

Opportunities for the Life Sciences Industry: American Recovery and Reinvestment Act to Deliver \$150 Billion for Healthcare

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President Obama signed H.R. 1, the American Recovery and Reinvestment Act of 2009 (Recovery Act) into law on February 17, 2009. The bill represents the largest investment in public works since the Great Depression.

The Recovery Act allocates more than \$150 billion to health related programs, and makes significant down payments on medical research, comparative effectiveness initiatives, and health information technology. The chart below describes the major health provisions in the Recovery Act.

HEALTH CARE SPENDING: AMERICAN RECOVERY & REINVESTMENT ACT		
Investment Area	Funding	Programs
Administration on Children & Families	\$5.15 B	Head Start and Early Head Start; Children & Family Services programs.
Administration on Aging	\$100 M	Nutrition services
Comparative Effectiveness Research	\$1.1 B	Dispersed to AHRQ, NIH and HHS to "conduct or support research to evaluate and compare the clinical outcomes, effectiveness, risk, and benefits of two or more medical treatments and services that address a particular medical condition."
COBRA	\$24.7 B	65% subsidy of an individual's COBRA premium for up to 9 months.
Health Information Technology	\$19.2 B	Financial incentives to physicians and hospitals to encourage adoption of HIT; \$2 billion to ONCHIT for HIT grants and loans.
HRSA	\$2.5 B	Renovations and expansion of services provided at community health centers; training for health professionals.

Medicare	\$338 M	Payments to teaching hospitals, hospice programs, and long-term care hospitals.
Medicaid	\$87 B	Increased federal match for state Medicaid programs for two years.
NIH	\$10 B	Improvements to extramural and intramural facilities; grants to academic and other scientific researchers.
Prevention & Wellness	\$1 B	Clinical and community-based prevention activities to address chronic disease, immunization rates, and healthcare-associated infections.
Public Health and Social Services Emergency Fund	\$50 M	Improvements to the security of information technology.
TOTAL	\$151.138 B	

Opportunities for the Life Sciences Industry

While much of the Recovery Act funding will be parceled out to states in the form of enhanced Medicaid matches or used to subsidize expansion of insurance coverage for low-income and unemployed individuals, there are opportunities for private sector companies to apply for stimulus grants.

Health Information Technology

The Recovery Act includes the Health Information Technology for Economic and Clinical Health Act (HITECH Act), designed to move us toward the President's goal of providing all Americans with electronic health records by 2014. The Recovery Act requires development of national standards by 2010 that allow for the nationwide electronic exchange and use of health information; invests \$19.2 billion in health information technology (HIT) infrastructure and Medicare and Medicaid incentives to encourage adoption of HIT; and strengthens federal privacy and security law to protect identifiable health information from misuse.

Of the \$19.2 billion allocated for health information technology, \$17.2 billion is set aside for financial incentives to hospitals and providers to encourage the adoption of HIT. However, \$2 billion is earmarked for the Office of the National Coordinator for HIT for HIT affiliated grants and loans. Organizations seeking to develop HIT standards, infrastructure, and technology platforms may be eligible for these grants.

For additional information on this section of the Recovery Act, see our [Privacy Alert from February 25](#).

National Institutes of Health

The National Institutes of Health (NIH) received \$10.4 billion in the Recovery Act, an unprecedented flow of cash for the agency, which had an annual budget of less than \$30 billion in Fiscal Year 2008. Of the \$10.4 billion, the largest chunk—\$8.2 billion—is transferred to the Office of the Director, of which \$7.4 billion is designated for the individual Institutes for grants for scientific research. The remaining funds are for competitive awards for construction and renovation of extramural research facilities; renovation of NIH facilities; the purchase of equipment; and comparative effectiveness research.

The Director of the NIH has indicated that the Institutes will only fund projects that are expected to have a significant scientific impact within two years. Much of the \$8.2 billion for research will be allocated to Research Project Grants (known as "R01 grants", the most common grant application at NIH), which have already been received and reviewed by the Institutes. NIH may also fund supplemental grants and newly received R01s in certain areas. In addition, at least \$200 million will be used to fund "Challenge Grants." NIH Challenge Grants are two year grants of \$500,000 per year in 15 identified "challenge areas", including comparative effectiveness, enhancing clinical trials, and translational research. Life sciences companies may be eligible for certain Challenge Grants.

Comparative Effectiveness Research

The Recovery Act provides \$1.1 billion to "conduct or support research to evaluate and compare the clinical outcomes, effectiveness, risk, and benefits of two or more medical treatments and services that address a particular medical condition." The money is allocated to the Agency for Health Research and Quality (\$300 million); the NIH (\$400 million); and to the Secretary of Health and Human Services, to allocate at her discretion (\$400 million). Through its Challenge Grant program, discussed above, the NIH has already published numerous grant opportunities for comparative effectiveness research (CER). As required by the Recovery Act, the Federal Coordinating Council for CER was appointed in early March and the Institute of Medicine will publish a report recommending funding priorities in June. These entities will largely determine the direction of Recovery Act spending on CER, but there may be opportunities for the life sciences industry.

Prevention & Wellness

The Recovery Act provides for \$1 billion for "prevention and wellness." Some of this funding will be transferred to the Centers for Disease Control and Prevention to expand low income immunization programs. Fifty million dollars will be distributed to individual states for programs to prevent healthcare acquired infections. The remainder, \$650 million, will be given to the Secretary of Health and Human Services to carry out evidence-based and community-based prevention and wellness strategies authorized by the Public Health Service Act (PHSA) to address chronic disease rates. It is unclear whether this money will be spent on federal programs under the PHSA or whether it will be granted out to private entities to conduct chronic disease management initiatives. There may be opportunities for industry if grants to the private sector are made.

Be Prepared

The Office of Management and Budget (OMB) has released guidelines for all federal agencies, indicating that Recovery Act spending decisions must be transparent and available to the public. OMB has also recommended that agencies use [Grants.gov](#) to receive applications for federal funding opportunities. The Department of Health and Human Services is still developing plans for Recovery Act spending, but organizations can be prepared to apply for Recovery Act funding by immediately registering at [Grants.gov](#).

In addition to funding opportunities, the Recovery Act includes numerous tax incentives that may benefit the life sciences industry. For more information on Recovery Act tax provisions, see our [Tax Alert from February 27, 2009](#).

Foley Hoag can help you understand and take advantage of the Recovery Act. We can also provide information on the Massachusetts Life Sciences Initiative. For more information, see our [Practice Group Alert from February 11, 2009](#).