared to the version of the bill approved by the Committee on Energy and Commerce.

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