Report to the Secretary

Office of the Deputy Secretary
U.S. Department of Health and Human Services

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THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

January 15, 2009

Dear Mr. Secretary:

Today, we know more about human health than ever before, and many more promising discoveries lie ahead. Advances in science and technology are helping to transform the way we deliver healthcare. In the years ahead, new medical technologies, whether pharmaceuticals, biologic products or medical devices, will bring hope to millions and improve the quality of life of every American.

The development and delivery of these advances, however, is not without serious challenges. The Department of Health and Human Services (HHS) has recognized this, and over the last eight years, we have taken important steps to promote innovation and to create an environment that encourages the invention of new products while maintaining a rigorous review process to assess the safety of products and protect the health of the American people.

Because the Department has often done a better job of improving its role in the innovation process than of communicating those improvements, in the fall of 2008, with your support, I hosted a series of conferences around the country on HHS' role in the biomedical and device development process. At these meetings, senior officials from the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS), and the Agency for Healthcare Research and Quality (AHRQ) highlighted the work taking place in and among their agencies to facilitate the development of innovative medical technologies. Topics covered included:

- the role of basic, translational, and clinical research conducted and supported by NIH;
- the FDA's efforts to use state-of-the-art science in support of medical product development, and to promote consistency and efficiency in product review;
- CMS' perspective on how innovators can better navigate the current payment and coverage processes; and
- AHRQ's role in promoting quality research tools that can benefit innovators.

Equally important, these conferences gave doctors, researchers, and innovators the opportunity to exchange ideas with HHS officials and each other, underscoring the need for a transparent, two-way relationship between HHS and medical innovators. Although there was no consensus among the attendees, there were many common threads among their various comments.

What follows is a record of what individual attendees presented at the conferences, including details about many relevant HHS initiatives. This report highlights the work underway and serves as a signpost for continuing to address these ongoing challenges.

Sincerely,

Tevi D. Troy

II. CHALLENGES IN THE BIOMEDICAL INNOVATION PATHWAY

Breakthroughs in medical science have saved and extended millions of lives. They have cured deadly diseases and will be crucial to fighting illnesses in the future. However, the course for bringing new medical products to market is often costly and complex. If we are to reach the next level of life-saving therapies and products, which we are on the cusp of attaining, our process must evolve along with technology. Described below are some of the major procedural challenges discussed by attendees at HHS' Healthcare Innovation Conferences. This is by no means an exhaustive list, but it does reflect the concerns expressed most frequently by the attendees.

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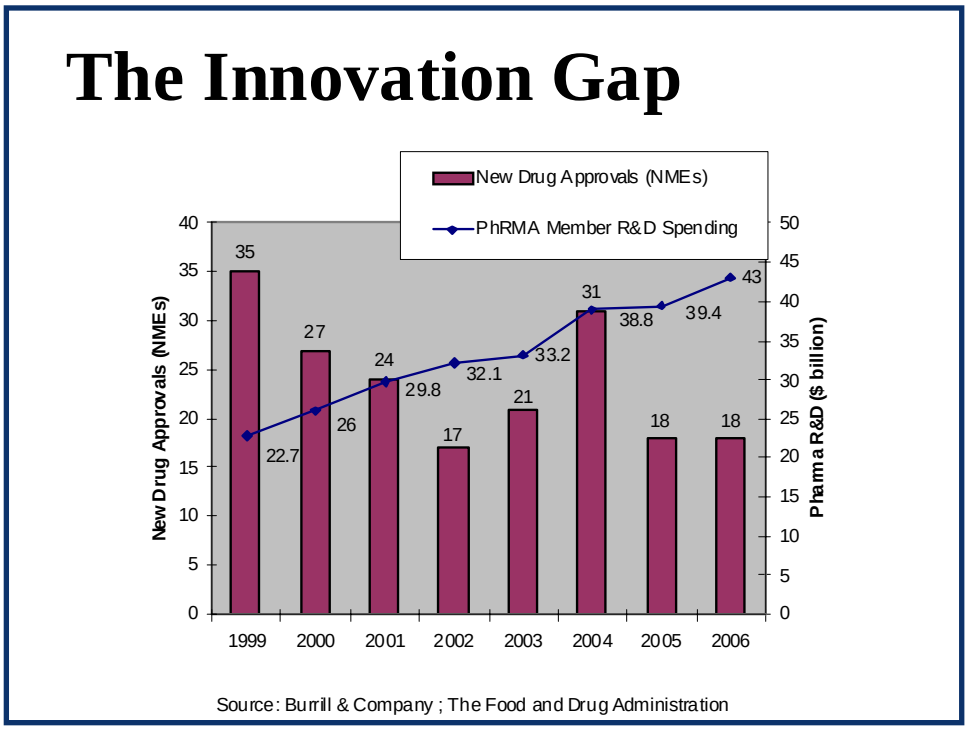
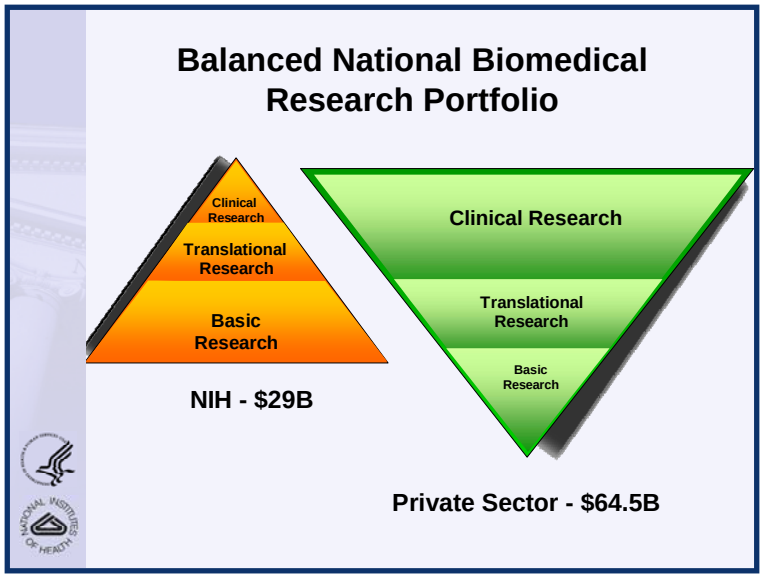
The Escalating Cost of Biomedical Research & Development (R&D). Despite record spending on biomedical R&D in the United States by both the public and private sectors, the number of innovative therapeutic products has been declining over the past decade. For example, today it can take up to 15 years and $1.3 billion to develop a new pharmaceutical product.[1] This is almost double the per-product cost of R&D compared to just five years earlier. Spending on biomedical R&D reached an all-time high of $122 billion in 2007, the lion's share coming from the pharmaceutical, biotechnology, and medical device industries.[2] The escalating cost of biomedical innovation naturally results in higher prices for products, which in turn decreases patient access to important medications and devices. In addition, the high costs of entry into the market can deter innovators and companies from pursuing new technologies altogether. For those who enter or remain in the market, it is increasingly challenging to ensure funding for each of the three stages of biomedical research: basic, translational, and clinical. Private industry's proportion of basic research spending has declined, while its spending on the final stages of clinical research has increased. This means less funding is used for the earlier stages of product development.



[1] DiMasi & Grabowski, Managerial Decision Econ, 2007; 28: 469-479.
[2] Research!America, *2007 US Investment in Health Research* (Washington, DC, Nov 2008)

The "Translational Gap" in Moving Biomedical Advances from the Laboratory to the Clinic. Despite enormous breakthroughs in scientific research – such as sequencing the human genome – the nation's ability to translate new discoveries into clinically viable products is severely hampered. Many factors contribute to this "translational gap." Private capital for the translational portion of the biomedical innovation process has become difficult to obtain. The cost and complexity of securing and enforcing patents remains a barrier to the translation of basic science into products. Innovators find it difficult to obtain intellectual property rights from various holders. Some conference attendees believe there is an increasingly expensive and failure-prone regulatory landscape for clinical trials. And both innovators and regulators encounter difficulties in accurately assessing and predicting the safety and efficacy of biomedical innovations in the early stages of product development. Addressing the translational gap is particularly difficult because it involves so many different factors, and the economic incentives to develop tools to facilitate translational research are not always present.



Biomedical Innovations Can Increase Short-Term Costs, but Decrease Long-Term Costs. One of the most pressing fiscal challenges facing the United States is the rising cost of healthcare – for which national expenditures are now estimated at some $2.1 trillion. The Congressional Budget Office recently concluded that roughly half of the increase in U.S. healthcare spending over the past several decades was associated with the expanded capabilities of medicine brought about by technological advances.[3] But some new technologies actually helped decrease other costs, such as reducing the length of hospital stays. A major challenge for both policy makers and innovators is trying to determine a way to balance the value realized from new technologies with the costs associated with paying for them. This must be done in a way that does not stifle innovation, as coverage and payment for new technologies are important drivers of innovation.

> **"[U]ncertainty is the most expensive part of the development process…"** - *Russell J Ivanhoe, M.D., Chief Medical Officer, Paracor Medical Inc., participant, San Francisco conference.*

[3] Congressional Budget Office, *Technological Change and the Growth of Healthcare Spending,* (Washington, DC, January 2008).

Comparative Effectiveness

In the most basic sense, comparative effectiveness refers to an evaluation of the impact of different options that are available for treating a particular medical condition. But there are many kinds of comparative effectiveness evaluations; for example, comparative effectiveness evaluations might:

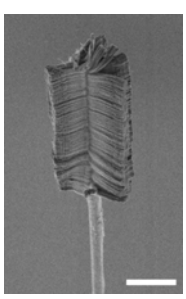
- Compare similar treatments, such as competing drugs, or might analyze very different approaches, such as surgery and drug therapy
- Look at the population-at-large, or might be focused on a particular category of patients
- Focus only on the relative medical benefits and risks of each option, or might also weight the financial costs and benefits

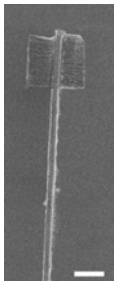
Conference participants posed several questions regarding comparative effectiveness:

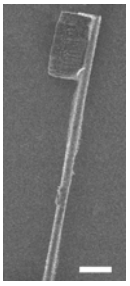
- What kind of entity ought to be doing this research or commissioning it?
- Who ought to set the agenda?
- Who ought to do the analysis?
- How should the results be used?
- What will be the impact on innovation?

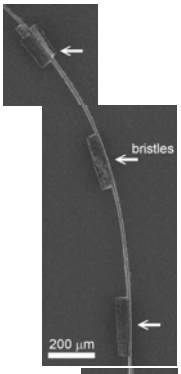
Uncertainties in the Biomedical Innovation Pathway. New and exciting technologies provide hope that pioneering new diagnostics, devices, drugs, and therapeutic interventions will be developed and made available to the public. However, the need to assess standards, clinical utility, safety, and cost all provide significant challenges and delays in translating scientific discovery to a marketable product. Biomedical innovation is fraught with uncertainty, risk, and a high probability of failure. Many new technologies – genomics, nanotechnology, advanced imaging, bioinformatics – offer great possibilities for the development of biomedical innovations. Yet these new technologies have also amplified the risk and uncertainty in the regulatory and payment pathways. Each of these new technologies raises questions about the safety, efficacy, and clinical use of products derived from these technologies. In many cases, the new technologies also challenge existing notions of how a biomedical innovation should be treated if it does not fall into a traditional regulatory or payment pathway, or straddles two existing pathways. In many cases, there may be a long lag between the emergence of a new technology and the issuance of regulatory guidance clarifying the pathway for product approval. Attendees noted that uncertainty can contribute to delays in the development and diffusion of new innovations, and can diminish investors' willingness to invest in new technologies.

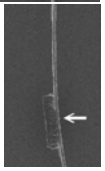
Nanotube brushes











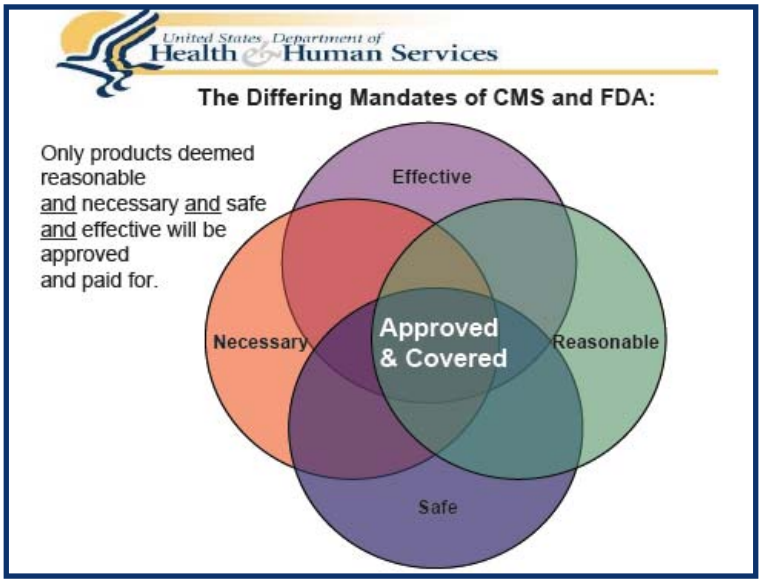
Patterned bristles

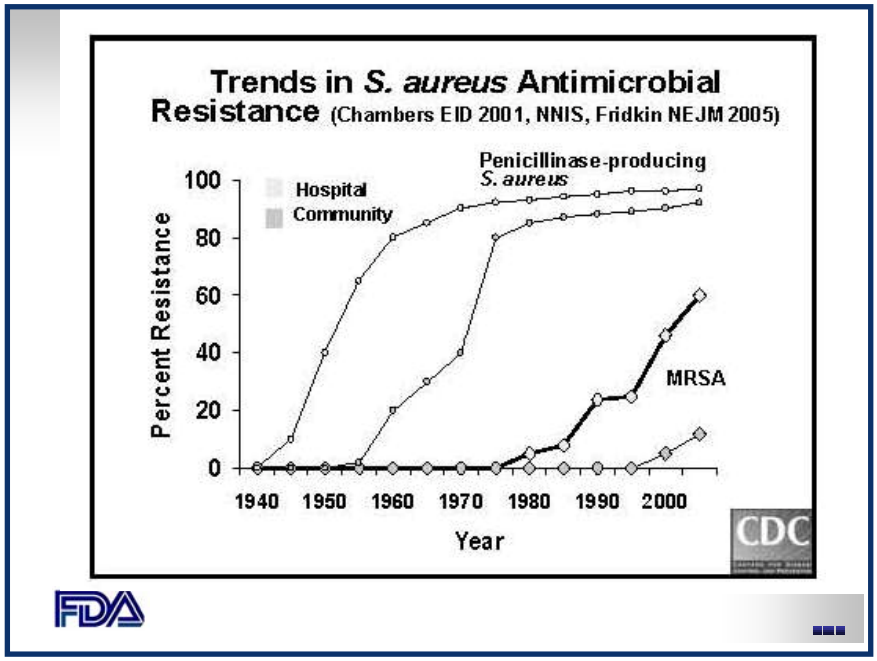
	Weight	Overall size (lateral)	Bristle number	Contact area (on a surface)	Contact area (in liquid)
Nanotube brush	< 50 µg	20 – 200 µm	6×10^6	4.24×10^3 µm^2 (28%)	3.8×10^7 m^2/m^3
Toothbrush	> 10 g	> 1cm	500	7.9 %	1.57×10^3 m^2/m^3

P. Ajayan, Rice University

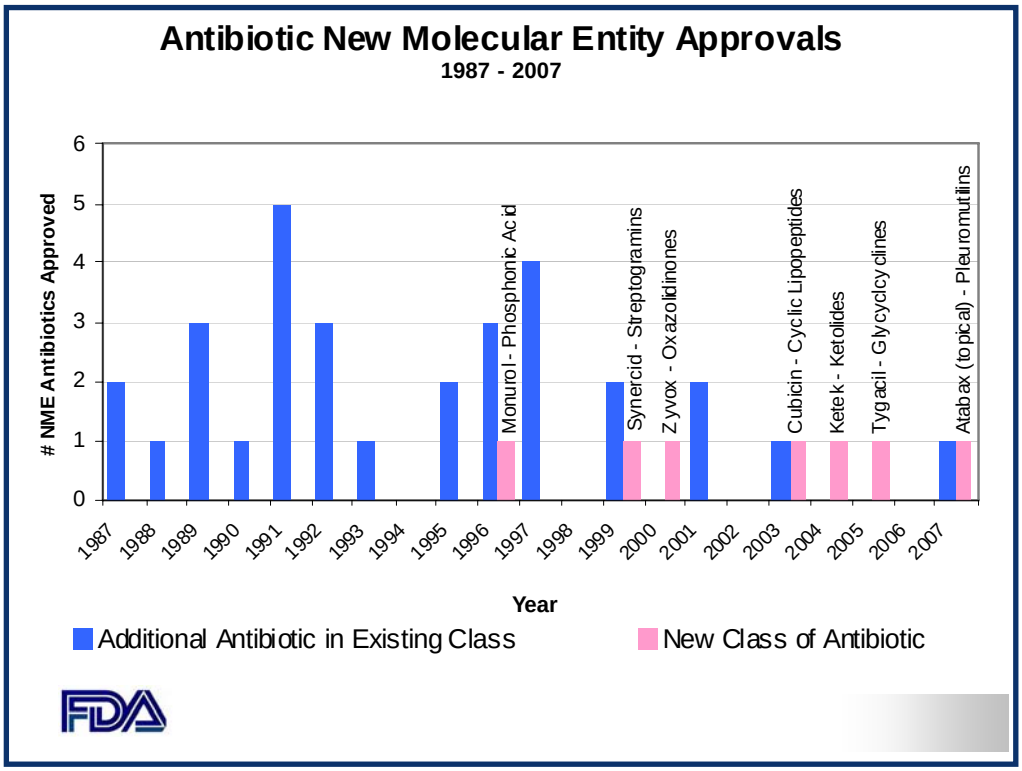
These are the world's smallest brushes, with bristles more than a thousand times finer than a human hair. Someday, brushes such as these may have biomedical applications, such as repairing damaged tissue or cleaning out arteries.
If such an application were made to the FDA today, the FDA would have to determine whether such a product is a device or a drug or something new altogether and how to assess the product's safety and effectiveness. These considerations inevitably take time, time during which patients may not have access to innovative care. As new technologies grow, FDA will inevitably face more challenges like this.

Differing Statutory Mandates of the HHS Agencies. Innovators at the conferences noted significant challenges in navigating the HHS system due to the differing mandates of the individual agencies. For example, NIH funds a wide range of basic, translational and clinical research that may or may not lead directly to a therapy for a disease. If a drug or device does result, the product must prove "safe and effective" to receive market clearance from the FDA, in accordance with the Federal Food, Drug, and Cosmetic Act. FDA approval, does not guarantee payment from CMS, which in most cases must judge the products to be "reasonable and necessary" in accordance with the statutory requirements of the Social Security Act. The level of evidence necessary to meet these statutory requirements is not always clear, according to some attendees. Still other agencies within HHS, such as AHRQ, may review evidence of product effectiveness using yet another set of metrics.





Coordination Among the HHS Agencies Involved in the Funding and Oversight of Biomedical Innovations.
Given the uncertainties inherent in the biomedical innovation pathway and their differing statutory mandates, attendees noted the importance of coordination among the HHS agencies. In recent years, HHS has made progress in coordinating and streamlining the efforts of the agencies involved in biomedical innovation process. Yet there are many areas in which coordination can still be improved. Some recommended that increased funding or intense public health concern for a targeted scientific field or disease area ought to be matched by a commensurate level of attention in other parts of HHS to ensure the existence of a clearly defined regulatory and payment pathway for innovations in the targeted field or area. The implication is that increased coordination and focus (e.g., NIH funding and FDA resources) on areas of interest could reverse troubling trends, such as the decrease in the annual number of antibiotics approved by the FDA at the same time that fighting antibiotic



resistant infections has become a critical priority for the Centers for Disease Control and Prevention (CDC). Others suggested that biomedical innovators who develop products in areas prioritized by HHS may nevertheless encounter challenges flowing from funding directives from Congress, limited knowledge of agency personnel of the workings of companion agencies, and cultural differences in how the HHS agencies operate.

Unintentional Adverse Impacts of HHS Agency Decisions on Biomedical Innovation. Although HHS aims to develop policies and regulations that will improve the health and well-being of the American people, attendees stated that inevitably some of HHS agencies' decisions have an adverse impact on biomedical innovation. A small regulatory change designed to solve one problem may create other, unanticipated problems. HHS, like all federal agencies, is required to assess the impacts of new regulations. However, it is not always possible to identify every potential outcome in advance. For example, payment for a particular treatment might be based on existing technology and may not account for alternatives that use different, less costly means (such as a different technology or different type of provider) to accomplish the same goal. Overcoming these unintentional hurdles as soon as they are identified, minimizing the harm created is a key challenge for HHS. To help meet this challenge, some attendees suggested that it is important for HHS personnel to have a better understanding of how their decisions influence industry.

> **"Continued cross-pollination of ideas for innovation and collaboration within HHS - at all levels - not just the executive levels - and with your external partners and constituents is something that should continue."** – *Christopher Perrera, HHS Client Manager, IBM, participant, Washington D.C. conference.*

Challenges in Navigating the HHS System. Despite HHS' attempts to provide avenues for dialogue and ongoing communication with innovators, it is often still challenging for innovators to navigate the HHS system. There are many gateways that innovators must successfully pass through to bring a promising biomedical innovation from concept through market clearance, payment, and clinical adoption by providers and patients. At each point, an innovator can encounter obstacles that may impede or block the full development of a life-saving product. Some innovators at the conferences raised concerns about a lack of clarity in the requirements or the processes by which HHS agencies make their decisions. Others believe there is no clear path for appeals in cases of delays or adverse decisions. These challenges may be especially distressing for innovators without expertise in navigating the funding, regulatory, and payment processes.

Risk Communication and Comprehension. Given the power of new biomedical innovations to improve the health and well being of the American people, it is not surprising that there is a great deal of interest among the media in the exploration of new scientific advances and role of the HHS agencies involved in funding and regulating biomedical innovation. Although this attention has led to a greater level of accountability and transparency, some have raised the concern that the media has helped to create unrealistic expectations about the speed at which biomedical innovations can be developed and made available to patients. Moreover, imbalanced media attention may contribute to a public misperception of the level of risk inherent in any new medical technology. Widely publicized safety recalls have focused on the drug review process. Safety issues have identifiable victims and easily generate media attention disproportional to actual risk. Yet the countless people who are helped by a new therapy are not highlighted or mentioned as often. Sometimes, media stories that focus only on risk spark Congressional hearings, which in turn spark more media coverage. Some attendees expressed concern that the FDA gets distracted from its core mission because it is dealing with the various demands placed on the agency in these circumstances.

Other attendees argued that, while it is vitally important for the FDA to be transparent and accountable to the public at all times, inaccurate risk communication or portrayals of normal scientific discourse as political controversy could cause the agency itself to become excessively risk averse. They fear that this could ultimately result in overly cautious decisions by FDA reviewers and leadership that deny patients access to new and potentially life-saving therapies.

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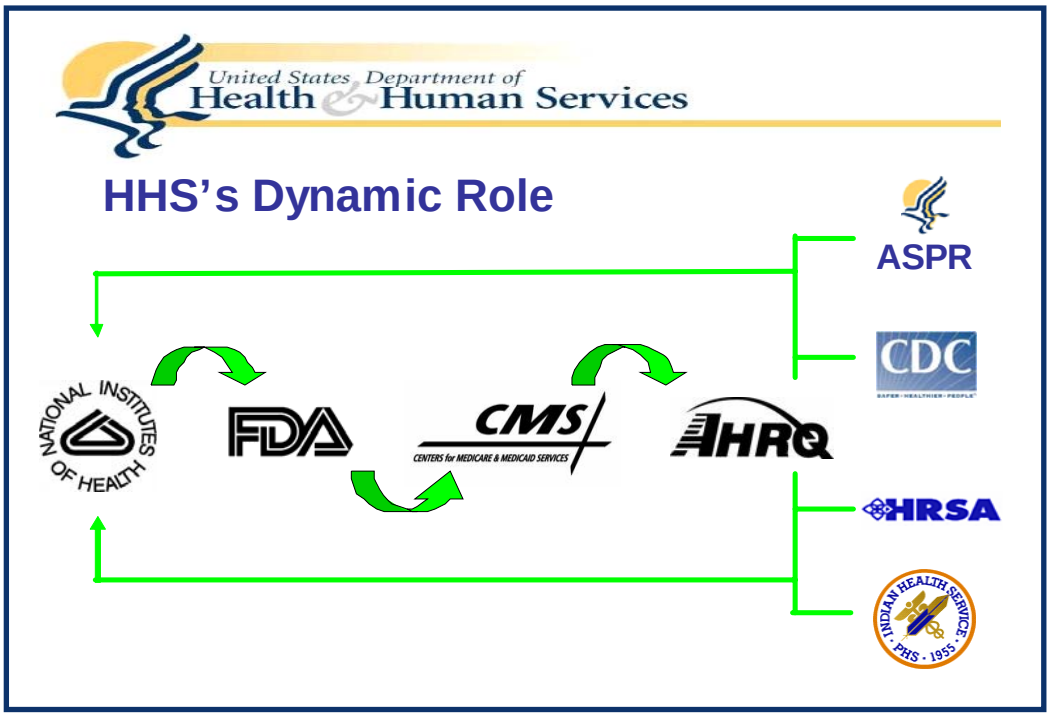
Some of these concerns are longstanding; others have emerged or intensified in recent years. Many conference attendees expressed concern that these challenges are now coalescing with a real impact on the pace of innovation. In the next section, we examine some steps, discussed at the Innovation Conferences, that HHS is taking to address these challenges.

HHS, however, is only one player in this landscape. Ensuring that Americans continue to have access to safe, high-quality, and innovative care will also require continued entrepreneurial risk-taking and passion for improving lives from innovators and healthcare practitioners, as well as by consumers making informed decisions.

The previous section contained many of the challenges identified by attendees as facing the healthcare industry. Challenges, however, can also create opportunities. HHS' important and dynamic role in developing and advancing new healthcare technologies makes it critical for HHS to consider and address these concerns.



HHS' role in the process begins with the research it funds through NIH. From there, it moves on to the role of regulator during the FDA review process. Once a product has been approved, someone must then pay for it in order for the product to be used. CMS determines which products will be covered and thus paid for by Medicare. As a leader in the industry, CMS' decisions often help to determine which products will eventually be covered by private insurance companies. Next, AHRQ may study the comparative effectiveness of a product. HHS' involvement does not end here. HHS and some of its grantees are also consumers and purchasers of health industry products. Resources from other divisions at HHS, such as the Office of the Assistant Secretary for Preparedness and Response (ASPR), the CDC, the Health Resource and Services Administration (HRSA), and the Indian Health Service (IHS), are used to purchase large numbers of healthcare industry products through programs such as the strategic national stockpile and IHS hospitals.

HHS has worked hard to develop and implement many programs and initiatives to help streamline this process. The following section outlines key programs presented by the various agencies at the Healthcare Innovation Conferences as examples of improvements to HHS' dynamic role in the innovation process.

Biomedical and Clinical Research

Over the last 40 years, substantial investments in biomedical research from NIH have helped halt and often eliminate many fatal conditions.

However, history demonstrates that no one can predict where the next great discovery or life-saving breakthrough will occur. Therefore, NIH employs a robust system to inspire bright minds to propose their best and most innovative ideas to tackle current and emerging public health problems. Proposals undergo a rigorous peer review process, and only those with the most promise receive support. The backbone of NIH research is the investigator-initiated project. These projects consistently provide discoveries that make Americans healthier and offer a training ground to the highly skilled individuals who work in the nation's healthcare innovation career fields.

Despite this proven strategy of supporting groundbreaking medical research, NIH recognized that there were still significant gaps in the area of biomedical research. No single agency – nor single Institute at NIH – was going to be able to tackle these gaps alone. Because of this, NIH launched the NIH ***Roadmap***. The goal of this initiative is to fill these fundamental knowledge gaps while developing transformative tools and technologies, and fostering innovative approaches to complex problems.

The NIH Roadmap was established as an NIH initiative in 2004 and passed into law by Congress in 2006. In FY 2008, Congress appropriated $498 million to support the initiative. This funding supports cross-cutting, trans-NIH research beyond the scope of any single NIH Center or Institute. Roadmap programs are typically supported for a limited duration of five to ten years. This approach keeps the fund nimble and enables NIH to respond to new opportunities and emerging challenges.

The Roadmap currently supports initiatives and activities organized along three major themes: New Pathways to Discovery, Research Teams of the Future, and Re-Engineering the Clinical Research Enterprise.

- *New Pathways to Discovery* advances our understanding of biological systems and helps build a better "toolbox" for medical research in the 21st century. Major types of projects developed under this initiative include a molecular libraries and imaging implementation group, a nanomedicine implementation group, and a structural biology implementation group. New program initiatives on the human microbiome and epigenomics were launched in FY 2007.

- *Research Teams of the Future* encourages scientists to test a variety of models for conducting research. The three important initiatives include: new types of awards to fund and encourage high-risk research; new types of awards to stimulate and foster interdisciplinary research; and public-private partnerships to foster relationships with industry, academia, and patient advocates in support of medical research.

- *Re-Engineering the Clinical Research Enterprise* accelerates and strengthens clinical research by adopting a systematic infrastructure that will better serve the evolving field of scientific discovery. Initiatives include the development of clinical research networks, clinical research policy analysis and coordination, and clinical research workforce training.

More information about the Roadmap is available at: http://nihroadmap.nih.gov/.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs were implemented by NIH, under the guidance of the Small Business Administration, in 1983 and 1994 respectively. These programs address the current fiscal challenges facing small businesses in the innovation research and technology transfer arenas. By statute, the programs are allocated 2.5% and 0.3%, respectively, of an institute's or center's extramural budget. These funds are then granted to domestic small businesses to engage in research or development that has the potential for commercialization. Both programs have a three phase strategy: phase I is a feasibility study, phase II is full R/R&D for two years with either a $750,000 (SBIR) or a $500,000 (STTR) award, and the final phase is the commercialization stage. Through a menu of technical assistance programs designed for companies' individual entrepreneurial and business training needs, programs provide commercialization assistance and facilitate partnering opportunities essential for helping small businesses cross what many refer to as, the "valley of death." These initiatives help bridge the translational gap to lead to commercialization.

More information is available at: http://www.sba.gov/SBIR/indexsbir-sttr.html#sbir.

"Valley of Death" is a term used to refer to the period between the laboratory bench and commercialization before life-saving therapies can reach broad numbers of patients. It involves developing pre-human testing, efficacy trials, production design, as well as other steps to determine whether a product will be safe and effective. It is a stage from which many potential products never emerge.

NIH's Public-Private Partnership Program, one of the Roadmap activities, has focused primarily of pre-competitive projects with the potential to provide needed tools, data, and principles to enhance the translation of discovery to the public. These partnerships bring industry, foundations, public and patient organizations together with government, and facilitate sharing of knowledge, tools and resources. Examples include:

- GAIN – the Genetic Association Information Network, which has applied new genome-wide scanning technologies in common diseases to seek new targets for drug development.
- The Biomarkers Consortium, seeking to identify and qualify new biological markers* to assist in clinical medicine, drug development, and regulatory decision-making; as well as a number of more focused projects examining therapeutic approaches in specific diseases.

Public-Private Partnerships allow innovators to gain access and to collaborate with Federal agencies and to enhance the efficiency and economy of the development pathway.

* "Biological markers or biomarkers are objective measurements of biological processes that can substantially improve the precision with which we evaluate disease risk, diagnosis, and progression, and guide treatment" (More information is available on The Biomarkers Consortium website: http://www.biomarkersconsortium.org/index.php?option=com_content&task=view&id=109&Itemid=61).

Product Development and Regulation

The FDA has primary responsibility for promoting and protecting public health by working to ensure safe and effective products reach the market in a timely manner. The FDA also monitors products for continued safety after they are in use and helps the public get accurate, science-based information needed to improve health. At the heart of all of FDA's regulatory activities is a judgment about whether a new product's benefits will outweigh its risks.

Responding to public demand for access to new therapies and industry demand for more timely and efficient reviews of new technologies, the FDA launched the ***Critical Path Initiative.*** This initiative is designed to facilitate a national effort to modernize the sciences through which FDA-regulated products are developed, evaluated, and manufactured. A major goal of this initiative is to reduce the unpredictability of medical product development through a concerted effort to modernize the scientific tools (e.g., in vitro tests, computer models, qualified biomarkers, and innovative study designs) and harness the potential of bio-information used to evaluate and predict safety, effectiveness, and manufacturability of candidate medical products.

In fiscal year 2008, Congress appropriated $8 million to support Critical Path projects in all FDA centers.

The Critical Path Initiative has made great strides. In March 2006, HHS Secretary Michael O. Leavitt and then-Acting FDA Commissioner Andrew von Eschenbach announced the release of *FDA's Critical Path Opportunities List*. The list described the areas of greatest opportunity for improvement in the product development sciences and provided 76 concrete examples of how new scientific discoveries—in fields such as genomics and proteomics, imaging, and bioinformatics—could be applied during medical product development to improve the accuracy of the tests used to predict the safety and efficacy of investigational medical products. Numerous collaborative efforts were launched in 2006, 2007, and 2008 that are addressing the hurdles identified under the Critical Path Initiative: more projects are underway.

The Critical Path Initiative holds great promise for addressing the challenges of rising research and development costs by identifying pathways for product approval that do not require proving already-tested biomedical phenomena and by identifying more easily measurable biomarkers and endpoints for clinical trials. Improvements in this area will also help address the translational gap.

FDA also launched the ***Sentinel Initiative*** on May 22, 2008, with the ultimate goal of creating and implementing the Sentinel System – a national, integrated, electronic system for monitoring medical product safety.

The Sentinel System will ultimately enable FDA to gather information about medical products by obtaining the answers to targeted questions (consistent with all applicable privacy and security safeguards) from existing data sources, such as health insurance claims data and other large healthcare information databases. These data sources, which will continue to be maintained by their owners, will allow the FDA to proactively monitor the safety of medical products that are on the market, thus providing the public, media, and Congress a more balanced and accurate view of the risks and benefits inherent in medical product.

Currently, a number of pilots are already beginning the process to assess and develop electronic databases that will directly inform FDA's Sentinel Initiative. Key examples include:

- FDA-CMS-ASPE Pilot on electronic drug safety surveillance (using Medicare data).
- OMOP (Observational Medical Outcomes Partnership with FNIH, FDA, PhRMA) to assess the value, feasibility, and utility of observational data to electronically identify and evaluate the safety risks and potential benefits of prescription drugs.
- eHealth Initiative (Collaboration with Healthcare System and Regenstrief Institute/Indiana Network for Patient Care and FDA as an advisor) to explore opportunities for using clinical information captured in the electronic databases of large health information exchanges to identify and assess safety signals associated with marketed pharmaceuticals.

Payment and Coverage

CMS is the largest purchaser of healthcare in the United States, serving 92 million Medicare, Medicaid, and SCHIP beneficiaries.

One of Medicare's primary objectives during its four decades of operation has been to make the best of modern medicine available to older and disabled Americans. In recent years, this has included encouraging the development of new devices and biotechnologies. For example, CMS has used Coverage with Evidence Development (CED), a process whereby Medicare provides coverage of a new technology while developing the evidence base regarding its reasonableness and necessity. By allowing CMS to promote new technology and explore the use of a product, CED ultimately helps close the gap between determining what is safe and effective in the eyes of the FDA and what is medically reasonable and necessary in the eyes of CMS. In addition, the Medicare payment systems for inpatient and outpatient procedures include add-on payments for new technologies. These additional payment mechanisms can help to address uncertainties in the biomedical innovation pathway and minimize the unintentional adverse impact created by Medicare payment systems' reliance on existing practices and technologies to set payment rates.

More information on Coverage with Evidence Development is available at: http://www.cms.hhs.gov/CoverageGenInfo/03_CED.asp.

As part of this effort to encourage innovation, in August 2008, CMS released the ***Innovators' Guide to Navigating CMS***. The Guide provides a practical "user's guide" to Medicare coverage, coding, and payment processes in a single document. The *Innovators' Guide* outlines CMS' processes and standards for approving coverage of new technology, including which circumstances call for a national or local coverage decision, or when a new technology might require a change in coding. The Guide also details how Medicare determines the level of payment for a drug or device that is new to the market. For example, for outpatient hospital services, the Guide provides a detailed explanation of the New Technology Ambulatory

More information on the Innovators' Guide is available at: http://www.cms.hhs.gov/CouncilonTechInnov/.

Payment Classification (APC) Groups used by CMS to gather cost data about a new technology service before it is placed in an APC with other clinically similar services. The Guide describes the New Technology APC application process, including the preconditions necessary for a new service to qualify for assignment to a New Technology APC, and how new technology payment rates are set. The Guide is a useful tool in addressing the challenge of navigating the HHS system.

As part of its efforts to address the relationship between biomedical innovations and increased costs, CMS has developed and implemented the ***Acute Care Episode Demonstration project***. The goal of the demonstration is to use a bundled payment to better align the clinical and financial incentives for both hospitals and physicians, leading to better quality and greater efficiency in the care that is delivered. A bundled payment is a single payment for all Medicare fee-for-service services furnished during an inpatient stay. The demonstration will also test the effect that transparent price and quality information has on beneficiary choice for select inpatient care.

More information is available at http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/, and click on "Medicare Acute Care Episode (ACE) Demonstration" under *Demonstration Project Name.*

Promoting Quality Research

AHRQ serves a vital role at HHS to improve the quality, safety, efficiency, and effectiveness of healthcare for all Americans. By evaluating and assessing the latest evidence, AHRQ's research is integral to the Department's ability to make informed diagnosis, treatment, and coverage decisions.

To address some of the growing concerns voiced about the lack of dialogue between HHS and stakeholders, AHRQ has developed a number of tools on its Website to help improve communication. One of AHRQ's web pages invites you to: suggest research, provide comments on draft reports and key questions for proposed research, read prior suggestions for research, and sign-up for email notifications of new reports.

More information on ways to provide input to AHRQ is available at: http://www.ahrq.gov.

Another important AHRQ initiative is the Health Care Innovations Exchange website. This program is designed to support healthcare professionals in sharing and adopting innovations that improve the delivery of care to patients. The site has a variety of different tools, from one entitled "Learn & Network," to guides that help determine if a particular innovation will be a good fit for a healthcare organization.

These AHRQ initiatives provide a forum for ongoing dialogue with the public and stakeholders regarding the impact of biomedical innovations. In turn, that dialogue helps AHRQ empower the medical community and other HHS agencies with information regarding the impact of innovations on the quality of care.

More information on the Health Care Innovations Exchange is available at: http://www.innovations.ahrq.gov/index.aspx.

IV. CONCLUSION

During the past century, we have made remarkable advancements in curing age-old illnesses and fighting previously incurable diseases. The engine behind these advances has always been fueled by human innovation. This creative impulse is a key part in the story of America. The world changes, new threats arise. We adapt, we innovate, we move forward. When new problems appear, we find the most amazing ways to solve them.

In the coming years, we will face considerable challenges. However, over the last few years we have made great progress in addressing many long-standing healthcare concerns. We have continually worked to create and sustain a system that encourages innovation and improvement while allowing quick, yet safe, implementation and availability of new medicines and technologies.

Although much has been accomplished, there is much more to do. NIH must continue to seek new ways of conceptualizing and addressing scientific questions and better facilitate the translation from discovery to patient care. The FDA must continue promoting collaboration among stakeholders in the research and development of publicly available scientific methodologies and technical tools that all can use to design safer and more effective products more efficiently. CMS must continue to move from paying for services to paying for value, while empowering beneficiaries and healthcare providers. AHRQ must harness knowledge to help patients and providers transform medicine to a new paradigm of quality and choice. HHS must orchestrate the actions of the various agencies involved into a cohesive health innovation policy.

Of course, this is not a simple task. For example, with respect to the FDA's role, I often think of how the approval process resembles a pendulum that swings back and forth. In the early 90s, as we searched for drugs to combat diseases such as HIV/AIDS, the pendulum moved in the direction of effectiveness. In this decade, however, the pendulum and the voice of the public, Congress, and the media have swung more in the other direction. In the coming years, we will continue to struggle with where the pendulum should in fact rest to maximize safety without stifling innovation that can and will save lives.

Yet the solutions to these intricate challenges are often far less complicated. In fact, sometimes they can be as simple as sitting down for a conversation. One of the attendees at HHS' initial healthcare innovation conference in Washington D.C., was a provider of healthcare products facing imminent bankruptcy due to payment problems and procedural questions. The conference resulted in clearer dialogue between the company and HHS personnel, who were then able to work with the company to clarify the issues, resolve the problems and avert bankruptcy – and thereby ensuring, consistent with applicable regulations, that thousands of patients could continue to benefit from the company's technology and hundreds of workers could remain employed. This was possible because of something as simple as two parties being able to communicate.

HHS has many tools it can use to help foster dialogue. One such tool is to publish items in the *Federal Register*. To follow through and broaden the outreach begun by the Innovation Conferences, HHS is issuing a formal Request for Information (RFI) to build on the dialogue at the conferences and initiate a formal process to begin addressing the issues raised by the attendees. The RFI, announced in the *Federal Register*, solicits information that will help HHS improve how it develops new medical technology with funding from NIH, regulates new medical

technology at the FDA, pays for new medical technology in CMS programs, and encourages and analyzes the use of new technology through AHRQ. We are interested in a wide range of potential improvements. In either case, we are soliciting information on those problems, potential options to reduce or eliminate those problems, and the likely costs and benefits of those options. Costs and benefits cover a wide range of factors, including incentives to create and bring new technologies to market in the future, incentives to control medical costs both currently and in the future, effects on quality of medical care and medical outcomes, effects on medical care providers, and ease of administration of the Medicare and Medicaid programs.

We must continue this open discourse and continue to build on each dialogue. We must guarantee that the process by which we turn medical ideas into life-saving therapies is transparent and easy to navigate. And we must assure that these breakthrough products are safe and effective.

The United States has always been the leader in fostering and encouraging new medical technologies. We have a huge responsibly to make sure this continues. However, as technology advances, our policies must keep up. Great tests lie ahead. Yet I know we can face them. I have this confidence because I know Americans never stop inventing or innovating, and I have seen what a powerful remedy technology can be. Although we do not know what challenges the coming years will hold, if we continue to encourage our innovative spirit, we can rest assured we will be ready to meet them.

Tevi D. Troy
Deputy Secretary of Health and Human Services

Some of the ideas we heard across the country include:

- Requiring that certain funds be set aside for purely basic research, and that other NIH grants go to basic and translation research that has a demonstrated or probable connection to an improved health care outcome.
- Moving away from a binary model of safety versus effectiveness, by having the FDA make sure consumers have information available to them about the spectrum of risks and benefit inherent in every drug, biological, and device – and how these risks and benefits may vary from person to person.
- Allowing FDA to approve applications on the basis of inferences from known biomedical effects, rather than always requiring clinical trial data on sizeable populations.
- Implementing value-based purchasing across different parts of Medicare, so that Medicare pays providers for value or outcomes provided to a beneficiary rather than for each service or good.
- Bringing AHRQ's insights and resources to bear on earlier stages of the innovation process, such as deciding what research to fund or pay for, rather than focusing on post-market evaluation.

V. ACKNOWLEDGMENTS

From Deputy Secretary Tevi D. Troy

I am deeply grateful to those who contributed to the success of these conferences and to the completion of this report.

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From FDA: Frank Torti, Principal Deputy Commissioner and Chief Scientist; Rachel Behrman, Associate Commissioner for Clinical Programs and Director of the Office of Critical Path Programs; Ashley Boam, Chief of the Interventional Cardiology Devices Branch (CDRH); Doug Throckmorton, Deputy Director of the Center for Drug Evaluation and Research (CDER); and ShaAvhrée Buckman, Acting Director of the Office of Translational Sciences (CDER).

From CMS: Kerry Weems, Acting Administrator; Herb Kuhn, Deputy Administrator and Acting Director of the Center for Medicaid and State Operations; Jeffrey Kelman, Chief Medical Officer of the Center for Beneficiary Choice; and Jeffery Rich, Director of the Center for Medicare Management.

And from AHRQ: Jean Slutsky, Director of the Center for Outcomes and Evidence, who participated in all five conferences.

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HEALTHCARE INNOVATION IN THE 21ST CENTURY:

HHS' Dynamic Role in the Biomedical and Device Development Process

www.hhs.gov/deputysecretary/innovationconference