The Federal Government’s Key Role in Healthcare Innovation

by
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The need for innovation in healthcare has never been greater. Healthcare spending in the United States is projected to grow 5.8 percent annually through 2020, placing increasingly larger burdens on American households and the economy with each passing year. By 2020, total healthcare spending will encompass 19.8 percent of the US gross domestic product (GDP), up from just 17.6 percent in 2012 and 16 percent in 2005.1 Innovative models of care and payment, new technologies, new products, and new approaches to prevention and patient engagement can help reduce costs and, equally important, improve overall patient health and outcomes. However, the current economic climate has dampened funding for healthcare research institutions, and many healthcare leaders now worry that cuts in federal and private funding of medical research will slow discoveries of new therapies and diagnostic tools.2 In addition, without new and innovative models of care delivery and financing to support wider access to care, dissemination of new treatments and therapies to patients in need will be delayed. The healthcare community must find ways to support continued innovation and advances in health services and products.

Concerns about spurring innovation are not limited to healthcare; the federal government has been engaged in a number of initiatives to promote innovation in energy, education, science, and other sectors. However, the government is uniquely positioned to address healthcare innovation because of its dominant role in healthcare funding and regulation. The Centers for Medicare and Medicaid Services (CMS) serves as the nation’s largest healthcare purchaser through its financing of Medicare and Medicaid programs, which together accounted for 35 percent of total national health expenditures in 2009.3 Through its budget of $6.1 billion, the Centers for Disease Control and Prevention (CDC) funds both research and services for population and public health.4 The federal government participates in and funds medical product research and development through the National Institutes of Health, which has an annual budget of over $30.7 billion.5 Federal funding also supports health and product development research within the Department of Defense; the Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services targets responses to pandemic infections and countermeasures to chemical, biologic and radiologic threats; and the Food and Drug Administration (FDA) regulates clinical research and medical product approval, marketing and distribution.

Booz Allen Hamilton recently sponsored a panel discussion on “The Federal Government’s Role in Medical Innovation.” The panel focused on federal programs, regulations and policies that can reduce barriers and foster innovation in healthcare delivery and medical product development in the United States. Participating on the panel and in the audience discussion were leading experts from payer, provider, and life science companies in the biotechnology and pharmaceutical sectors, as well as key policy makers and staff from government agencies. While participants acknowledged the challenges, they agree that government should play a continuing role—and, in some instances, a strengthened role—in promoting innovation in several key areas:

- Providing targeted funding to support development of product and service innovation at junctures where private funding is inadequate
- Facilitating collaboration by setting standards for information exchange and leading selected cross-sector initiatives
- Developing regulations and policies that incentivize innovation and promote the dissemination and widespread use of models, technology, and products
that demonstrate measurable gains in healthcare quality, efficiency and outcomes.

Finding agreement on the precise standards, regulations, funding levels, and other issues will require ongoing discussion and negotiation among all members of the healthcare community. Nevertheless, federal organizations are playing an essential role in fostering innovation, and their activities provide many opportunities for payers, providers, life science companies, researchers, and other stakeholders to leverage government programs and resources while partnering to spur much-needed innovation.

**Federal funding can jump-start innovation in healthcare products and services at critical junctures where private funding is inadequate.** Health information technology can cut costs and improve care delivery in countless ways, from reducing complications in patient care and enhancing coordination across care settings to streamlining administrative processes and providing information on healthcare quality and outcomes. Federal funding and incentives are already being used in a variety of programs to support the adoption of electronic medical records and quality reporting among providers. The Health Information Technology for Economic and Clinical Health (HITECH) Act is designed to speed up investment by practitioners in electronic medical records and processes, which can improve care coordination and tracking of health outcomes. Signed by President Obama in 2009, HITECH authorized $19.2 billion for enhanced Medicare and Medicaid payments to providers who adopt “meaningful use” of health information technology into their practices between 2011 and 2015. Meaningful use was defined to include standards for electronic health records and their use in tracking medication, lab tests, prescribing and provider communication. The Congressional Budget Office predicted that these incentives would lead to the adoption of electronic health records by 90 percent of physicians and 70 percent of hospitals by 2019.7

The CMS Innovation Center is funding an array of initiatives to test care delivery and payment models to address critical needs in the current healthcare system, such as strengthening primary care delivery and medical homes, increasing coordination between...
health and social services, and improving care and outcomes for the most vulnerable populations, including those who are chronically ill, poor and/or elderly. In November 2011, CMS announced the Health Care Innovation Challenge, a $1 billion nationwide funding initiative to test creative ways for delivering high quality medical care and reducing costs in a variety of populations and settings. The initiative is also seeking innovations in workforce development and deployment. Providers, payers, local government, public-private partnerships, and multi-year collaborative projects have been encouraged to apply for funding. It is hoped that after successful models are created, they can be replicated and sustained through the healthcare financing system.

Federal agencies also play an important role in supporting the development of new products, particularly in addressing industry’s need for pre-competitive information about basic mechanisms of disease and biomarkers and surrogate endpoints that can predict treatment response and outcomes. The National Institutes of Health (NIH) has traditionally been a major source of funding for basic science research, which does not provide economic returns sufficient to attract private investment, but which provides critical foundational knowledge for developing innovative products. One example of a federal program supporting medical product development is the Foundation for NIH’s Biomarkers Consortium, which funds multiple projects across a variety of disease areas including Alzheimer’s, diabetes, cancer in order to discover and qualify biomarkers to support drug development. Another federal organization, BARDA, provides direct funding to address public health emergencies. It manages Project BioShield, which includes the procurement and advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents, as well as pandemic influenza and other emerging infectious diseases. An example of innovation from the Pandemic Influenza program is BARDA’s Mix and Match study assessing various combinations of antigens and adjuvants to obtain a more robust immune response. BARDA also helps facilitate cooperation among companies in the early, pre-competitive stages of research, thus fostering greater innovation and sharing of expertise.8

The federal government can facilitate innovation by setting standards and rules for information sharing among stakeholders and by leading cross-sector collaborative initiatives. In order to speed innovation and reduce the cost, organizations must share insights learned during health system reform, health care delivery, and medical product research. As a market regulator, the federal government is in a unique position to develop information sharing standards and guidelines that will facilitate appropriate data sharing and collaboration while protecting intellectual property and individual rights to privacy. For example, the Health Insurance Portability and Affordability Act (HIPAA) protects patients’ information and sets standards for secure and consistent data exchange. HITECH Act provisions strengthen data security and privacy protections and specify penalties for data breaches.9 Additionally, in 2013, the government will require the collection and submission of quality indicators by providers, which will facilitate quality measurement and improvement.

Federal-sponsored collaboration and information exchange can also play a critical role in supporting medical product development and management of medical product risk and benefit. In some instances, the federal government has spearheaded public and private-sector data sharing to facilitate clinical research in areas on unmet medical needs. The FDA’s Critical Path Initiative (C-Path) brought together more than 54 public and private-sector organizations to improve the efficiency and quality of clinical trials. C-Path led the development of an information database of approximately 4,000 Alzheimer’s subjects from eleven industry-sponsored clinical trials; the database is accessible to researchers for the design of future
clinical trials and the identification of potential therapies that have a positive effect on disease progression. Similarly, the FDA sponsored Mini-Sentinel project supports data exchange among 17 clinical and payer partner organizations. This collaborative facilitates the analysis of data from more than 100 million patients to assess the safety risks of medical products. This system enhances the FDA’s ability to conduct proactive surveillance of safety events and supports the acceleration of product approval with limited safety data. It also provides an opportunity to identify patient populations for which the product risk to benefit ratio may not be appropriate. Identifying the higher risk populations and limiting product use in these groups can help keep products on the market for other patient populations.10

**Federal policies and regulations can support processes and provide incentives that promote the widespread adoption of proven interventions.** Policies and regulations can support the development of innovative health service delivery and financing models, reduce the time-to-market for biologics, drugs and devices, and incentivize sustainable private investment in efficient, high quality delivery models and in medical product innovation. CMS has established an innovative program to develop Accountable Care Organizations—new models of care in which physicians, hospitals, and health plans collaborate to provide integrated services to Medicare patients who were previously utilizing fee-for-service care. These new organizations can participate in shared-savings or shared-risk arrangements: If CMS quality standards for care are achieved, they are eligible for financial benefits from cost savings. To facilitate these changes in care delivery, regulations that had prohibited certain “anticompetitive” negotiations between hospitals, physicians, and health plans were modified to allow collaborative care, and financial incentives promoting efficiency while maintaining quality were established.11

In the medical product sector, the FDA has established a number of initiatives to speed product development and approval through enhancements of regulatory science. Regulatory transparency and predictability are especially important to investors, because clear standards regarding the evidence needed for product approval, reimbursement, and comparative effectiveness will enhance the efficiency of research and reduce investment uncertainty. In October 2011, Commissioner Dr. Margaret Hamburg launched a program for “Driving Biomedical Innovation: Initiatives for Improving Products for Patients,” which includes creating a rapid drug development pathway for targeted therapies.12 The FDA will host a series of scientific meetings to recommend steps for accelerating regulatory processes when an investigational drug being studied for a serious disease shows exceptional promise during early stages of development. New regulatory guidance will specify enrichment strategies for patient selection to support targeted drug development and expedited approval.

Financial incentives for innovation investment can also be provided via tax policy, such as the Therapeutic Discovery Project Tax Credit included in the Affordable Care Act. Extended exclusivity for therapeutics and medical devices may also spur innovation and increase investment in research. Exclusivity has already been proven to work for companies developing “orphan drugs,” and such policies could be expanded to focus on other areas where new treatments and products will improve health outcomes.

**Next Steps: Strengthening the Public-Private Innovation Partnership**

Leading experts in government, industry, and Congress have offered a number of recommendations for ensuring the government’s continued role in promoting innovation and for strengthening some aspects of its activities and responsibilities in each of the three main areas. Among their recommendations:

- **Provide continued funding for key federal research initiatives that complement and support private-sector research.** Budget constraints could hinder the ability of both the NIH and CMS under the president’s proposed FY 2013 budget. Although the NIH budget contains targeted funding for programs such as the National Center for the Translational
Sciences and fighting Alzheimer’s disease, some experts contend that many medical researchers will struggle under NIH’s flattened budget. Similarly, budget constraints may slow CMS’s push for innovations in health IT. At the FDA, funding for the biosimilars approval pathway and enhancing FDA’s generic drug review capacities could crowd out spending in other areas. The healthcare community should work to ensure that funding for critical research initiatives is maintained.

- **Extend the uses of successful innovative programs.** Among the programs that have applications beyond their initial use, the FDA’s new Sentinel drug safety surveillance system is being considered for a number of valuable “secondary” uses, including gathering evidence for comparative research and post-marketing activities for pharmaceutical manufacturers. The Accountable Care Organizations (ACOs) created by the Affordable Care Act also offer opportunities for building on their initial value. The extension of successful models to other organizations and to other payers beyond Medicare would provide for broader impact on quality and savings. In addition, the extensive cost and outcome data generated by the ACOs’ increased use of electronic health records could yield valuable data for comparative research.

- **Continue regulatory reform.** Sen. Kay Hagan (NC) recently introduced the Transforming the Regulatory Environment to Accelerate Access to Treatments (TREAT) Act proposing changes at the FDA. Among its provisions, the TREAT Act would accelerate the review and approval process for treatments of serious life threatening diseases with unmet needs; establish an Office of the Chief Innovation Officer at FDA to identify innovative approaches to ensure rapid development, testing, and review of drugs and devices, including the development of pilot programs; and enhance FDA’s access to external scientific and medical expertise. Similar legislation—the Faster Access to Specialized Treatments (FAST) Act—has been introduced in the House by Reps. Cliff Stearns (FL) and Ed Towns (NY). The FAST act would enable sponsors to request fast track designation for drugs that demonstrate potential to address unmet medical needs for treatment of serious or life-threatening conditions. Fast track designation would enable the FDA to provide for accelerated approval of such products based on either a surrogate endpoint likely to predict clinical benefit or a clinical endpoint likely to predict an effect on irreversible morbidity or mortality. These proposals, along with many of the changes proposed in the reauthorization of the Prescription Drug User Fee Act (PDUFA)—including enhanced efficiency and communication during the review process for new products, increased staff to review biomarkers and pharmacogenetic markers, and enhanced outreach and inclusion of patient advocacy groups in the review of benefit and risk assessments—could help foster continued medical product innovation.

**Conclusion**
The federal government plays a crucial role in promoting innovation across a wide spectrum of healthcare activities. Stakeholders in both the public and private sectors can work together to address the challenges of sustaining innovation and seek opportunities to accelerate innovation. Federal funding for healthcare information technology infrastructure, basic science and translational research and other “public goods” helps fuel innovation, as do clear standards for exchange of information about scientific advances, patient needs, and health outcomes. Transparent regulations can support rapid development, approval and adoption of strong delivery systems, high quality care, and medical product advances. Federal healthcare policy can incentivize sustained private investment in the healthcare sector. The success of these efforts is critical to driving innovation to reduce healthcare costs, expand access to quality healthcare, develop new cures, and improve health outcomes.
Methodology

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Booz Allen’s health practice integrates and applies industry expertise in supply chain, clinical, scientific, emerging global standards, and innovative health technologies, and includes more than 500 professionals with PhDs or master-level degrees in health-related disciplines. For over 20 years, Booz Allen has partnered with federal healthcare organizations on key strategic programs, including:

- Working with the FDA since 2004 to evaluate and improve regulatory processes including New Drug Applications/Biologic License Application (NDA/BLA) review, post-marketing commitments, and Risk Evaluation and Mitigation Strategies (REMS).20
- Partnering with the NCI Center for Biomedical Informatics and Information Technology (CBIIT) to design the pilot and structure for the entire caBIG® program. Booz Allen provided expertise and assistance in multiple areas, including bio-banking and pathology, data sharing standards, infrastructure, and the deployment of software tools nationwide. Booz Allen guided the efforts of 57 National Cancer Institute (NCI)-designated cancer centers as they participated in the program, and assisted outreach and recruitment efforts to solicit cancer center participation in the program.
- Partnering extensively with CMS, contributing expertise and stakeholder analyses to help the agency shape the policy, design, and roll out the Medicare prescription drug benefit (Part D) in 2007; and continuing to assist Part D quality assurance, monitoring of provider marketing practices and payment audits. Booz Allen is also supporting the development and implementation of health insurance exchanges as mandated in the Affordable Care Act.
- Booz Allen also has long-stranding portfolios of assignments with the Department of Veterans Affairs, Military Health Services, Center for Disease Control and Prevention, and Agency for Healthcare Research and Quality.

Booz Allen is committed to helping clients solve their toughest problems, working with them side by side to help them achieve their missions and delivering results that endure.
Notes


2 See, for example, "Gone Tomorrow: A Call to Promote Medical Innovation, Create Jobs, and Find Cures in America," The Council for American Medical Innovation, June 10, 2010.

3 NHE Fact Sheet, CMS


5 Ibid.


8 See "BARDA Strategic Plan 2011-2016."


12 "Driving Biomedical Innovation: Initiatives to Improve Products for Patients," FDA, October 2011.

13 Research!America’s Statement in Response to President Obama’s FY 2013 Budget, February 13, 2012.


18 H.R., 4132, introduced March 5, 2012.


About the Authors

Lucy Stribley is a leader in Booz Allen Hamilton’s Life Sciences practices, with over 19 years of consulting experience and 15 years focused on healthcare. As a Principal, she focuses strategy, process analysis and evaluation, and information technology for federal and commercial health clients. She has over 13 years’ experience working with the U.S. Food and Drug Administration (FDA), supporting all of the centers and offices. Stribley has also supported U.S. Army Medical Research and Materiel Command (USMRMC), Centers for Medicare and Medicaid Services, National Institutes of Health, commercial pharmaceutical and biotechnology manufacturers, and not-for-profit clients.

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