



CONGRESSIONAL BUDGET OFFICE  
COST ESTIMATE

June 18, 2008

**H.R. 1108**  
**Family Smoking Prevention and Tobacco Control Act**

*As ordered reported by the House Committee on Energy and Commerce  
on April 2, 2008*

**SUMMARY**

H.R. 1108 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 by the bill. CBO estimates that:

- Enacting H.R. 1108 would reduce direct spending, on net, by \$0.3 billion over the 2009-2013 period and by \$0.5 billion over the 2009-2018 period.
- Federal revenues would decline by \$0.1 billion over the 2009-2013 period and by \$0.4 billion over the 2009-2018 period.
- Considering both the revenue and direct spending effects, enacting the bill would reduce budget deficits (or increase surpluses) by a total of \$0.2 billion over the 2009-2013 period and \$31 million over the 2009-2018 period.
- In addition, CBO estimates that implementing the bill would increase spending subject to appropriation by about \$3 million over the 2009-2013 period, assuming the availability of the necessary funds.

H.R. 1108 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 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 more than \$1.1 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.

H.R. 1108 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 H.R. 1108 is shown in the following table. The costs of this legislation fall primarily within budget functions 370 (commerce and housing credit) and 550 (health).

## **BASIS OF ESTIMATE**

For this estimate, CBO assumes that H.R. 1108 will be enacted near the start of fiscal year 2009, 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.

|  | By Fiscal Year, in Millions of Dollars |      |      |      |      |      |      |      |      |      |           |           |
|--|--|------|------|------|------|------|------|------|------|------|-----------|-----------|
|  | 2009                                   | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2009-2013 | 2009-2018 |
| <b>CHANGES IN DIRECT SPENDING</b>                    |  |      |      |      |      |      |      |      |      |      |           |           |
| Collection of New Fees <sup>a</sup>                  |  |      |      |      |      |      |      |      |      |      |           |           |
| Estimated Budget Authority                           | -249                                   | -477 | -506 | -535 | -566 | -600 | -635 | -673 | -712 | -755 | -2,333    | -5,708    |
| Estimated Outlays                                    | -249                                   | -477 | -506 | -535 | -566 | -600 | -635 | -673 | -712 | -755 | -2,333    | -5,708    |
| Spending of Fees by FDA to Regulate Tobacco Products |  |      |      |      |      |      |      |      |      |      |           |           |
| Estimated Budget Authority                           | 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     |
| Medicaid   |  |      |      |      |      |      |      |      |      |      |           |           |
| Estimated Budget Authority                           | -1                                     | -2   | -4   | -6   | -8   | -9   | -11  | -13  | -14  | -16  | -19       | -82       |
| Estimated Outlays                                    | -1                                     | -2   | -4   | -6   | -8   | -9   | -11  | -13  | -14  | -16  | -19       | -82       |
| Total Changes  |  |      |      |      |      |      |      |      |      |      |           |           |
| Estimated Budget Authority                           | -15                                    | -29  | -33  | -36  | -40  | -43  | -47  | -51  | -54  | -59  | -151      | -405      |
| Estimated Outlays                                    | -200                                   | -204 | -12  | 69   | 45   | 18   | -17  | -55  | -58  | -63  | -302      | -477      |
| <b>CHANGES IN REVENUES</b>                           |  |      |      |      |      |      |      |      |      |      |           |           |
| Estimated Revenues                                   | -6                                     | -14  | -23  | -31  | -40  | -49  | -58  | -67  | -75  | -83  | -114      | -446      |
| <b>NET IMPACT ON THE FEDERAL BUDGET<sup>b</sup></b>  |  |      |      |      |      |      |      |      |      |      |           |           |
| Estimated Net Effect <sup>c</sup>                    | -194                                   | -190 | 11   | 100  | 85   | 67   | 41   | 12   | 17   | 20   | -188      | -31       |

Notes: FDA = Food and Drug Administration. Components may not sum to totals because of rounding.

- a. H.R. 1108 would specify that assessments on manufacturers and importers of tobacco products be recorded in the federal budget as offsetting receipts (a credit against direct spending).
- b. In addition to the direct spending and revenue effects shown in the table, CBO estimates that implementing H.R. 1108 would have discretionary costs of about \$3 million over the 2009-2013 period, assuming the availability of appropriated funds.
- c. Negative numbers indicate a reduction in the deficit (or an increase in the surplus); positive numbers indicate the opposite.

H.R. 1108 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 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 requirements for manufacturers and importers; and
- Enforcing compliance with requirements specified in the bill.

H.R. 1108 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 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, H.R. 1108 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.

### **Impact of FDA Regulation of Tobacco on the Use of Tobacco Products in the United States**

CBO estimates that consumption of tobacco products in the United States would decline as a result of enacting H.R. 1108. The expected effect 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 augment 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.<sup>1</sup> 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.

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 health 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.

Based on information from academic and other researchers, CBO estimates that H.R. 1108 would result in a further reduction in the number of underage tobacco users of roughly 10 percent. CBO also estimates that, as a consequence of this legislation, smoking by adults overall would decline by amounts reaching about 2 percent after 10 years. CBO incorporates these projected changes in its estimates of the impact of the bill on Medicaid spending and on receipts from excise taxes on tobacco products.

## **Direct Spending**

CBO estimates that enacting H.R. 1108 would reduce direct spending, on net, by \$0.3 billion over the 2009-2013 period and by \$0.5 billion over the 2009-2018 period. The legislation would affect direct spending 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 mandatory offsetting receipts;

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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. 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.

- Spending of those fees by FDA to regulate tobacco products as authorized by the bill would increase direct spending for such activities; and
- 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.

**Collection of New Fees.** To fund FDA's administrative costs for new regulatory activities relating to tobacco products authorized by the bill, H.R. 1108 would require the quarterly assessment of fees on manufacturers and importers of such products approximately equal to \$90.1 million in 2008, \$249.1 million in 2009, \$477.0 million in 2010, \$505.6 million in 2011, \$535.3 million in 2012, \$566.0 million in 2013, \$600.0 million in 2014, \$634.9 million in 2015, \$673.1 million in 2016, \$712.3 million in 2017, and \$754.7 million in 2018 and each subsequent year. H.R. 1108 would specify that such collections be recorded in the federal budget as offsetting receipts. (Offsetting receipts are a credit against direct spending.) Fees collected in excess of the amounts authorized to pay for FDA's administrative costs would be deposited in the general fund of the Treasury. For the purpose of this estimate, we assume that H.R. 1108 will be enacted near the start of fiscal year 2009; as a result, we estimate that no fees would be collected for fiscal year 2008.

In total, we estimate that enacting the bill would increase offsetting receipts from assessments on manufacturers and importers of tobacco products by \$2.3 billion over the 2009-2013 period and by \$5.7 billion over the 2009-2018 period.

**Spending of Fees by FDA to Regulate Tobacco Products.** Spending of the new fees assessed by FDA to regulate tobacco products would be classified as direct spending because the authorized amounts would be available for obligation without further appropriation action. The bill would authorize the following amounts to fund FDA's costs associated with regulating tobacco products: \$85.0 million in 2008, \$235.0 million in 2009, \$450.0 million in 2010, \$477.0 million in 2011, \$505.0 million in 2012, \$534.0 million in 2013, \$566.0 million in 2014, \$599.0 million in 2015, \$635.0 million in 2016, \$672.0 million in 2017, and \$712.0 million in 2018 and each subsequent year. Such amounts would be available for obligation 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.) CBO estimates FDA's activities required by the bill would increase direct spending by \$2.1 billion over the 2009-2013 period and \$5.3 billion over the 2009-2018 period.

After accounting for the offsetting receipts collected from assessments on manufacturers and importers of tobacco products authorized by the bill, CBO estimates that implementing the new regulatory program established by the bill would reduce direct spending for FDA activities, on net, by almost \$0.3 billion over the 2009-2013 period and by \$0.4 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. (See the discussion of the effect of the bill on tobacco use in the section entitled "Impact of FDA Regulation of Tobacco on the Use of Tobacco Products in the United States.") 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 \$19 million over the 2009-2013 period and by \$82 million over the 2009-2018 period.

**Other Effects on Direct Spending.** Under H.R. 1108, 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. 1108 would not have a significant effect on direct spending from the collection of criminal fines over the 2009-2018 period.

## Revenues

CBO estimates that enacting H.R. 1108 would decrease federal revenues, on net, by \$0.1 billion over the 2009-2013 period and by \$0.4 billion over the 2009-2018 period. That estimate 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
- Fines associated with violations of certain new requirements imposed by the bill would be recorded as revenues in the federal budget.

**Excise Taxes.** CBO expects that enacting H.R. 1108 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 \$0.1 billion over the 2009-2013 period and \$0.5 billion 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 1 percent of receipts from excise taxes on tobacco expected under current law.

**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 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 H.R. 1108 would be roughly \$1 million annually.

**Effects of Fees on Taxes.** The imposition of fees to fund FDA's activities under the bill would have the effect of reducing collections from federal corporate, individual, and payroll taxes. This would result from the effect of the fees on taxable income. The resulting reduction in federal receipts would be approximately 25 percent of the fee imposed. However, because the legislation designates the fee as an "offsetting receipt," this effect is not included in the estimate pursuant to longstanding Congressional scorekeeping procedures.

## **Spending Subject to Appropriation**

CBO estimates that implementing H.R. 1108 would increase spending subject to appropriation by about \$3 million over the 2009-2013 period for the FTC and the Government Accountability Office (GAO) to conduct studies required by the bill, assuming the availability of the necessary funds. The costs for FDA to administer the new regulatory activities authorized under H.R. 1108 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. We expect that the legislation would not have a significant effect on spending by other federal programs whose funding is subject to appropriation.

**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. H.R. 1108 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 the FTC's current authority to FDA. In addition, the bill would require that the FTC conduct a study on the tobacco industry and issue two separate reports within 10 years of enactment. Over the 2009-2013 period, CBO estimates that completing the first report would cost about \$2 million, assuming the availability of the necessary funds.

**Other Provisions.** H.R. 1108 would require GAO to conduct two studies: one on cross-border trade in tobacco products and one on the use of tobacco products by youth and certain issues related to the fee program. CBO estimates that conducting such studies would cost roughly \$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 under the bill would not be significant.

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

H.R. 1108 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 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. 1108 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 \$1.1 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 \$20 million in 2009, with that reduction growing to almost \$340 million

in 2013. Similarly, CBO estimates that state and local governments would see a decline in sales-tax revenues of about \$190 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 \$155 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**

H.R. 1108 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. The aggregate payments would be approximately equal to \$249.1 million in fiscal year 2009, \$477.0 million in fiscal year 2010, \$505.6 million in fiscal year 2011, \$535.3 million in fiscal year 2012, and \$566.0 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. 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 similar to part 897 of the tobacco regulations promulgated by the Secretary of HHS in 1996 and subsequently invalidated by the Supreme Court. Many 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 or otherwise alter the composition and testing of tobacco products. CBO cannot estimate the potential cost of these provisions because we have no basis for predicting how they would be implemented.

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.

## **PREVIOUS CBO ESTIMATE**

On January 30, 2008, CBO transmitted a cost estimate for S. 625, the Family Smoking Prevention and Tobacco Control Act, as ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on August 1, 2007. CBO estimated that enacting S. 625 would have no net budgetary impact over the 2009-2018 period, considering both the effects on revenue and direct spending. The difference in the estimates reflects differences in the bills.

**ESTIMATE PREPARED BY:**

Federal Spending: Food and Drug Administration—Julia Christensen  
Medicaid—Robert Stewart  
Federal Trade Commission—Susan Willie

Federal Revenues: Andrew Langan

Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum

Impact on the Private Sector: Patrick Bernhardt

**ESTIMATE APPROVED BY:**

G. Thomas Woodward  
Assistant Director for Tax Analysis

Keith J. Fontenot  
Deputy Assistant Director for Health and Human Resources,  
Budget Analysis Division