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# Science and Technology Policy: Issues for the 108th Congress, 2nd Session

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## Summary

Science and technology have a pervasive influence over a wide range of issues confronting the nation. Decisions on how much federal funding to invest in research and development (R&D), and determining what programs have the highest priority, may have implications for homeland security, new high technology industries, government/private sector cooperation in R&D, and myriad other areas. This report provides an overview of key science and technology policy issues pending before Congress, and identifies other CRS reports that treat them in more depth. This report is updated occasionally. Many of the CRS reports cited herein are updated more frequently and should be consulted for timely information.

For FY2005, the Bush Administration is requesting $132 billion for research and development (R&D), an increase of $6 billion over the FY2004 appropriation. The FY2005 request, like those of the recent past, proposes large increases for defense and homeland security R&D, while the remaining agencies would receive modest increases or reductions. Funding for basic research would increase by 0.6% in FY2005, while applied research would remain level. The five-year goal of doubling the budget for the National Institutes of Health (NIH) was essentially accomplished in FY2003, with more modest growth since then (the FY2005 request is a 2.5% increase over FY2004).

In addition to debating the level of federal funding needed to support R&D (particularly at the Department of Defense and Department of Homeland Security), the 108th Congress is addressing a wide range of science and technology policy issues, from the funding of cloning and stem cell research, to the deployment of "broadband" technologies to allow high speed access to the Internet. Several energy issues are being debated, including President Bush's Hydrogen Fuel Initiative to develop hydrogen-fueled automobiles and for other applications. Agricultural biotechnology and global climate change research pose complex issues on both the domestic and international levels. Funding for aeronautics R&D, nanotechnology, and space programs (including President Bush's new space exploration goals for the National Aeronautics and Space Administration, NASA) are receiving congressional attention.

Congress also continues to debate ways to lower the costs of pharmaceuticals without hindering drug innovation. Because the federal government funds basic research in the biomedical area, some believe that the public is entitled to commensurate consideration in the prices charged for resulting drugs. Conversely, others argue that government intervention in drug pricing would be contrary to long-standing technology development policies associated with encouraging technological innovation. The role of the federal government in technology development is being debated as well.

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# Science and Technology Policy: Issues for the 108th Congress, 2nd Session

## Introduction

Science and technology are an underpinning of, and have a pervasive influence over, a wide range of issues confronting the nation. Decisions on how much federal funding to invest in basic and applied research and in research and development (R&D), and determining what programs have the highest priority, could have implications for homeland security, new high technology industries, government/private sector cooperation in R&D, and myriad other areas.

Following are brief discussions of some of the key science and technology issues pending before the 108th Congress. Additional in-depth CRS reports and issue briefs on these topics, many of which are frequently updated, are identified at the end of each section.

## Research and Development Budget: Policy Issues

### FY2005 Research and Development Budget

The Bush Administration requested $131.9 billion in federal research and development (R&D) funding for FY2005. This is $5.9 billion above the estimated $126 billion that was appropriated for federal R&D in FY2004. The President's R&D request mirrors recent past proposals with large increases for defense and homeland security R&D, while the remaining agencies are proposed to receive modest increases or reductions in their respective research programs. The President has requested $26.8 billion for basic research, a 0.6% increase over FY2004. However, if the National Institutes of Health (NIH)-proposed basic research increase is excluded from this total, basic research funding would decline 2.5%. Funding for applied research would be flat in FY2005 with a proposed budget of $28.5 billion.

Funding for the Administration's three interagency R&D efforts would be mixed. The National Nanotechnology Initiative, which has received annual double-digit increases over the past four years, would increase 2% to $982 million. Support for the Networking and Information Technology R&D initiative would remain at $2.008 billion, with NSF's share of this research expected to reach $761 million. Finally, funding for the Climate Change Science Program would decline 2.1% to $1.958 billion.

For FY2005, total defense R&D (the sum of the Department of Defense's (DOD) R&D programs and the Department of Energy's (DOE) defense-related R&D

activities) is proposed to increase 6.4% to $74.2 billion, while civilian R&D would increase 2.7% to $57.7 billion. For FY2005, defense R&D would account for 56% of all federal R&D expenditures, while civilian R&D would account for 44%. In FY2001, the ratio was 51% defense, and 49% civilian.

The Administration is requesting $1.2 billion for R&D in the Department of Homeland Security (DHS), a 15.5% increase over FY2004. Funding for basic and applied research is proposed to increase 152% to $431 million, reflecting DHS's objective of funding more long-term research. While the Administration is seeking a 6.6% increase for DOD's R&D programs, basic and applied research are proposed to decline 5% and 12% respectively. The Administration has requested $28.6 billion for NIH, a 2.6% increase over FY2004. The National Science Foundation's (NSF) budget would increase 2.9%, to $5.7 billion. However, the Administration has proposed to cut NSF's Educational Directorate 18% below FY2004.

A number of agencies would see funding for their R&D programs decline below FY2004 levels, including DOE (-2.0%), Agriculture (-2.6%), Interior (-4%), the National Oceanographic and Atmospheric Administration (-8%), and the National Institutes of Standards and Technology (-17%), which also includes a proposal to eliminate the Advanced Technology Program.

Congress has completed work on one of its appropriations bills, approving a record $69.853 billion for the Department of Defense's RDT&E budget. The House has passed 10 of its appropriations bills. Based on current House actions CRS estimates that federal R&D spending will increase in FY2005, primarily because of the large increase in DOD's budget. The research and experimental (R&E) tax credit expired on June 30th. A number of bills have been introduced to extend the R&E tax credit either permanently or for a specified period of time. (see CRS Report RL31181)

## Defense Research and Development

Nearly all of what DOD spends on Research, Development, Test and Evaluation (RDT&E) is appropriated in Title IV of the defense appropriations bill. The Bush Administration's amended request for FY2005 Title IV RDT&E was $67.9 billion. This is $3.2 billion above the amount made available in Title IV dollars for FY2004. The five-year budget plan estimates $352.9 billion for RDT&E through FY2009. This is about $20.5 billion more than what the Administration budgeted for RDT&E last year. RDT&E funds are also requested as part of the Defense Health Program ($72 million) and the Chemical Agents and Munitions Destruction Program ($167 million).

While the FY2005 RDT&E request would boost RDT&E funding overall, the proposed increases are focused on development activities. Basic research and applied research are proposed at levels below FY2004 funding in absolute terms, declining 5% and 12% respectively. The decline is greater when factoring in inflation. Over half of DOD's basic research budget is spent at universities and represents the major contributor of funds in some areas of science and technology. Much of the support of research at DOD laboratories comes from applied research accounts. The S&T funding request, which consists of basic and applied research and advanced development (6.1, 6.2 and 6.3 activities in the RDT&E account) is 2.6% of the overall DOD topline of $401.7 billion. This is below the 3% target that both the Bush

Administration and Congress have set. The budget request for Missile Defense RDT&E was $9.1 billion (an increase of $1.5 billion over the amount available for Missile Defense in FY2004). Increases were sought in most of the program line items, except advanced technology development and advanced component development of boost phase systems. Missile Defense Headquarters also requested an increase of $50 million as the Administration continues to plan to bring an operationally capable test facility in Alaska on line and to expand it in FY2004/FY2005. The budget request for the Defense Advanced Research Projects Agency (DARPA) was $3.1 billion, an increase of about $300 million.

The FY2005 appropriations bill (P.L. 108-287) provided $69.3 billion for title IV RD&TE. This includes three general reductions. The bill also appropriated $507 million for RDT&E in the Defense Health Program and $205 million in RDT&E for the Chemical Agents and Munitions Destruction Program. S&T received $13.3 billion, greater than 3% of the total DOD appropriation, excluding the additional war-related appropriations in Title IX. However, this figure does not include S&T's share of the general reductions made to RDT&E funding in Sections 8105, 8122, and 8131 of the bill. The Missile Defense Agency received $9.0 billion in RDT&E funding and DARPA received $3.1 billion.

## Information Quality Act Implementation and Peer Review

Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554, 44 U.S.C. 3504 (d)(1) and 3516), generally known as the "Information Quality Act" (IQA) or the "Data Quality Act," directed the Office of Management and Budget (OMB) to issue government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." OMB published those guidelines in final form on February 22, 2002 (67 FR 8452). The IQA also instructed agencies to issue their own guidelines and to establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency, and to report periodically to the Director of OMB on the number and nature of complaints received and how such complaints were handled by the agency.

The IQA builds upon existing agency responsibilities to assure the quality of information collected, used, or disseminated to the public. Supporters of the act contended that the law and the OMB and agency guidelines would improve the quality of agency science and regulation, help agencies defend their regulations against lawsuits, and reduce the number of lawsuits filed. However, opponents said the act and the guidelines were tools by which regulated parties could slow and possibly stop new health, safety, and environmental regulations, and revise or eliminate existing standards. Opponents have also noted that since "quality" is a subjective term and some regulations are based on "best available data," regulations could be arbitrarily rejected under this new law.

Because of the scant legislative history of the IQA and its lack of detail, OMB's guidance interpreting key provisions in the act has a major effect on its implementation. In those guidelines, OMB noted that the act applies to virtually all

federal agencies and established the broad scope of the guidelines by defining "information" as "any communication or representation of knowledge such as facts or data, in any medium or form." Similarly, the guidelines define "dissemination" as any "agency initiated or sponsored distribution of information to the public." OMB indicated that "quality" encompasses elements of utility, objectivity, and integrity, and said agencies can generally presume that data are "objective" if they have been subject to an independent peer review process.

In April 2004, OMB provided Congress with a report on the implementation of the IQA during FY2003. The report said the agencies received only about 35 substantive correction requests during the year, and said it was "premature to make broad statements about both the impact of the correction request process and the overall responsiveness of the agencies." Many other correction requests listed in the report were on minor issues or involved matters that had been dealt with before the IQA was enacted. OMB indicated that the correction requests came from all segments of society, and said there was no evidence that the IQA had affected the pace of rulemaking. However, OMB Watch (a public interest group) said OMB's report was "seriously flawed" in that it understated the number of correction requests and did not disclose that nearly three-quarters of the requests were from industry. A major test of the IQA's effectiveness is whether agencies' denials of correction requests are subject to judicial review. In June 2004, a U.S. District Court ruled that the act does not permit judicial review with regard to its provisions, and the Department of Justice filed a brief in another case stating that the IQA does not permit judicial review.

In a development closely related to the issue of information quality, in September 2003, OMB published a proposed bulletin on "Peer Review and Information Quality" (68 *Federal Register* 54023) that would, when made final, provide a standardized process by which all "significant regulatory information" would be peer reviewed. OMB received nearly 200 comments on the proposed bulletin, and published a "substantially revised" peer review bulletin in April 2004 (69 *Federal Register* 23230). In essence, the revised bulletin requires agencies to take three actions (to the extent permitted by law): (1) have a peer review conducted on all "influential scientific information" that the agency intends to disseminate (changed from "significant regulatory information" in the proposed bulletin); (2) have all "highly influential scientific information" reviewed according to more specific and demanding standards; and (3) indicate what "influential" and "highly influential" information the agency plans to review in the future. The revised bulletin defines "influential" scientific information as information that the agency can reasonably determine will, when disseminated, have a "clear and substantial impact on important public policies or private sector decisions." The term "highly influential" is defined as influential information that either the disseminating agency or the OIRA Administrator determines could affect important public policies or private sector decisions of more than $500 million in any year, or involves "precedent setting, novel, and complex approaches, or significant interagency interest."

OMB and supporters of the proposed bulletin indicate that peer review standards across the government are currently inconsistent, and that more consistent use of peer review can increase the technical quality and credibility of regulatory science. They also assert that peer review can protect science-based regulations from political criticism and litigation. Opponents view the peer review bulletin as an effort to inject

political considerations into the world of science, and to use the uncertainty that inevitably surrounds science as an excuse to delay new rules that could be costly to regulated entities. Others have expressed concerns that the bulletin could create a centralized peer review system within OMB that would be vulnerable to political manipulation or control by regulated entities. For further information see *Ensuring the Quality of Data Disseminated by the Federal Government: Workshop Report*, report of the Ad Hoc Committee on Ensuring the Quality of Government Information, National Research Council, National Academies Press.

## Government Performance and Results Act (GPRA) and the President's Management Agenda

The Government Performance and Results Act of 1993 (GPRA), P.L. 103-62, is intended to produce greater efficiency, effectiveness, and accountability in federal spending and to ensure that an agency's programs and priorities meet its goals. It also requires agencies to use performance measures for management and, ultimately, for budgeting and to provide Congress with annual performance plans and performance reports. Some commentators have pointed out that it is particularly difficult to define priorities in terms of expected outcomes for most research and to measure the results quantitatively, since research outcomes cannot be defined well in advance and often take a long time to demonstrate.

Recently, agencies have been required to identify more precisely their goals for R&D and measures of R&D outcomes. As underscored in *The President's Management Agenda,* beginning in FY2001 and in each year thereafter, the Bush Administration has emphasized the importance of performance measurement, including for R&D. In a memorandum dated June 5, 2003, signed jointly by the OSTP Director and the OMB Director regarding planning for the FY2005 R&D budget requests, the Administration announced that its effort to base budget decisions on program performance would continue and be expanded (OMB M-03-15). OMB referred to this memo again in the FY2006 R&D budget guidance, which reiterated the importance of performance assessment for R&D programs (OMB M-04-23). These memos, as well as section 5 on "Research and Development," of OMB's *Analytical Perspectives, Budget of the U.S. Government, FY2005*, discussed requirements for agencies to use specific OMB-defined criteria to measure the outcomes of basic and applied research, focusing on measures of relevance, quality, and performance. R&D projects relevant to industry are to meet additional criteria relating to the appropriateness of public investment, demonstrate a capability to measure benefits, and identify decision points to transition the activity to the private sector. Several agencies, including the National Aeronautics and Space Administration (NASA), NSF, and NIH, are revising their strategic plans, annual performance plans, and annual performance reports required by GPRA, to describe their activities in terms of the new OMB criteria.

The Administration is assessing some R&D programs by use of a new Program Assessment Rating Tool (PART), which uses the OMB R&D criteria. PART results were summarized in Section 5 of *Analytical Perspectives, Budget of the U.S. Government, FY2005* and specific rating levels for federal programs and agencies were arrayed in a FY2005 budget document, *Program Assessment Rating Tool,*

*Program Summaries*, [http://www.whitehouse.gov/omb/budget/fy2005/pdf/ap_cd_rom/part.pdf]. PART assessments were used in decision-making about the FY2005 budget requests . As indicated by the assessments made so far and by observers' comments, more analytical work and refinement of R&D goals and measures is needed before performance measures can be used with confidence to recommend budget levels for most R&D. There are also questions about integrating GPRA and PART assessments and about whether GPRA and PART assessments are used in making congressional authorizations and appropriations decisions (Amelia Gruber, "Lawmakers Remain Skeptical of Linking Budget, Performance," *GovExec.com*, Jan. 13, 2004, and GAO, *Performance Budgeting: Observations on the Use of OMB's Program Assessment Rating Tool for the Fiscal Year 2004 Budget*, GAO-04-174, Jan. 2004). The Department of Energy, one of the first agencies to use the OMB criteria, has started to use the results of the R&D investment criteria, according to OMB, to help analyze its portfolio of investments in relation to producing public benefits.

Congress may increase attention to the use of R&D performance measures in authorization and appropriations actions especially as constraints on discretionary spending grow. But some observers say that many congressional staff are not yet comfortable with using performance measurement data to make budget decisions and prefer to use traditionally formatted budget information, which focuses on inputs, rather than outputs. In its March 5, 2003 "Additional Democratic Views and Estimates on the FY2004 Budget for Civilian Science and Technology Programs," the minority staff of the House Science Committee criticized the way the Administration used performance metrics in making R&D budgetary decisions, faulting the judgments that are used to rate programs and saying that political decisions appear to supersede the use of metrics in some decision-making. The majority staff did not comment on this topic in their "Views and Estimates" on the FY2004 budget.

**For Further Information**

CRS Report RS20257, *Government Performance and Results Act: Brief History and Implementation Activities*

CRS Report RL32164, *Performance Management and Budgeting in the Federal Government: Brief History and Recent Developments*

## Science and Technology Education

An important aspect of U.S. efforts to maintain and improve economic competitiveness is the existence of a capable scientific and technological workforce. A January 2004 report of the National Science Foundation (NSF), *Science and Engineering Indicators 2004*, states that between the years 2000 and 2010, employment in science and engineering fields will increase at more than three times the rate for all other occupations. In addition, approximately 86% of the increase in science and engineering will be in computer-related positions. Simultaneous with predictions of the future scientific workforce are data reporting a decline in the number of students seeking degrees in certain fields. While 33% of the undergraduate degrees awarded are in science and engineering, the portion of degrees earned in the physical sciences, mathematics, computer science, and engineering has been static or declining. Disciplines that have witnessed an increase in degrees earned have been

primarily psychology and the biological sciences. There is growing concern by many in the scientific community, industry, research-driven federal agencies, and Congress about the production of the nation's science and engineering personnel.

On December 19, 2002, President Bush signed into law the National Science Foundation Authorization Act of 2002 (P.L. 107-368, H.R. 4664). One of the components of the legislation is Mathematics and Science Education Partnerships (MSEP), operating in both the National Science Foundation and the Department of Education. Under MSEP, competitive grants are awarded to institutions of higher education to evaluate and enhance the effectiveness of elementary and secondary science and mathematics education. Another component of the authorization is the Tech Talent portion. This section addresses the decline in the scientific and technical workforce and provides support for the expansion of undergraduate reforms that have been demonstrated to be successful in increasing the number and quality of students in science, mathematics, and engineering. Funding allows for support of mentoring programs to enhance student persistence to degree completion.

It is anticipated that the 108th Congress will continue to examine the decline in the nation's scientific and technical workforce and to seek further solutions for improving aspects of undergraduate science and mathematics education. In addition to the decline in the production of U.S. scientists and engineers, there is the added congressional interest in the aging of the current science and engineering workforce. The Senate Governmental Affairs Committee has held hearings to discuss the personnel problems facing the National Aeronautics and Space Administration, including the aging of its workforce. Congress may examine how other federal agencies are addressing their scientific and technical workforce needs.

**For Further Information**

CRS Report 98-871 STM, *Science, Engineering, and Mathematics Education: Status and Issues*

## Foreign Science and Engineering Presence in U.S. Institutions and the Labor Force

The increased presence of foreign students in U.S. graduate science and engineering programs continues to be of concern. Enrollment of U.S. citizens in graduate science and engineering programs has not kept pace with that of foreign students in those programs. In many institutions, foreign graduate students on temporary visas comprise 40% to 50% of some science and engineering programs. In addition to the number of foreign students, a significant number of university faculty in the scientific disciplines are foreign, and foreign-born doctorates are employed in large numbers by industry.

Many in the scientific and engineering communities maintain that in order to compete with countries that are rapidly expanding their scientific and technological capabilities, the United States needs to bring in those whose skills will benefit society and will enable us to compete in the new-technology-based global economy. Individuals supporting this position believe instead of limiting the number of foreign

students, the conditions under which foreign talent enters U.S. colleges and universities and the labor force should be more carefully scrutinized and controlled to address any security concerns. Furthermore, there are those who contend that the underlying concerns of foreign students in graduate science and engineering programs is not necessarily that there are too many foreign-born students, but that there are not enough U.S. students entering the disciplines.

The debate on the presence of foreign students in graduate science and engineering programs and the workforce has intensified as a result of the terrorist attacks of September 11, 2001. Concerns have been expressed about certain foreign students receiving education and training in sensitive areas. In addition, there has been increased discussion about the access of foreign scientists and engineers to R&D related to chemical and biological weapons. The 107th Congress passed two laws (the USA PATRIOT Act, P.L. 107-56; and the Enhanced Border Security and Visa Entry Reform Act, P.L. 107-173) that included tightened visa-oversight procedures, student visa-related provisions, the tracking of foreign students attending institutions of higher education, and proposals for reducing the number of H-1B visas. The academic community is concerned that more stringent requirements on foreign students may have a negative impact on enrollments in colleges and universities. Others contend that a possible reduction in the immigration of foreign scientists may impact negatively on the competitiveness of U.S. industry.

In May 2004, several higher education organizations released a combined statement on the impact of the new visa policies on higher education and the scientific enterprise. They maintain that the new visa procedures have made the visa system "inefficient, lengthy, and opaque,"and have led to "unintended consequences detrimental to science, higher education, and the nation." During the 108th Congress, the visa and student tracking system for foreign students may be reviewed and evaluated. Also, there may be dissension regarding the increased scrutiny of foreign students from countries that sponsor terrorism, and the restrictions placed on the participation of foreign students and scientists in military-sponsored projects and other types of R&D.

**For Further Information**

CRS Report 97-746, *Foreign Science and Engineering Presence in U.S. Institutions and the Laborforce*

# Homeland Security Issues

## Counterterrorism R&D

Since the terrorist attacks in 2001, additional federal funding has been devoted to counterterrorism R&D, and new planning and coordination mechanisms have been established both in individual agencies and in the White House's Office of Homeland Security (OHS), Office of Science and Technology Policy (OSTP), and National Science and Technology Council (NSTC). In addition, the Homeland Security Act of 2002 (P.L. 107-296) consolidated some R&D activities and coordination

responsibilities in the new Department of Homeland Security (DHS), especially in its Directorate of Science and Technology. Policy issues during the second session of the 108th Congress have included implementation of the Homeland Security Act, especially with regard to the Directorate of Science and Technology; coordination of programs and priorities across agencies and within DHS; and funding.

During the first session, oversight of Homeland Security Act implementation focused on the establishment of the Directorate of Science and Technology. The Under Secretary and other key personnel were selected, a management organization was announced, staff were hired, the first two rounds of extramural research proposals were solicited, and the Homeland Security Advanced Research Projects Agency (HSARPA) was established. Some of these activities, such as the pace of progress in staff hiring and the processing of research proposals, have continued to draw attention during the second session. Other issues receiving attention include establishment of the Homeland Security Institute, designation of additional university centers of excellence, commercialization of technologies developed with DHS support, relationships with federal laboratories, and establishment of the Homeland Security Science and Technology Advisory Committee.

Coordination of federal counterterrorism R&D is a particular challenge because relevant programs exist in many different agencies and accurate information about their activities can be difficult to obtain. The R&D programs of DHS account for only about one-third of total expenditures. Other agencies with large counterterrorism R&D responsibilities include the National Institutes of Health (focused on bioterrorism) and the defense and intelligence agencies. Also involved are the Departments of Justice, Commerce, and Agriculture, the National Science Foundation, the Environmental Protection Agency, and others. Under the Homeland Security Act, DHS has some authority to coordinate and help set priorities for other federal homeland security R&D, including human health-related R&D. What that authority will mean in practice remains to be seen. The heads of other agencies have no formal role in DHS's R&D priority-setting and coordination, and conversely, the role of the DHS Secretary in setting priorities for those agencies is undetermined. DHS's effectiveness in planning and coordinating R&D may depend upon the Secretary's ability to influence other agencies through his interactions with existing counterterrorism coordination mechanisms in OSTP, NSTC, and interagency committees. DHS has announced plans to coordinate all federal homeland security R&D by Fall 2004.

Internal coordination within DHS may also be an issue. Although most of the Department's R&D activities are within the Directorate of Science and Technology, a substantial portion are in other DHS agencies. The FY2004 homeland security appropriations conference report (H.Rept. 108-280) expressed concern about the potential for duplication, waste, and inadequate management oversight, and directed DHS to "consolidate all Departmental research and development funding within the science and technology programs in the FY2005 budget request." The Department's response to this direction has been of congressional interest in the second session, particularly with respect to the R&D programs of the Coast Guard and the Transportation Security Administration. There has also been continued congressional oversight of how DHS sets priorities among its various R&D programs and of how it utilizes the R&D capabilities of the national laboratories.

Federal funding for counterterrorism R&D has increased significantly since the terrorist attacks in 2001. In FY2004, the government-wide total exceeds $3 billion, compared with less than $600 million in FY2001. Total federal funding requested for homeland security R&D, including facilities construction, is estimated at $4.2 billion for FY2005. The DHS Directorate of Science and Technology, which came into existence for the first time during FY2003, received $918 million in FY2004 appropriations. For FY2005, $1,039 million was requested, with total DHS R&D funding requested at $1,216 million. Although congressional action on FY2005 appropriations is not yet complete, it appears that funding for counterterrorism R&D has not been seriously affected by the constrained budget environment of the second session of the 108th Congress. Moreover, the Administration has made homeland security a priority for interagency R&D planning as agencies develop their FY2006 budget requests.

**For Further Information**

CRS Report RS21270, *Homeland Security and Counterterrorism Research and Development: Funding, Organization, and Oversight*
CRS Report RL31914, *Research and Development in the Department of Homeland Security*
CRS Report RL32481, *Homeland Security Research and Development Funding and Activities in Federal Agencies: A Preliminary Inventory*
CRS Report RL32482, *Federal Homeland Security Research and Development Funding: Issues of Data Quality*

## Bioterrorism Countermeasures R&D

Federal bioterrorism research and development funding is concentrated in three departments: the Department of Homeland Security (DHS), the Department of Health and Human Services (HHS), and the Department of Defense (DOD). DHS bioterrorism R&D focuses on non-medical countermeasures such as biological agent detectors. HHS, largely through the National Institutes of Health, has the principal responsibility for medical bioterrorism countermeasures R&D. DOD has a significant bioterrorism countermeasure R&D program with both medical and non-medical aspects. The DOD programs focus on protecting warfighters and tends to emphasize prophylactic measures, such as vaccines and remote sensing systems.

The three agencies' programs have potential for either synergy or redundancy. Strong executive branch management and Congressional oversight may be crucial maximizing synergy and avoiding redundancy. Building on the framework described by the Homeland Security Act (P.L. 107-296), Homeland Security Presidential Directive (HSPD) 10, entitled "Biodefense for the 21st Century," issued April 28, 2004, details specific biodefense R&D roles for departments and officials and methods to ensure cooperation and coordination. Because of this issue's importance and the significant funding that Congress has appropriated for biodefense, coordination and implementation of this HSPD are likely to remain areas of Congressional interest and oversight.

Other topics of potential Congressional interest include whether the increase in biodefense-related basic research funding has affected research quality. Because there

is a finite pool of highly experienced researchers, it is possible that too much money is going to lower quality proposals. Additionally, the large influx of money may be drawing good scientists into the field at the expense of other important research areas.

Pharmaceutical and biotechnology companies have traditionally transitioned promising basic research through development into approved drugs. However, these companies have been reluctant to develop and manufacture new biomedical countermeasures because of concerns about intellectual property rights, liability, and the lack of significant commercial markets for these products. To address some of these concerns, the Project BioShield Act of 2004 (P.L.108-276) was enacted. The main provisions of Project BioShield include (1) relaxing procedures for HHS's bioterrorism-related procurement, hiring, and awarding of research grants; (2) providing a market guarantee for countermeasure producers by allowing the HHS Secretary to contract to procure countermeasures that have up to eight more years in development; and (3) authorizing the HHS Secretary to allow the emergency use of unapproved biomedical countermeasures. The DHS Appropriations Act, 2004 (P.L. 108-90) provided $5.6 billion for the Project BioShield-related procurement of biomedical countermeasures for the Strategic National Stockpile for FY2004 through FY2013. For more information on Project BioShield, see CRS Report RS21507 *Project BioShield*.

It is not yet clear whether Project BioShield will spur the development of enough countermeasures to adequately address the bioterrorism threat. Other incentives that may encourage private sector participation in biomedical countermeasure R&D include liability reform, tax credits, and additional patent protections to offset risk and developmental costs. Some of these may be subject to congressional consideration during the 108th Congress.

**For Further Information**

CRS Report RL32549 *Project BioShield: Legislative History and Side-by-Side Comparison of H.R. 2122, S. 15, and S. 1504*, by Frank Gottron

CRS Report RS21270 *Homeland Security and Counterterrorism Research and Development: Funding, Organization, and Oversight*, by Genevieve J. Knezo

## Bioagent Lab Registration and Security

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) included provisions to bolster public and private lab security and reduce the likelihood of unauthorized access to potentially dangerous biological agents and toxins. The provisions significantly expanded the government's Select Agent program [http://www.cdc.gov/od/sap]. Under that program, the Centers for Disease Control and Prevention (CDC) developed a list of select agents — viruses, bacteria, fungi, and toxins that may pose a severe threat to public health and safety — and required labs that ship or receive listed agents to register with the agency. P.L. 107-188 requires all facilities possessing select agents, not just those shipping or receiving such agents, to register with HHS.

P.L. 107-188 instructed the HHS Secretary, in consultation with the Attorney General, to establish lab safety and security requirements for registered facilities

"commensurate with the level of risk to public health and safety," and institute background screening for all persons seeking access to select agents. It also mandated the creation of a national database with information on all facilities and persons handling select agents and directed HHS biennially to review and, if necessary, revise the list of select agents. P.L. 107-188 gave the Department of Agriculture (USDA) similar authority to develop a list of biological agents and toxins that may pose a severe threat to crops and livestock and to regulate facilities that possess, use, or transfer those agents and toxins. It instructed HHS and USDA to coordinate their activities regarding so-called overlap agents and toxins that appear on both agencies' lists. Both the bioterrorism law and the USA PATRIOT Act prohibit certain groups of individuals — based on criminal history, immigration status, and other factors — from having access to select agents.

Congress expanded the select agent program in response to concerns that the anthrax used in the 2001 U.S. mail attacks may have been obtained from a U.S. research facility. Alarmed by reports of weak security at labs where researchers study potentially deadly viruses and bacteria, lawmakers sought to improve lab security without unduly impeding vital biomedical and biodefense research. While some academic and industry scientists have praised the government for striking an appropriate balance between science and security, many in the research community are critical.

In December 2002, HHS and USDA issued interim final regulations to implement the new program. All labs possessing or working with select agents had to submit a detailed security, training, and record-keeping plans in order to be registered by either HHS or USDA. In addition, researchers had to undergo a security background check by the Federal Bureau of Investigation (FBI). Institutions had to be in full compliance by November 12, 2003. Any institution that had not been granted a certificate of registration by that date would not be permitted to possess, use, receive, or transfer select agents. Researchers, biosafety experts, and lab administrators complained that the deadline was unrealistic. They warned that the substantial work needed for compliance might interrupt, delay, and possibly discourage research.

Governmental officials estimated that more than 1,600 labs and about 20,000 researchers would seek registration under the program. While submissions were in fact much lower (about 9,000 individuals and 500 labs), the FBI was unable to complete all the security checks, and HHS and USDA were unable to finish reviewing all the lab registration applications in time to meet the November 12 deadline. Thus, on November 3, 2003, in order to avoid a disruption of ongoing select agent research, CDC and USDA issued revised regulations allowing labs and researchers to obtain a "provisional" certification, provided they have submitted all the appropriate paperwork. As of November 1, 2003, the FBI had processed roughly 5,000 of the 9,000 applications received. FBI officials said that it might take months to complete the task.

P.L.107-188 prohibits federal agencies from releasing information about registered facilities. There is some confusion as to whether this provision applies to sharing information with state governments for the purpose of identifying vulnerabilities and emergency planning. While states and individual labs are not subject to the prohibition, CDC urges them to consider security risks that may result

from disclosing information about select agents. Such disclosures were part of the routine conduct of scientific inquiry prior to 2001.

Some scientists may have discontinued research on select agents because of the security requirements and out of fear that breaking the new law, even inadvertently, could result in stiff criminal penalties. On December 1, 2003, a federal jury cleared Thomas Butler, a microbiologist at Texas Tech Health Sciences Center, of charges that he illegally transported plague bacteria into and around the United States, and then lied to FBI agents when he reported some vials missing. However, Butler was convicted of numerous counts of defrauding Texas Tech by diverting clinical trial payments to his personal use.

**For Further Information**

CRS Report RL31263, *Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188): Provisions and Changes to Preexisting Law*

## Public Access to Scientific Information

The development of policies regarding access to scientific and technical information, to help protect the nation against terrorist attacks, requires policymakers to balance scientific and security priorities. Such policies address national security, scientific communication, and also constitutional and statutory protections that permit public access to information used for accountability and oversight. Historically, the U.S. government has used classification procedures to protect scientific and technical information that might compromise national security. Fundamental scientific information whose release does not compromise security is to remain unclassified pursuant to Executive Order 12958 and National Security Decision Directive 189. After the 2001 terrorist attacks, the government widened controls on access to information and scientific components. Policies are being implemented to deny access to federally owned information labeled "sensitive but unclassified" (SBU) or "sensitive homeland security information" (SHSI). This includes information that agencies previously posted on websites or made available upon request. Consideration is being given to preventing publication of some non-federally owned scientific and technical information.

Some critics say that criteria for identifying SBU information have not been defined clearly, causing inconsistency among agencies. White House directives and federal agencies have used the term in various ways when labeling and safeguarding information. Some agencies refer to definitions for controlled information, such as for "sensitive," found in the Computer Security Act, or to information exempt from disclosure through the Freedom of Information Act (FOIA) or the Privacy Act. Those laws give agencies discretion and allow for interpretation and risk analysis to identify information to be safeguarded. The White House and the Department of Justice recently broadened the application of SBU to help deter terrorism and gave agencies responsibility to identify and withhold from the public SBU and SHSI. Critics say that the absence of a clear definition complicates the design and implementation of policies to safeguard such information.

P.L. 107-296, the Homeland Security Act, requires the President to prescribe and implement procedures for agencies to identify and safeguard sensitive but unclassified homeland security information (Secs. 891 and 892). OMB had planned to issue related guidance in 2003, but it was not released. On July 29, 2003 in Executive Order 13311, the President delegated his responsibility for this function to the DHS secretary, which has not yet issued guidance. Issues of possible interest to Congress include identification of factors to define SBU, especially since agencies are given discretion under FOIA and the Computer Security Act to define information subject to nondisclosure; design of an appeals process; assessment of the pros and cons of wider SBU controls; and possible classification of federally-owned basic research information, since heads of some agencies performing basic research recently were given original classification authority.

Traditionally, the federal government has supported the open publication of federally funded, extramural research results conducted by nongovernmental scientists. In cases where release of fundamental research results might compromise national security (e.g. atomic energy and cryptography research, as well as some inventions governed by patent laws), federal policy prescribes use of classification to limit dissemination. The terrorist attacks of 2001 have increased scrutiny of nonconventional weapons and a series of research publications have increased concerns over whether publication of some federally funded extramural research results could threaten national security. As a result, some have suggested that such research results should be reviewed for security implications before publication, while others say that such review would damage scientific progress and productivity. Open questions remain as to who would review these research results and at what point in the research process. Some, but not all, scientists and publishers have begun to implement voluntary self-regulatory measures regarding publication of potentially sensitive manuscripts. Some claim that such a review process might be most effective if performed by a federal agency. The Department of Health and Human Services, following some recommendations presented by the National Academies report, *Biotechnology Research in an Age of Terrorism*, is establishing a federal advisory board, the National Science Advisory Board for Biosecurity, which will provide guidance for the identification of research that may require special attention or security. The controls designed by professional groups undoubtedly will be guided by federal policy as it develops.

**For Further Information**

CRS Report RL31695, *Balancing Scientific Publication and National Security Concerns: Issues for Congress*

CRS Report RL31845, *'Sensitive But Unclassified' and Other Federal Security Controls on Scientific and Technical Information: History and Current Controversy*

## Information Technology Management for the Department of Homeland Security

One of the biggest challenges facing the Department of Homeland Security (DHS) is the ongoing effort to consolidate the computer and communications systems

of the 22 agencies that comprise the Department. In many respects, DHS will function as a virtual department, connecting new and existing agencies into a network that capitalizes on their knowledge assets to facilitate information sharing and enhanced communication. Organizationally, this will involve breaking down the "stovepipes" that have previously separated the agencies and developing an encompassing organizational culture that promotes cooperation and information sharing. Technologically, this will involve integrating existing systems and infrastructures while simultaneously infusing new technologies as they are become available. The 108th Congress is monitoring the Department's progress.

A critical variable that will contribute to the success or failure of these objectives is the development and implementation of an enterprise architecture for the Department. An enterprise architecture serves as a blueprint of the business operations of an organization, and the technologies needed to carry out these functions. It is designed to be comprehensive and scalable, to account for future growth needs.

As the Department moves forward with its enterprise architecture plans, it may encounter several issues. Its enterprise architecture will be used to identify common functions and eliminate redundancies among its component agencies. This will require making choices between competing systems and reallocating resources and staff accordingly. In doing so, DHS may need to improve the interoperability of its systems as well, by selecting common data formats, equipment, and processes. This, in turn, would enable DHS to carry out its information sharing responsibilities, as described in the Homeland Security Act. Since some of these information sharing initiatives will involve agencies and organizations at the federal, state, and local levels, as well as agencies within the Department, additional coordination with these external partners would be necessary to ensure the smooth flow of information and compliance with security procedures. Other oversight issues Congress may address are whether to include funding, information security, outsourcing, and technology development. In addition, given the interrelationships between DHS and other departments, the impact of the DHS enterprise architecture on related e-government initiatives currently underway may come up for consideration.

## Data Mining

Data mining is emerging as one of the key features of many homeland security initiatives. Data mining involves the use of data analysis tools to discover previously unknown, valid patterns and relationships in large data sets. In the context of homeland security, data mining is often viewed as a potential means to identify terrorist activities, such as money transfers and communications, and to identify and track individual terrorists themselves, such as through travel and immigration records.

Data mining is carried out in both the private and public sectors. Some common uses include detecting fraud, assessing risk, and measuring and improving program performance. While data mining represents a substantial advance in the type of analytical tools currently available, some of the homeland security data mining applications represent a significant expansion in the quantity and scope of data to be analyzed. Two efforts that attracted a high level of congressional interest are Total Information Awareness (TIA) project, which now has been discontinued, and the

proposed Computer Assisted Passenger Prescreening System II (CAPPS II) project, which is being replaced by the Secure Flight passenger screening program, administered by the Transportation Security Administration.

While technological capabilities are important, there are other implementation and oversight issues that can influence the success of a data mining project's outcome. One issue is data quality, which refers to the accuracy and completeness of the data being analyzed. A second issue is the interoperability of the data mining software and databases being used by different agencies. Interoperability is a critical part of the larger efforts to improve interagency collaboration and information sharing through e-government and homeland security initiatives. A third issue is privacy. Questions that may be considered include the degree to which government agencies should use and mix commercial data with government data, whether data sources are being used for purposes other than those for which they were originally designed, and possible application of the 1974 Privacy Act to these initiatives. It is anticipated that congressional oversight of data mining projects will grow as data mining efforts continue to evolve.

**For Further Information**

CRS Report RL31798, *Data Mining: An Overview*

# Technology Development Issues

## R&D Partnerships and Intellectual Property

A major emphasis of R&D-related legislative activity has been to augment research in the private sector through efforts to encourage firms to undertake cooperative R&D arrangements. Various laws, including the Stevenson-Wydler National Technology Innovation Act (P.L. 96-418) and the "Bayh-Dole" Act (P.L. 96-517), as amended, have created an environment conducive to joint ventures between government and industry, or between industry and universities, as well as among companies. To date, Congress has determined that providing title to inventions made under federal funding to contractors and/or collaborating parties should be used to support innovation. In return for patent ownership, Congress has accepted as satisfactory the anticipated payback to the country through goods and services to improve our health, welfare, and standard of living. These benefits have been considered more important than the initial cost of the technology to the government or any potential unfair advantage of one company over another in a cooperative venture.

As such cooperative efforts become more widespread, new and additional issues have emerged. Concerns have been expressed regarding the cost of drugs developed in part with federal funding or in conjunction with federal agencies. Conflicts have surfaced over federal laboratories patenting inventions that collaborating parties believe to be their own. In some agencies, delays continue in negotiating cooperative research and development agreements (CRADAs) because of disagreements over the dispensation of intellectual property. Questions have been raised as to the effects of

patenting early stage discoveries (e.g. research tools) on additional innovation. The National Institutes of Health has encountered difficulties obtaining for government-sponsored research new experimental compounds developed and patented by drug companies because of concerns over diminished effectiveness of the intellectual property if additional applications are discovered. Given these issues, additional decisions may need to be made on how to maintain a balance between the importance of bringing new products and processes to the marketplace and protecting the public investment in R&D.

**For Further Information**

CRS Issue Brief IB89056, *Cooperative R&D: Federal Efforts to Promote Industrial Competitiveness*
CRS Issue Brief IB85031, *Technology Transfer: Use of Federally Funded Research and Development*
CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*
CRS Report RL30320, *Patent Ownership and Federal Research and Development (R&D): A Discussion of the Bayh-Dole Act and the Stevenson-Wydler Act*
CRS Report RL32324, *Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship*
CRS Report 98-862, *R&D Partnerships and Intellectual Property: Implications for U.S. Policy*

## Advanced Technology Program

The Advanced Technology Program (ATP) was created by P.L. 100-418, the Omnibus Trade and Competitiveness Act of 1988, to encourage public-private cooperation in the development of pre-competitive technologies with broad application across industries. Administered by the National Institute of Standards and Technology (NIST), a laboratory of the Department of Commerce, this activity has been targeted for elimination as a means to cut federal spending. Critics argue that R&D aimed at the commercial marketplace should be funded by the private sector, not by the federal government. Others stress that ATP is market driven and that investments in research are shared by industry and the public sector.

Beginning several years ago, the House of Representatives attempted to terminate ATP, but strong support provided by the Senate led to continued funding. The Bush Administration also proposed eliminating the program in its FY2002, FY2004, and FY2005 budget requests. These actions have renewed the debate over the role of the federal government in promoting commercial technology development. In arguing for less direct federal involvement, opponents of the Advanced Technology Program believe that the market is superior to government in deciding which technologies are worthy of investment. They prefer mechanisms that enhance the market's opportunities and abilities to make such choices. It is also suggested that agency discretion in selecting one technology over another can lead to political intrusion and industry dependency. On the other hand, supporters of direct methods maintain that reliance on indirect measures can be wasteful, inefficient, and ineffective and can compromise other goals of public policy in the hope of stimulating innovative performance. Proponents of ATP argue that it is important to put the nation's scarce

resources to work on those technologies which will have the greatest promise as determined by industry and supported by the private sector's willingness to match federal funding. They assert that the government serves as a catalyst for companies to cooperate and undertake important new work, which would not be possible without federal participation. As the 108th Congress continues the appropriations process, these issues are expected to be debated.

**For Further Information**

CRS Issue Brief IB91132, *Industrial Competitiveness and Technological Advancement: Debate Over Government Policy*
CRS Report 95-36, *The Advanced Technology Program*
CRS Report 95-50, *The Federal Role in Technology Development*

## Prescription Drugs: Costs, Availability, and Federal R&D

Congressional interest in methods to provide drugs at lower cost, particularly for the elderly, has focused attention on several areas where the federal government has programs and policies associated with the development of pharmaceuticals and their availability in the marketplace. Various federal laws, including the Stevenson-Wydler Technology Innovation Act (P.L. 96-418) and the "Bayh-Dole" Act (P.L. 96-517), facilitate commercialization of federally funded R&D through technology transfer, cooperative R&D, and intellectual property rights. The current approach attempts to balance the public's interest in new and improved technologies with concerns over providing companies valuable benefits without adequate accountability or compensation to the nation. However, questions have been raised as to whether or not this balance is appropriate, particularly with respect to drug discovery. In the debate, some argue that the government's financial, scientific, and/or clinical support of biomedical R&D entitles the public to commensurate considerations in the prices charged for any resulting drugs. Others view government intervention in price decisions based upon initial federal R&D funding as contrary to a long-term trend of government promotion of innovation, technological advancement, and the commercialization of technology by the business community.

Supporters of the current approach to technology development argue that existing incentives have given rise to robust pharmaceutical and biotechnology industries. Critics maintain that the need for such incentives in the pharmaceutical and/or biotechnology sectors is mitigated by industry access to government-supported work at no cost, monopoly power through patent protection, and additional regulatory and tax advantages such as those conveyed through the Hatch-Waxman Act (P.L. 98-417). That act, which made several major changes to the patent laws, has had a significant positive effect on the availability of generic substitutes for brand name drugs. After patent expiration, generics generally are rapidly available at lower prices. Concurrently, given the increasing investment in R&D and the gains in research intensity of the pharmaceutical industry, it appears that the law has not deterred the search for and the development of new drugs. Yet, over the 20 years since passage of the legislation, concerns were expressed as to whether or not implementation of certain portions of the law had led to unintended consequences. Some argued that brand name companies and/or generic firms exploited provisions of the act to prevent the timely introduction of lower cost drugs. Other observers asserted that no such

pattern of abuse was evident and that while a few isolated cases of misinterpretation of the law had arisen, these could be addressed through existing procedures. However, Title XI of P.L. 108-173, the Medicare Prescription Drug and Modernization Act of 2003, as signed into law on December 8, 2003, made changes to the Hatch-Waxman Act as it pertained to the listing of pharmaceutical patents in the Orange Book maintained by the Food and Drug Administration, patent challenges by generic firms, and the award of market exclusivity, among other things. It remains to be seen how these provisions affect the availability and cost of prescription drugs.

**For Further Information**

CRS Report RL32377, *The Hatch-Waxman Act: Legislative Changes in the 108th Congress Affecting Pharmaceutical Patents*
CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984*
CRS Report RL31379, *The Hatch-Waxman Act: Selected Patent-Related Issues*
CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*
CRS Report RL32324, *Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship*
CRS Report RL30320, *Patent Ownership and Federal Research and Development (R&D): A Discussion of the Bayh-Dole Act and the Stevenson-Wydler Act*
CRS Report RL32400, *Patents and Drug Importation*

# Telecommunications and Information Technology Issues

## Broadband Internet Access

Broadband Internet access gives users the ability to send and receive data at speeds far greater than conventional "dial up" Internet access over existing telephone lines. New broadband technologies — primarily cable modem and digital subscriber line (DSL), as well as satellite and fixed wireless Internet — are currently being deployed nationwide by the private sector. Many observers believe that ubiquitous broadband deployment is an important factor for the nation's future economic growth. At issue is what, if anything, should be done at the federal level to ensure that broadband deployment is timely, that industry competes on a "level playing field," and that service is provided to all sectors of American society.

During the 107th Congress, legislative proposals centered on two approaches: easing certain legal restrictions and requirements on incumbent telephone companies that provide broadband access (the "Tauzin-Dingell" legislation), and providing federal financial assistance, such as grants, loans, or tax credits for broadband deployment in rural and economically disadvantaged areas. In the 108th Congress, legislation has been introduced to provide financial assistance to encourage broadband deployment, and to allocate additional spectrum for use by wireless broadband applications (see CRS Issue Brief IB10045 and CRS Report RL30719 for information

on pending legislation). On February 20, 2003, the FCC adopted new rules which lift most obligations on incumbent telephone companies to provide competitors access to their broadband networks. Meanwhile, on March 26, 2004, President Bush endorsed the goal of universal broadband access by 2007. This was followed, on April 26, by the release of an Administration broadband policy endorsing: a ban on broadband taxes, more spectrum for wireless broadband, standards for broadband over power lines, and rights-of-way on federal lands for broadband providers.

**For Further Information**

CRS Issue Brief IB10045, *Broadband Internet Access: Background and Issues*
CRS Report RL30719, *Broadband Internet Access and the Digital Divide: Federal Assistance Programs*
CRS Report RL32421, *Broadband over Powerlines: Regulatory and Policy Issues*

## Transition to Digital Television

Digital television (DTV) is a new service representing the most significant development in television technology since the advent of color television in the 1950s. Congress and the FCC have set a target date of 2006 for broadcasters to transition to DTV, cease broadcasting their analog signals, and return their existing analog television spectrum licenses to be auctioned or used for other purposes, such as public safety telecommunications. If and when analog signals are turned off, consumers will not be able to receive over-the-air television broadcast signals unless they have a digital television or connect their existing analog televisions to converter boxes. The Balanced Budget Act of 1997 (P.L. 105-33) requires the FCC to grant extensions for reclaiming the analog television licenses in the year 2006 from stations in television markets where at least 15% of television households do not receive digital signals.

While the transition to DTV is proceeding, most observers believe that the widespread adoption of DTV by consumers will not be achieved by 2006, and that television stations will continue to broadcast both analog and digital signals past the 2006 deadline. The key issue facing Congress and the FCC is: What steps, if any, should be taken by the government to ensure a timely, efficient, and equitable transition to digital television? Congressional committees continue to monitor the pace and progress of the digital transition, and a number of options for action in the 108th Congress have been proposed. These include mandating digital tuners; mandating cable and satellite television carriage of digital signals; ensuring the vacating of analog spectrum by a date certain; legislating a process whereby interoperability standards and copyright protection technologies will be implemented; and extending and/or altering the transition deadlines.

**For Further Information**

CRS Report RL31260, *Digital Television: An Overview*
CRS Report RL31375, *Meeting Public Safety Spectrum Needs*
CRS Report RS21570, *Spectrum Management: Public Safety and the Transition to Digital Television*

## Spectrum Management and Wireless Technologies

Spectrum policy issues before the 108th Congress are characterized by economic, technological and regulatory complexity. An increasing number of public comments, including two recent reports from the General Accounting Office, criticize the effectiveness of spectrum management and policy in the United States. Members of Congress, through hearings and public statements, have expressed a willingness to address spectrum management issues during the 1st Session of the 108th Congress. Spectrum, a valuable resource governed by available technology, is regulated by the federal government with the primary objectives of maximizing its usefulness and efficiency, and to prevent interference among spectrum users. To minimize interference, users are assigned radio frequencies within spectrum bands allocated for defined uses. Spectrum policy covers both satellite and terrestrial (primarily antenna-broadcast) transmissions.

The development and implementation of better wireless communications technologies is critical for maximizing the efficiency of spectrum resources. Spectrum management policies ideally should take into account the impact of new technology, or — since it is difficult to predict the development paths of new technologies — allow for flexibility and accommodation in spectrum allocation. Although flexibility may be desirable in policy-making, most existing wireless technologies are inflexibly constructed to work on a limited range of specific frequencies.

Spectrum is integral to wireless technology and so its management is connected to many issues that may be of interest to Congress. These include new technologies such as "third-generation" (3G) cell phone services, wireless Internet, Ultra-Wideband (UWB) and location-finding technology. The latter includes applications for wireless enhanced 911.

CRS Report RL31764, *Spectrum Management: Auctions*
CRS Report RS21508, *Spectrum Management: Special Funds*
CRS Report RS21570, *Spectrum Management: Public Safety and the Transition to Digital Television*
CRS Report RL32408, *Spectrum Policy: Public Safety and Wireless Communications Interference*
CRS Report RS20993, *Wireless Technology and Spectrum Demand: Third Generation (3G) and Beyond*.
CRS Report RS21028, *Wireless Enhanced 911 (E911): Issues Update*
CRS Report RL32126, *911 Call Center Legislation: S. 1250 and H.R. 2898*

## Networking Information Technology Research and Development

At the federal level, almost all of the funding for information science and technology and Internet development is part of a single government-wide initiative, the Networking and Information Technology Research and Development program (NITRD). This program was previously called the Computing, Information, and Communications program (CIC) (1997-2000) and, prior to that, the High Performance

Computing and Communications program (HPCC) (1992-1997). The NITRD is an interagency effort to coordinate key advances in information technology (IT) research and leverage funding into broader advances in computing and networking technologies. Under the NITRD, participating agencies receive support for high-performance computing science and technology, information technology software and hardware, networks and Internet-driven applications, and education and training for personnel. For FY2005, the President has requested a budget of $2.0 billion for NITRD activities. The majority of funding goes to the National Science Foundation, National Institutes of Health, National Aeronautics and Space Administration, Defense Advanced Research Projects Agency, and the Department of Energy's Office of Science. Research emphases are focused on six program component areas (also called PCAs): high-end computing research; human computer interaction and information management; large-scale networking; software design and productivity; high-confidence software and systems; and social, economic, and workforce implications of IT and IT workforce development. Key issues facing congressional policymakers include is NITRD accomplishing its goals and objectives to enhance U.S. information technology research and development; is the funding level appropriate or should it be changed to reflect changing U.S. priorities; and what should be the private sector's role in this federal initiative?

**For Further Information**

CRS Issue Brief IB10130, *Federal Networking and Information Technology Research and Development Program: Funding Issues and Activities*

## Internet Privacy

Internet privacy issues encompass a range of concerns: the monitoring of electronic mail (e-mail) and Web usage by law enforcement officials or employers, the information policies of website operators concerning the collection and dissemination of personally identifiable information (PII), and the extent to which "spyware" is emplaced on computers without the user's knowledge.

In the wake of the September 11, 2001 terrorist attacks, debate over the issue of monitoring of e-mail and Web usage by law enforcement and government officials has intensified, with some advocating increased tools for law enforcement to track down terrorists, and others cautioning that fundamental tenets of democracy, such as privacy, not be endangered in that pursuit. Congress passed the USA PATRIOT Act (P.L. 107-56), and an amendment to it as part of the Homeland Security Act (P.L. 107-296), that makes it easier for government and law enforcement officials to monitor Internet activities, and for Internet Service Providers to voluntarily disclose the content of e-mails under certain conditions. The 108th Congress and public interest groups are monitoring how the USA PATRIOT Act is implemented.

The debate over website information policies focuses on whether industry self-regulation or legislation is the best route to assure consumer privacy protection on commercial websites. The issue is how to balance consumers' desire for privacy with corporate interests in collecting certain information on visitors to their websites. Congress passed the Children's Online Privacy Protection Act (COPPA, P.L. 105-277) to protect the privacy of children under 13 as they use commercial websites.

Many bills have been introduced since then to protect those not covered by COPPA, but the only legislation that has passed addresses information collection practices by federal, not commercial, websites, notably the E-Government Act (P.L. 107-347).

Spyware has become a focus of congressional concern in the 108th Congress. There is no firm definition of spyware, but one example is software products that include a method by which information is collected about the use of the computer on which the software is installed, and the user. When the computer is connected to the Internet, the software periodically relays the information back to the software manufacturer or a marketing company. Some spyware traces a user's Web activity and causes advertisements to suddenly appear on the user's monitor — called "pop-up" ads — in response. Software programs that include spyware can be sold or provided for free, on a disk (or other media) or downloaded from the Internet. Typically, users have no knowledge that the software they obtained included spyware and that it is now resident on their computers. Congress is debating what restrictions, if any, should be placed on spyware. Several bills are pending. See CRS Report RL31408 for information on Internet privacy-related legislation.

**For Further Information**

CRS Report RL31289, *The Internet and the USA PATRIOT Act: Potential Implications for Electronic Privacy, Security, Commerce, and Government*
CRS Report RL31408, *Internet Privacy: Overview and Pending Legislation*

## E-Government

Electronic government (e-government) is an evolving concept, meaning different things to different people. E-government initiatives vary significantly in their breadth and depth from state to state and agency to agency. For policymakers, a central issue is oversight of the coordination and implementation of the disparate e-government initiatives across the federal government.

Pursuant to the July 18, 2001 OMB Memorandum M-01-28, an E-Government Task Force created a strategy for achieving the Bush Administration's e-government goals [http://www.whitehouse.gov/omb/inforeg/egovstrategy.pdf]. In doing so, the Task Force identified 23 interagency initiatives designed to better integrate agency operations and information technology investments. These initiatives, sometimes referred to as the Quicksilver projects, are grouped into five categories; government-to-citizen (G2C), government-to-government (G2G), government-to-business (G2B), internal effectiveness and efficiency, and addressing barriers to e-government success. Examples of these initiatives include an e-authentication project led by the General Services Administration (GSA) to increase the use of digital signatures, the eligibility assistance online project (also referred to as GovBenefits.gov) led by the Department of Labor to create a common access point for information regarding government benefits available to citizens, and the Small Business Administration's One-Stop Business Compliance project, being designed to help businesses navigate legal and regulatory requirements. A 24th initiative, a government wide payroll process project, was subsequently added.

On December 17, 2002, President Bush signed the E-Government Act of 2002 (P.L. 107-347) into law. The law contains a variety of provisions related to federal government information technology management, information security, and the provision of services and information electronically. One of the most recognized provisions involves the creation of an Office of Electronic Government within OMB. The Office is headed by an Administrator, who is responsible for carrying out a variety of information resources management (IRM) functions, as well as administering the interagency E-Government Fund provided for by the law.

For the 108th Congress, oversight of the Quicksilver projects and the implementation of the E-Government Act are significant issues. Also, several issues are arising out of efforts to mediate the differences and capitalize on the similarities between e-government and homeland security priorities. In addition, the movement to expand the presence of government online raises as many issues as it provides new opportunities. Some of these issues concern: security, privacy, management of governmental technology resources, accessibility of government services (including "digital divide" concerns as a result of a lack of skills or access to computers, or disabilities), and preservation of public information (maintaining comparable freedom of information procedures for digital documents as exist for paper documents). Although these issues are neither new nor unique to e-government, they do present the challenge of performing governance functions online without sacrificing the accountability of or public access to government that citizens have grown to expect. (See CRS Report RL31057.) For a discussion of evolving policies related to scientific and technical information access, see the "Public Access to Scientific Information" section earlier in this report.

**For Further Information**

CRS Report RL31057, *A Primer on E-Government: Sectors, Stages, Opportunities, and Challenges of Online Governance*

CRS Report RL31289, *The Internet and the USA PATRIOT Act: Potential Implications for Electronic Privacy Security, Commerce, and Government*

## Open Source Software

Open source software refers to a computer program whose source code, or programming instructions, is made available to the general public to be improved or modified as the user wishes. In contrast, closed source, or proprietary, programs, which comprise the majority of the software products most commonly used, are those whose source code is not made available and can only be altered by the software manufacturer. Some examples of open source software include the Linux operating system and Apache Web server software.

The use of open source software by the federal government has been gaining attention as organizations continue to search for opportunities to enhance their information technology (IT) operations while containing costs. For the federal government and Congress, discussion over the use of open source software intersects several other issues, including, but not limited to, the development of homeland security and e-government initiatives, improving government information technology management practices, strengthening computer security, and protecting intellectual

property rights. In the 108th Congress, the discussion over open source software is revolving primarily around information security and intellectual property rights. However, issues related to cost and quality are being raised as well.

For proponents, open source software is often viewed as a means to reduce an organization's dependence on the software products of a few companies while possibly improving the security and stability of one's computing infrastructure. For critics, open source software is often viewed as a threat to intellectual property rights with unproven cost and quality benefits. So far there appear to be no systematic analyses available that have conclusively assessed security issues for closed source versus open source software. In practice, computer security is highly dependent on how an application is configured, maintained, and monitored. Similarly, the costs of implementing an open source solution are dependent upon factors such as the cost of acquiring the hardware/software, investments in training for IT personnel and end users, maintenance and support costs, and the resources required to convert data and applications to work in the new computing environment. Consequently, some computer experts suggest that it is not possible to conclude that either open source or closed source software is inherently more secure or more cost efficient.

The growing emphasis on improved information security and critical infrastructure protection overall will likely be an influential factor in future decisions on whether to implement open source solutions. The rapidly changing computer environment may also foster the use of a combination of open source and closed source applications, rather than creating a need to choose one option at the exclusion of another.

**For Further Information**

CRS Report RL31627, *Computer Software and Open Source Issues: A Primer*

# Biomedicine Issues

## National Institutes of Health: Funding and Organizational Issues

Congress doubled the NIH budget in the five years from FY1999 to FY2003, giving the agency increases of 14%-15% per year as the budget grew from its FY1998 base of $13.6 billion to the FY2003 level of $27.1 billion. Since then, the FY2004 appropriation and the FY2005 administration request have increased the budget by much smaller amounts, to $27.9 billion for FY2004 (a 3% increase) and $28.6 billion requested for FY2005 (a 2.6% increase). In looking ahead to the post-doubling years, many in the research advocacy community had urged Congress and the President to provide NIH with funding increases of about 8%-10% per year in order to maintain support of research grants, keep young investigators in the pipeline, and capitalize on the momentum of discoveries in both basic and applied research. While that approach still has some support in Congress, the FY2004 appropriation and the administration and congressional proposals for FY2005 reflect the constraints of competing priorities

for discretionary spending, including support of other fields of science and homeland security needs.

In the FY2005 request, NIH emphasized funding for research project grants over some other activities, such as facilities construction. Nevertheless, the extramural research community is expecting cutbacks in grant budgets, tight competition for new awards, and postponement of some large projects previously anticipated, including clinical trials. Advocates warn that research advances on the major chronic conditions that burden our society, such as heart disease, cancer, stroke, and diabetes, may be slowed.

Along with past budget growth, NIH has also seen its organizational structure expand markedly. The agency is comprised of 27 semi-autonomous institutes and centers, loosely coordinated by the central Office of the Director. As new entities have been created by Congress, each with its own mission, budget, staff, review office, and other bureaucratic apparatus, the costs and complexities of administering the enterprise have multiplied. Further, NIH wishes to emphasize a culture of multi-disciplinary teamwork, but many observers fear that the present structure of multiple independently operated institutes may undermine important initiatives in cross-disciplinary research, especially in fields such as neurosciences. Similar themes were sounded in a July 2003 report from the Institute of Medicine on the organizational structure of NIH. It recommended that there be more multi-institute strategic initiatives, with a stronger role for the NIH director, more support of "risky" research, and rethinking the appropriate number of NIH units. An effort termed the "NIH Roadmap for Medical Research" [http://nihroadmap.nih.gov], launched in September 2003, has identified critical scientific gaps that may be constraining rapid progress in biomedical research, and has set out a list of NIH-wide priorities and initiatives to address them. Three broad areas focus on new paths to biological discoveries, more interdisciplinary research, and improving clinical research. Congress may wish to undertake additional oversight or reauthorization activities to assess NIH's stewardship of its resources and air various management issues.

Another area of oversight interest is the potential for conflicts of interest when NIH scientists engage in outside consulting work with pharmaceutical or biotech companies, or receive awards or other forms of compensation from entities that might compete for NIH funds. The concern is greatest in the case of scientists who have decision-making authority on grants, but many do not. Congressional investigations of specific questionable situations are underway, together with broader probes of the ethics policies and practices of other federal agencies in the area of employees' outside consulting arrangements. NIH is responding to the specific inquiries, and has issued new guidelines with tighter limits on permissible activities. NIH is also undertaking more general assessments of principles and guidelines to maintain transparency while preserving the recognized benefits of public-private interactions in promoting the translation of research discoveries to real-world health practices and products.

**For Further Information**

CRS Issue Brief IB10129, *Federal Research and Development Funding: FY2005*

## Human Cloning and Embryonic Stem Cell Research

Embryonic stem cells have the ability to develop into virtually any cell in the body, and may have the potential to treat medical conditions such as diabetes and Parkinson's disease. Human embryonic stem cells are derived from very early embryos (5-days-old) that were created via in vitro fertilization (for infertility treatment or for research purposes). Work on human embryonic stem cells is controversial, in the opinion of some individuals, because the cells are located within the embryo and the process of removing them destroys the embryo. Other sources of embryonic stem cells are five-day old cloned embryos or five-to-nine-week-old embryos obtained through elective abortion.

Debate over the difficult ethical issues surrounding embryo research was rekindled in February 2004 with the announcement by South Korean scientists of the first human embryonic stem cell line derived from a cloned human embryo. One year earlier, in December 2002, a representative of Clonaid announced the alleged birth of the first cloned human. To date, tests to determine the authenticity of that announcement have not been performed. In November 2001, controversy erupted when Advanced Cell Technology (ACT) announced the creation of the first cloned human embryos (which survived only for a few hours). ACT intended to use the embryos to derive stem cells to produce new disease therapies. Some believe barring such research is unconscionable, and others believe that it would be ethical to clone human embryos to help infertile couples conceive. However, those opposed to the use of cloning technology on human embryos believe both uses raise profound moral and ethical questions.

President Bush announced in August 2001 that, for the first time, federal funds would be used to support research on human embryonic stem cells, but funding would be limited to "existing stem cell lines." The National Institutes of Health (NIH) has established the Human Embryonic Stem Cell Registry which lists stem cell lines that are eligible for use in federally funded research. Although 78 cell lines are listed, 21 embryonic stem cell lines are currently available. Scientists are concerned about the quality, longevity, and availability of the eligible stem cell lines. For a variety of reasons, many believe research advancement requires new embryonic stem cell lines, and for certain applications, stem cells derived from cloned embryos may offer the best hope for progress in understanding and treating disease. A significant cohort of pro-life advocates support stem cell research; those opposed are concerned that the isolation of stem cells requires the destruction of embryos.

Letters from Congress, one signed by 206 Members of the House and a second signed by 58 Senators, have been sent urging President Bush to expand the current federal policy concerning embryonic stem cell research. However, Congress has raised an impediment to such research by adding the Dickey Amendment to each Labor, HHS and Education appropriations act from FY1997 through FY2004. The Dickey Amendment prohibits HHS from using appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. As a result, federal funds can not be used for most forms of human embryo research including the isolation of new stem cell lines or the cloning of human embryos for any purpose.

The Bush Administration established the President's Council on Bioethics in November 2001 to consider all of the medical and ethical ramifications of biomedical innovation. In July 2002, the Council released its report on human cloning, which unanimously recommended a ban on reproductive cloning and, by a vote of 10 to 7, a four-year moratorium on cloning for medical research purposes. The Council released a second report on the issue, *Monitoring Stem Cell Research*, in January 2004.

In light of the December 2002 Clonaid announcement, many expected the 108th Congress to address cloning issues early in the first session. In February 2003, the House passed legislation nearly identical to that which passed the House in the 107th Congress. The bill would ban the process of cloning as well as the importation of any product derived from an embryo created via cloning. It would ban not only reproductive applications, but also research on therapeutic uses, which has implications for stem cell research. Critics argue that the measure would curtail medical research and prevent Americans from receiving life-saving treatments created overseas. Legislation has also been introduced in the Senate, but supporters reportedly do not have the 60 votes needed to overcome a filibuster.

**For Further Information**

CRS Report RL31358, *Human Cloning*
CRS Report RL31015, *Stem Cell Research*
CRS Report RL31422, *Substantive Due Process and a Right to Clone*
CRS Report RS21044, *Background and Legal Issues Related to Stem Cell Research*
CRS Report RL31142, *Stem Cell Research and Patents: An Introduction to the Issues*
CRS Report RS21517: *State Laws on Human Cloning*
CRS Report RL31211: *Cloning: A Select Chronology*

## Human Genetics

Collectively, genetic diseases and common diseases with a genetic component pose a significant public health burden. With completion of the human genome sequence, scientists will now focus on understanding the clinical implications of the sequence information. Clinical genetic tests are becoming available at a rapid rate. Testing is regulated by the federal government and tests are beginning to be included in health insurance benefits packages.

The National Human Genome Research Institute (NHGRI) supports genetic and genomic research, investigation into the ethical, legal and social implications surrounding genetics research, and educational outreach activities in genetics and genomics for HHS. In FY2004, NHGRI's budget was $478 million. The Genomes to Life initiative builds on the Department of Energy's integral role in the Human Genome Project. In FY2005, the proposed budget to support the initiative is $170 million.

Genetic discrimination and privacy continue to be outstanding issues in the second session of the 108th Congress. On October 14, 2003, the Senate passed the Genetic Information Nondiscrimination Act of 2003 (S. 1053) by a vote of 95-0. The House version (H.R. 1910) currently has 237 co-sponsors and is pending action in

three House committees: Energy and Commerce, Ways and Means, and Education and Workforce. S. 1053 is supported by consumer groups, the medical profession, researchers, the medical products industry (including pharmaceutical companies), and President Bush, and is opposed by some members of the health insurance industry and the U.S. Chamber of Commerce. Two related bills have been proposed. H.R. 3636 is more restrictive than S. 1053 and H.R. 1910, limiting the scope of protections to prohibitions on the health insurer's use of genetic information garnered from predictive testing. S. 16 is a broad equal rights bill, which includes the major provisions of S. 1053 for prohibiting genetic discrimination in employment and health insurance as a separate title on genetic nondiscrimination (Title VIII).

**For Further Information**

CRS Report RL32478, *Genetic Testing: Scientific Background and Nondiscrimination Legislation*
CRS Report RL32081, *Genetic Nondiscrimination in Insurance and Employment: Side-by-Side Analysis of Leading Bills of the 108th Congress*
CRS Report RL30006, *Genetic Information: Legal Issues Relating to Discrimination and Privacy*

# Energy Issues

## Hydrogen Fuel and Fuel Cell Vehicles

Hydrogen fuel and fuel cell vehicles have been the focus of increased attention, especially with the announcement of the President's Hydrogen Fuel Initiative during the January 2003 State of the Union Address. As part of the Department of Energy budget request for FY2004, the Administration sought an increase of approximately $70 million for hydrogen fuel and fuel cell research, and the Administration is seeking similar funding for FY2005. Over five years, the Administration is requesting a total funding increase of $720 million. This initiative would fund research on hydrogen fuel and fuel cells for transportation and stationary applications, and would complement the existing FreedomCAR initiative, which focuses research on the development of advanced technologies for passenger vehicles. In the FY2004 Energy and Water Development (P.L. 108-137) and Interior and Related Agencies (P.L. 108-108) appropriations bills, Congress approved an increase of approximately $50 million for the initiatives ($20 million less than the Administration request).

In addition to appropriations legislation, the 108th Congress is considering comprehensive energy legislation (H.R. 6). Among other provisions, the conference report on H.R. 6 (H.Rept. 108-375) would authorize hydrogen and fuel cell R&D funding above the Administration's request. However, a Senate cloture vote on the bill at the end of the first session failed. It is unclear what action will be taken on the bill in the second session. The 108th Congress is also considering reauthorization of the Transportation Equity Act for the 21st Century (TEA-21, P.L. 105-178). Provisions for vehicle and infrastructure tax credits, additional research and development funds, funding for demonstration projects, and other incentives for hydrogen and fuel cell vehicles could be included in TEA-21 reauthorization.

Issues facing Congress on hydrogen fuel and fuel cell vehicles include the proper role of the government in the research and development of consumer products; the potential role for the government in expanding hydrogen fueling infrastructure; safety standards, codes, and liability concerns surrounding new technology and a new system for delivering energy; and issues related to future market penetration of fuel cell vehicles.

**For Further Information**

CRS Report RS21442, *Hydrogen and Fuel Cell Vehicle R&D: FreedomCAR and the President's Hydrogen Fuel Initiative*
CRS Issue Brief IB10128, *Alternative Fuels and Advanced Technology Vehicles: Issues in Congress*

## Reprocessing of Spent Nuclear Fuel

Spent fuel from commercial nuclear reactors still contains most of its original uranium, as well as plutonium created from some of the fuel's uranium during reactor operation. A fundamental issue in nuclear policy is whether spent fuel should be "reprocessed" to extract its plutonium and uranium for use in new reactor fuel, or whether spent fuel should be directly disposed of without reprocessing. Nuclear power supporters point out that huge amounts of energy could be produced from the uranium and plutonium in spent fuel. However, plutonium can also be used for nuclear weapons, so groups concerned about nuclear weapons proliferation contend that federal support for spent fuel reprocessing could undermine U.S. nuclear nonproliferation policies.

In the 1950s and 1960s, the federal government expected that all commercial spent fuel would be reprocessed, even though existing "light water reactors" — the type still in use today — produced relatively little plutonium and could not fission all the isotopes of the plutonium that they did produce. The federal government's nuclear strategy called for the eventual replacement of light water reactors with "breeder reactors" that would convert enough uranium into plutonium to fuel a growing fleet of commercial breeder reactors indefinitely.

In the 1970s, however, concern increased about the weapons-proliferation implications of nuclear reprocessing, while the growth of nuclear power was far slower than initially projected. President Carter halted commercial reprocessing efforts in 1977, along with a demonstration breeder reactor. President Reagan restarted the breeder demonstration project, but Congress halted further funding in 1983. Nevertheless, Congress continued to fund a breeder-related research and development program, called the Advanced Liquid Metal Reactor (or the Integral Fast Reactor). To address weapons proliferation concerns, spent fuel from this reactor was to be reprocessed with an electrometallurgical system designed to only partially separate plutonium and uranium. Congress halted funding for the Advanced Liquid Metal Reactor in 1993, but appropriations continued at a lower level for research on the associated electrometallurgical reprocessing technology.

The Bush Administration's energy policy, issued in early 2001, called for renewed federal support for nuclear reprocessing and related technologies. The

Department of Energy is implementing that policy through the Advanced Fuel Cycle Initiative (AFCI), which was first funded in FY2003 and then increased by Congress for FY2004. The Administration's FY2004 budget request described the program as developing "proliferation resistant" reprocessing and fuel fabrication technologies, in conjunction with development of advanced reactors that would use the new fuel technology. As described by the budget request, some of these technologies would be similar to those used in the breeder reactor effort and its successor programs. The Administration's FY2005 request would cut AFCI funding by 31%, to $46.3 million. The House-passed FY2005 Energy and Water Development Appropriations Bill (H.R. 4614) would boost AFCI funding to $68.0 million.

The Administration contends that in addition to extending nuclear fuel supplies, the Advanced Fuel Cycle Initiative could significantly reduce the volume and long-term toxicity of nuclear waste. Separating plutonium and other long-lived radioactive isotopes from spent fuel and splitting them or "transmuting" them into shorter-lived isotopes would reduce the hazardous life of nuclear waste from 300,000 years to less than 1,000 years, asserts the Administration. Critics of the program counter that spent fuel reprocessing in the past has generated large quantities of radioactive waste that can create significant management and disposal problems. They also contend that reprocessing is not economically viable and continues to pose the same weapons proliferation risks that prompted President Carter to end it in the 1970s.

**For Further Information**

CRS Issue Brief IB88090, *Nuclear Energy Policy*

## ITER

ITER is an international scientific collaboration to construct a facility for fusion energy research. The partners include the European Union, Japan, Russia, the United States, China, and South Korea. Canada withdrew its participation in December 2003. The design phase of the project has concluded, and negotiations are currently under way prior to site selection and the start of construction. The United States withdrew from the design phase of ITER in 1998 at congressional direction, largely because of concerns about cost and scope. The project has since been restructured, and in January 2003, the Administration announced its intention to reenter the project. The total cost of ITER is estimated to be $5 billion over the next 10 years. Only a small portion of that would be required in FY2005 since construction has not yet begun. Key issues in the second session of the 108th Congress have been the cost of U.S. participation, the budget impact of ITER on the rest of the U.S. fusion program, and the debate over site selection.

# Agricultural Biotechnology (Genetically Engineered Crops)

Since the first genetically engineered (GE) crops (also known as genetically modified or GM crops) became commercially available in the mid-1990s, U.S. soybean, cotton, and corn farmers have been rapidly adopting them in an effort to

lower production costs and raise crop yields. Meanwhile, a so-called second generation of GE commodities, now under development, could shift the focus of agricultural biotechnology from the input side (i.e., farm production benefits) to the output side (i.e., consumer benefits). This second generation of GE products also may find widespread pharmaceutical and industrial uses. Beyond GE crops, products from GE animals also are being developed and tested.

As applications of biotechnology in agriculture spread, the policy debate over costs and benefits could intensify. Among the issues are: the impacts of GE crops on the environment and on biodiversity; questions among some consumer groups regarding the safety of GE foods, and whether they should be specially labeled; support for, and conduct of, agricultural biotechnology research; and issues surrounding intellectual property and patent ownership rights.

Some major U.S. agricultural export destinations, notably the European Union (EU), take a much more restrictive approach to regulating agricultural biotechnology than the United States, presenting obstacles for U.S. farm exports. A U.S. complaint regarding the EU's *de facto* moratorium on approvals of new GE crops is now before the World Trade Organization (WTO). Also, would agricultural biotechnology improve (according to proponents) or undermine (according to opponents) food security in developing countries? Another issue is whether current U.S. regulation and oversight of biotechnology — with various responsibilities spread primarily among the U.S. Department of Agriculture, the Food and Drug Administration, and the Environmental Protection Agency — remain appropriate, particularly as newer applications (e.g., biopharmaceuticals) emerge that were not in development when the current regulatory regime was established. In this vein, USDA's Animal and Plant Health Inspection Service (APHIS) published a notice of intent January 23, 2004 (69 FR 3271) to prepare an environmental impact statement (EIS) on its regulations governing GE organisms, and requested public comment on a number of issues. APHIS anticipates completing the draft EIS by the end of 2004.

In the 107th Congress, lawmakers included both in the 2002 farm law (P.L. 107-171) and in trade promotion legislation (P.L. 107-210), provisions aimed at supporting use of GE farm products, including new programs to challenge foreign barriers to U.S. exports of such products, and to educate the public on GE-based foods. In the 108th Congress, the conference report to accompany the FY2004 Consolidated Appropriations Act (H.Rept. 108-401; P.L. 108-199) notes that $3.3 million is provided to USDA for "cross-cutting trade negotiations and biotechnology resources." Pending bills (H.R. 2447, H.R. 3472) would create an interagency task force to promote the benefits of agricultural biotechnology. On the other hand, a series of other bills (H.R. 2916 through H.R. 2921) would prescribe changes intended to mandate GE food labeling; broaden FDA oversight; protect consumers from potential legal and environmental risks from agricultural biotechnology; and tighten rules for handling GE pharmaceutical and industrial crops, among other things. (For status of current legislation, see *Agricultural Biotechnology* in the CRS Agriculture Policy Electronic Briefing Book.) The House Agriculture Committee held hearings on agricultural biotechnology on March 26 and June 17, 2003, and one of its subcommittees held a similar hearing on June 23, 2004.

**For Further Information**

CRS Report RL31970, *U.S. Agricultural Biotechnology in Global Markets: An Introduction*
CRS Report RS21556, *Agricultural Biotechnology: The U.S.-EU Dispute*
CRS Report RS21418, *Regulation of Plant-Based Pharmaceuticals*
CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*
CRS Trade Electronic Briefing Book, *Biotechnology and Agricultural Trade*
CRS Issue Brief IB10131, *Agricultural Biotechnology: Overview and Selected Issues*

## Global Climate Change

Congress has maintained an active and continuing interest in the implications of, and the issues associated with, possible global climate change for the United States. In December 1997, the parties to the United Nations Framework Convention on Climate Change (UNFCCC) agreed to the Kyoto Protocol to establish binding commitments for reductions in greenhouse gases for the 38 developed countries of the world, including the United States, and the economies in transition (former Communist nations). However, the Kyoto Protocol has not yet received the required number of ratifications to enter into force. If the Protocol were to enter into force, and if the United States were to ratify the Protocol, the nation would be committed to reducing its net average annual emissions of six greenhouse gases to 7% below baseline levels (1990 for carbon dioxide) during the period covering the years 2008 to 2012. At present, U.S. emissions are above baseline levels.

The United States "signed" the protocol, but President Clinton during his term did not submit it to the Senate for advice and consent to ratification. In March 2001, the Bush Administration indicated its opposition to the Kyoto Protocol and essentially rejected it, citing possible harm to the U.S. economy and lack of developing country participation.

On February 14, 2002, President Bush announced a U.S. policy framework for global climate change — a new voluntary approach for meeting the long-term challenge of climate change. The centerpiece of this announcement was a plan to reduce greenhouse gas emission intensity of the U.S. economy by 18% over the next 10 years, from a present value of 183 metric tons of emissions per million dollars of gross domestic product (GDP) to 151. Greenhouse gas intensity measures the ratio of greenhouse gas emissions to economic output. The Administration stated that the goal was to be met through voluntary efficiency improvements. President Bush also outlined a Climate Change Research Initiative (CCRI) and a National Climate Change Technology Initiative (NCCTI), along with a new Cabinet-level Committee on Climate Change Science and Technology Integration to oversee their implementation. The CCRI focuses on short-term, policy-relevant objectives of climate change science. An existing U.S. Global Change Research Program (USGCRP) supports long-term, fundamental, scientific research objectives.

Both the new CCRI and the existing USGCRP were combined for the first time into the Climate Change Science Program (CCSP) in the FY2004 budget. The

FY2004 funding estimate includes $2.0 billion (CCRI + USGCRP) for research managed by the CCSP and some $1.2 billion for technology research and development in the NCCTI. Although the total funding estimate for CCSP in FY2004 is up about 13% over the FY2003 actual level, that portion of the funding allocated to the embedded CCRI is up about 310% from $41 million in FY2003 to an estimated $168 million in FY2004. The FY2005 budget request proposed a total spending level of $1.958 million for research managed by the CCSP, an amount $43 million or 2.2% below the FY2004 funding estimate of $2.0 billion. Although the FY2005 CCSP request was down 2.2%, that portion of the funding allocated to the embedded CCRI, once again, was up $70 million or 42% from the $168 million FY2004 estimate to a proposed $238 million for FY2005. Some $2.0 billion was proposed in the FY2005 budget for technology research and development in the NCCTI, an amount $0.8 billion or 67% above the FY2004 funding estimate of $1.2 billion. An issue of continuing concern for Congress is the extent to which such large increases as those enjoyed by the CCRI in the current fiscal year and, albeit to a somewhat lesser extent, in the FY2005 proposed budget represent new money versus how much is attributable to the reclassification of ongoing research programs.

The Administration released a new *Climate Change Science Program Strategic Plan* on July 24, 2003. The plan includes five major research goals and dozens of specific research targets and papers with deadlines. The National Research Council of the National Academy of Sciences conducted an independent review of the *Strategic Plan* and in April of 2004 published its overall assessment in a 51-page report, *Implementing Climate and Global Change Research: A Review of the Final U.S. Climate Change Science Program Strategic Plan* (available at [http://www.nap.edu/books/0309088658/html/] ). To complement the *CCSP Strategic Plan*, the Department of Energy, on December 2, 2003, released two long awaited reports from the U.S. Climate Change Technology Program that present a portfolio of federal R&D investments in climate change technology development, and highlight President Bush's initiatives in technology and international cooperation. The reports are titled, respectively, *Technology Options for the Near and Long Term*, and *Research and Current Activities*.

Discourse in Congress over the prospect of global warming and what the United States could or should do about it has yielded, over the last several years, a range of legislative proposals. Arguments have been presented that policy actions to reduce emissions of carbon dioxide and other greenhouse gases should be taken now, in line with the intent of the Kyoto Protocol. Alternative arguments have called for delay, citing challenging issues that were regionally complex, politically delicate, and scientifically uncertain; the need to expand technological options for mitigating or adapting to the effects of any climate change; and the associated high cost of certain mitigation schemes that would prematurely replace existing capital stock before the end of its economic life. Issues before the 108th Congress include regulating not only emissions of carbon dioxide, but of other pollutants that may contribute to global climate change (sulfur dioxide and nitrogen oxides) in so-called "multi-pollutant" legislation (see CRS Report RL31779); greenhouse gas reduction and carbon dioxide emissions trading systems (see CRS Report RS21581 and CRS Report RS21637); energy issues relevant to climate change, especially those associated with encouraging or authorizing energy efficiency and alternative energy sources; carbon sequestration technologies and methodologies; federal and national response strategies vis-a-vis the

prospect of abrupt climate change, climate change impacts, and climate system surprises; performance and results of federal spending on climate change science programs and climate change technology programs and, more broadly, on global change research programs; and long-term research and development programs to develop new technologies to help stabilize greenhouse gas emissions.

**For Further Information**

CRS Issue Brief IB89005, *Global Climate Change*
CRS Issue Brief IB10041, *Renewable Energy: Tax Credit, Budget and Electricity Production Issues*
CRS Issue Brief IB10020, *Energy Efficiency: Budget, Oil Conservation, and Electricity Conservation Issues*
CRS Report RL30692: *Global Climate Change: The Kyoto Protocol*

## The National Nanotechnology Initiative

Nanotechnology is the creation and utilization of materials, devices, and systems with novel properties and functions through the control of matter atom by atom, or molecule by molecule. Such control takes place on a scale of a fraction of a nanometer to tens of nanometers. Ten nanometers is equal to one ten thousandth the diameter of a human hair. Academic and industry scientists working in this field contend that research in nanoscience will lead to revolutionary breakthroughs in such areas as medicine, manufacturing, materials, construction, computing, and telecommunications.

The Administration requested a total of $982 million for the NNI in FY2005, a 2% increase over the FY2004 estimated funding level of $961 million. The FY2004 amount is $112 million above the President's request. However, almost all of this increase was the result of the Defense Advanced Research Projects Agency reclassifying over $100 million of existing research activities as nanotechnology research.

The Bush Administration designated the National Nanotechnology Initiative (NNI) as a multi-agency research initiative. On December 3, 2003, President Bush signed P.L. 108-153, the "21st Century Nanotechnology Research and Development Act (S. 189). Also referred to as the National Nanotechnology Program (NNP), the act authorizes $3.7 billion, between FY2005 and FT2008, for the five agencies included in the legislation: NSF, DOE, NASA, NIST, and the Environmental Protection Agency (EPA). The act directs the National Science and Technology Council (NSTC, part of the White House's Office of Science and Technology Policy) to work with the five participating agencies to establish priorities and coordinate the NNP activities.

The NNI is divided into five major themes. The *first* consists of long term basic research which is essential for establishing a fundamental knowledge of nanoscale phenomena. One of the fundamental challenges facing researchers is to try to control and manipulate matter at the ultimate frontier where, for example, as you move from 1 to 100 nanometers, the texture of atomic and molecular matter can suddenly change

from soft, to hard, to brittle, and back to soft again without explanation. The *second* is entitled Grand Challenges. It includes support for interdisciplinary research and education teams, including centers and networks that work on major long-term objectives. The *third* is Centers and Networks of Excellence with the primary objective of supporting research activities that cannot be conducted through the traditional mode of single investigator, small groups, or with current research infrastructure. Further, each center is expected to establish partnerships with industry, and/or one of the national laboratories. The *fourth* is the creation of a research infrastructure for metrology, instrumentation, modeling and simulation, and facilities. Finally, the *fifth* is the potential ethical, legal, and social and workforce implications related to the development and deployment of various nanotechnology capabilities.

Congressional issues for the NNI include the implementation of P.L. 108-153; reviewing the effectiveness of interagency coordination, and procedures to identify important areas of future nanotechnology investments; reviewing the level of NIH participation in the NNI given that many of the near term applications for nanotechnology will be associated with advancements in medicine; and examining the extent to which the nation's university research enterprise is capable of educating future scientists and engineers who are prepared to participate in nanotechnology related interdisciplinary research activities. Congress may also want to examine concerns that have been raised about potential environmental and health impacts associated with the development and use of nanoscale materials.

## Aeronautics R&D

Aeronautics R&D contributes to increasing air traffic capacity, reducing the impact of aircraft noise and emissions, improving aviation safety and security, and meeting other needs such as national defense and commercial competitiveness. Despite an increase in FY2004, NASA funding for aeronautics R&D is down by about half from its FY1998 peak. Supporters argue that more R&D in this area is needed to maintain the health of the U.S. aviation industry and the international competitiveness of U.S. aircraft manufacturers, so the future of aeronautics R&D funding has received close congressional attention in the second session of the 108th Congress. Also of interest has been the January 2004 realignment of NASA management, which created an Office of Aeronautics from the former Office of Aerospace Technology, and the November 2003 assessment of the program by the National Research Council ([http://books.nap.edu/html/atp/0309091195.pdf]). The aeronautics policy debate in Congress has continued to make reference to the November 2002 report of the congressionally established Commission on the Future of the United States Aerospace Industry ([http://66.77.20.156/assets/aerospace /02-218/docs/AeroCommission.pdf]). The Commission's recommendations included specific goals for improved aviation system capacity, safety, speed, noise, and emissions, as well as a significant increase in federal support for basic aerospace research.

# Space Program Issues

## NASA: President Bush's Exploration Initiative

In the wake of the February 1, 2003 space shuttle *Columbia* tragedy (see CRS Report RS21408), a reexamination of the National Aeronautics and Space Administration's (NASA's) human space flight program is underway. On January 14, 2004, President George W. Bush made a major space policy address in which he announced new exploration goals for NASA (see CRS Report RS21720). The policy calls for NASA to build a Crew Exploration Vehicle enabling Americans to return to the Moon in the 2015-2020 time frame (the last Americans walked on the Moon in 1972). Eventually, astronauts would go to Mars and "world's beyond," though no time frame was set for those missions. In the nearer term, the space shuttle would return to flight and be used to complete construction of the International Space Station, and then retired. That is anticipated in 2010, the year by which the Columbia Accident Investigation Board said the shuttle system would have to be recertified if NASA plans to continue flying it. U.S. research aboard ISS would be redirected to focus only on that needed to support the goals of sending astronauts to the Moon and Mars, instead of the broadly based multidisciplinary research program that had been planned. According to a FY2004-2020 budget chart released by NASA the same day, U.S. involvement in the space station would end by FY2017.

That NASA budget chart (dubbed the "sand chart" and available at [http://www.nasa.gov/pdf/54873main_budget_chart_14jan04.pdf]) suggests that approximately $150-170 billion would be spent from FY2004-2020 on the new initiative. Most of the funding would come from redirecting funding within NASA's already anticipated budgets, not from new money. NASA FY2005 budget materials describe the entire NASA budget request for FY2005-2009 ($87.1 billion) as the budget for the "exploration vision," of which $31.4 billion is "exploration specific." For FY2005, the "exploration specific" request is $4.5 billion, out of a total NASA FY2005 budget request of $16.2 billion. No cost estimate was provided for completing the entire initiative.

Among the issues Congress is considering regarding the initiative is how much it will cost to fulfill all that the President envisions, including sending people to Mars, and what impact the funding will have on other NASA activities and on non-space national priorities. The wisdom of terminating the space shuttle program in 2010, four years before the new Crew Exploration Vehicle is expected to be ready, is being questioned because U.S. astronauts would have to rely on Russia to take them to and from the space station at time when research critical to achieving the President's other goals is underway. Other questions include how the United States will fulfill its commitments to its partners in the ISS program (Russia, Europe, Canada, and Japan) without the shuttle, the extent to which robotic probes can explore space without the high cost and risk for sending humans, and the role of the private sector in achieving future space goals.

Though not directly related to the President's initiative, another controversial issue is NASA's decision to curtail shuttle servicing missions to the Hubble Space Telescope. NASA Administrator O'Keefe announced that decision two days after

President Bush's speech, leading some to conclude that the decision was a result of the new budget priorities within the agency. Mr. O'Keefe insists that it was based on shuttle safety concerns and the need to use the shuttle to complete construction of the International Space Station. Without another shuttle servicing mission, Hubble is expected to end its scientific observations in 2007-2008 instead of 2010 as previously planned because its batteries and gyroscopes need to be replaced. For more on the Hubble decision, see CRS Report RS21767.

**For Further Information**

CRS Report RS21720, *Space Exploration: Overview of President Bush's New Exploration Initiative for NASA, and Key Issues for Congress*
CRS Report RS21408, *NASA's Space Shuttle Columbia: Quick Facts and Issues for Congress*
CRS Report RS21767, *Hubble Space Telescope: NASA's Decision to Terminate Shuttle Servicing Missions*
CRS Report RS21744, *The National Aeronautics and Space Administration (NASA): Overview, FY2005 Budget in Brief, and Issues for Congress*
CRS Issue Brief IB93026, *Space Launch Vehicles: Government Activities, Commercial Competition, and Satellite Exports*
CRS Issue Brief IB93017, *Space Stations*

## National Security Space Programs

DOD and the intelligence community conduct a space program larger in terms of funding than NASA. Tracking the overall funding amount for the national security space program is difficult because it is not consolidated into a single account. According to the DOD Comptroller's office, DOD received $18.4 billion for space activities in FY2003; $20 billion in FY2004; and is requesting $21.7 billion for FY2005. The national security space program involves building and launching satellites for communications, navigation, early warning of missile launches, weather, intelligence collection, and other purposes. It also includes technology development efforts related to space-based interceptors as part of the Missile Defense Agency's goal to develop a ballistic missile defense system.

DOD's efforts to build new early warning satellite systems are especially controversial. The Space Based InfraRed System-High (SBIRS-High) program, that would use satellites in geostationary orbit (22,500 miles above the equator) and in highly elliptical orbits, would replace the existing series of Defense Support Program early warning satellites that alert the National Command Authority to foreign missile launches. The Space Tracking and Surveillance System (STSS, formerly SBIRS-Low) would consist of a "constellation" of many satellites in low Earth orbit dedicated to missile defense — tracking the missile from launch, through its "mid-course" phase when warheads are released, to its terminal phase when warheads reenter the atmosphere. The 108th Congress is continuing its close scrutiny of these programs because of the technical and cost issues they have encountered, resulting in overruns and schedule delays. Another program of particular interest is DOD's Evolved Expendable Launch Vehicle (EELV) program. The program's goal was to reduce the cost of launching satellites by 25%, but a downturn in the commercial launch services market is leading to higher costs for government users. Some are questioning

whether the government can afford to keep both EELVs (the Delta IV and the Atlas V) in operation.

**For Further Information**

CRS Report RS21148, *Issues Concerning DOD's SBIRS and STSS Programs*
CRS Issue Brief IB92011, *U.S. Space Programs: Civil, Military, and Commercial*
CRS Issue Brief IB93062, *Space Launch Vehicles: Government Activities, Commercial Competition, and Satellite Exports*

## Commercial Space Programs and the Health of the U.S. Aerospace Industry

Some space activities are conducted by private sector companies on a commercial basis, rather than by the government. These include commercial communications satellite services, imaging ("remote sensing") satellites, and space launch services. These commercial space activities present their own issues. Regarding commercial communications satellites, for example, questions have arisen about launching U.S.-built satellites on foreign launch vehicles. The issue is how to prevent U.S. technology from getting into the wrong hands when U.S.-built satellites are launched by foreign countries, while preserving the health of the U.S. aerospace industry by not undercutting the market share of U.S. satellite manufacturing companies through excessive regulation that drives buyers to non-U.S. firms. Congressional debate is focused on whether the State Department or the Commerce Department should have jurisdiction over granting export licenses for commercial communications satellites. The controversy erupted in the late 1990s when a special congressional committee (the Cox committee) concluded that China was benefitting militarily by launching U.S.-built satellites. At the time, the export of such satellites was under the jurisdiction of the Commerce Department. In response, Congress shifted jurisdiction to the State Department to help ensure better technology controls. U.S. satellite manufacturers claim that the State Department's restrictive export environment hurts their business and want jurisdiction returned to Commerce.

Concerns about the overall health of the U.S. aerospace industry are being debated in the context of a report from the congressionally established Commission on the Future of the U.S. Aerospace Industry (see CRS Report RS21455). Separately, today's commercial space activities are viewed by many space advocates as only the first wave of opportunities for a 21st century commercial space industry that could reduce the need for government-funded programs in certain areas. Efforts have been underway for some years in Congress to stimulate companies to build new space launch vehicles or invest in new space industries (such as space tourism or building space factories), including tax incentives and loan guarantees. Legislation has been introduced in the 108th Congress (see CRS Issue Brief IB93062 for current legislation).

**For Further Information**

CRS Issue Brief IB92011, *U.S. Space Programs: Civil, Military, and Commercial*

CRS Report RS21455, *The Aerospace Commission Report: A Synopsis, and Commission Recommendations for Congressional Action*

# Appendix: List of Acronyms

| | |
|---|---|
| ATP | Advanced Technology Program |
| CCRI | Climate Change Research Initiative |
| CCSP | Climate Change Science Program |
| DARPA | (Department of) Defense Advanced Research Projects Agency |
| DHHS | Department of Health and Human Services (alternatively, HHS) |
| DHS | Department of Homeland Security |
| DOD | Department of Defense |
| DOE | Department of Energy |
| DTV | Digital Television |
| FCC | Federal Communications Commission |
| FDA | Food and Drug Administration |
| FOIA | Freedom of Information Act |
| GE | Genetically Engineered |
| GPRA | Government Performance and Results Act |
| GSA | General Services Administration |
| HHS | (Department of) Health and Human Services (alternatively, DHHS) |
| MEP | Manufacturing Extension Partnership |
| NAS | National Academy of Sciences (which together with the National Academy of Engineering and the Institute of Medicine form the "National Academies") |
| NASA | National Aeronautics and Space Administration |
| NIAID | National Institute of Allergy and Infectious Diseases (part of NIH) |
| NIH | National Institutes of Health (part of the Department of Health and Human Services) |
| NIST | National Institute of Science and Technology (part of the Department of Commerce) |
| NITRD | Networking Information Technology R&D |
| NNI | National Nanotechnology Initiative |
| NSF | National Science Foundation |
| NSTC | National Science and Technology Council (part of OSTP) |

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| OHS | Office of Homeland Security (in the White House) |
| OMB | Office of Management and Budget |
| OSTP | Office of Science and Technology Policy |
| R&D | Research and Development |
| R&E | Research and Experimentation |
| RDT&E | Research, Development, Test and Evaluation |
| SBU | Sensitive But Unclassified |
| SHSI | Sensitive Homeland Security Information |
| USDA | U.S. Department of Agriculture |
| USGCRP | U.S. Global Change Research Program |