



CONGRESSIONAL BUDGET OFFICE  
COST ESTIMATE

September 26, 2006

**H.R. 5533**  
**Biodefense and Pandemic Vaccine and Drug Development Act of 2006**

*As ordered reported by the House Committee on Energy and Commerce  
on September 20, 2006*

**SUMMARY**

H.R. 5533 would create an office at the Department of Health and Human Services (HHS) called the Biomedical Advanced Research and Development Authority (BARDA). BARDA would oversee advanced research and development of products to defend against bioterrorism and pandemic influenza. The bill also would establish the National Biodefense Science Board, an advisory group that would provide scientific guidance to HHS on issues involving chemical, biological, radiological, and nuclear agents. Additionally, the bill would require HHS to establish a team of experts at the Food and Drug Administration (FDA) to provide technical assistance to drug manufacturers when shortages of certain vaccines and drugs occur. H.R. 5533 also would clarify that Project BioShield, a program that provides incentives to companies to manufacture vaccines and drugs, covers certain products—so-called qualified and security countermeasures—that address public health threats caused by acts of terrorism.

The bill would authorize the appropriation of \$160 million for each of fiscal years 2007 and 2008 for activities related to the operation of BARDA. The bill also would authorize the appropriation of \$1 million for each of fiscal years 2007 and 2008 for the National Biodefense Science Board. CBO estimates that \$1 million a year would be necessary for FDA to implement activities outlined in the bill. Assuming appropriation of the authorized and necessary amounts, CBO estimates that implementing H.R. 5533 would cost \$33 million in 2007 and \$319 million over the 2007-2011 period. Enacting the bill would not affect direct spending or receipts.

H.R. 5533 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

## ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 5533 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars				
	2007	2008	2009	2010	2011
<b>CHANGES IN SPENDING SUBJECT TO APPROPRIATION</b>					
<b>BARDA</b>					
Authorization Level	160	160	0	0	0
Estimated Outlays	31	148	101	24	8
<b>National Biodefense Science Board</b>					
Authorization Level	1	1	0	0	0
Estimated Outlays	1	1	0	0	0
<b>FDA</b>					
Estimated Authorization Level	1	1	1	1	1
Estimated Outlays	1	1	1	1	1
<b>Total Changes</b>					
Estimated Authorization Level	162	162	1	1	1
Estimated Outlays	33	150	102	25	9

## BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 5533 will be enacted before the end of calendar year 2006, and that the authorized and necessary amounts will be provided each year.

### Biomedical Advanced Research and Development Authority (BARDA)

H.R. 5533 would establish BARDA as a new agency within HHS. BARDA would provide incentives and guidance for research and development of products to counter bioterrorism and pandemic influenza. The bill would authorize the appropriation of \$160 million for each of fiscal years 2007 and 2008 for activities to be performed by this new agency. Those activities would include facilitating collaboration among government, private industry, and academia; encouraging advanced research and development of those products; and promoting scientific innovation to reduce the time and cost of development. Specifically, BARDA would direct and coordinate research and development activities for countermeasures to

bioterrorism and pandemic influenza at HHS. The agency also would offer grants, awards, and prizes to industry to provide incentives to develop certain countermeasures deemed priorities.

For this estimate, CBO assumes that spending by BARDA would follow historical spending patterns for similar research and development activities in health care and defense programs. Assuming appropriation of the authorized amounts, CBO estimates that BARDA spending would total \$31 million in 2007 and \$312 million over the 2007-2011 period.

### **National Biodefense Science Board**

The bill would authorize the appropriation of \$1 million for each of fiscal years 2007 and 2008 to establish the National Biodefense Science Board, an advisory group that would provide scientific and technical guidance to HHS on current and future chemical, biological, radiological, and nuclear agents. Assuming appropriation of the authorized amounts, CBO estimates that provision would cost \$2 million over the 2007-2008 period.

### **Food and Drug Administration (FDA)**

H.R. 5533 would require the FDA to provide technical assistance to drug manufacturers in cases where there are shortages of certain vaccines and drugs that the Secretary deems priorities for addressing a public health threat. Based on similar technical-advisory activities conducted by HHS, CBO estimates that the program would require funding of about \$1 million a year. CBO estimates that this provision of the bill would cost \$1 million in 2007 and \$5 million over the 2007-2011 period, assuming appropriation of the necessary amounts.

### **INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT**

H.R. 5533 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

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