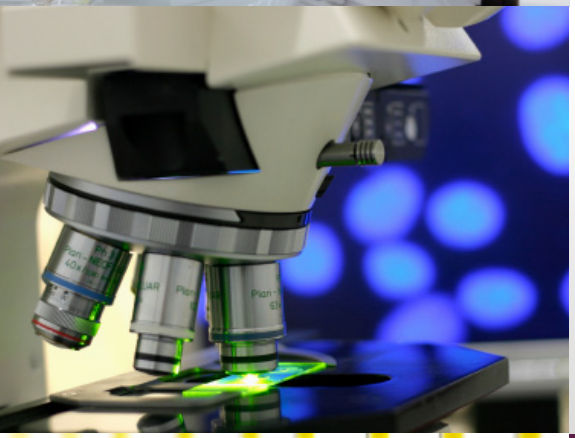

Innovation Nation:

Recognizing the Benefits of Innovation in Health Care

DISRUPTIVE WOMEN IN HEALTH CARE ®

February 2011

Elvis, The Patent Office, and Innovations in Health Care:

A New Disruptive Women in Health Care eBook on Innovation to Launch

By Robin Strongin. As a member of the National Press Club, I was invited to a private tour of the amazing exhibit: *Elvis 1956*. The exhibit featured remarkable photographs by Alfred Wertheimer who traveled with Elvis during his breakout year (Elvis was only 21!).

Amy Henderson, an incredible cultural historian with the Smithsonian led our tour. Her knowledge of The King was matched by her knowledge of the spectacular building in which the exhibit was housed, the Old U.S. Patent Office, now a national landmark and home to the Smithsonian American Art Museum and National Portrait Gallery. Fun Fact: In the 1850s, Clara Barton worked in the building as a clerk to the Patent Commissioner, the first woman federal employee to receive equal pay.

At one point during our tour, Amy explained to our group that after the White House and other buildings were burned by the British in the 1800s, three buildings were to be rebuilt first: the White House, the Treasury Building and the Patent Office. She wondered why the Patent Office. Then she explained: It was a time in our history when there was an enormous sense of Manifest Destiny, a belief in our greatness. Her words: "*Our inventiveness was a barometer of our greatness….thus, the need for an enormous patent building*."

Even before the inventions were born, there was a recognition by our forefathers that innovation matters.

Established in 1995, the U.S. Patent and Trademark Museum strives to educate the public about the patent and trademark systems, and the important role intellectual property protection plays in our nation's social and economic health.

From the Patent Museum's website: Today, America's inventive spirit is one of our most treasured and envied assets. The U.S. Patent and Trademark Office works to record, share, and preserve this inventive spirit.

Just as Elvis disrupted the music world with his innovations and genius, the Patent and Trademark Office is there for those innovators waiting to disrupt the health care status quo. And just as our forefathers saw the vast potential of innovation, so too our Disruptive Women. We will be blogging about innovations in health care; innovation broadly defined.

We will be launching this series shortly and compiling the posts into an eBook. In the meantime, I am interested in hearing what you think are the most important innovations in health care.

Thank You. Thank You. Thank You Very Much.

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"Recent advances in biomedical research have provided a huge opportunity to develop a new generation of cures and treatments that could dramatically improve the lives of Americans and people around the world."

- Kathleen Sebelius, 2011

Secretary, Health and Human Services

Does Innovation in Health Care Matter?

Disruptive Women in Health Care Answers this Question in a New eBook

By Robin Strongin. Throughout the entire congressional debate on health reform, this is a question that kept popping into my mind, probably because innovation was such a non-factor in the debate itself. In hours of discourse over how to expand coverage to millions of uninsured Americans while cutting health care costs, there was rarely a mention of the role innovation must play in shaping our remodeled 21st century health care system.

And in those infrequent instances when the topic did arise, it was often in a negative way. More than a few policymakers cited innovation as a primary cost driver, making health care too expensive for too many. That criticism isn't limited, by the way, to politicians and pundits.

So, isn't it time that we have this discussion? Is innovation an aspect of American health care that should be downgraded or minimized in order to increase affordability? Or is it the linchpin of our efforts to achieve the goals – cost containment, quality enhancement, sustainability – of health reform?

In setting the framework for this discussion, there are a couple of key points that need to be made. First, innovation needs to be given a broad definition. It's not just the development or enhancement of pharmaceutical products and medical devices, though continued innovation in the life sciences is vital. Looking at the challenges facing our health care system, we also have to think of innovation in terms of medical practice protocols, how care is delivered and even the way in which health insurance plans are designed and health care is regulated and paid.

We need to encourage coverage, treatment and technological solutions that result in not just more people having health insurance, but in achieving better outcomes and a healthier population.

We can create effective structures like health insurance exchanges and delivery reform demonstration projects, but that won't change the fact that the rising incidence of chronic disease is pushing our national health care bill skyward. New innovations, in both treatments and technologies, as well as patient engagement, are vital in combating the chronic disease crisis.

Case in Point: A recent Alzheimer's Association report projects that developing new treatments that would slow the progression of Alzheimer's by five years would save Medicare and Medicaid $100 billion per year by 2030.

So, let's begin this discussion on the role innovation plays in our health care future. There is a legitimate point to be made that innovation becomes counterproductive if it elevates costs to the point of making care inaccessible.

At the same time, I think of the 2009 article in which Harvard Business School professor and health policy analyst Clayton Christensen, PhD wrote entitled, "How to Revive Health Care Innovation," in which he noted that it was the disruptive innovation of angioplasty that made cardiac care more affordable and more convenient than open-heart surgeries and that, in turn, lipid-lowering pharmaceuticals were disruptive to angioplasty in the same way.

The question then, is how do we reproduce that model of progress for all of health care, and should that be one of our national priorities? In the posts that follow a number of Disruptive Women bloggers and few guest experts offer their insights. We look forward to your thoughts and comments as well.

We need to encourage coverage, treatment and technological solutions that result in not just more people having health insurance, but in achieving better outcomes and a healthier population...new treatments that would slow the progression of Alzheimer's by 5 years would save Medicare and Medicaid $100 billion per year by 2030.

Robin Strongin
President & CEO, Amplify Public Affairs
Founder, Disruptive Women in Health Care blog
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A National Dialogue for Health Care Innovation:

Encouraging Innovation As A Means To Make Health Care More Affordable

By Mary Grealy. In recent years, there has been nothing particularly innovative about the way we've developed health policy in this country.

As was fully displayed during last year's health reform debate, health issues have generated confrontation, shouting, posturing and hard divisions between opposing camps with cooperation and compromise nowhere in sight. Even when solutions emerge from this acrimonious environment, they don't enjoy consensus support from the public.

As we look at the issues that affect the future of American medical innovation, we can and must do better. Whether we're talking about payment reform, better means of health care delivery or the development of new drugs and devices to combat the growth of chronic disease, it's critical that we encourage innovation as a means to make health care better and more affordable. Instead of always blaming technology for runaway health care costs, how should policymakers distinguish between innovation and other factors that impact health costs (ie, rising rates of chronic disease and the aging of our population)? Instead of yelling at each other, we need to find ways to bridge our differences and make genuine progress toward the objectives our society needs to achieve.

That's why the Healthcare Leadership Council, a coalition of chief executives from all sectors of American health care, has launched the National Dialogue for Healthcare Innovation (NDHI). Co-chaired by Dr. David Barrett, the CEO of the Lahey Clinic, and Bill Hawkins, the chairman and CEO of Medtronic, the NDHI is an effort to create a forum in which health leaders with diverse views can sit down together to better understand each other's perspectives and start the process of building consensus.

The first NDHI event took place on October 4, 2010. Its focus: a summit on physician-industry collaboration. This is the kind of complex, important and potentially thorny issue NDHI was created to address. The health care industry has a history of working with physicians to gain the expertise necessary to ensure that new medications and medical devices are safe and effective for patients. Yet, there are concerns about conflict of interest issues and the need to make these industry-physician agreements fully transparent.

Instead of always blaming technology for runaway health care costs, how should policymakers distinguish between innovation and other factors that impact health care costs?

At the NDHI summit, over 75 leaders from industry, academia, government and patient groups spent the day discussing the importance of collaboration, the strengths and vulnerabilities in current practices and the perspectives of health care payers, private insurers and the legislative and executive branches of government. There were disparate viewpoints and disagreements, but there was also a shared determination to work together to develop solutions that benefit patients while also protecting consumers.

Most encouragingly, summit participants showed an interest in continuing to work together well after the summit concluded. And that work is ongoing as we gather a better understanding of the physician-industry collaboration principles that already exist in different industries, the physician community and other sectors and, optimally, continue the process of developing a broad consensus on this issue.

There are a host of other innovation-focused issues, from patent policy to reimbursement formulas to liability laws, which need this kind of vigorous yet reasoned and reasonable dialogue. We believe strongly that the NDHI can be the forum at which leaders with strong ideas and positive intent can work collaboratively toward a better health care system.

Innovation is vital in order to achieve the quality health care America needs. Idea-sharing and consensus-building are vital in order to build the policies that encourage that innovation.

Mary Grealy
President, Healthcare Leadership Council
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Innovation In And Beyond The Vial:

Reducing Immunization Costs

Though seemingly counterintuitive, increasing vaccine use can also bring down costs. An expensive program is one that is not reaching all the people who can benefit.

By Lois Privor-Dumm, MBA. There is a wealth of new vaccines available to prevent many important causes of disease. Sometimes I wonder whether vaccine innovations actually reduce costs. New technologies often result in more costly vaccines, with some over $100 per dose. Looking at price alone, however, doesn't tell the full story. Costs come in many forms and so do savings.

As pressures on health budgets increase, so does the need for innovative approaches to reduce the cost of immunization programs. These innovations come in many forms, emphasizing the need to look not only at technology, but other ways to make programs more efficient and vaccines more accessible. Though seemingly counterintuitive, increasing vaccine use can also bring down costs. An expensive program is one that is not reaching all the people who can benefit.

Development Innovations and Process Improvements

When products aren't readily available to meet the needs of the population, for example during flu season or pre-pandemic, cost to society can become very high. Not only is there the risk of death, but hospitalizations and lost time at work all of a sudden make the cost of a $15 or even $50 flu vaccine not so expensive.

Understanding the importance of technologic innovation to reduce development and production time, the Centers for Disease Control and Prevention, recently announced $2 billion to achieve these goals for pandemic flu vaccines. Companies have developed novel ways to reduce vaccine development time; in one case, for example, through a surrogate human immune system. Other companies are working collaboratively on synthetic strains of flu vaccines.

Technological innovations in vaccine delivery systems that do not require needles, such as intranasal or Jet Injector technologies, can eliminate the cost of disposable syringes and may reduce the amount of vaccine required as a result of improved immune responses through some of these delivery mechanisms.

Development of pneumococcal common protein vaccines, is another approach to broadening protection and reducing high cost and complexity associated with pneumococcal conjugate vaccines. Technologies that offer improved stability and the possibility of storage outside of the cold chain also reduce costs of refrigeration and wastage as a result of spoilage.

Cold chain to deliver vaccines can be costly. Project Optimize, (PATH/WHO) is rethinking the vaccine supply chain in a number of different countries. Solar battery-free refrigerators, which will now be used in Tunisia is one approach to achieve zero-energy cost supply chain.

Dr. Orin Levine, the Executive Director of my center, the International Vaccine Access Center (IVAC) at Johns Hopkins, recently wrote about an innovation that provides a different way to reduce cost. Mozambique, with the assistance of Village Reach, a Seattle based NGO, reduced vaccine delivery costs by more than 17% - primarily by good management, but also through the innovative use of existing wireless and Internet technologies. Cell phones or hand-held PDA's have been used to communicate inventory levels, flag problems with the cold chain and help get product to where it needs to be. In the case of Mozambique, they reduced stock out rates from 80% to 1% through good management and managed to reach that "last mile." Good inventory management can also reduce wastage rates, which in some countries can be pretty significant and costly.

Text messages or SMS are another approach to reducing immunization program costs. It seems counterintuitive to reduce vaccine costs by using more, but it does in several ways. First, vaccines are only cost-effective if used properly. Text messages (SMS) have been shown to increase coverage rates in India, Zambia, Ghana and even the US. The goal is to receive the right number of doses at the right time to optimize impact. An SMS program can also build demand, which attracts suppliers, creating competition and reduced prices.

Cell phone technology can also be used to deliver conditional cash transfers (CCTs), payments made to poor families to encourage a particular behavior such as bringing a child to a health center to receive preventative care. Although CCTs have shown mixed results, they have only been studied in a few places and are likely to also encourage optimized use of vaccines and build demand.

Innovations in both the cost of the product and improving the efficiency of delivery systems have been shown to effectively reduce costs.

The cost of the product itself is only a portion of the total vaccine cost. To lower costs, particularly for developing countries, which account for the majority of the childhood disease burden, innovative financing mechanisms have contributed largely to the world's ability to finance vaccine. The Advance Market Commitment, helped revolutionize the ability to get new technologies to large numbers of people with high rates of disease nearly a decade sooner than they might have otherwise. Not only does this benefit those who receive the vaccine, but it also helps create economies of scale and more predictable demand, making development of vaccines for low income countries, a much more attractive proposition.

Innovations in both the cost of the product and improving the efficiency of delivery systems have been shown to effectively reduce costs. Continued thinking about the product "outside the vial" is only going to result in more vaccines, delivered to more people sooner than ever before.

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Bending the Cost Curve without Bending the Innovation Pipeline:

New Research on Generic Drugs, Innovation and Savings

By Nancy Johnson. Too often, when we talk about innovation, there's a 'yes…but' quality to the discussion. Yes, we appreciate the concept of developing new medicines and technologies to extend and enhance human life, but we increasingly question whether the cost of innovation is commensurate with the value it delivers.

Logically, if the weight of public and policymaker opinion continues in this direction, that innovation undermines the greater national goal of affordability, then this will inevitably lead to policy actions that reflect this line of thinking. We're already seeing this to some degree with the weighty pharmaceutical and device taxes that are part of the new health reform law and the creation of an independent board with the power to slash Medicare reimbursements. While the intention makes sense, it is not clear this path will yield the intended, and worse, may contribute to unintended and undesirable consequences.

There's too much at stake, both economically and in terms of societal well-being, to travel far down this path without having an absolute certainty that innovation does, in fact, make health care less affordable. Do we just take it on faith that innovation drives costs skyward, or is there empirical evidence that says otherwise?

To be sure, the literature includes a wide range of research on the relationship between innovation, costs, prices, and value. Like almost every aspect of health care policy and research, this one is layered in complexity. Sound bites can be misleading, definitions matter, and important findings can be misconstrued for political purposes and philosophical positioning.

So much has been written about the relationship between prescription drugs, costs, and prices. What does the literature say about the drug prices as they relate to health care cost growth?

Last month, Dr. Ernst Berndt of the Massachusetts Institute of Technology and Murray Aitken of IMS Health published the working draft of a paper that makes an important contribution to this debate. Berndt and Aitken take on one of the widely accepted statements about the relationship between innovation and affordability – that prescription drugs are getting more and more expensive – and ask whether this thesis is supported by available pricing data.

The authors took a look at the Hatch-Waxman Act, the legislation crafted by Congress in 1984 that granted drugmakers a period of market exclusivity on their new products and then promoted consumer access to generic versions of those drugs once that period ended. Some have suggested that the effects of Hatch-Waxman are tilted too far toward the interests of pharmaceutical companies, as exemplified by the regular reports issued by AARP monitoring drug price increases. In fact, AARP said the prices for the top 217 branded drugs went up 8.3 percent in 2009 even though the consumer price index declined.

But AARP and other drug price critics are failing to take into account the impact of generic drugs and how patterns of drug use change over time.

That's what Berndt and Aitken examined – not the price of name-brand pharmaceuticals in a vacuum, but rather the real-world purchasing of consumers, health insurance companies and pharmaceutical benefit managers. And when viewed through that prism, the average price per prescription, between 2006 and 2009, actually declined by 21.3 percent.

Bottom Line: any brand price increases were more than offset by lower costs for generics.

Real drug prices have also been falling in the Medicare Part D prescription drug program. In the first two years of the program, cumulative spending was $69 billion, significantly lower than the $105 billion projected by government budget authorities.

If, in fact, pharmaceutical price escalation was causing hardship for consumers, then policymakers would feel compelled to take strong,

AARP and other drug price critics are failing to take into account the impact of generic drugs and how patterns of drug use change over time.

if not extraordinary measures, such as pricing caps or some other form of real or de facto price controls.

But, as the evidence makes clear, that is simply not the case. Consumers are paying less, not more, for the medicines they need.

What is clear is that, 25 years after its enactment, the Hatch-Waxman measure is still having its desired effect. A period of market exclusivity and patent protection is serving as an incentive for innovative pharmaceutical companies to develop new medications to meet patient needs. Yet, there is still ample space for generics to yield affordability and accessibility.

With our society's health compromised by a variety of threats, from the rapid rise in chronic disease to the escalating number of antibiotic-resistant superviruses, this is not a time to curtail medical innovation. And as the Berndt-Aitken analysis shows, it's not clear there's a compelling reason to do so.

While Berndt and Aitken look specifically at drugs, one can make a similar case for many surgical procedures that use a non-invasive approach taking longer to perform and costing a little more in some cases, but reducing the overall cost of the episode of care and improving patient recovery. As new approaches in homecare monitoring develop, we will see the same phenomena illustrated.

Innovation increases cost at first and then lowers costs as competition creates cheaper but better technologies.

While advances in medical science enable us to diagnose and treat a far greater number of illnesses, it is duplication, waste, errors, and overuse that are our enemy. They are fostered by a care delivery system based on fee for service payments and penalizing coordinated and integrated care. Only innovation and better coordinated care can improve quality, reduce costs and save our health care system.

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Innovations in Health Care From A Caregiver's Perspective

By Stephanie Mensh. My husband Paul Berger and I had only been married for 4 years when he had his stroke at age 36. I've been a caregiver for over 20 years now. Looking back, there have been many innovations in our health care system that have made overcoming stroke and chronic disabilities a little easier and our lives better. And, there are some that have made things harder, too.

Medical technology--drugs and devices--have improved so much over the past 20 years that if Paul's aneurysm had ruptured today, he might have recovered with little or no disability. The CT scan he had 20 years ago was state-of-the-art, but the neuroradiologist could not localize Paul's aneurysm. Today's CT scans are so much better and MRIs are readily available in most cities and large towns that I'm sure they could find it immediately.

His only treatment choice back then was to open his skull, expose his brain, and place a metal clip on the aneurysm. Today, neurosurgeons have an option of a minimally invasive procedure to thread a coil and/or stent up through the blood vessel to block off the aneurysm.

Twenty years ago, to learn all I could about aneurysms and stroke, I had to find a medical textbook. Fortunately, I worked in the same building as the American Medical Association's Washington, DC office, and was able to find a book on neurosurgery. Today, you can "Google" aneurysm and stroke and find thousands of entries, with excellent sources accessible online like the National Institutes of Health, leading research and treatment centers like the Mayo and Cleveland Clinics, and information for patients from the medical specialty societies and volunteer health organizations. And with online support groups, there are opportunities to chat with other caregivers, for a comforting sense that you are not alone.

Medical technology—drugs and devices—have improved so much over the past 20 years that if Paul's aneurysm had ruptured today, he might have recovered with little or no disability.

Taking advantage of everyday technology like computers and cell phones have offered more options, for example, Lingraphica and other makers of assistive communication devices have been able to shrink the size of their products from the bulky laptop-type devices of 15 years ago to "apps" for cell phones.

Indeed, the computer, the Internet, and cell phones have made caregiving easier by improving access to information, building communication options, and knowing that Paul and I can reach each other immediately with a click of the mouse or cell phone speed-dial.

From Public Information to Private Rooms

Recently, the *Washington Post* wrote about the "new" trend in hospital remodeling to provide more private rooms (see: http://www.washingtonpost.com/wp-dyn/content/article/2010/10/09/AR2010100902400.html).

Twenty years ago, the old George Washington (GW) Hospital rehab floor had mostly double rooms, but they also had a few with four beds. One of the staff at the time told me that the rehab patients enjoyed the camaraderie. During the day, the patients were in and out of the room, but they did spend hours either sitting in the hallway or in their beds with their roommates. After work and on weekends when family visited, the cramped space made the time together difficult.

Today, the new GW Hospital rehab floor has many private rooms, and the philosophy that the patients need the quiet time after a day of vigorous therapy activities. It is a great program, with state-of-the-art facilities.

In my opinion, having helped my mother through hip surgery last year and paying extra for the private room, this phase reflects both positives and negatives. The positives: the family has more room to visit, and the patient can get more rest. Also, there is more room for your own private duty nurses or aides to attend the patient. The negatives: family members staying over and/or private duty attendants are an absolute necessity because the hospital nursing staff is stretched too thin. Years ago, you had to fight to stay over or have private attendants; today, the staff welcomes and encourages the extra help.

Not everything has improved, however. Twenty years ago, Paul stayed in the hospital receiving inpatient recovery and rehabilitation services for three months. Today, Medicare and private health insurance coverage for post-stroke rehabilitation is severely limited, and I have not met anyone in recent years that had the generous coverage that Paul enjoyed immediately after his stroke.

Even so, physical, occupational, speech therapy, rehabilitation and caregiving approaches continue to advance, with many new drugs and devices available to enhance treatment and function.

Stephanie Mensh
Consultant
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The Value of Innovation:

My Case for Personalized Medicine

By DCPatient/Donna Cryer, JD. There are countless articles and books on innovation – incremental innovation, radical innovation, disruptive innovation. I would argue however, with a nod to the authors of *Blue Ocean Strategy*, that unless innovation is value innovation, providing some deliberate and distinguished combination of factors or service to improve the experience or effectiveness for relevant stakeholders, while reducing costs, it is not innovation at all, but simply something new.

That said, I am eager to make the case for personalized medicine as a value innovation.

The most common definition of personalized medicine is genomic-based risk assessment, diagnosis, treatment. Personalized medicine, broadly construed, also comprises technology-supported medical practice able to aggregate data on a population level to a degree that positive or adverse outcomes can be spotted in sub-populations of patients. Personalized medicine also provides for care in the context of an individual's culture, values, and health literacy levels. The uniting concept is a health care framework that gets the right treatment for the right patient at the right time, creating a safer, more effective, more cost-efficient health care system. Think of personalized medicine as producing Me drugs rather than Me-too drugs.

The value of personalized medicine is best perceived using a systems view of cost and experience across identification, diagnosis, and treatment of a disease. Imagine oncology

today without personalized medicine: A young woman would not know that she has a genetic predisposition to a cancer, (especially if she has no family history to raise red flags). Because neither she, nor her physician have this personal genetic information available, they do not start an early or aggressive schedule of mammography or other screening. A lump in her early 30s is dismissed. When she does develop cancer, there is no way of determining what type of specific cancer it is; she is given a treatment she does not respond to; other treatments are attempted, but ultimately she dies. Without personalized medicine to help inform her health care decisions, the cost of her care is needlessly expensive and the clinical outcome is tragic.

The greatest threat to continued value innovation in personalized medicine is the lack of coherent reimbursement and regulatory frameworks that recognize the value of genomic-based diagnostics and therapies.

A personal example – as a liver transplant patient, I have blood analysis done several times a year to review my liver enzymes, levels of medication, and other markers. Recently, my physician and I have added a test that provides an assessment of my immune system's individualized response to the immunosuppressive medications prescribed. This test gave unique information -- despite my dosage, my immune system was still very active, putting me at possible risk for rejection of my organ.

As a liver transplant patient…I am eager to make the case for personalized medicine as a value innovation.

Where traditional tests would have led to reduction of my immunosuppression, given my apparent stability using traditional tests, the personalized test compelled a different treatment decision. Without this test it was likely that, as in the past, I (and my insurance company) would have incurred tens of thousands of dollars for liver biopsy; greatly increased dosages and numbers of IV medications; hospitalizations; and the extreme but foreseeable possibility, rejection or retransplantation which would put the dollar figure in the hundreds of thousands. Avoidable for about $600.

Although my personalized immune test has been FDA-cleared, current Centers for Medicare and Medicaid coverage and reimbursement determinations under the constraints of the laboratory fee schedule processes (i.e., cross walks, gap fills, or code-stacking), basically attempts to match this sophisticated new technology to old payment systems. The result: a level of reimbursement that does not even cover the costs of performing the test correctly, let alone reflect its value. The likely consequence of this inadequate reimbursement level is that despite the overall system-wide cost savings the test could provide (i.e., decreased need for additional liver biopsies and hospitalizations), hospitals will stop performing the test because they lose money each time they perform it. The bottom line: patients and physicians will lose access to this test and the important clinical decision support it provides.

The Bible warns against pouring new wine into old wineskins as unworkable. Our current system for determining the reimbursement for personalized therapies is just as unsustainable.

Donna Cryer, JD
CEO, Cryer Health
Guest Blogger

The New ROI:
Return on Innovation

By Debra R. Lappin. A recent survey of 6,000 people across six countries found that a majority believe that the United States will lose its billing as the most innovative country in less than 10 years. Aside from the competitive and reputational repercussions of such a drop, losing ground in innovation, especially medical innovation, means significantly less hope to discover cures, invent devices, and fundamentally bend the cost curve for health care, thus having a positive impact on the nation's deficit.

America's medical innovation enterprise will lead our nation out of the current economic recession. It provides excellent jobs in the public and private sectors, and improves health for all Americans. Medical innovation industries continue to be an important source of high-wage jobs, and while other other sectors have been negatively impacted by the recession, medical innovation sectors have fared better and appear to be rebounding more quickly than other sectors from the economic downturn. Health care and biomedical fields are expected to generate more new jobs than most other industries between 2008 and 2018.

From a health perspective, a single discovery in the world of chronic diseases resulting from investment in medical innovation today has the potential to save billions – if not trillions – of dollars tomorrow. This is what I call the new ROI, or return on innovation. And it is something I am advocating for through my role as president of the Council for American Medical Innovation (CAMI).

This past summer, CAMI commissioned a study by Battelle that offered a road map on what the U.S. needs to do to retain its leadership position in medical innovation. In particular, continued American leadership in medical innovation will require strong presidential vision, new public-private partnerships to promote medical innovation, a better investment climate, a smarter regulatory infrastructure and a stronger educational system.

Let me focus on two of those areas where I believe we have the best opportunity to enact change in the near term.

Right now, public sector research helps fund many early-stage breakthroughs, but private sector investment is critical to bring these innovations to market, where they often lag behind. We must bridge this "valley of death" and bring new cures, devices, treatments and technologies to market more quickly. As a nation, we have combined public and private forces to meet similar challenges in the past, whether it is the launch of

our system of national labs, placing a man on the moon or rising to the challenge of building new capacity as the era of the semiconductor emerges. Nothing less is required today.

At the same time, the private sector needs a climate that welcomes and supports entrepreneurial activity and venture capital investment. The nation's research and development tax credit—which lets firms write off a portion of the costs of innovation—is significantly lower than that offered by our global competitors. In fact the OECD ranks the U.S. 17th in terms of the "generosity" of our tax incentives for research and development. A predictably more generous R&D tax credit will help the US maintain its medical innovation and global leadership in an increasingly competitive global marketplace, and will work to retain and grow our technology-driven, cutting-edge businesses and the high-wage, high-quality jobs they provide.

The Battelle study presents a call for a unified national medical innovation policy agenda that adopts a range of strategies such as the ones I listed above. This call comes at a time when the medical innovation enterprise that distinguishes our nation faces serious threats that could result in its decline. To ensure the health of our nation and economy, we must reverse this trend before it's too late.

Health care and biomedical fields are expected to generate more new jobs than most other industries between 2008 and 2018.

Debra Lappin
Executive Director, Council for American Medical Innovation
Guest Blogger

Innovation Flashback:

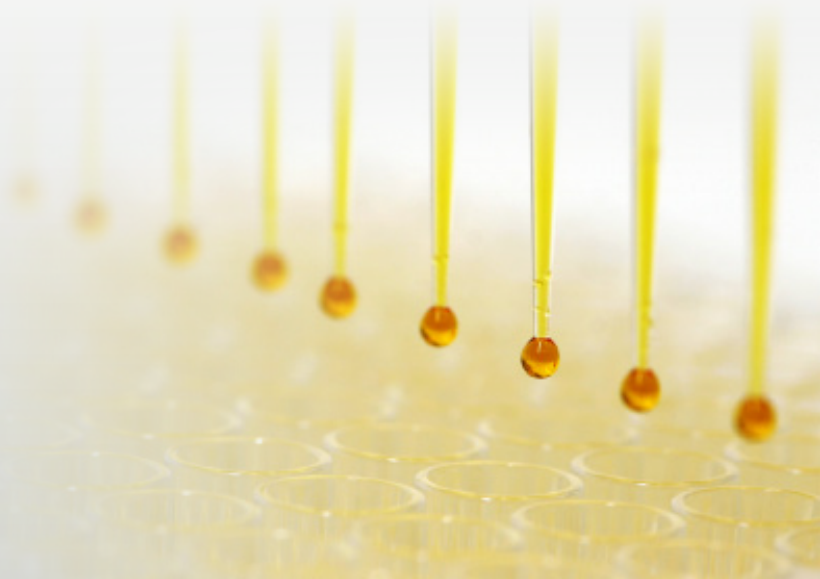
The Dialogue of Device Innovation

By Candace Littell, MBA. One of my favorite techniques in movies and television is the "flashback" – a scene that takes the main story back in time in order to recount events leading up to the present. Often viewed in chronological order, flashbacks form and develop the present story, scene or character.

The concept of flashback came to mind as I recently reviewed a new, innovative medical technology which I refer to here as *NewPro*. While I could of course understand *NewPro* as it existed today, I had no background in how it had come into being. What were the events leading up to its introduction? Out of the thousands of medical device and diagnostic products that are developed each year, why did *NewPro* make it to market while others did not? What factors were responsible for its development?

Experience tells me that the circumstances and events leading to the development of *NewPro* are likely similar to those surrounding innovation for the vast majority of other medical technologies.

Like many other medical technology innovations, especially breakthrough or new technologies, *NewPro* would likely have found its origin in a small or start-up company. Backed by venture capital and sometimes in partnership with larger companies, these smaller firms often play a unique role in early stage development. As efforts to bring *NewPro* to market progressed, the company may have been acquired by a larger firm that could navigate the later stages of the innovation process and introduce the product into medical practice. A larger firm would also possess the necessary resources for ongoing product refinements and improvements.



NewPro would likely have followed a process of innovation consisting of four elements. It began with an invention, an idea that medical care could be improved or performed in an entirely different way. Invention led to development of a model of the product, a so-called prototype. Then development began, where clinicians and company engineers performed testing and evaluation, and refinements were discovered and integrated into product design. This stage concluded upon regulatory approval for marketing. Once cleared for marketing, adoption into clinical practice began. Here, in the process of product diffusion, health care providers and payers determine that *NewPro* is worth adopting. Finally, as adoption occurs, innovation begins anew, as the process of feedback yields product refinements and new clinical applications.

Certainly, breakthrough innovations often occur, but many medical technologies evolve through generations of incremental change that can lead to the ultimate transformation of a technology over time.

Behind this apparent structured process, however, I expect there was much variability in the development of *NewPro*. Lines between the stages of innovation would blur, and the process would proceed in a non-linear fashion. Innovation might not proceed smoothly and continuously from concept to product. It might start and stop. Product testing would generate new information that redirects the course of product development. More data, more experience, and more interaction with users could yield information vital to *NewPro*'s refinement. And the uncertainty surrounding this process may have resulted in skepticism and resistance, both within the company developing *NewPro*, as well as among product users, government regulators, payers, and investors. Close collaboration among many parties was critical – perhaps clinicians, researchers, universities, government agencies, company or industry experts and others – in order to transform what was an idea into a viable medical product. Through this "dialogue of device innovation" *NewPro* emerged in form and clinical application.

Returning to the present, as *NewPro* is now used in everyday clinical practice, ideas flow continuously between the company and clinical users. And so begins a process of incremental product improvement. Certainly, breakthrough innovations often occur, but many medical technologies evolve through generations of incremental change that can lead to the ultimate transformation of a technology over time. Often it is difficult to trace the origins of a product or clinical application(s) in use today, given the many generations of refinement that have occurred over the years. This also means that the pace of innovation is fast and the life cycle of many medical technologies is very short. In fact, *NewPro* is expected to be on the market less than 18-24 months before the next generation is introduced.

Clearly, this new and innovative product *NewPro* promises to improve the health and quality of life for the patients who receive it. It began with an idea arising in a small company, one of many such firms that are often the incubators for new, breakthrough medical technologies. It has evolved through a uniquely dynamic, complex and incremental process that often yields uncertainty and unexpected results. And its development was set in the day-to-day, long-running dialogue between clinical users and technology developers.

While these "innovation flashbacks" help inform our understanding of these products today, they also hint at the potential for continued innovation tomorrow. Looking forward, the next generation of *NewPro* is less clear. Many factors will affect the ongoing cycle of innovation including health reform, regulatory and legal developments and new payment paradigms. Not surprisingly, flash forward scenes are more difficult to envision.

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A Disruptive Innovation in Care Delivery:

Nurse Practitioners Fill The Primary Care Gap

By Tine Hansen-Turton, JD. In the face of an acute primary care physician shortage, and the steady reduction in the number of physicians who are willing to accept Medicaid and Medicare, it is unclear whether our existing primary care system will be able to meet the needs of the 30 + million Americans who shortly will become insured as a result of national health reform.

Health care delivery is strained under tremendous pressure from the demands of chronic health issues, downward trends in third party payments, and while insurance coverage will address some of these issues, many of these problems may persist even when near universal insurance coverage is achieved in the United States. So what else needs to happen to make health care reform a success?

In recent years, a series of "disruptive innovations," (as coined by Harvard Business Professor, Clayton Christensen, PhD), in the health care sector have capitalized on non-physician providers, such as nurse practitioners. Their ability to provide high-quality primary and preventive care in retail-based settings such as convenient care clinics (also known as retail-based clinics) and in community-settings, such as nurse-managed health clinics has been well documented.

Research by RAND Corporation and publications in *Health Affairs*, the Institute of Medicine and Robert Wood Johnson Foundation's Future of Nursing report and peer-reviewed journals have documented that retail-based clinics and nurse-managed health clinics provide safe, accessible, affordable care to millions of Americans without threatening continuity of care. Nurse practitioners practicing in these independent settings already touch 20 + million or more people annually. Consumers gravitate to both models because they are accessible, affordable, provide quality care but most importantly, they are convenient in their locations, hours and ease of use. For health care reform to be successful, we need to embrace these and many other disruptive innovations.

First, nurse practitioners proved their worth by silently filling the health care needs of underserved populations in rural and urban settings. Over time, and thanks to national and state legislative and regulatory reforms that have taken place over decades, including those recently led by governors in Pennsylvania and Massachusetts, nurse practitioners gained public support, were defined in law as primary care providers, and now are legally authorized to prescribe medications and provide care that is a comparable in scope to that of a primary care physician in all 50 states. Today, they are known by most Americans and have become a household name and provider of choice.

Disruptive innovation does not happen overnight or without a strategy – rather, innovation is built on a series of innovations that happen over time; time needed to grow and mature outside the limelight.

Disruptive innovation does not happen overnight or without a strategy – rather, innovation is built on a series of innovations that happen over time; time needed to grow and mature outside the limelight. Neither the convenient care clinics nor nurse-managed health clinics would exist without the nurse practitioner in the primary care service seat.

The nurse practitioner workforce, 150,000 strong today, with an annual growth rate of 5,500, was first established in the late 1960s as a response to a physician shortage and a belief that nursing could play a critical role in primary care. It grew slowly over a 30 year period. Like *Thomas the Little Tank Engine*, it stayed focused and gained steam as the number of providers grew.

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Innovation and the Coverage Tollgate

By Lynn Shapiro Snyder, JD. I have been a managed care, Medicare and Medicaid attorney for over 30 years. Although this focus includes compliance and enforcement work, I also do a lot of work helping entrepreneurs bring new ideas to the health care marketplace. Providing strategic, legal and regulatory assistance for some of these innovations has been some of the most rewarding work for me.

It used to be the case that when an innovator wanted to launch a new drug or device in the United States, the key regulatory tollgate was the federal Food and Drug Administration (FDA). That standard focuses on safety and efficacy. Once that tollgate was satisfied, the company could promote its product, and the product would enjoy general distribution in the marketplace. Those days are over.

Two new additional tollgates include access to identifier codes - especially for certain medical devices and coverage for the innovation. The focus of this blog is on the new coverage challenges to innovation.

In the United States, we have a wide variety of payers of health benefits. There are publicly funded payers such as Medicare and Medicaid. There are privately funded payers such as self-funded employers and private health insurance plans. Traditionally, the scope of covered benefits focused more on illnesses. The new benefits focus on prevention and population health management. There are enumerated benefits, enumerated exclusions and general coverage phrases like covering what is “reasonable and necessary.”

More and more payers will be offering similar benefits as Title I of federal health reform is implemented. This is because a proposed federal regulation will be issued soon by Department of Health and Human Services to define the “Essential Health Benefits Package” for individual and small group health plans. This benefits package is supposed to be comparable to coverage by existing employer plans.

Who decides whether an innovation fits within an existing covered benefit or whether a new coverage decision is needed so that patients can get access to the innovation? And, what is the criteria for confirmation of coverage? Is it enough that the innovation is comparable to existing options? Does it have to be breakthrough? While there is a whole body of literature about randomized control trials and other data points needed to establish FDA approval, what should be the study protocol to establish a positive coverage determination by the payer? Finally, should the new cost of the innovation even play a role in the coverage decision-making process? These are the key questions across payers.

Centers for Medicare & Medicaid Services (CMS) uses the MEDCAC - the Medicare Evidence Development & Coverage Advisory Committee to provide independent guidance and expert advice on specific clinical topics (see https://www.cms.gov/FACA/02_MEDCAC.asp). In its deliberations, the MEDCAC reviews and evaluates available evidence, including medical literature and technology assessments, and listens to public testimony. The Committee then makes coverage recommendations to CMS based on its review. Private payers usually have some type of technology assessment processes.

In recent years, to facilitate access to some innovative products, CMS also has adopted some conditional coverage strategies. For example, see CMS's website about conditional coverage with evidence development at https://www.cms.gov/mcd/ncpc_view_document.asp?id=8. The idea is to allow the product to obtain coverage so that it can enter the market and then capture data to earn the right to stay in the market. Otherwise, it can be a Catch-22 - without access to the market, it is difficult for the innovator to demonstrate its value proposition to a payer.

There also are some new and some not so new regulatory players in this space. CMS is still a major player in the area of coverage - with its National Coverage Determinations and local coverage determinations at the claims administrator levels. However, the most important regulatory player in this space is the Agency for Healthcare Quality and Research (AHRQ), which "supports health services research that will improve the quality of health care and promote evidence-based decisionmaking." (see http://www.effectivehealthcare.ahrq.gov/index.cfm/what-is-the-effective-health-care-program1/). AHRQ addresses key coverage issues using comparative effectiveness research (CER) conducted through its Effective Health Care program. AHRQ also was a key recipient of funds under the federal stimulus legislation.

Health reform also heralded a new institute, the Patient-Centered Outcomes Research Institute (PCORI), charged with establishing national clinical comparative effectiveness research priorities as well as providing federal funding to conduct CER. Health care innovations need to focus on these types of coverage and outcomes tollgates as we move from a fee for service model to an evidence-based bundled payment model.

While implementation of health reform continues to roll out, one of the key themes for public comment should be the need to maintain a flexible process for adopting health care innovations, especially within the context of coverage for health benefits.

Finally, not all widgets of health care innovation require a specific coverage determination by a payer. Innovations may be subsumed inside already existing bundled payments such as innovations that minimize the likelihood of "never events" happening in the inpatient setting. These are desired innovations, and they likely are subsumed either in the DRG or in avoiding reductions in payments. Coverage is subsumed inside the existing bundled payment for the episode of care. Other innovations may be more process oriented, such as innovative techniques to avoid unnecessary re-admissions to hospitals.

While implementation of health reform continues to roll out, one of the key themes for public comment should be the need to maintain a flexible process for adopting health care innovations, especially within the context of coverage for health benefits. Without such flexibility, certain innovations with great value propositions may never get to market.

"To raise new questions, new possibilities, to regard old problems from a new angle, requires creative imagination and marks real advance in science."

- Albert Einstein

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By Rosa M. Abrantes-Metz, PhD. There is nearly universal agreement that changes are needed in the US health care system. The price of health insurance is high and continuing to rise, and many are priced out of the market. There is certainly room for reform. But reform must be discussed in the right way, using the right measures. Total spending (or "total costs," as some call it), is simply the wrong way to frame the problem.

Defining The Cost and Price of Medical Innovation:
An Economic Framework

Much of the health care reform debate focused on containing costs. A common approach to attain this goal is limiting medical innovation, which will reduce the quantity and quality of health care in the future relative to what might otherwise have been.

Critics of the U.S. system note that the US spends a greater share of its GDP on "health care" than does any other advanced economy. Even those skeptical of many reform proposals accept this as intrinsically undesirable. Everyone seems to agree that the level of health care spending is too high, and its rate of growth unsustainable, despite evidence by several renowned economists that the benefits from this spending have been worth while.

In my view, this metric – total expenditures – is a very poor guide for policymakers. It is easy to imagine good, positive changes which every consumer of health care would welcome but which increase – not decrease – total costs. And it is easy to imagine policies which are designed to curb costs but which result in less (and less effective) health care for all. Controlling costs should not be the main objective of policy.

But we must be very careful to distinguish *costs* (total spending) from *prices*. Prices inform the relative expense of one item or procedure over another. It is perfectly reasonable to lament the high *price* of health care. Most of us would prefer to face lower prices than higher, and most of us would welcome a general decline in the

Once we realize that a decline in price could lead to an increase in total expenditures, we are forced to question whether expenditure is as useful a metric for policy as many people would suggest.

price of health care since that would mean, all else equal, that more people could more easily afford more of it.

Costs, on the other hand, are total expenditures – the total dollars spent. Cost is price times *quantity*. The price of an aspirin is $1, and we might feel that this is too high since some can't afford it. When we buy 10 aspirin, the total cost becomes $10. But if the price *falls* to $0.75 and we then buy 20 (either because some of us buy more than we did before, or because new people are able to afford it for the first time, or both), the total cost rises to $15. Once we realize that a decline in price could lead to an increase in total expenditures, we are forced to question whether *expenditure* is as useful a metric for policy as many people would suggest.

It must be understood that increasing coverage and reducing total spending are almost surely incompatible objectives. When we decide that it is socially unacceptable to have so many uninsured people and take the most direct route and subsidize their purchase of health insurance, we need to understand what the main consequences will be. Such a policy has the immediate effect of raising costs, since we now have more social dollars chasing the same amount of health care. It will also have the effect of raising prices, since initially there are no more doctors, nurses, or hospital beds than there were before the subsidies began. Prices – including salaries to doctors and nurses – will rise, and this will over time lead to more people entering the health care industry and thus a greater supply and consumption of "health care." The policy will succeed – we will see an increase in coverage – but only through the mechanisms of *higher* prices and *higher* costs.

If policy makers decide that the rise in prices and costs is itself undesirable and prohibit those increases through price controls and the like, we may not see an increase in actual coverage. We will have more dollars chasing the same amount of health care, but prices will not be permitted to rise, and so no new providers of health care will enter the industry. The result will be rationing.

It is worth considering how people intend to control costs. One way is to limit new innovation. The newest procedures are often the most expensive. Some have suggested that we create expert panels to evaluate the cost/benefit tradeoffs of these newer procedures (though it must be asked, cost and benefit to whom?) One can raise several broad objections to this course of action. First, recent empirical estimates put the contribution of technological innovation to total cost growth at no more than 33%[1] even when relevant contributing factors are not accounted for - not at least 50% which some have argued. Second, the "cost" of such innovation is also the revenue to such innovation, which is what induces future innovation.

1. Rosa M. Abrantes-Metz, PhD, 2010. "The Contribution of Innovation to Health Care Costs: Is it Really at Least 50%?" Working Paper.

It is easy to imagine a drop in *price* leading to increased *costs* by inducing a more than offsetting increase in consumption. I gave the example above in terms of aspirin. This is the first indication that cost is a very poor metric for discussing health care reform. Consider a second example: a pharmaceutical breakthrough leads to a treatment for a condition which was previously untreatable. People now spend money on something which literally didn't exist before. "Health care costs" therefore rise. But no one is worse off than before the breakthrough, and many people are better off. Shouldn't this be a welcome development?

Imagine a new medical procedure doubles the 5 year survival rate for a heart transplant, but costs 50% more than the old procedure. Many rational consumers choose the newer, better, more expensive procedure. "Health care costs" again rise. But by what rationale would this seem socially undesirable?

I would make three additional and, I would hope, obvious points.

First, the cost of health care is also the revenue to health care. That is what pays doctors, nurses, research scientists, and everyone else in the industry.

Second, it must never be forgotten that each and every person who makes a decision to spend resources on health care has decided that the expected benefit outweighs the cost to her. If there is a concern that we are making socially inefficient decisions, then the nature of the problem is that the cost to the consumer of health care does not fully reflect the cost to society. A significant wedge exists between private and social costs. Can the solution really be to increase this wedge even more?

Finally, as it relates to the rate of growth in health care costs, I cannot help but note that if it is indeed "unsustainable," then it will not be sustained. It will slow of its own accord because, simply, it has to. Why does it require a dramatic policy response to contain that which policy advocates themselves assert must eventually contain itself? Its "unsustainability" is only a problem if we want to sustain it but cannot.

Rosa M. Abrantes-Metz, PhD
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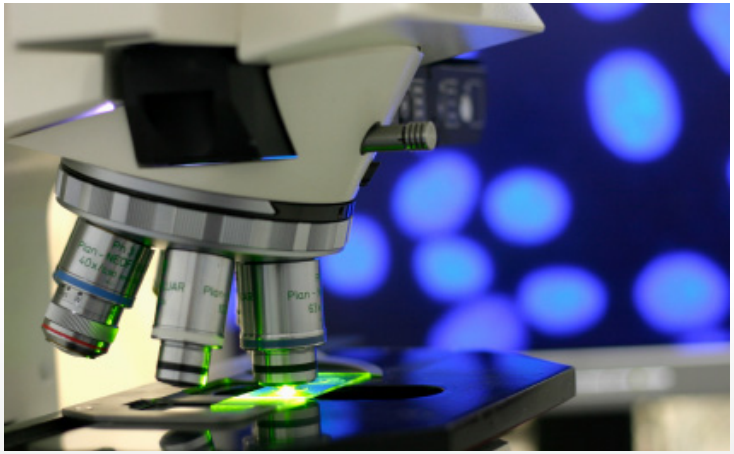
Guest Blogger

Colliding or Converging Forces?

FDA Regulatory Reform and Medical Product Innovation



By Leah R. Kendall, JD.

Everything changes and nothing remains still.
-Heraclitus, as interpreted by Plato

Scathing letters from disgruntled FDA scientists, revamping enforcement policy and pillars of regulatory paradigms, communications from Congress suggesting the need for and then questioning said revamping, rescinding market clearances, promises to seek criminal sanctions on executives …. The sky is falling! Or is it?

It's easy to sound like Chicken Little in today's regulatory world. Over the past year, those of us in the medical device and biotechnology sector have watched our U.S. Food & Drug Administration (FDA) transform before our very eyes. We have grappled with stalled marketing application reviews, an Agency that seems suddenly skittish to give informal feedback, and the reality of a "new FDA." Some of us are enduring warning letters, consent decrees, or more informal methods of regulatory scrutiny.

Regulated industry, public health groups, and the government alike are intensively monitoring the proposals for reforming the FDA's medical device marketing clearance ("510(k)") process and the use of science in decision-making. The purpose of this blog post is not to analyze the specific content of those proposals (that would require a book, not a blog post). Suffice it to say that they have been the topic of numerous public comments, passionate discussion and debate, not to mention significant media coverage. While some proposals seem to have general support, others have received significant pushback. Indeed, several weeks ago, several members of Congress (which, as you may remember, originally called for reform of the market clearance process) wrote to FDA Commissioner, Dr. Margaret Hamburg to express concern with the implementation of some of the proposals in the FDA report.

What does this FDA regulatory reform mean for innovation? Is the reform colliding with innovation, unnecessarily impeding its growth? Should FDA continue on its previously well worn path, simply interpreting existing requirements to ever-increasing innovative technologies?

That's one possibility, but on the other hand, there exist convincing reasons to think about innovation in broader terms – terms that embrace not only medical or technological innovation, but also innovation with respect to the health regulatory paradigms that support (dare I say, foster?) medical product and treatment innovations.

So what are those reasons? Here's some food for thought.

One is that, in spite of what has at times seemed like a firestorm with respect to FDA regulation, vast numbers and types of exciting medical technologies continue to spring forth. Consider, for example, the promise of mobile health technologies ("mHealth") and health IT, the growth of which is predicted to be enormous. And mHealth is not some theoretical, futuristic idea. "Traditional" medical device companies are diving head-first into the mHealth arena.

The FDA has publicly communicated its plan to regulate health IT, and the Agency already is grappling with marketing submissions for mobile phone applications ("apps") and other mHealth devices.

There continues to be tremendous growth in combination products (products that combine two or more differently-regulated FDA articles (pharmaceutical products, medical devices, and/or biological products), and companion diagnostics and personalized medicine. Setting aside the ethical debate, stem cell therapy is seeing exciting innovation as well. Earlier last month, a patient was treated with human embryonic stem cells for the first time.

And the list goes on. As I read my daily e-mails from the various medical device and biotech trade journals, the innovation is striking – it is all around us. For now at least, the FDA's regulatory reform does not seem to be stifling innovation, although I suppose time will tell.

Further, isn't some reform beneficial – and arguably, necessary – for supporting innovation? At a basic level, the FDA has as its mission protecting the public health. The FDA strives to ensure only safe and effective medical products reach the market. In this way, consumers may have confidence in the products they use, which drives innovation and investment. Continuing with this line of reasoning, if the FDA requires modification or evolution of its laws or regulations to ensure the public health is protected, then the Agency should pursue those reforms (following all due process, of course).

There exist convincing reasons to think about innovation in broader terms – terms that embrace not only medical or technological innovation, but also innovation with respect to the health regulatory paradigms that support (dare I say, foster?) medical product and treatment innovations.

Reform also helps to provide the entities developing and funding medical product innovation some predictability in FDA requirements and expectations.

Take mHealth as an example. For years now, the Agency has interpreted existing laws and regulations to various types of products incorporating software. But as industry experts have observed, the explosion of innovation in mHealth is taxing the boundaries of FDA interpretation and leaving industry in a state of confusion.

Reform that leads to clearer regulatory expectations, additional guidance, and more transparency in Agency decision-making furthers innovation, in that it allows industry and the investment community to plan ahead, work toward defined regulatory goals and objectives, and develop and market products in light of clearly defined requirements and benchmarks. All of which are good things.

In summary, certainly the FDA's proposals have the potential to change the regulatory landscape significantly and should not be implemented without careful consideration of the near- and long-term consequences, which means a healthy dose of public review and comment. However, driving innovation should not be viewed in terms of medical technology only, but also innovation – progress and evolution – with respect to regulation itself. I look forward to joining my peers in continuing to think about how best to encourage innovation in all of those respects.

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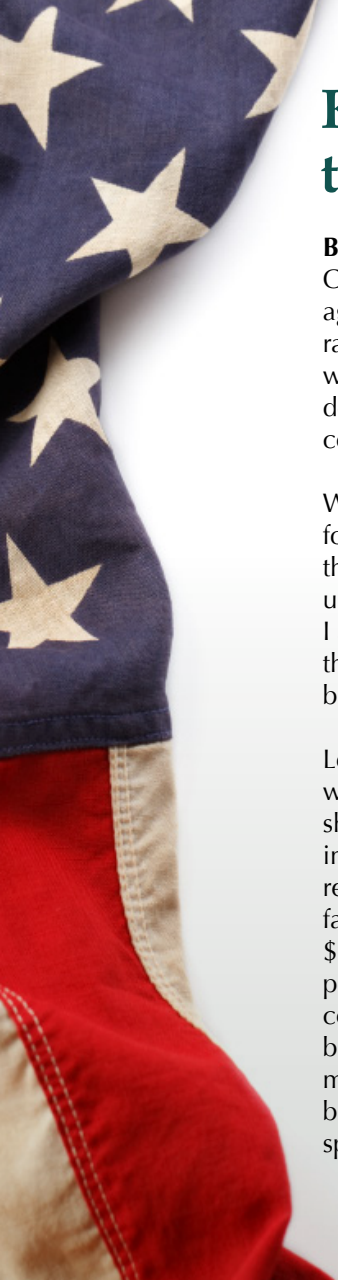
Guest Blogger

"I was taught the way of progress was neither swift nor easy."
- Marie Curie



Killing Innovation the American Way

By Glenna Crooks, PhD. I'm on the Finance Committee of my condo association. A few weeks ago, the Board accepted our recommendation to raise monthly fees by 3%, of which the majority will build a larger reserve fund. The increase will no doubt be controversial when it becomes public in the coming weeks.

We have insurance against the usual risks but can foresee events that insurance won't cover, like work that will improve the 'street appeal' of the property or upgrades required by changes to city building codes. I agree with the approach; it's better to be prepared than to be caught short and 'paying as you go' to build reserves is less painful than the alternatives.

Leadership of other buildings in our neighborhood were not thoughtful and owners were caught short when old lobbies required refurbishing, city inspections required roof repairs or new fire codes required new alarm systems. As a result, owners faced multi-year annual assessments – in the range of $30,000-40,000 annually for up to three years. Many people, but especially the elderly on fixed incomes, could not afford the amounts. They had no choice but to sell, placing a large number of units on the market, driving prices down and finding prospective buyers reluctant to buy property encumbered by special assessment price tags.

I was one of those prospective buyers and so on my list of property specifications was not only size and features of the unit, but the quality of condo leadership as well. I wanted a Board that was smart and visionary, with a President willing to act like a leader. Better to invest small amounts along the way than to deal with disastrous consequences from the failure to do so.

Does this relate to innovation in health care? You bet it does. Plenty. Where health care innovation is concerned, we've got precious few reserves and leaders don't seem to notice.

Perhaps you don't care about US-based innovation. I do. For many decades, the US has been the source of most of the world's health care science-driven, venture-supported innovation. I'd like that to continue, but it appears those days are over. I'm declaring the US innovation patient in the terminal stages, likely to be dead unless a miracle happens.

How did this happen? We not only helped rebuild the health care infrastructures in Europe and Japan after WWII, we built our own and then we reached out to others in the world. Some magician did not pull today's health care capacity from his hat. The 'Great Generation' came home from the war and went to work. Clinicians, hospitals, diagnostics and medicines are here for us today because taxpayers, employers, investors, entrepreneurs, philanthropists and patients did the hard work of making it happen. They invested in it and paid for it. They took risks. Sometimes they succeeded; sometimes they failed.

They made the US the source of the world's innovation. Yes, we paid for it. Yes, health care was more expensive here. Yes, lots of the world got a free ride. So what? It was an investment in *our* lives and productive capacity and it paid off well in the highest standard of living anywhere. 'A car in every garage and a chicken in every pot' promise became multiple cars, multiple houses and more food discarded in a meal than many of the world's people eat in a day.

Innovation is not easy, but we in America have done it before and we can do it again.

Had we waited for Europeans, Asians, Africans or South Americans we might still be waiting for medical specialists, intensive care nurseries, artificial hips, widespread dialysis and the majority of medicines we take for granted. If we waited on others, we'd still be waiting today.

Instead, we created advances and not only did we benefit, we exported our science and gained good will from it. We donated medical services and products during times of national disasters and wars. Our vaccines prevented – even eradicated – diseases that might have infected us. Our medicines, even when sold at lower prices in egregiously price-controlled markets – returned some funds to the US and we used them to employ scientists and keep the innovations coming. Our innovative health products industry became one of America's most consistently able to contribute to a favorable balance of trade.

Rather than be grateful to those who came before us and encouraged by their courage and foresight to do likewise for future generations, we're taking a different and distressingly unproductive tack today. We're ungrateful, unwilling to invest and especially unwilling to allow failure – an occasionally inevitable outcome of trying to make things better.

I'm told that health care is a 'negative good;' that is, people don't want it. Not me. When I see a physician or pick up a prescription, I'm glad for it. Both help me stay alive, working and enjoying life. I feel good about it because I have conditions that can be treated but I feel even more keenly positive because I also have three inherited conditions that cannot. There is no medicine to cure – or even to treat – those three and I'm left with only lifestyle management as a result. Regardless of how well I do, one of them is likely to shave decades off my life.

I'll admit my own situation makes me angry when I talk with people who have conditions that result primarily from unhealthy lifestyles, when the condition worsens because they are non-adherent on widely-known health promotion measures and especially when they don't do the easy part and just take a medicine.

I get even angrier when they complain about the $2 per day co-pay on a drug as they chow-down on premium coffee and an 800-calorie sticky bun. Or, when my own wealthy uncle, who can afford global treks in his retirement, "bitches" about the cost of the $4 per day anti-malarials prescribed for when he goes on safari.

In past months I've come to grips with my own reality: I'll be lucky to keep the great physicians I have. Some are nearing retirement, others are burning out and neither of us really understands the impact of health reform. I don't expect them to produce innovations in their medical practices; they're barely keeping pace with what they must do to stay in practice. I also don't expect to see an innovation in medicines that might help my conditions. We've undermined that sector, too. They're firing scientists, you know. That's a really, really bad sign.

So to those who are interested at all in reviving this near-terminal US innovation patient, here's my advice.

First, let's stop wringing our hands about the impending tsunami of Alzheimer's disease, diabetes, cardiovascular disease, depression and cancer and get busy to find solutions.

Second, let's remind the rest of the world that the more than 80% of 13,000 medicines available today and 50% of the HIV/AIDS medicines are generics that would not be available had they not been developed principally by US companies and paid for mainly by Americans.

Third, let's stop blaming the very people, companies and organizations trying to serve our health care needs. Let's thank all those trying to innovate and treat them better so they can get on with their jobs. Innovation is not going to come from:

- Cash-strapped hospitals,
- Clinicians who can't inhale for risk of a lawsuit,
- Diagnostics/products companies who can't get clear guidance from regulators about what will constitute a satisfactory clinical study,
- Payers who place financing hurdles in the way of new approaches to care,
- Patients who expect to live unhealthy lifestyles and have the consequences underwritten by others,
- Academics with little 'on the ground' experience but lots of 'ivory tower' critique in whatever-you-name-it-journal,
- Politicians too willing to pounce for the sake of headlines, and
- Other countries who could pay more of their way, but don't.

Innovation is not easy, but we in America have done it before and we can do it again. It's about time we got started or future generations won't have bragging rights, they'll have blaming rights.

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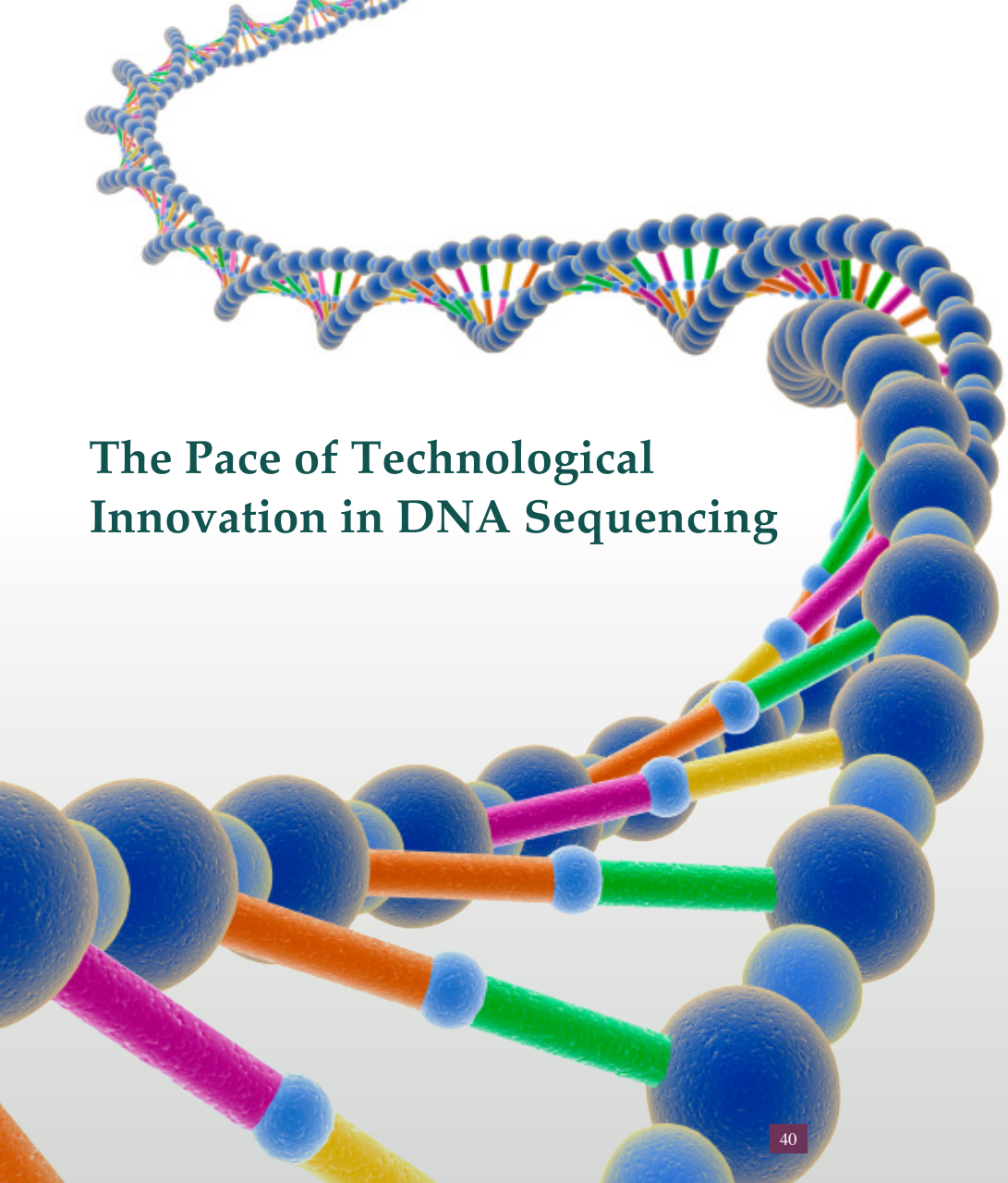

The Pace of Technological Innovation in DNA Sequencing

By Patrice Milos, PhD. Well, it seems as though I've made a habit of annual posts to Disruptive Women in Health Care, and in hindsight the timing seems just about right as we attempt to trace the path of innovation in genomic technologies and their application to health care.

By stepping back, once a year, I use the opportunity to reflect on the rapid pace of technology development in the area of DNA sequencing and pose the question – "Does this rapid pace translate into something meaningful for patients?" Hopefully as you read this synopsis you'll come away with an understanding that technology alone isn't enough, but the emergence of new critical success factors suggests the answer is yes!

Indeed from just one year ago, the cost of DNA sequencing has declined precipitously – a year ago, a complete human genome sequence cost somewhere between $50,000-100,000. Today, the cost is closer to $10,000 with the promise of the $1,000 genome over the horizon. New companies have entered the market and the competition continues unabated with desktop machines promising to enable complete genome sequencing shortly. Yet while this addresses the continued

Technology must intersect with the physician and be fully challenged, debated, tested and valued before we realize the full potential of any technological innovation.

technological innovation, does it deliver impact on health care? Not quite yet, but if you'll allow me, I'll digress some and tell you why I believe this will change shortly.

Having spent the better part of my career in the field of personalized medicine, I have had the opportunity to know many people who are passionate about this field and contribute in major ways to the pace at which this field is developing. One of these individuals is Mark Boguski, an MD and PhD. Mark is presently an Associate Professor of Pathology at Beth Israel Deaconess Medical Center and the Center for Biomedical Informatics at Harvard Medical School. Mark has held numerous influential positions during his career including a major leadership role at the Novartis Biomedical Institute, a founding directorship of the Allen Brain Institute and was a founding scientist at the National Center for Biotechnology Information. Mark's and my path have crossed many times over the years but a key hallmark of Mark's career is that he is always ten steps ahead of the field and can see well what the future holds. (See page 53 of this ebook for a video presentation by Dr. Boguski).

I reflect on Mark's experiences for you as earlier this year he invited me over to Beth Israel to meet with him and Jeffrey Saffitz, MD, PhD and Chief of the Department of Pathology at Beth Israel. We discussed the pace of technological innovation in DNA sequencing and agreed that the business investments will ultimately deliver on the promise of the $1000 genome.

Yet they shared their concern that those closest to the patient – physicians and namely pathologists, who have often led the innovative use of new technologies, remain behind in this race if we are to fully integrate our new knowledge into patient care.

We talked about our shared vision for effectively translating genomic sequence data into useable information for patient health care and the key role the pathology discipline should play in shaping this new world of sequence based diagnostics. At the same time we have shared a common understanding of the critical need to ensure that our new physicians were well equipped to deal with this new information.

And once again, Mark is leading the way to a future where all the pieces come together to deliver on the promise of innovation. At Beth Israel, Mark, Jeffrey and colleagues have created a new pathology program which is meant to fill the gap – bringing together

pathology and laboratory medicine, genetic counseling services and health information technology. Entitled the Genomic Medicine Initiative, this program is intended to prepare new physicians for the dawning era emerging from the technological innovation of DNA sequencing technologies.

When I went to visit Mark and Jeffrey some six months later, they were already in the midst of experimentation to prove out their hypotheses, executing full genome sequencing studies of a select group of patients to allow integration with health data to begin the experimentation necessary to fully realize the potential of the information, all with medical students watching, learning and fully accepting the reality of the new technologies.

Initially, much of their effort will likely be focused on cancer, the area where the most fundamental discoveries of genetic differences found in the tumor offer guidance for therapeutic intervention based on the genetic underpinning of the disease. During this visit, it was clear to me that their "Call to Action" was being heard and being translated into countless numbers of new medical professionals. I look forward to my next visit with them.

And thus, a picture emerges as one considers scientific innovation. A former Pfizer colleague and I always used to say, "technology delivers and delivers at a pace far faster than one imagines." Yet scientific innovation alone is not sufficient for effective integration into our health care system.

Technology must intersect with the physician and be fully challenged, debated, tested and valued before we realize the full potential of any technological innovation. We are at the early stages of this in the field of DNA sequencing but when medical centers such as Beth Israel take on the challenge, as they are doing, we are sure to see the full course of innovation delivered.

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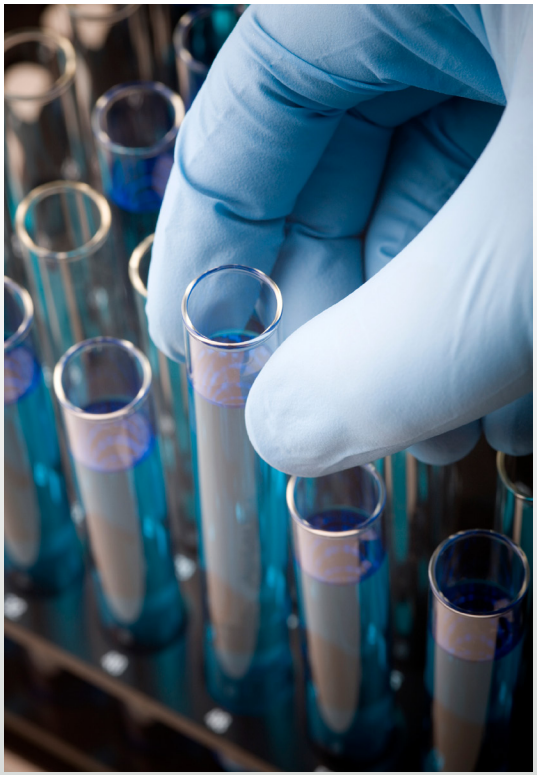
"We've discovered the secret of life."

- Francis Crick

Where Innovation Meets Innovation



By Julie Murchinson, MBA. While many have argued that health reform and other federal regulatory posturing has left true innovation in health improvement for consumers and patients nearly impossible, the "innovation" concept seems to be the buzz word du jour across the health care industry.

Some organizations like Kaiser Permanente have been threading innovative approaches through aspects of their work for years with the Innovation Consultancy, the Innovative Learning Network and the Garfield Innovation Center, a living laboratory where ideas and solutions are tested in a real-world simulation.

The rest of the industry is seeing new life forms that are inspiring and organizing innovation start to take hold. For example, Health 2.0 and other conferences are showcasing and tracking the latest and greatest innovations in web-2.0 ideas and iphone apps for health care. The California HealthCare Foundation recently started an Innovation Fund "to support entrepreneurs with business concepts that have the potential to significantly lower the total cost of delivering care or to substantially improve access to care."

The federal government is even joining the movement through its establishment of the CMS Innovation Center to test new payment methods through new models of health care delivery, the creation of the Community Health Data Initiative that is making publicly available data more accessible for innovators to use to develop products and by creating financial and non-financial challenges like the VA Innovation Initiative to create new solutions around new data availability or a specific goal/problem.

So, the question is…how well are these innovations being designed for and absorbed into the current health care marketplace to actually improve the efficiency and/or effectiveness of the health care system?

One indication the industry is attempting to absorb innovative technologies and solutions is the emergence of executive-level accountability for innovation among health systems, pharmaceutical companies, health plans and other health care companies. Following in the footsteps of Fortune 500 companies in other sectors, many large health care companies and organizations are establishing an Innovation Officer role, presumably to improve their brand and increase revenues in this time of incredible change and uncertainty. According to 2009 research conducted by Accenture's Innovation Performance Group, establishing an executive as an innovation leader increases a company's chances to drive higher innovation performance and capabilities than those who do not establish such a role. This is mostly because they do not let as many new ideas languish without the proper structure and internal champion and, better yet, manage innovation as a business process.

So, the question is…will these innovation seekers believe the value of solutions professed by the innovators mentioned above and manage innovations well to a fruitful result or will the same macro issues stalling progress in health improvement for consumers and patients prevail?

Innovation may be a proxy for many things, but these two ends of the spectrum demonstrate the existence of significant new idea generation with an increased focus on transforming the business of health care with new, revenue-generating or value-creating ideas.

If innovation is the marriage of ideas that drive revenue with purchasers who can put them to work, then we may just be on to an opportunity to move progress in health improvement forward. That said, it requires the former to prove their value and the latter to be comfortable with a potentially non-linear, longer-term road to the new nirvana.

...establishing an executive as an innovation leader increases a company's chances to drive higher innovation performance and capabilities than those who do not establish such a role.

Julie Murchinson, MBA
Executive Director, Health Evolution Partners Innovation Network
www.disruptivewomen.net/authors/#jmurchinson

Jack Lewin, MD has been the Chief Executive Officer of the American College of Cardiology (ACC) since November 2006. Under Dr. Lewin's leadership, ACC has continued to build upon its standing as a national leader in advocacy, with a particular focus on reforming Medicare, Medicaid, and the financing and delivery of quality health care. We had the opportunity to ask Dr. Lewin about his thoughts on innovation in the medical sector; below are his responses.

November Man of the Month:
Jack Lewin MD

Q: The American College of Cardiology's mission is transforming cardiovascular care and improving heart health through continuous quality improvement, patient-centered care, payment innovation and professionalism. How big a role does innovation play in ACC achieving this mission?

Innovation is necessary to reduce morbidity and mortality - we have seen a 30 percent reduction in cardiovascular mortality nationally within the past 10 years because of new therapies, prevention, systems of care, and innovation. As the US works towards a decrease in health care costs and works towards promoting sustainability, we have to prevent falling into a trap of slowing the pace of innovation. The big secret in US health care is that a systematic increase in quality is the way to reduce costs by reducing admissions, readmissions, and complications, and by improving outcomes. Without innovation we will see the increase in people with obesity and diabetes that require expensive treatments we can't afford. We have to keep moving to create new and better therapies to arrest chronic cardiovascular disease, more effectively treat acute crises, and prevent diseases through earlier diagnosis.

Q: In a recent blog you said, "I was a speaker last week in another roundtable on "innovation," something our nation is trashing as we pursue perfection in patient safety." Can you elaborate on the relationship between innovation and patient safety? Is there anything that can be done to alleviate some of the concerns surrounding medical innovation so that it can flourish?

Today's regulatory agencies in the US have become more conservative than in the EU, UK, and elsewhere in the world. Unfortunately this is forcing the US research and biotech industries offshore. From the point of view of CMS and the federal government, the focus is so fixed on cost containment that the agencies don't think about how to jump beyond the problem of rising costs by reducing the need for outdated therapies and diagnostic devices and replacing them with better ones that essentially reduce morbidity and decrease overall costs. Investing in comparative effectiveness research is investing in innovation, but not if it turns into a strategy of purely cost containment in an ever-narrowing context.

The FDA has become obsessed with concerns around individual patient safety, which is admirable; but if the quest for innovation requires a zero tolerance for adverse events, we will be scientifically paralyzed. Patient safety certainly shouldn't be deemphasized, but we have tools such as registries that can increase post market surveillance and give new therapies the opportunity to safely reach patients-in-need sooner, and keep the research infrastructure and culture of innovation alive in the US. The "TAVI," transcatheter aortic valve intervention, is a good example. This percutaneous valve replacement technology was developed in the US, but has been implemented in the UK, Europe, Canada and Asia because we are too risk adverse to bring this potentially lifesaving technology to the elderly who are not candidates for open chest surgery. This is taking patient safety to an extreme that is stifling innovation and needed medical and life saving progress.

Q: What are some promising innovations in the field of cardiology?

Promising innovations include the TAVI percutaneous valve replacements as well as new devices that provide ventricular assistance and support, and new short-term uses for ventricular assist devices. Cardiovascular genetics and cardiovascular cell therapies are also an expanding frontier. There are new therapies on the horizon such as warfarin alternatives for safer anticoagulation, along with better pharmacologic ways of preventing and treating coronary artery disease, heart failure, arrhythmias, diabetes and hypertension.

Q: What role do you think health reform will play in the world of medical innovation?

The future of health reform is uncertain. There is a need to better promote current evidence at the point of care. A health care payment model that incentivizes quality at an affordable cost is an essential part of the agenda. This health care model should provide incentives to promote comparative effectiveness research to answer the many clinical questions and should promote health IT and clinical registries to help us more effectively track how we are doing with current and emerging therapies. These kinds of goals tend to be what I call "faith-based" provisions in the Affordable Care Act. We need to design systems to make these goals implementable!

Q: How important is technology in innovation? Do you know of any examples worth sharing?

Technology has become a key part of medical innovation. Electronic health records (EHRs) will make a huge difference when fully implemented. Other notable innovations include home monitoring devices and telemedicine outreach to rural communities and places with limited access. Clinical decision support systems are also needed, such as ACC's PINNACLE registry, which allows evidence to become part of what is routinely possible and expected at the point of care, with electronic feedback systems to constantly track comparative quality of care, appropriateness of care, outcomes and patient satisfaction. This is the way to improve quality, lower costs, address disparities, and create a learning health care system.

Q: It seems innovation is disruptive; is the disruption it causes positive or negative in your opinion?

The disruption of innovators can be both positive and negative. Anytime there is rapid progress there is the risk that valuable elements of the present can be left behind. Disruptive innovators challenge the status quo, which is critically important. The US could be headed towards mediocrity if we choose to drive into the future with our eyes on the review mirror. We need to embrace change and seek a better future through innovation, while making sure we retain what works in the past and present of health care as we speed into the future.

Q: What are some words of wisdom to follow when working on an innovation?

Go for it! You won't always succeed, but so what? If you have an idea or see an opportunity for change in an area where there is a void, just go for it.

Q: Anything else you would like to say on the topic of innovation in health care?

Let's get on with embracing change. America has the best health care system in the world, and it's time to fix it! We waste a lot of time bragging about the very positive aspects of our health care, while we have de-emphasized the fact that we are spending two times as much per capita as other developed nations, without an acceptable return on investment.

I believe we have the best-trained work force and the best health care technology in the world. When it's at its best, the US health care is the best. Unfortunately, all too often we are not at our best. There are too many unanswered clinical questions in health care that plague us, and there are gaps in quality that need to be addressed. So let's get on with discovering, developing, and implementing the next generation of exciting therapeutics and devices to continue to reduce morbidity and mortality, disparities, and gaps in patient safety, while we increase prevention, team-based systems of care, outcomes and heart health.

"All truths are easy to understand once they are discovered; the point is to discover them."

- Galileo Galilei

Video References

How the Recession Has Affected Medical Research – A Conversation with NIH Director Francis Collins, M.D., Ph.D.
http://bigthink.com/ideas/24149

BioTech Governor of the Year Bio – Governor O'Malley of Maryland accepting his award and discussing the importance of prioritizing biotech research
http://biotech-now.org/2010/05/06/bio-governor-year-governor-o-malley-md

Academia in Drug Discovery – Conversation with Dr. Francis Collins and Dr. Margaret Hamburg (Commissioner, Food and Drug Administration)
http://www.kauffman.org/KauffmanMultimedia.aspx?VideoId=109466058001&type=R&tag=innovation

Boguski Talks Genes – Dr. Mark Boguski explaining the evolution of the use of human genomics in the diagnosis and treatment of disease
http://runningahospital.blogspot.com/search?q=genomics

Educate to Innovate – President Obama's initiative aiming to improve the participation and performance of America's students in science, technology, engineering, and mathematics (STEM)
http://www.whitehouse.gov/issues/education/educate-innovate

2008 National Medal of Science Laureate Dr. Francis Collins – Discussing his role as the head of the Human Genome Project, the motivations and inspirations for his research and the innovations it fostered
http://www.youtube.com/watch?v=8JZePaN-qWA

Select Resources on Innovation and Competitiveness

R&D Forecast report by **Battelle** talks about the innovation crisis and continuing rise of China as a global R&D powerhouse. Now second only to the United States in R&D funding, China is realizing the benefits of an unprecedented investment in education. As a result, highly skilled workers will substantially boost China's annual GDP growth rate for a generation, to a level of more than $120 trillion by 2040. Discusses how limited budgets and development times are affecting the entire global researcher community, and how U.S. researchers in particular are more challenged in these respects. When asked about the connections between global issues and their future R&D efforts, researchers identified areas including health care for the aging, demand for renewable energy, and global population growth as key concerns that the global research community must address.
http://www.battelle.org/aboutus/rd/2011.pdf

The biopharmaceutical sector is an important contributor to the economy, creating high-wage, revenue-generating jobs. Recognizing this, **PhRMA** commissioned **Battelle** to examine state efforts to target the industry for economic growth and development. The report, **Driving State Economic Growth in the 21st Century: Advancing the Biopharmaceutical Sector**, describes the current state of the sector and the range of state government efforts to nurture the growth of the industry. It also documents the economic value of this sector and describes a range of policies that can create a climate favorable to sustaining and expanding this sector. http://www.phrma.org/profiles_and_reports

The **Brookings Institution**, the **Center for American Progress**, the **Council on Competitiveness**, and the **National Association of Development Organizations** co-hosted an event on innovation clusters in late 2010. State and local policymakers, members of the Obama administration, and leaders from the business, academic, and philanthropic sectors discussed the significance of regional innovation clusters on the future of the American economy. Links to the event and relevant papers are available at:
http://www.brookings.edu/events/2010/0923_innovation_clusters.aspx

The **Milken Institute** prepared a report **Jobs for America: Investments and Policies for Economic Growth and Competitiveness** that analyzes two different approaches to how the United States can retain and create new jobs – one on the policy side and the other on the investment side. The report concludes that US infrastructure is "now strained and aging. Modernizing in multiple areas represents an opportunity to create thousands of jobs and jumpstart the economy in the near term." **Jobs for America** analyzes the potential effects of 10 different infrastructure projects: highway and transit projects; broadband; offshore drilling and onshore exploration and development of oil and natural gas resources; drinking water and wastewater infrastructure; the smart grid; nuclear energy; renewable energy; the updated air traffic control system; inland waterways; and clean coal. For every $1 billion invested in these projects, slightly more than 25,000 jobs are created.
http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=38801227&cat=resrep

The **Council for American Medical Innovation (CAMI)**, the **Administration**, the **National Academies**, and a range of organizations have called on a renewed focus on **STEM (Science, Technology, Engineering and Mathematics)** education in the US to increase our ability to innovate and create jobs in the US. One such organization is http://nstacommunities.org/stemedcoalition/ but the Administration's Science and Technology Advisors have also made a number of recommendations in this area: http://www.whitehouse.gov/administration/eop/ostp/pcast/docsreports

The **Center for American Progress** recently released a report on **US competitiveness** and how to build a new foundation for a competitive 21st century American economy in an increasingly global environment. The report and additional information is available at: http://www.americanprogress.org/projects/doing_what_works/

There are a range of competitiveness and innovation indicators that suggest the US is increasingly lagging behind other countries including the latest **National Science Foundation** science and engineering indicators: http://www.nsf.gov/statistics/seind10/ **Scientific American** has developed a range of materials providing indicators of global ranking on various innovation and competitiveness measures: http://www.saworldview.com/worldview-scorecard

The Treatment – Article from *The New Yorker* by Malcolm Gladwell on why it is so difficult to develop drugs for cancer (May 17, 2010)
http://archives.newyorker.com/global/print.asp?path=/djvu/condenast/newyorker/2010

The Case for Personalized Medicine:
http://www.personalizedmedicinecoalition.org/sites/default/files/TheCaseforPersonalizedMedicine_5_5_09.pdf

Personalized Medicine Coalition Backgrounder:
http://www.personalizedmedicinecoalition.org/sites/default/files/personalmed_backgrounder.pdf

Results for Life – Backgrounder on Genetic Testing:
http://www.labresultsforlife.org/news/Binder_Backgrounder.pdf

Gone Tomorrow? A Call to Promote Medical Innovation, Create Jobs and Find Cures in America:
http://www.americanmedicalinnovation.org/sites/default/files/Gone_Tomorrow.pdf

No Refills – Article from The Atlantic on the Difficulties of Introducing New Pharmaceuticals in the US market:
http://www.theatlantic.com/magazine/print/2010/07/no-refills/8133/

Changing the Trajectory of Alzheimer's Disease: A National Imperative (May 2010):
http://www.alz.org/documents_custom/trajectory.pdf

Innovation Policy on a Budget: Driving Innovation in a Time of Fiscal Constraint:
http://www.itif.org/files/2010-innovation-budget.pdf

Pulse of the Industry: Medical Technology Report 2010 (Ernst + Young):
http://lifechanginginnovation.org

Charting Nursing's Future, Nursing's Prescription for a Reformed Health System:
Use Exemplary Nursing Initiatives to Expand Access, Improve
Quality, Reduce Costs, and Promote Prevention:
http://www.rwjf.org/files/research/20090408chartingnursing9.pdf

American Journal of Nursing, Nurse-Managed Health Centers, Key to a Healthy Future:
http://journals.lww.com/ajnonline/Fulltext/2010/09000/Nurse_Managed_Health_Centers.17.aspx

General Website Links

AARP Center to Champion Nursing in America: http://championnursing.org/

Advanced Medical Technology Association (Advamed): http://advamed.org and http://www.lifechanginginnovation.org

American Clinical Laboratory Association: http://www.clinical-labs.org/

Aspen Institute: http://www.aspeninstitute.org/

Biotechnology Industry Organization (BIO): http://www.bio.org

Council for American Medical Innovation (CAMI): http://www.americanmedicalinnovation.org/

Faster Cures: http://fastercures.org

Healthcare Leadership Coalition (HLC): http://www.hlc.org/

Innovation.org: http://www.innovation.org/

Institute of Medicine: http://www.iom.edu/

Institute for Nursing Centers: http://www.nursingcenters.org/

National Nursing Centers Consortium: http://www.nncc.us/

National Science Foundation: http://www.nsf.gov/

OECD: http://www.oecd.org

Personalized Medicine Coalition: http://www.personalizedmedicinecoalition.org/

Personalized Medicine Conference – Partners Healthcare: http://www.personalizedmedicineconference.org/

Pharmaceutical Research and Manufacturers of America (PhRMA): http://www.phrma.org

Research!America: http://www.researchamerica.org/

Stroke Survivor: http://www.positivepowerpublishing.com/index.html

The Foundation for Innovation in Medicine: http://www.fimdefelice.org/

World Health Organization: http://www.who.int/en/

Federal Links

Centers for Disease Control and Prevention: http://www.cdc.gov/

CMS Innovation Center: http://www.innovations.cms.gov/

National Institutes of Health (NIH): http://www.nih.gov

Office of the US Trade Representative: http://ustraderep.gov/

White House Office of Science and Technology Policy: http://www.whitehouse.gov/administration/eop/ostp

White House Office of Science and Technology Policy Blog: http://www.whitehouse.gov/administration/eop/ostp/blog