

Report on the
Strategy for Health Care through Bio and
Information Standards and Technologies Conference



September 24 - 25, 2007

National Institute of Standards and Technology (NIST)

Gaithersburg, Maryland

Lead Organizers:

The Biotechnology Council

National Institute of Standards and Technology

Program Committee

JEROME H. GROSSMAN, M.D., Honorary Conference Chair

MICHAEL J. ROZEN, M.D., Conference Chair

MICHAEL D. AMOS

RICHARD DOYLE

BARBARA DUNLAVEY

STEVEN GRIMES

DONNA HUDSON

BETTIJOYCE B. LIDE

CHRIS McMANES

JAYNE ORTHWEIN

DEBORAH RUDOLPH

PAT SCHASSBURGER

JUNE WISPELWEY

Executive Summary

Developing an Economic Strategy for Health Care Through Standards and Technologies

Under the auspices of the IEEE, IEEE-USA and the National Institute of Standards and Technology (NIST), the Biotechnology Council co-sponsored a conference on *Economic Strategy for Health Care through Standards and Technologies* at NIST headquarters in Gaithersburg, Maryland, on 25 September 2007. The goal was to initiate a dialogue toward developing a strategic plan for the United States to address the growing need for new technologies to help avert the impending economic crisis in health care and to improve quality.

Conference attendees reported that a long-term economic health care strategy should accommodate both new philosophies and new technologies. To accomplish this goal, conference participants agreed that:

1. The current state of health care expenditure is neither sustainable nor commensurate with desired outcome metrics of lower cost and improved quality.
2. Current economic models and research strategies are not sufficient to provide for the development of new diagnostic, therapeutic or preventative approaches; the diagnostic testing required for reversing the increasing trend of health spending; and meeting expectations for quality of life.
3. A paradigm shift in health care delivery is only possible with implementation of biological and information technologies and appropriate standards.
4. The implementation of these technologies and standards require a long-term economic strategy that facilitates identification and implementation of the most promising and necessary technologies and their validation and standardization requirements.
5. Research and academic expenditures for ground-breaking, government-supported, scientific studies need to be supported by long-term economic strategy.
6. A national process for developing a long-term economic strategy should be developed and involve all health care stakeholders. It should be led by a neutral entity that has the support of government and industry in a public/private partnership. An example of such a neutral entity could be the U.S. Office of the Organization for Economic Cooperation and Development (OECD), because it is already part of the larger global effort.

Major technological breakthroughs in disease diagnosis and treatment and health care delivery since the 1970s have been significant but have also come at a steep cost. Health care spending now constitutes nearly one-fifth of the U.S. economy. In 2002, U.S. health care spending was nearly \$2 trillion. Health spending in the United States overall is expected to double to \$4.1 trillion by 2016, consuming 20 percent of the nation's gross domestic product (GDP), up from the current 16 percent, according to a 2007 federal study. By then, the study predicts, the government will be paying 48.7 percent of the nation's health care bill, up from 38 percent in 1970 and 40 percent in 1990. While the heavy emphasis on disease diagnosis and treatment and health care delivery has contributed to our nation spending the largest percentage of its GDP on health care, commensurate desired outcomes have not been achieved. The United States ranks 28th in life expectancy and approximately 47 million Americans are uninsured. The current pattern of escalating health care spending will continue unless there is a major paradigm shift.

Conference presenters and attendees discussed the need for a shift toward a more proactive approach for prevention of disease in concert with diagnosis and treatment, and for more efficient, quality-centric delivery of care. Shifting to predictive, patient-centered, individualized, participatory health care delivery must incorporate new measurement technologies at the molecular level, and in vitro visualization technologies to prevent occurrence and/or progression of disease. A shift of such magnitude can only happen by developing and implementing breakthrough biomeasurement, bioinformatics, biologically-based and health information technologies that can be integrated with current efforts to improve health care delivery. The advent of these new technologies will generate tremendous amounts of data, requiring advanced computational analysis with detailed mathematical modeling and algorithms to identify significant pieces of information. It is possible that by 2018, each individual patient will have billions of data points. Then the challenge will be to develop the IT for health care that reduces this staggering data dimensionality into simple hypotheses about health and disease.

The 21st century will be defined by new technologies and the technical infrastructures that will support such a paradigm. Before these technologies can be realized and commercialized, however, a long-term economic health care strategy must be established, with clear metrics for measuring and determining the value of emerging bio and information technologies. Creating this strategy will facilitate proper allocation of financial resources and ensure a focus on implementing the most promising technologies. We need to address both the incentives for, and the economic implications of, investments in breakthrough technologies and the related standards and measurements that will enable commercialization and wide application.

Understanding the vision and the technology gaps that stand in the way of achieving that vision, and addressing a method for measuring market performance of technologies to fill those gaps, are critical first steps in planning for investments into new technologies and widely accepted standards and breakthrough measurements. This strategy is required for financing innovations in the research infrastructure to transform the way the United States views and delivers health care.

Further discussion is required about methods and tools to help policy-makers and decision-makers understand the economic realities of bio and information technology investments, and make informed high-value decisions to improve the quality of care and enhance wellness, while minimizing costs. Conference attendees agreed that technological innovations must improve the quality and convenience of care, support efforts to control health care costs and increase access to affordable and effective health care, and to benefit both individual patients and society at large, in the United States and globally.

Summary of Pre-Conference Workshop

1:00 PM - 1:10 PM

Welcome by Biotechnology Council and NIST

Michael Rozen and Jerome Grossman

Conference Chair, Dr. Michael Rozen, and the Honorary Conference Chair, Dr. Jerome Grossman provided the welcome and introduction for the conference on **Developing an Economic Strategy for Health Care through Standards and Technologies**. They stressed that the goal of the conference was to initiate a dialogue and begin a journey on developing a U.S. strategic plan to address the growing need for new technologies that will help avert the impending economic crisis in health care, and to improve health care quality. They further stated that we must develop and understand the vision, the technology gaps that stand in the way of achieving that vision, and address the various methods for measuring market performance of technologies to fill those gaps. These are critical first steps in the process of planning for investments in new technologies, developing acceptable standards, and providing incentives to foster major breakthroughs in health care solutions. A long-term economic strategy is required for financing innovations in the research infrastructure to transform the way health care is viewed and delivered in the United States.

1:15 PM - 1:20 PM

Introduction of Kick-off Speaker

Mike Amos

Dr. Michael Amos provided an introduction to the conference, framing economic, R&D, and philosophical issues surrounding the economic sustainability for the current health care system. He began by describing the trends in increasing prevalence of the most costly to treat diseases, and showed projections for increasing U.S. health care spending -- particularly for the aging population. While some say that the U.S. economy can handle the ever-increasing financial burden, it was argued that simply spending more on the diagnostics and therapeutics of existing diseases did not address the issue of preventing disease, along with pain and suffering. Particularly relevant is the decreasing rate of new innovations in therapeutics and diagnostics over the past 20 years, despite spending trillions on R&D. Also relevant is the increasing complexity of getting diagnostics and therapeutics approved for patient care. Dr. Amos asked the participants to consider if it makes sense to continue on the current path or should we be shifting to a more preventative approach for health care. Is it possible to have a positive impact on disease and economic trends by focusing more on the causes of disease, the biomarkers of disease development and preventative medicines to keeping more people healthy? Dr. Amos indicated that for such a shift to occur, both new research philosophies and new innovative technologies for research, health status monitoring, and interventions (medical

and surgical) would be required. Would the major investment to support such a major shift in our approach to health care make good economic and societal sense? He closed by asking the participants to openly share their thoughts on these major questions and offer their ideas.

1:20 PM - 2: 30 PM Presentation by Kick-off Keynote Speaker with Q&A
Leroy Hood

Dr. Leroy Hood's keynote address provided a vision for the future of medicine and offered solutions for problems plaguing the current system.

- 1.) Medicine will change over the next 10-20 years. It is critically important for the United States to formulate a 20-year economic health care strategy for bio and information technologies. He described how medical research will shift from using reductionism approaches to one called "Systems Medicine" that uses thousands of computer-integrated biomeasurements to enable the understanding of human health through understanding the individual human body as a system. This research shift is made possible through comprehending information held in the genome that can be mapped into a digital, computer-compatible form, along with all associated information about gene expression products (proteins, and RNAs) -- the digitized genome, coupled with knowledge of the system's environmental exposures as interpreted by analyzing molecular and higher level phenotypic information. These analyses will make systems medicine a reality within the next 5-10 years.
- 2.) A fundamentally different health care system will be created -- one that is predictive, preventative, personal and participatory, termed P4 Medicine.
- 3.) Economic strategies must be developed to support cost-effective development of new validated and standardized technologies (i.e., biotech and IT) that would, in turn, support the development of systems medicine approaches.
- 4.) There are numerous needs and gaps, (e.g., standards and measurement and informatics technologies), impeding the development of improved bio-measurements, computational and systems medicine tools.
- 5.) Health care is a global undertaking.

6.) Dr. Hood presented the concept of “organ-specific blood protein fingerprints” developed using a systems medicine approach for discovery and translation into clinical practice. The blood plasma/serum pool is the only logical human sample from which to distinguish health from disease because blood bathes nearly all human organs and tissues, and it carries away the organ-specific proteins they shed and secrete. The different types and amounts of those proteins directly reflect the health status of each of the more than 50 major organs of the human body. It is from the quantification of combinations of those proteins, or organ-specific blood protein fingerprints (at least 50 individual organ-specific proteins), that predictive medicine will emerge -- these fingerprints will be the “biomarkers” of the future. After his formal presentation, Dr. Hood challenged the breakout session invitees to resolve the goals given to each group.

Report of Breakout Groups

Breakout 1: A Personalized Medicine World

The vision of personalized medicine (PM): *Driving the diagnostic to prognostic paradigm shift*
-- Strategies for driving toward capabilities to predict disease development through routine health monitoring biomeasurement technologies:

- What exactly does personalized medicine mean
- Basic information needed about a patient for personalized medicine
- The economic importance of predicting disease
- Payer/provider's perspective of personalized medicine
- Pharma/Biotech perspective of personalized medicine
- Drug and diagnostic discovery: today's state of affairs -- high development costs and failure rates
- What data are needed to improve the discovery process
- Expanding the thinking from mostly "diagnose and treat" to a greater emphasis on prevention and wellness.

What is Personalized Medicine?

Personalized Medicine makes use of biomeasurement, bioimaging, bioinformatics, genomics, proteomics, and metabolomics to provide preventive and diagnostic care tailored to an individual's genomic profile in areas such as risk prediction, wellness biomarkers, pharmacogenomics and pharmacoproteomics (measures the response of organ-specific blood fingerprints to drugs in individual patients -- either in the context of clinical trials, or in personalized medicine). Personalized medicine enables individuals to proactively avoid risky behaviors, and enables health care providers to predict the likelihood of disease onset and create biocompatible treatments matched to the patient's genetic makeup and environmentally-derived constitution.

Summary of Participant Discussion

Discussion among the participants focused on how to make technical innovations relative to personalized medicine. Some of the philosophical issues raised included:

- Is health care innovation the same as other innovations?
- Disruptive innovation leads to opportunity through the creation of new companies optimized to take advantage of the innovation (hence new administrative structures). It opens access to capital resources from many different sources. Existing companies may try to transform themselves -- but this type of transformation is difficult.
- Does medical digitization, together with many other aspects of P4 medicine, improve the quality of health care, and promote decreasing health care costs at the same time? For example, how does health IT, including electronic health records and a nationwide health care information network, improve quality and accessibility and reduce the costs of health care? How do we advance adoption of these technologies?
- How do we bring together expertise in areas such as integrated health records and genetic diagnosis? Indeed, IT for health care will have to be transformed. It must seamlessly integrate basic research with translation medicine using data from the core of contemporary medicine. It will also be required to play a critical role in educating physicians and patients as to the content and implications of P4 medicine.

Some fundamental approaches were discussed:

1. Data may be collected for a specific individual, or based on group tests.
2. What data to collect and how to collect it are important issues.
3. Biomarkers -- physical, cellular or molecular indicators -- or a panel of indicators of an individual's health status, will play a big role in medicine.

While supercomputers may provide a technological solution, different health IT vendors and health care researchers will take different approaches to the analysis, integration and management of health care related data, necessitating some degree of standardization. New quantitative methods are needed for database searches. But most challenging will be integrating patient data with patient records, in a manner that facilitates P4 medicine.

It was noted that U.S. physicians already provide personal health care. One barrier to providing better individualized health care is the inefficient delivery of care due to rising costs. Some suggestions for addressing this situation included:

- Retail clinics -- expand availability and provide additional competition.
- Electronic health records (EHRs) and personal health records (PHRs): use EHRs and PHRs to connect delivery and biomedical issues.

Much of the discussion centered on economic and business models. The relative roles of the marketplace and government were discussed. What incentives exist for implementing personalized medicine? An analysis based on return on investment (ROI) has to look not only at the capital amount invested, but also at the return on investment. However, non-financial incentives have to be considered as well, including the benefits of health and wellness versus pain and suffering. We note that it is very difficult to estimate ROI for emerging and transforming technologies, and strategies for medicine.

In summary, participants agreed that biomarkers will play a significant role in disease discovery and treatment. However, we need to think in terms of biology and information, not software and technology. The future of medicine will be transformed by creating technologies that make it possible to digitize the enormous amount of biological information in humans (several orders of magnitude too complicated for anyone to comprehend), capturing it in a form that can be used in computers for data integration, analysis and visualization, and displaying the analyzed and integrated data in a form that doctors and patients can understand. Re-education will be necessary. Physicians need to be made aware of how to use the data. Finally, cost remains an issue. Can the United States afford the cost of basic research in this area? The discovery of biomarkers has proven very difficult. Enormous resources have gone into programs that use reductionist methods to identify single proteins that are clinically relevant, with almost nothing to show for it. Fortunately, new strategies are emerging for generating biomarkers that have enormous promise (e.g., organ-specific blood protein fingerprints) and what remains is to generate the resources for discovery, validation and typing. The technologies for doing so are already here (mass spectrometry and microfluidic protein chips).

Breakout 2: Discovery Technologies

Biochemical Measurement and Visualization Technologies for drug, diagnostics and predictors discovery: Assessment of the current state of the art, and establishing a vision for the future:

- What are our current capabilities for identifying and using biomarkers (predictive and diagnostic), and imaging data now for patient care -- molecular pathology, laboratory diagnostics (from clinical chemistry to Mammaprint™), and medical diagnostic imaging (from x-rays to functional MRI, and beyond)?

- Envision what gene sequencing and expression technologies will be needed.
- The realities of biomarker and therapeutic development using current approaches -- why we aren't better at it, and why is it so expensive? What is the best strategy for discovering and deploying blood protein biomarkers? Why are blood biomarkers superior to others? What are all the potential types of blood biomarkers?
- It will be critical to develop new chemistries for creating high affinity and high specificity protein-capture agents.
- *Visualization* -- What will be the best way to present the various data to medical doctors and other health care practitioners?
- The shift from only single biomarkers to complex signatures. The need to talk clearly about the implications of this shift. For example, the organ-specific blood fingerprint approach specific for all diseases arising from the corresponding organ biomarkers are not for individual diseases, rather the fingerprints will distinguish health from disease -- and identify all disease.
- Economic incentives for integrated approaches to technology development and integrated approaches to diagnostics
- The need for more comprehensive information on the human system, including whole genome sequencing of individual and longitudinal analyses of blood protein organ-specific fingerprints.
- Measurements: quantity, sensitivity, specificity, and low cost/high speed.

Summary of Participant Discussion

Current capabilities were discussed for the ID and use of biochemical (predictive and diagnostic) and imaging data for patient care and molecular pathology. These included laboratory diagnostics (from clinical chemistry to mammaprint) and medical diagnostic imaging (from x-rays to MRIs).

For the most part, it was agreed that the technology required to enable personalized medicine does not currently exist. The learned experts participating in the conference agreed the concept of discovering or validating new therapeutic candidates based on simple metabolic pathways is no longer a viable approach for the future. Likewise, the clinical utility of the single protein biomarkers for disease diagnosis is ineffective (as we have seen from PSAs). Rather, the future will use multi-parameter blood fingerprints.

Up until just recently, medical research and development approaches have depended upon an overly simplistic view of biology. Research has involved a reductionist approach that focuses on studying individual small parts of massive complex biomolecular and cellular networks, and then attempting to make educated guesses relevant to the entire system. Reductionism has nearly reached its limit of success, reflected by the dramatic slowing of new drugs and biomarkers discovered and marketed since 1995. It was agreed that research approaches and technology development need to focus on the understanding of human health based on the fact that humans are a complex functional system of biomolecules. The human biological system must therefore be studied as a system and the data generated from such studies is different than that obtained from pathway analysis and single biomarker studies. These types of data are commonly referred to as complex biomolecular signatures and the complex profile of the biomolecules associate with a particular malady is its “disease signature.” By studying humans and model organisms as systems, scientists will obtain a level of understanding about human health that could never be achieved through reductionist methods.

Systems Medicine and “Signatures”

Medical researchers have largely attempted to study human health by performing experiments on separate, discrete biochemical “pathways.” This type of study began to change as a result of the Human Genome Project, where newly developed, high-throughput DNA sequencing, gene expression analysis, and IT tools made it possible to begin thinking of the biochemistry of bioorganism function, not as discrete “pathways,” but as a massively complex “system, or network” of interacting biological processes. These systems interconnect in a manner better described as a network, with functional node of hundreds of separate proteins that dovetail with hundreds of other functional nodes of hundreds of separate proteins. Disease occurs when one or more of the networks becomes altered (by mutation or environmental factors such as infectious organisms) and cannot perform its duties effectively. As a result, the expression of information (mRNA and proteins) is altered in a manner that changes dynamically during disease progression. This altered information expression encodes the pathophysiology of the disease and leads to new opportunities to take a systems view of diagnosis, therapy and even prevention. Scientists have been able to discover the genetic mutations for many diseases where only a single gene/expressed protein is affected (e.g., hemophilia, cystic fibrosis, etc.). And it was once believed that with our current technologies, it would just be a matter of time and effort until all of the disease genes were determined and we had new cures (as was the hype from the early days of the human genome project). However, it did not turn out that way.

Unfortunately, the causes of the most common and most costly diseases (cardiovascular disease, chronic lung disease, cancers and autoimmune diseases) that affect greater than two-third of Americans, have proven much more difficult to determine. Such diseases are not usually the result of defects in one gene, but a combined manifestation of changes in multiple genes as a result of genetic polymorphisms and multiple environmental influences that occur often over the course of lifetimes. It is for this very reason that medical science has hit a major roadblock. The current reductionist research approach is not at all compatible with the need to

analyze the many thousands of events necessary to understand why people develop cancers, etc., and the technologies do not exist that are capable of cost-effectively performing the required biochemical measurements. Medical researchers need to know:

- 1) What is the “signature” of people express when developing their disease?
- 2) What is the signature of their individual disease (their “disease signature”)?
- 3) What information can scientists take from those signatures to develop laboratory tests and cures (drugs that do not cause more harm than good)? It is only through the use of computer-integrated, multiparameter measurements of all the relevant biomolecules (DNA, RNA, proteins, sugars and metabolites) that change when transitioning from “health” to pre-disease, and full-blown disease.

A “signature” is a unique health status descriptor, often comprised of several quantitative and/or qualitative measurements of biomolecules, cellular events, phenotypic observations and intermolecular interactions in complex living system networks. Such measurements may be performed by either a single, or by several, methods (immunoassay, microscopy, physical methods such as mass spec). Thousands of individual measurements may comprise a signature. Such measurements may include, but are not limited to:

- 1) Fluctuations in concentrations of native gene expression products (mRNA and proteins) in cells and/or body fluids
- 2) Appearance of new gene expression products as a result of disease (e.g., in cancer or autoimmune disease)
- 3) Alterations in how proteins, DNA, RNA, sugars and lipids interact with one another
- 4) Changes in protein structure (e.g. phosphorylation)
- 5) Changes in how existing proteins function or how a new protein that forms as a result of the disease operates
- 6) Changes in cellular function and activity.

Computers integrate and analyze these and other bits of information taken from multi-parametric measurements, and present the information in a form that can be used to understand differences between a healthy biological system and the prediseased, or diseased system. Such measurements allow scientists to visualize subtle but medically significant changes in the ebb and flow of thousands of molecular actions in the system interacting. Without the ability to first measure and then digitize the information for computer manipulation, such changes could never be recognized by any humans.

Analysis of Complex Biomolecular Signatures

Although considerable progress has been made in developing multiplex gene expression, analytical techniques that measure mRNA levels, and the technologies required to perform the measurements needed for signature analysis do not currently exist.

The next generation of health assessment laboratory tests and therapeutic or preventative interventions will be based on data generated with technologies and research approaches that embrace system complexity. These data will not be simple blood protein quantities or linear cellular pathways. Data required for signature analysis will include measurements of:

- Dynamically changing mRNA levels (10,000s)
- Dynamically changing protein levels (100s - 1000s)
- Dynamically changing protein/protein interactions (10^6)
- Dynamically changing DNA/protein interactions (100s)
- Dynamically changing mRNA and protein modifications (100s)
- Dynamically changing protein localizations (100s).

In the future, each person would have their “wellness signature” tested every year or so. Doing so will inherently create the ability to compare the wellness signature against their own “normal” signature. As a result, the patient will become their own control for distinguishing health from disease. In the initial discovery phase, such comparisons will be accomplished by using large populations of “disease free” individuals as controls. But it is likely that there will be so much variation among healthy individuals, due to extensive human genetic polymorphisms, that each individual will soon become their own control -- as mentioned above. This research and these comparisons will enable the discovery of the mechanisms that cause diseases. And out of that comes the discovery of biomarkers (“disease and pre-disease signatures”), for predicting and diagnosing diseases. However, translating those biomarker discoveries into clinical practice will require new approaches for test developers, standards developers and regulators. These new approaches will become necessary because each person’s own “wellness signature” will change over their lifetime -- to reflect their own lifestyle, environmental exposures and disease development. Therefore, each person’s own series of “signatures” taken over the course of their lifetime must serve as the control for the next time they get tested. “Self controls” is a new concept that will require new approaches to assay development, standardization and regulation. It is unclear how the issue related to human polymorphisms will be handled in large population studies.

Mammaprint and OncoType Dx are new in vitro diagnostic multivariate index assays (IVD-MIA) diagnostics that analyze mRNA expression signatures. Several new proteomic platforms are being developed -- intended for proteomic signature analysis. Regarding therapeutics, the most logical way to predict if a drug candidate, cell or gene therapy, or an implanted prosthetic material is safe and effective, is to measure their impact on the entirety of the complex system with which they are intended to interact. To do that, researchers need to compare the normal signature of a model system to any deviation from normal, when perturbed by a drug cell or material (metal, ceramic or plastic).

Potential Impact

New multiparameter technologies will enable the production of signatures capable of being used by medical researchers and physicians to analyze the behavior of the biochemical networks within individual organs. Such signatures will be highly accurate snapshots over time of how the organs are performing. Such information will be used to monitor health, predict disease onset, alter lifestyles, determine appropriate treatments for diseases and monitor therapies to determine efficacy and safety. The technological capability to perform complex signature analysis will enable researchers to advance far beyond the results obtained using reductionist research approaches. New measurement technologies and the infrastructure to support their development, deployment and utilization will enable the nearly complete understanding of biological systems and help take the guess work out of therapeutics development and health status testing (molecular imaging and laboratory blood tests). Such new measurement technologies are an absolute requirement for personalized medicine to become a reality. They would enable individualized disease prevention and treatment, as well as safe and effective use of biocompatible prosthetic materials, and engineered replacement tissues and organs.

Visualization Hurdles

One of the hurdles of visualization will be how best to present the various data to medical doctors and other health care practitioners.

Conclusions

Conference participants agreed that research philosophies and technical approaches for discovery of new drugs, cell and gene therapies, and biochemical biomarkers (laboratory medicine and diagnostic imaging) must change dramatically.

Breakout 3: Health Care Informatics

Revolutionizing bio and health care informatics -- IT infrastructure for PM and for safer, more affordable, and more accessible health care delivery:

- Implementation/Integration of Electronic Health Records and Personalized Health Records
- Standards harmonization, conformance testing, certification
- Roadmap toward a Nationwide Health Information Network
- Detailed mathematical modeling and computational analysis
- Data reduction, filtering, mining for knowledge management, secondary uses, etc.
- Semantic interoperability (including consumer terminology integration).

At the heart of the health care informatics issues:

- 1) The integration of fundamental research approaches with translation approaches and core digital medicine, in a manner that supports inward migration as basic research becomes translational, and translational becomes digital core
- 2) The need to educate patients and physicians.

Summary of Participant Discussion

Workgroup participants discussed goals for capturing, maintaining and disseminating appropriate health care informatics and using that information for disease management, monitoring and prevention. They emphasized that data security, integrity, robustness, usability, interoperability, conformance testing, certification, adoption, and timeliness were core components. They stated that health care informatics expectations should focus on what is realistically achievable within a five to ten-year time frame, and should be commensurate with clinician needs, desires, skills, capabilities and limitations.

Participants discussed the need for establishing protocols for creating unique universal identifiers for health care measurements, devices, records and patients, or what alternative technologies would be effective. They also discussed NIST's role in standards harmonization, measurement and conformance testing, certification and security.

Participants raised concern that the volume of data being generated far exceeded the capability to analyze and process the information resulting in key information being lost in a sea of data.

Participants stated that databases must be able to support robust mathematical modeling and the creation of data filters for data reduction, data mining and appropriate secondary data uses.

Participants agreed that a long-term economic strategy was necessary for revolutionizing bio and health care informatics and IT infrastructure.

Breakout 4: Harsh Realities

Changing paradigms will create disruptions and shift economic burdens, incomes and expenditures: societal, legal, regulatory and political realities.

Summary of Participant Discussion

Workgroup participants agreed that shifting the health care paradigm to truly personalized medicine with increased wellness and longer life will produce significant disruptions in health research, funding, care delivery and reimbursement. This shift will mean extreme changes to the current research system. For example, instead of funding disease specific research, research will focus on larger interdisciplinary approaches encompassing measurement science, biology, bio-informatics and system biologists. Economic strategies need to be formulated to enable this transformation, in light of these harsh realities. Current predictive models of care delivery and outcomes need to be reevaluated based on in depth longitudinal (year after year) patient monitoring including blood protein bio markers and response to therapies. Current metrics and models for pathology and biology and measuring the response to therapeutics are not consistent with emerging technologies of blood/protein bio markers and with the changed paradigm of quality of life outcomes.

The paradigm shift will also require reevaluating the legal and regulatory barriers to interoperability, information aggregation, disease data base analysis and information sharing.

Another harsh reality is who receives the privileged treatments of preventive care, acute care, or even end of life care? Economic realities currently dictate the level of care, especially preventative, that an individual may receive.

How should new economic strategies address these apparent inequities? The role of government and the private insurance industry in this paradigm shift may produce significant realignment of health care expenditures.

In conclusion, effectively dealing with the harsh realities of a health system paradigm shift will require a long-term economic strategy that is graduated and realistic in its five and ten-year goals; one that will acknowledge that while improvements can benefit all, inequities will continue to exist in the short-term.

Breakout 5: Changing Research Approaches

Driving a systems research philosophy paradigm shift – infrastructure requirements and changing the way research is funded to drive toward systems approaches:

- Pros and cons of reductionism
- Pros and cons of systems biology approaches to disease process, therapeutic and biomarker discovery
- What can be done to enable better therapeutics, predictors and diagnostics
- National infrastructure needed for PM and health care delivery
- Engaging the best and brightest researchers
- The need to change the training of young scientists to a cross-disciplinary and systems-approaches-to-biology approach
- The need for basic research funding in systems biology to better understand human physiology
- The need to have access to high throughput measurement and computational facilities for those carrying out systems research.

The importance of strategic partnerships (from academia, industry, government, etc.) for attacking the really big problems of contemporary biology and medicine (e.g., P4 medicine).

Summary of Participant Discussion

The paradigm shift to personalized medicine requires multidisciplinary research with the formation of unique partnerships and consortia. These changing research approaches necessitate realignment of funding priorities and incentives. These new approaches require new skills, new training programs, and innovative technologies, which in turn necessitate realignment of funding options and incentives.

Goals and focus areas for research should address the following concerns:

- Personalized medicine is a driver for a systems development approach. The systems level should be defined first, along with those requirements needed to drive the research on system components.
- New systems concepts, like personalized medicine, cannot be advanced too much without advances in the black boxes that make up the system.
- Balance is required. Independent funding of research on black boxes, beyond some practical limit, impacts system design and results in inefficiencies in development costs.
- The ultimate system goal is transforming medicine from a primary focus on disease to one on improving wellness.

In summary, the national infrastructure needs for personalized medicine are radically different from conventional health care. A new infrastructure and standards are needed to facilitate changes. It will be necessary to overcome the natural resistance to change found in any entrenched system. By improving existing medical care, we can provide short-term benefits. A transition strategy for implementing new technology paradigms for personalized medicine can be provided. The next technology paradigm will require a varied set of new infrastructures, in which privacy will take a higher priority. However, the transition strategy may require parallel systems for years.

Featured Conference Presentations

The Role of Biotechnology and Bioinformatics in FDA's Critical Path Initiative

Janet Woodcock, Deputy Commissioner/Chief Medical Officer

U.S. Food and Drug Administration

Dr. Woodcock's talk focused on the major issues facing drug development and how improved biomarker discovery and qualification, together with bioinformatics, could have a positive impact on health care innovation. She began by framing the problem. Current drug development productivity is in crisis, with ever-increasing investment and decreasing output. This problem is occurring because drug development is very challenging; pipeline problems are persisting post-Phase 1. The failure rate is increasing, and drug safety issues lead to calls for larger and longer pre-market trials. The rising costs of development, coupled with continuing high clinical failure rate, are on a collision course with societal demand for more certainty prior to product approval. Despite these problems, unmet medical needs persist and never has there been more scientific opportunity for addressing them. A new development model or paradigm is needed.

Launched in 2004 with the *Innovation/Stagnation* white paper, the Critical Path Initiative calls for rapidly incorporating new science capabilities into medical product development pathways, to improve the informativeness of the process, as well as its predictability.

The 2006 Critical Path Report and List included 76 scientific projects as examples of the needed approach. Areas that could have a large impact on health care economics are:

- 1) New biomarkers consisting of genomic, proteomic, metabolomic and other molecular in vitro assays, and molecular and functional imaging in vivo and
- 2) Bioinformatics, which will be the means to connect biomarker information with natural history, clinical trial and surveillance data to provide the clinical meaning. As a result, many new therapeutic products will result from biotechnology approaches combining biomarkers and bioinformatics.

The future of drug development must change and needs to involve new preclinical toxicology and clinical development approaches to facilitate the move from empirical evaluations to quantitative model-based learn-confirm cycles. Such new approaches will result in improved predictive capacity of the drug development system.

Biotech 2007: A Global Transformation

G. Steven Burrill, Chief Executive Officer, Burrill & Company

Mr. Burrill's talk described the major shift occurring in the biotechnology community, particularly in the medical area. The future will see a transformation from the traditional chemistry approach of one-size fits-all drugs, and the use of drugs used to treat people after diagnostics are performed; to a world of personalized delivery of biochemical based drugs used in concert with diagnostics (theranostics). The emphasis will focus on preventing sickness and on foods that promote health, rather than just used for survival. Future developments will enable not only changing the health care environment, but *Transforming the World*.

Mr. Burrill described how four potentially preventable disease groups (cardiovascular, cancer, diabetes and obesity) constitute 74 percent of our health care spending. He described the future of stem cell therapies and other transformational technologies. Mr. Burrill emphasized the need to shift to *systems approaches* to discover *biosignatures* of human body health and disease to enable predictive and preventative medicine approaches.

Consumers: Shifting the Health Paradigm

Peter Neupert, Corporate Vice President, Health Solutions Group, Microsoft Corporation

Mr. Neupert described disruptive new technology being developed at Microsoft to help revolutionize the future of medicine. A Copernican shift in health care management is underway. The current health care universe revolves around the physician, but will shift to the consumer -- the patient will be the center of the health care universe. They are making this shift out of necessity because of the serious gaps in the current system. Mitigation of chronic conditions will depend on lifestyle changes driven by Internet-obtained information. This shift will be a critical driver to improved health care economics. Information systems and paradigms will be needed to help shift care from high-cost venues (hospitals) to more economic options such as home-based settings.

The consumer will play a growing role in making health care economic and clinical decisions. Microsoft will try to power this disruptive change of the consumer taking charge of their own data. He introduced the *data liquidity* concept as the "*free flowing of information across the ecosystem.*" We are at a threshold in biological sciences when it comes to beginning to better understand how the human body works. Gaps exist in the system of how we measure our health care delivery. The exponentially growing amount of data on individuals that will be generated over the next few years makes developing data information systems critical. P4 medicine is exciting, but more information systems to manage the data liquidity are needed to

make it a reality. Consumers want to interact to obtain health care information. Our current HC system is too focused on acute problems. A radical shift to wellness needs to be empowered using online tools and requires a focus on personal prevention.

New emphasis needs to be placed on measurements to determine best practices for health care delivery to enable better evidence-based medical approaches and P4 medicine. Microsoft has launched a new Surface computing product that, along with other Microsoft systems, are expected to enable dramatically changed workflow systems. New systems are being launched that drive the Copernican shift, integrating cross disciplinary approaches to understanding how our bodies work and use sharable data, supported by good standards. A major problem with standards is the speed with which technology is being developed. These data must be accessible, reusable and valuable. The system should be made available to the public free-of-charge.

Mr. Neupert advocated public/private partnerships in standards development to enable consumer-based health care information management systems and for government support. New policy and standards will enable the revolutionary changes needed to advance medicine.

New measurements will enable analysis of the genome and biochemical changes over their lives, due to environment exposures to make consumer-based decisions, while appropriately interfacing with the health care professionals. Computers can now use machine learning tools capable of detecting variations in large data sets that cannot be detected by humans. This new capability will drive the Copernican shift to consumer-focused wellness approaches. The creation of open systems for data management will enable the much needed Copernican shift and improve health care economics.

Approaches To Developing Government R&D Programs

Gregory Tassey, Senior Economist, National Institute of Standards and Technology

Dr. Tasse

y's talk presented an economic model for disaggregating the traditional "black-box" characterization of an industrial technology into three major elements: generic technology platforms, proprietary technologies, and supporting infratechnologies. These elements are critical for the development of government R&D policies because they reflect distinctly different investment incentives and therefore suffer from different degrees of underinvestment at different points in a technology's life cycle. Such a model is particularly critical for an emerging technology, such as biopharmaceuticals, because its complexity makes description and measurement of the adequacy of investment in each technology element difficult. The structure of the model determines the economic data collected to inform government R&D program development. Underinvestment in one of these elements can significantly constrain progress in the other two and therefore retard the industry's progress. For example, a NIST study estimated that mitigating underinvestment in a range of infratechnologies (bioimaging, biomarkers, bioinformatics, and gene expression analysis) could reduce the average cost of developing a new drug through FDA approval by 30 to 57 percent. The study also indicated that improved infratechnologies could reduce the average annual manufacturing costs for the biopharmaceutical industry by 23 percent.

Pre-Conference Workshop

September 24, 2007

The Road to Nirvana: The Economics of Revolutionizing Health Care through Innovations in Bio and Health Information Technologies and Standards

1:00 PM - 1:10 PM	Welcome by Biotechnology Council and NIST
1:15 PM - 1:20 PM	Introduction of Kickoff Speaker (Mike Amos)
1:20 PM - 2:00 PM	Presentation by Kickoff Keynote Speaker (Leroy Hood) Keynote topic themes: <ol style="list-style-type: none">1. Formulating a 25-year economic <i>Health Care Strategy for Bio and Information Technologies</i>2. Patient-centric health care, including IT and up-streaming issues3. Economics of new technologies (i.e. biotech and IT) in a cost-effective manner4. Needs and gaps, e.g., standards and measurements5. U.S. health care in a global environment
2:00 PM - 2:15 PM	Q & A
2:15 PM - 2:30 PM	Challenge to the Invitees for the Breakout Sessions (See Attached)
2:30 PM - 3:00 PM	Afternoon Break and Networking
3:00 PM - 4:30 PM	Breakout Work sessions
4:35 PM - 5:30 PM	Report Back Progress
5:30 PM - 5:45 PM	Wrap-up (Leroy Hood)
5:45 PM - 8:30 PM	Reception and Networking for All Meeting Attendees

BREAKOUT SESSION CHALLENGES:

1. How do you define the problem?
2. Whose problem is it?
3. What organizations should be engaged in the strategic planning process?
4. Who should support and fund this process?
5. How do you economically define the role of standards and technology?
6. What process is needed for identifying/implementing highest near-term impact technologies?
7. Are the current models appropriate for determining ROI and breakeven for new bio and IT technologies? What should these methods for evaluation be?
8. What are the next steps?
9. What are reasonable targets?
10. What other groups should be included? E.g., Government; Pharmaceuticals?

About the Biotechnology Council

<http://ewh.ieee.org/tc/biotech/>

The Biotechnology Council was founded in 2004 to facilitate the advancement of biotechnology by the integration of engineering, medicine and science for the benefit of humanity. Members include the American Society of Mechanical Engineers, the Biomedical Engineering Society, the Health Care Information and Management Systems Society, the Institute of Electrical and Electronics Engineers, and the Society for Biological Engineering.

About the IEEE

www.ieee.org

The Institute of Electrical and Electronics Engineers (IEEE) is the world's leading professional association for the advancement of technology. Through its global membership, the IEEE is a leading authority on areas ranging from aerospace systems, computers and telecommunications to biomedical engineering, electric power and consumer electronics, among others.

About IEEE-USA

www.ieeeusa.org

IEEE-USA advances the public good and promotes the careers and public policy interests of more than 215,000 engineers, scientists and allied professionals who are U.S. members of the IEEE. IEEE-USA is part of the IEEE, the world's largest technical professional society with 375,000 members in 160 countries.

About NIST

www.nist.gov

The National Institute of Standards and Technology (NIST) is a non-regulatory agency of the U.S. Department of Commerce. NIST promotes U.S. innovation and industrial competitiveness by advancing measurement science, standards and technology in ways that enhance economic security and improve our quality of life.

Note: *Conference materials including presentations and videos are available at the conference web site:*
www.itl.nist.gov/Healthcare/conf/.

Conference Program

September 25, 2007

- 7:00 AM - 8:30 AM **Registration and Continental Breakfast**
- 8:30 AM - 8:40 AM **Welcome: Biotechnology Council**
Michael J. Rozen, M.D., Conference Chair
- Welcome: Sherrod Brown, U.S. Senator, State of Ohio and**
 Member, U.S. Senate Health Subcommittee
- Introduction of Jerome Grossman, Honorary Chair**
 Senior Fellow and Director, Harvard/Kennedy School Health Care
 Delivery Project; Chairman Emeritus of New England Medical
 Center; and Past Member of the Boston Federal Reserve Board
- 8:40 AM - 8:50 AM **Welcome: James Turner, NIST Deputy Director**
- 8:50 AM - 9:00 AM **Introduction and Welcome: Constance Morella**
 U.S. Ambassador to the Organization for Economic Cooperation
 & Development
- 9:00 AM - 9:15 AM **The Acceleration in the "Yield" From Bioeconomics**
Jerome Grossman, M.D.
- 9:15 AM - 9:30 AM **Technology Innovation Program**
Marc Stanley, Acting Director Technology Innovation Program
 NIST
- 9:30 AM - 10:00 AM **Keynote Address: Consumers: Shifting the Health Paradigm**
Peter Neupert, Corporate Vice President for Health Strategy,
 Microsoft Corporation
- Featured Presentations:**
- 10:30 AM - 11:00 AM **The Role of Biotechnology and Bioinformatics in FDA's Critical**
Path Initiative
Janet Woodcock, Deputy Commissioner of Operations, FDA
- 11:00 AM - 11:30 AM **Biotech 2007: A Global Transformation**
Steven Burrill, CEO, Burrill & Company

11:30 AM - 12:00 PM	<p>Approaches To Developing Government R&D Programs Gregory Tassej, Senior Economist, NIST</p>
12:00 PM - 12:40 PM	<p>The Potential of Biotechnology and Bioinformatics for Public Health Anthony Arundel, SGEAU, OECD</p>
2:00 PM - 3:30 PM	<p>Marketplace Economics Roundtable</p> <p>Moderator: Vijay Vaitheeswaran, Correspondent to The Economist</p> <p>Participants:</p> <p>Patrick Yang, Executive VP, Genentech</p> <p>Allan Korn, M.D., Senior VP, Medical Director, BC/BS</p> <p>Mitchell K. Higashi, Senior Director, Health Economics & Outcomes Research, GE Health Care</p> <p>G. Steven Burrill, CEO, Burrill & Company</p> <p>Greg Tassej, Senior Economist, NIST</p> <p>Marcel E. Salive, MD, MPH, FACPM is Director of the Division of Medical and Surgical Services (CMS)</p>
3:45 PM - 5:15 PM	<p>Assessing Emerging Technology Benefits and Barriers Roundtable</p> <p>Moderator: David Whitlinger, President and Board Chairman, Continua</p> <p>Participants:</p> <p>Mostafa Analoui, Senior Director, Pfizer Global R&D</p> <p>Deepak Ayyagari, PhD. Secretary, Continua Health Alliance; Principal Scientist, Personal Health Care Technologies, Sharp</p> <p>Rainu Kaushal, Department of Medicine, Brigham and Women’s Hospital; Appointment at Weill-Cornell School of Medicine</p>
5:15 PM - 5:30 PM	<p>Closing Remarks</p>

CONFERENCE GOAL:

To initiate a dialogue on developing a strategic plan for the Nation to address the growing need for both new bio and health information technologies, and broadly adopted standards enabling interoperability among the biological, biomedical and health delivery systems that implement these technologies, to help avert the impending economic crisis in health care and to improve quality, value and accessibility. Additionally, to discuss methods and tools to help policy and decision makers understand the economic realities of Bio and Information Technology investments for making informed high-value decisions.

Economically, how do we get from here to there?

THE PROBLEM:

The major technological breakthroughs in disease diagnosis and treatment in the health care industry since the 1970s have been significant, but have also come with a price: health care spending now constitutes nearly one-fifth of the U.S. economy. In 2002, U.S. health care spending was nearly \$2 trillion and is expected to exceed \$4 trillion by 2015. Until now, the emphasis in health care has been on diagnosis and treatment. The current pattern of escalating health care spending will only continue, unless there is a major paradigm shift toward a more proactive approach for prevention of disease, in concert with diagnosis and treatment. This shift can only happen by developing standards and breakthrough measurements in (for example) biologically based technologies, bioinformatics and health information technologies that can be integrated with current efforts to improve health care delivery.

The focus of the workshop is to identify the economic realities and needs for investment (near-term and long-term) into standards and measurements in bioinformatics, biologically-based technologies, and information technology to drive the paradigm shift to a patient-centric, integrated, distributed health care delivery system that enhances quality and promotes consumer empowerment.

GOALS:

- Draw attention to the issue.
- Define perceived next steps and process.

ISSUES:

1. THE VISION: Where could we go? What could we accomplish? How do we:
 - a. Expand coverage through broader accessibility?
 - b. Improve quality and reduce medical errors?
 - c. Meet needs of aging population facing potential significant physician shortage?

2. THE REQUIREMENTS: What bio and information standards and technologies are needed to service this vision?
 - a. For communication, quality, value, interoperability.
 - b. To ensure availability of the right information at the right time -- Wrong information, wrong time, wrong place, wrong patient = MEDICAL ERRORS.

3. BARRIERS and OBSTACLES: Whose job is it to define and remove them? What is the process?
 - a. Policy?
 - b. Funding?
 - c. Technologies?
 - d. Measurements?
 - e. Standards?

4. JOURNEY: How do we get from here to there?
 - a. How do we define the value proposition?
 - b. What are next steps in defining a sustainable economic and technology strategy for health care bio and information technologies?
 - c. What do we economically and technically need to achieve consumer empowerment and patient-centric health care?
 - d. What is value proposition to the country? To the world?

Conference Background Statement

Strategy for Health Care through Bio and Information Standards and Technologies

The major technological breakthroughs in disease diagnosis and treatment in the health care industry since the 1970s have been significant, but have also come with a price. Health care spending now constitutes nearly one-fifth of the U.S. economy. In 2002, U.S. health care spending was nearly \$2 trillion and is expected to exceed \$4 trillion by 2015. Until now, the emphasis in health care has been on diagnosis and treatment. The current pattern of escalating health care spending will only continue unless there is a major paradigm shift toward a more proactive approach for prevention of disease in concert with diagnosis and treatment. This shift can only happen with the development of breakthrough biomeasurement, bioinformatics, biologically-based and health information technologies that can be integrated with current efforts to improve health care delivery. There is a need to address the economic implications of such developments.

The 21st century will be defined by new technologies and the technical infrastructures that will support such a paradigm. However, breakthroughs in measurement capabilities are necessary to clear a path to market before these technologies can be realized and commercialized. Breakthroughs in biomeasurement, bioinformatics, biologically-based and health information technologies and the development, and broad adoption of standards for interoperability among biological, biomedical, and health delivery systems, will be critical enablers of the health care delivery paradigm shift. Both incentives for and the economic implications of investments in breakthrough technologies and related standards and measurements that will enable commercialization and wide application must be addressed.

The Biotechnology Council and the National Institute of Standards and Technology (NIST) will conduct an inaugural conference on *Developing an Economic Strategy for Health Care through Standards and Technologies*. The goal is to initiate dialogue on developing a strategic plan for the Nation to address the growing need for new technologies to help avert the impending economic crisis in health care and to improve its quality. Understanding the vision, the technology gaps that stand in the way of achieving that vision, and addressing a method for measuring market performance of technologies to fill those gaps are critical first steps in the process of planning for investments into new technologies, widely accepted standards and breakthrough measurements. A long-term economic strategy for financing innovations in the research infrastructure to transform the way health care is viewed and delivered in the United States is also needed.

Discussions will take place about methods and tools to help policy- and decision-makers understand the economic realities of bio and information technology investments, and make informed, high-value decisions to improve quality of care and enhance wellness, while minimizing costs. Technological innovations that improve the quality and convenience of care, support efforts to control health care costs, and increase access to affordable and effective health care, benefit both individual patients and society-at-large, both in the United States and globally.

Conference Scope

The conference will bring together key government, industry, academic and research leaders and patient advocates to discuss mechanisms for assessing the economic benefits and opportunities of bio and information technologies and standards in the life sciences and health care delivery, and their role in bridging health care system gaps. The goal is to help attendees understand the economics of Bio and Information Technology, and learn useful approaches for evaluating promising technologies. Attendees should gain an appreciation and understanding of key factors that drive the development and implementation of these technologies in the life sciences and health care markets, and the mechanisms for evaluating the cost-benefits of these technologies.

Charge to Conferees

- Identify the economic realities and gaps in current investment priorities for biomeasurement (biochemical and imaging), bioinformatics, and biologically-based and health information technologies needed to drive the paradigm shift to a patient-centric, integrated, distributed health care delivery system that enhances quality and promotes consumer empowerment.
- Develop a long-term strategic investment plan to address the identified gaps.

Welcome Letter

Dear Colleagues:

Welcome to the inaugural event of the transdisciplinary *Conference on Economic Strategy for Health Care through Bio and Information Standards and Technology*. The goal of this conference is to improve the quality of health care, and patient wellness and outcomes, by transforming the delivery of health care from a central, hospital/insurance-based system to one that is more patient-centered, competitive and economical. This Bioeconomics Conference will focus on developing a long-term economic strategy for the development and implementation of bio and information technologies, in support a paradigm shift in our health care delivery.

The conference brings together major stakeholders from industry, academia and government to discuss the current status, important components/ingredients, new technologies, and policies to facilitate distributed, patient-centered, health care in the future.

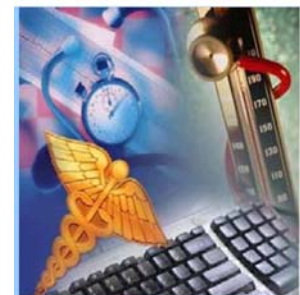
Due to its complexity and scope, the improvements in health care require researchers, engineers and providers from many traditional disciplines to collaborate and tackle the challenges together. Thus, this conference on health care is sponsored by NIST (National Institute of Standards and Technology) and the Biotechnology Council (consisting of ASME, BMES, HIMSS, IEEE, and SBE/AICHE, a group of over 700,000 technical members). These societies are formally known as: American Society of Mechanical Engineers (ASME), Biomedical Engineering Society (BMES), Health Care Information and Management Systems Society (HIMSS), Institute of Electrical and Electronics Engineers (IEEE), and Society for Biotechnology (SBE). We would like to express our sincere appreciation of the financial and programmatic support from NIST and all of the societies.

We, the Program Committee members and speakers, have worked hard to develop an exciting conference program that we feel will generate discussions, and will benefit the forward motion of this important issue in the 21st century. For your benefit, we brought together a very select group of leaders, researchers, and decision-makers from academia, industry and government with expertise in the Bio, Health Care, Pharma, Economics and Information fields.

Thank you for participating. We hope you will enjoy the program, meet new people, exchange ideas, and learn about technical and non-technical issues and opportunities associated with this future health care paradigm.

Sincerely yours,

Richard Doyle, P.E.
Biotechnology Council Chair
Doyle and Associates
5677 Soledad Road
La Jolla, CA 92037
Phone 858-775-9893
FAX 858-454-3454
Home 858-459-6504
Email: r.doyle@ieee.org



SPEAKER BIOS

MICHAEL D. AMOS

Dr. Michael Amos is the Biosciences Advisor to the Director of the Chemical Science and Technology Laboratory (CSTL), National Institute of Standards and Technology (NIST), Technology Administration, U.S. Department of Commerce. Dr. Amos received his B.S. degree in General Sciences from Virginia Commonwealth University, Richmond, Virginia and his Ph.D. in Basic Medical Sciences from the University of South Alabama, College of Medicine in Mobile, Alabama. His graduate area of emphasis was in microbiology and immunology, and his thesis research was in regulation of the immune system. From there, he furthered his training at the University of Alabama at Birmingham, College of Medicine as a postdoctoral fellow in the Departments of Microbiology and Rheumatology, studying the molecular immunology of rheumatoid arthritis. He has held various industry research, marketing and business development positions in the fields of biopharmaceuticals, nutraceuticals, drug delivery, transgenic, immunodiagnostics, molecular biology and molecular pathology. He is also a founder of two biotechnology companies. Dr. Amos joined NIST in 2002 as a Program Manager and Biologist in the Chemistry and Life Sciences Office of the Advanced Technology Program (ATP), an extramural funding arm of NIST, established to accelerate private sector high-risk, high-reward technology development projects. At ATP, he managed projects on stem cells, nanotechnology, immunotherapeutics, cancer vaccines, neurobiology, protein therapeutics, drug discovery, gene therapy, metabolic engineering, and medical devices. Dr. Amos is a leader in the field of autoimmune immunodiagnostics and serves on the Autoimmune Disease Coordinating Committee of the National Institutes of Health. Mike joined CSTL in 2006, and serves as biosciences advisor to NIST, and as a liaison to industry, academia and other government agencies in the bioscience and health care areas. Dr. Amos serves as the Department of Commerce representative on the HHS Secretaries Advisory Committee on Genetic, Health and Society.

MOSTAFA ANALOUI

Mostafa Analoui, Ph.D., is the Senior Director and Site Head for Groton/New London, Global Clinical Technology at Pfizer Global Research and Development in Connecticut. He is also adjunct Professor of Radiology and Oral Pathology, Medicine at Indiana University Schools of Medicine and Dentistry. Dr. Analoui is actively involved in management and development of novel technologies and methodologies to support drug development. Dr. Analoui was previously the Director of Oral and Maxillofacial Imaging Research at Indiana University, and Associate professor of Biomedical Engineering and Electrical & Comp Engineering at Purdue University. In addition to industry leadership in the biomedical field, he lectures nationally and internationally. He has also served on various scientific and business advisory committees. Dr. Analoui has authored more than 120 publications, including journal articles, book chapters and technical reports.

ANTHONY ARUNDEL

A Canadian citizen, Anthony Arundel studied physical geography and biology at Simon Fraser University in Canada, and completed a Masters in the Economics of Innovation at the University of Maastricht. He has been a Senior Researcher at MERIT since 1995. In 2005 MERIT merged with UNU-INTECH to form UNU-MERIT, a joint research institute of the United Nations University and the University of Maastricht. Mr. Arundel is both a Senior Researcher and the Coordinator of the research group *Knowledge and Industrial Dynamics* at UNU-MERIT. While maintaining his position at UNU-MERIT, in February 2007 Mr. Arundel joined the OECD as a Senior Research and Policy Analyst responsible for the Bioeconomy 2030 project within the OECD's International Futures Programme. He is also conducting some of the project research, including an analysis of clinical trial and field test data to estimate the types of biotechnology health and agricultural products that should reach the market between 2012 and 2015.

Mr. Arundel's research and more than 60 publications cover the innovation strategies of firms, knowledge transfer to firms from the public science sector, intellectual property rights, innovation indicators, environmental health, eco-innovation, and biotechnology. The latter includes research on the diffusion of environmental biotechnology, the adoption of genetic engineering and marker assisted selection by seed firms, and the therapeutic value of biopharmaceuticals. He is also active in developing and improving innovation indicators for the European Commission, and in the production of biotechnology metrics for the OECD.

G. STEVEN BURRILL

G. Steven Burrill, CEO of Burrill and Company, has been involved in the growth and prosperity of the biotechnology industry for more than 40 years. An early pioneer, Mr. Burrill is one of the original architects of the industry, and one of its most avid and sustained developers. He currently serves as Chair of the Board of Pharmasset (NASDAQ: VRUS), and is a member of the Boards of Directors of Catalyst Biosciences, DepoMed (NASDAQ: DEPO), Intranasal, Phytomedics, Proteogenix, Proventys, Targacept (NASDAQ: TRGT) and XDx. Prior to founding Burrill & Company in 1994, he spent 28 years with Ernst & Young, directing and coordinating the firm's services to clients in the biotechnology/life sciences/high technology/manufacturing industries worldwide. In 2002, Mr. Burrill was recognized as the biotech investment visionary by the prestigious *Scientific American* magazine (*The Scientific American 50*).

Mr. Burrill is a founder and currently serves as the Chair of the Board of the Foundation for the National Medals of Science and Technology. Additionally, he serves as Chair of the Board on Campaign for Medical Research, as well as Chair of the San Francisco Mayor's Biotech Advisory Committee (MAYBAC). Other not-for-profit activities include serving on the Boards of Directors for the Bay Area Science Infrastructure Consortium, BayBio, California Health Care Institute, The Exploratorium, Genetics Policy Institute, The Kellogg Center for Biotechnology, Kramden Institute, The National Health Museum, and Research! America. He also serves as an advisor at the MIT Center for Biomedical Innovation.

JEROME H. GROSSMAN

Dr. Jerome Grossman's principal activity is as Senior Fellow and the Director of the Health Care Delivery Project. In this position at Harvard, he will be bringing his expertise in the health care system and information technology, and his experience in community services to develop innovations and reforms in the medical care delivery system. He is Chair Emeritus of New England Medical Center, where he served as Chair and CEO from 1979 to 1995 and Professor of Medicine at Tufts University School of Medicine. Currently, he is an Adjunct Professor of Medicine at Tufts University School of Medicine and Honorary Physician at the Massachusetts General Hospital where he served full-time from 1966 to 1979. Dr. Grossman was a member of the founding team of several health care companies, including Meditech, a medical software company, as well as Tufts Associated Health Plan, Chartwell Home Therapies, and Transition Systems, Inc., a medical care information management company.

Named to the Institute of Medicine of the National Academy of Sciences in 1984, he has served as Chair of four committees on issues concerning utilization management and guidelines. More recently he has served on the Committee for Quality of Health Care in America. He was the first IOM member to chair a National Academy of Engineering Committee on the Impact of Academic Research on Industrial Performance, and is now serving as Co-chair of the NAE/IOM Workshop on Engineering and Health Care Delivery Systems. From 1999 to 2005, he was appointed to the National Academies Council on Government-University-Industry Research Roundtable (GUIRR). He became Chair of the President's Circle at the National Academy of Sciences in 2005. Dr. Grossman also served as Scholar-in-Residence at the Institute in 1996. While at New England Medical Center, he founded The Health Institute in 1988, whose work involves research and development programs and practical applications in the area of medical outcome, functional health status, the relationship of doctors and patients, and the relationship of the health status to other non-biologic factors in society-at-large, such as income and education.

He serves as a director/trustee of a number of organizations including: The Mayo Clinic Foundation, Penn Medicine (University of Pennsylvania Medical School and Health System), the Stryker Corporation, Eureka Medical, Inc., and the Committee for Economic Development. His past services include the Board of the Federal Reserve Bank of Boston from 1990 to 1997 serving as chair from 1994 to 1997, Wellesley College and the Massachusetts Institute of Technology. He and his wife Barbara live in Boston, Massachusetts.

MITCHELL K. HIGASHI

Dr. Mitchell Higashi is Senior Director, Health Economics & Outcomes Research in the Global Marketing Organization at GE Health Care. He is responsible for publications and promotional support for the Cardiology and Health Care IT segments. His role is to communicate the clinical and economic benefits of GE Health Care's technology and services. He is based at Research Park in Wauwatosa, Wisconsin. Prior to joining GE, Mitch was the North American Head of Outcomes Research for GlaxoSmithKline, responsible for the cardiovascular and diabetes portfolio. During this time, his team's work on the cost-effectiveness of diabetes medications was featured in the *Wall Street Journal*. He is a co-chair for the International Society of Pharmacoeconomics & Outcomes Research, and serves on the corporate advisory board for the University Of Washington School Of Pharmacy. He is a JAMA published author whose work in molecular diagnostics has been featured on National Public Radio. He is a graduate of the Wharton School (AMP), with a Ph.D. in Pharmaceutical Sciences from the University of Washington.

RAINU KAUSHAL

Rainu Kaushal, M.D., M.P.H., is Assistant Professor of Public Health at the Weill Medical College of Cornell University, and Instructor in Medicine at Harvard Medical School and Staff Physician at Brigham and Women's Hospital, Children's Hospital, and Massachusetts General Hospital. Her research interest is patient safety. Dr. Kaushal has conducted a study assessing rates of medication errors and adverse drug events in hospitalized children in two academic hospitals. She further analyzed these data to determine prevention strategies for serious medication errors. Dr. Kaushal is also analyzing these data to assess patient-specific risk factors for serious medication errors.

Dr. Kaushal directed a study assessing the impact of clinical pharmacists in decreasing serious pediatric medication errors, including a cost-effectiveness analysis. She is also directing a study evaluating the role of electronic prescribing in decreasing serious errors in the neonatal intensive care unit. Dr. Kaushal is principal investigator for three other projects, including an evaluation of ambulatory pediatric medication errors and adverse drug events and prevention strategies in this setting, a cost-effectiveness analysis of computerized physician order entry, and an analysis of federal policy options to improve the adoption of computerized physician order entry. She is also excited to be the principal investigator on a study looking at the present costs and structure of a national health information infrastructure.

ALLAN M. KORN

Allan Korn, M.D., FACP, is Chief Medical Officer and Senior Vice President for Clinical Affairs for the Blue Cross and Blue Shield Association (BCBSA), a national federation of 39 independent, locally operated Blue Cross and Blue Shield companies that collectively provide health care coverage for more than 98 million -- nearly one-in-three of all Americans.

Dr. Korn serves as Medical Director for BCBSA and oversees the Technology Evaluation Center (TEC), an independent, applied health service research organization that uses an evidence-based methodology for the assessment of clinical technologies. He also represents BCBSA with governmental agencies, regulatory bodies and accrediting entities, and oversees the National Council of Physician Executives made up of senior BCBS Plan physicians that advise the Association.

Before joining BCBSA, Dr. Korn served as Vice President and Chief Medical Officer for Blue Cross and Blue Shield of Illinois. From 1994 until 1996, Dr. Korn was Senior Vice President, Medical Affairs for Premier Health Alliance, where he provided strategic direction and product development for risk-adjusted IP and OP clinical data systems. Earlier, he served as a Principal for William M. Mercer, Inc. and as Vice President, Medical Affairs for Health Care Compare/Affordable Health Care Network. From 1976 until 1986, he was an internist at St. Mary's Medical Center in Evansville, Indiana. Dr. Korn received a Bachelor of Science and Medical Degrees from Tufts University. He completed his internship and internal medicine residency at Chicago Wesley Memorial Hospital and at the Mayo Clinic.

Dr. Korn is certified by the American Board of Internal Medicine, is a Fellow of the American College of Physicians and is a member of the American Medical Association. He is a member of the Board of Directors of e-Health Initiative, Bridges to Excellence, is a member of the Hospital Quality Alliance and Ambulatory Care Quality Alliance and sits on the Steering Committees of Prometheus and Connecting for Health. He has served on several Institute of Medicine Roundtables.

BETTIJOYCE B. LIDE

Bettijoyce Lide is Scientific Advisor for Health Information Technology in NIST's Information Technology Laboratory. She serves project lead for the NIST-Department of Health and Human Services (HHS)/Office of the National Coordinator for Health Information Technology (ONC) interagency agreement. In that capacity, she has led a NIST team in support of the broad range of initiatives in ONC that are critical to meet the President's mandates for the majority of Americans to have electronic health records, and for the development of a nationwide health information network by 2014.

Prior to that, Bettijoyce Lide was with the Advanced Technology Program (ATP). Her most recent responsibilities in that program were Program Manager, Competitions Manager, and Group Leader for the Administrative Support Group. As Program Manger, she worked with industry, academia, and other organizations to design and implement the Information Infrastructure for Health Care Program, through which she managed projects of cutting-edge research and organized national workshops to set priorities and share results. As Competitions Manager, Mrs. Lide designed, developed and implemented customer-oriented proposal solicitation and evaluation structures; and served in numerous roles during competitions. As Group Leader, she supervised the Document Control room and staff; and was responsible for the security and workflow of all competition-related documents. Previous responsibilities included helping to establish the policy and operational framework for the ATP when it was initially established, establishing a secure local area network, and designing and developing a database system for ATP records management.

Earlier, Bettijoyce Lide served as Scientist and Programmer, and Group Leader, Data Systems Development Group, Standard Reference Data. She was recognized as a principal authority on the application of computer technology to the storage, analysis, retrieval, and dissemination of evaluated chemical and physical data. She managed and directed the development of computerized databases and software as output from the program; researched, selected, and implemented the purchase and installation of a NIST(NBS)-wide typography system; authored the first scientific database management system to handle chemical and physical data; and, served on national and international committees to foster collaboration in this area.

Mrs. Lide is the recipient of the Department of Commerce Bronze Medal *"for outstanding service in the use of computers in data activities in the Office of Standard Reference Data."* She has twice received the George A. Uriano Award, once *"for leadership and vision in working with the health care industry,"* and again *"for leadership in improving the efficiency and effectiveness of the Advanced Technology Program competition process."*

CONSTANCE A. MORELLA

Ambassador Constance A. Morella was appointed by President George W. Bush to serve as United States Permanent Representative to the Organization for Economic Cooperation and Development (OECD) on July 11, 2003, and unanimously confirmed by the Senate on July 31, 2003. She is the first United States Ambassador to the OECD ever to have served in the United States Congress.

From 1987 until January 2003, Ambassador Morella represented Maryland's 8th Congressional District in the U.S. House of Representatives. Her career in public service began with her appointment to the first-ever Montgomery County, Maryland Commission for Women in 1972. Ambassador Morella was elected to the Maryland General Assembly in 1978 and became the first woman member of the Assembly ever elected to the U.S. Congress. During her sixteen years in the House of Representatives, Ambassador Morella developed a national reputation as a leader in efforts to promote economic growth through science and technology and she was a leading advocate for women, children and families.

In the Congress, Ambassador Morella served as a senior member of the House Committee on Science and chaired one of its key panels, the Subcommittee on Technology, from 1995 until 2000. In this role, she spearheaded the enactment of landmark legislation to promote technology transfer from federal labs to private industry, and she was a key supporter of biotechnology and advanced scientific research. Ambassador Morella was also a longtime member of the Committee on Government Reform, on which she chaired the Subcommittee on the District of Columbia and served as a senior member of the Subcommittee on Civil Service. She also served as a member of the House Select Committee on Aging.

A strong supporter of economic growth through free trade, Ambassador Morella was in the forefront in the Congress on matters of trade and foreign policy. She advocated liberalized trade rules and heightened international engagement. As Chair of the Congressional Caucus for Women's Issues, she advanced efforts to promote access to micro-enterprise capital among women in developing countries. For her many efforts, Ambassador Morella has received numerous awards and recognitions. She was inducted into the Maryland Women's Hall of Fame, was named "Washingtonian of the Year" by *Washingtonian* magazine, and received a wide range of honors, including outstanding Public Service Awards from the American Medical Association, the American Bar Association, and the prestigious Hubert H. Humphrey Civil Rights Award from the Leadership Conference on Civil Rights "*for selfless and devoted service in the cause of equality.*"

Prior to her service in the U.S. Congress and the Maryland Legislature, Ambassador Morella was a Professor of English at Montgomery College in Rockville, Maryland. She also served as a Visiting Fellow at Harvard's Kennedy School of Government. Ambassador Morella holds an A.B. from Boston University, an M.A. from American University, and 10 honorary doctoral degrees.

PETER M. NEUPERT

As corporate vice president for the Health Solutions Group at Microsoft Corp., Peter Neupert is responsible for Microsoft's collaboration with the health care ecosystem to address global infrastructure issues of significant scale. Under his strategic direction, the Health Solutions Group is developing applications and solutions for clinical and business requirements of health care professionals in the enterprise, and which enable improved personal health management for consumers.

Before rejoining Microsoft, Neupert served as president and chief executive officer of Drugstore.com Inc. from July 1998 to April 2001, and then as chair of the board of directors from July 1999 to September 2004. Neupert led Drugstore.com to become a top online retail store and information site for health, wellness, and beauty, and pharmacy products. Neupert served in various capacities at Microsoft from 1987 to 1998. He started at Microsoft as the director of operating systems responsible for shipping OS/2, and later was responsible for MSNBC as vice president of News and Publishing for the interactive media group. Neupert served on President Bush's Information Technology Advisory Committee (PITAC) from 2003 to 2005. On that committee, he co-chaired the Health Information Technology subcommittee and helped drive the report *Revolutionizing Health Care through Information Technology*, published in June 2004 by PITAC. In 2000, Neupert received an Ernst & Young Entrepreneur of the Year award for his work at Drugstore.com. He is an active member of the Institute of Medicine's Roundtable on Evidence-Based Medicine and sits on the Pacific Health Summit Advisory Board, as well as the boards of infiLearn.com and Cranium, Inc. Neupert holds a master's degree in business administration from the Tuck School of Business at Dartmouth College and a bachelor's degree from Colorado College.

MICHAEL J. ROZEN

Michael J. Rozen, MD, Orthopaedic Surgeon, graduated from The Ohio State University College of Medicine, took his surgical training at The Strong Memorial Hospital at The University of Rochester, and completed his Orthopaedic residency at The University of Cincinnati. Board certified and a fellow in The American Academy of Orthopaedic Surgeons, he was president of Reconstructive Orthopaedics and engaged in private practice from 1974 through 1996. During this period he founded the Center for Spinal Deformity at The Children's Hospital of Cincinnati, was instrumental in implementing the statewide school screening program for spinal deformity, was Director of Orthopaedics at a major metropolitan hospital, and was a member of various quality assurance committees, including The Quality Assurance Committee of the State of Ohio Bureau of Workers Compensation. He was founder of Ohio Comp, a worker compensation management system, and co-founder of Recorth, which provided Independent Disability Evaluations. For five years, he was chair of Tri-State Health Decision Resources; a community based health care reform initiative and a founding board member of The Center for Health Ethics. During that time he also held leadership positions in Cincinnati community workgroup for health care connectivity, the Tri-State Community Health Status Project and the Outcomes Management Taskforce. He was also on the board of the Ohio Corporation for Health Information, a statewide effort to electronically link the public and private health care sector. His past business experience includes participation in the boards of many companies including Jacor Communications. He was Chief Privacy Officer and Vice President for Consumer Affairs at WellMed, Inc. and has frequently spoken and authored on Privacy, Security and Confidentiality of health information and ethical issues surrounding consumer health records. He was also President of the National Emergency Health Data Center and a member of Leadership Cincinnati.

Dr Rozen has served as President and Chair of Hi Ethics and is one of the founders of the eHealth Initiative. He is a past board member of URAC and numerous other health advisory boards including The HIPAA Short Notice Workgroup, the Health Care Security Certification and Accreditation Taskforce and the editorial board of In-Confidence. He is immediate past Chair of the Chair of The Medical Technology Policy Committee of IEEE-USA and Vice Chair of the Technology Policy Committee of IEEE-USA with special focus on eHealth issues.

In addition to his work on health care privacy and security issues, Dr. Rozen is very interested in the incorporation of information and communication technologies into health care delivery and in using quality metrics for benchmarking evidence-based medicine for promulgating best health care practices. He is passionate in promoting patient-centric health care and the adoption of biomedical technologies to enhance health care delivery.

MARCEL E. SALIVE

Marcel E. Salive, MD, MPH, FACPM is Director of the Division of Medical and Surgical Services within the Coverage and Analysis Group of the Centers for Medicare & Medicaid Services (CMS). The Division is responsible for developing and maintaining national coverage decisions for Medicare, in broad fields of medicine and surgery, using a rigorous and open evidence-based process. The work involves searching for evidence, evaluating it, synthesizing and developing a coverage recommendation. Previously, Capt. Salive served as a Medical Officer at NIH, 1999-2003, where he managed large prevention clinical trials. From 1996 through late 1999, he managed the Epidemiology Branch, an intramural product safety research program in the Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER). He is board certified in general preventive medicine & public health and received his training in the specialty at Johns Hopkins University.

MARC G. STANLEY

Marc Stanley currently serves as Director of the Advanced Technology (ATP), at the National Institute of Standards and Technology (NIST). Mr. Stanley served as the Associate Director for the Program from 1993 to 2001.

Before coming to NIST, Mr. Stanley was the Associate Deputy Secretary of the U.S. Department of Commerce by Presidential appointment. He has served as a senior policy advisor to NIST Directors, as a consultant to the Department Commerce's Technology Administration, and as Assistant Secretary for Congressional and Intergovernmental Affairs at the Department of Commerce. Mr. Stanley earned a B.A. from George Washington University and a Bachelor of Law degree from the University of Baltimore.

GREGORY C. TASSEY

Gregory Tassez is Senior Economist for the National Institute of Standards and Technology. His major fields of research are the economics of high-tech industries, strategic planning and economic impact analysis, and technology-based economic growth policies. Dr. Tassez has a B.A. in physics from McDaniel College and a Ph.D. in economics from The George Washington University. He has published over 30 articles in policy and economics journals, and written four books, including *The Economics of R&D Policy* and, most recently, *The Technology Imperative*.

JAMES M. TURNER

Dr. James M. Turner is the Acting Director and Deputy Director of the U.S. Department of Commerce's National Institute of Standards and Technology (NIST). As Deputy Director, Turner manages NIST's daily operations and assists in setting strategic directions. The agency promotes U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology. NIST has an operating budget of about \$843 million and employs about 2,900 scientists, engineers, technicians, support staff and administrative personnel at two main locations in Gaithersburg, MD, and Boulder, Colorado. Along with the Department of Energy Office of Science, and the National Science Foundation, NIST is slated for substantial budget increases for its core research programs under the President's American Competitiveness Initiative.

Prior to joining NIST on April 16, 2007, Dr. Turner served as the Assistant Deputy Administrator for Nuclear Risk Reduction in the Department of Energy's National Nuclear Security Administration. In that position, he was responsible for major projects in Russia to permanently shutdown their last three weapons-grade plutonium-production reactors. He also worked with foreign governments and international agencies to reduce the consequences of nuclear accidents by strengthening their capability to respond to nuclear emergencies. Prior to that assignment, Dr. Turner held several senior management posts at DOE concerned with laboratory oversight and with nuclear safety and the safeguarding of nuclear weapons both here and abroad.

He holds degrees in Physics from the Massachusetts Institute of Technology (Ph.D.) and Johns Hopkins University (B.A.), and taught for five years as an Associate Professor of Physics and Engineering at Morehouse College. Among other honors, he has received the U.S. Government Presidential Rank Award for Meritorious Service, three times received the U.S. Department of Energy Exceptional Service Award, and earned the Secretary of Energy Gold Award and the National Nuclear Security Administration's Gold Medal. Dr. Turner is an active member of the American Physical Society, the American Chemical Society, the American Nuclear Society, the American Association for the Advancement of Science, the Council on Foreign Relations, and the World Affairs Council.

Dr. Turner is a native of Washington, D.C., is married, and has five children and one grandchild. He enjoys doing yoga and Tai Chi. He and his wife, Paulette, reside in Olney, Maryland.

VIVJAY V. VAITHEESWARAN

Vijay Vaitheeswaran a global correspondent for *The Economist*. He joined the magazine's staff as the London-based Latin America Correspondent in 1992. Two years later, he opened its first bureau in that region in Mexico City. He wrote about political, financial and cultural developments in that part of the world until 1997, when he returned to the editorial headquarters in London. As the newspaper's Global Environment & Energy Correspondent, he covered the politics, economics, business and technology involved in those topics from 1998 to 2006. Vijay is a term member of the Council on Foreign Relations. He has lectured at Stanford, Yale and Oxford, and is an adjunct faculty member at New York University. He is a commentator on NPR and Marketplace radio, and a regular guest on the BBC, PBS's NewsHour, ABC's Nightline and other television programs. He is also the author of a book on the future of energy, *POWER TO THE PEOPLE: How the Coming Energy Revolution will Transform an Industry, Change our Lives, and Maybe Even Save the Planet* (www.vijaytothepeople.com). Harvard's John Holdren, reviewing the book in *Scientific American*, called it "by far the most helpful, entertaining, up-to-date and accessible treatment of the energy-economy-environment *problematique* available." Vijay holds a degree in mechanical engineering from the Massachusetts Institute of Technology. He lives in New York.

DAVID L. WHITLINGER

David Whitlinger serves as the director of Health Care Device Standards and Interoperability for the Intel Corporation in its Digital Health Group. Mr. Whitlinger is responsible for Intel's health care device interoperability strategies and the standards development to support those strategies. He is currently leading a large, cross-industry consortium, the Continua Health Alliance, focused on establishing an eco-system of interoperable, personal telehealth systems. Mr. Whitlinger has been with Intel since 1993, and prior to establishing the Health Care Device Standards Group, he worked on a wide variety of wireless standards. As a result, Mr. Whitlinger and his team are leaders in many standards organizations throughout the world, including: Health Level Seven (HL7); Integrating the Health Care Enterprise (IHE); IEEE 1073; Bluetooth SIG; WiMedia Alliance; Homeplug Alliance; UPnP Forum; Oasis; WSI; and, the Digital Living Network Alliance (DLNA). He also served on the Bluetooth SIG Board of Directors for several years. Mr. Whitlinger is the author of five research journal articles, four of which focused on breast cancer DNA analysis. Mr. Whitlinger was awarded a degree in Computer Engineering from the University of New Mexico.

JANET WOODCOCK

Janet Woodcock, MD is the Deputy Commissioner for Operations of the FDA. She is responsible for overseeing Agency operations and cross-cutting regulatory and scientific processes at FDA. Dr. Woodcock served as Director, Center for Drug Evaluation and Research at FDA 1994-2005. She previously served in other positions at FDA including Director, Office of Therapeutics Research and Review and Acting Deputy Director, Center for Biologics Evaluation and Research. Dr. Woodcock received her M.D. from Northwestern Medical School, and completed further training and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

PATRICK Y. YANG

Patrick Yang is Executive Vice President, Product Operations at Genentech. In this role, he is responsible for Genentech's Process Development, Engineering, Manufacturing, Facilities, Supply Chain Management, and Manufacturing Collaboration functions. Yang is a member of Genentech's executive committee. Yang joined Genentech in 2003 as vice president, South San Francisco Manufacturing and Engineering, and most recently served as senior vice president, Product Operations. Prior to joining Genentech, Yang spent 11 years at Merck & Company in various leadership positions. Most recently, he held the position of vice president, Supply Chain Management, in Merck's Manufacturing Division. In this role, he led the worldwide materials management, planning, global procurement, distribution/logistics, management engineering, third party manufacturing, automation and manufacturing support functions for Merck's manufacturing plants around the globe. Previous to that position, he was Merck's Vice President, Asia/Pacific Manufacturing Operations. Yang was promoted to Senior Vice President, Product Operations in December 2004. In January 2006, Yang was promoted to Executive Vice President.

Prior to joining Merck in 1992, Yang spent 12 years at General Electric, serving in several research, engineering, technology and manufacturing leadership roles with increasing scope of responsibilities. Before working for General Electric, Yang spent five years in aerospace control systems research and development with Life Systems, Inc. Yang holds a Bachelor of Science from the National Chiaotung University in Taiwan, a Master of Science in Electrical Engineering from the University of Cincinnati, and a doctorate in Electrical Engineering and Computer Science from Ohio State University.