science progress

Paving the Way for Personalized Medicine

Facilitating Inter-Agency Coordination for the Integration of Personalized Medicine into Our Health Care System

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Introduction

Much Promise and Many Questions

There are promising developments heralding the arrival of personalized medicine, a new medical field where the results of genetic tests or other biomarker assessments are used to tailor drugs and treatments to individual patients. A year ago, for example, the Food and Drug Administration approved maraviroc, the first drug designed specifically for HIV patients who have a particular genetic mutation of the virus. This was the first time a drug had been approved upon the condition that patients first have a genetic test.[1] Similarly, in July scientists at the Van Andel Research Institute published a paper reporting that high expression of the gene known as MET increases the aggressiveness of certain types of breast cancer. This means that the MET gene can be used as a target for new cancer therapies that may inhibit MET's expression, thereby slowing down the most aggressive forms of breast cancer.[2]

In spite of this kind of progress on the scientific front, Americans today remain guinea pigs in a "one-size-fits-all" approach to medicine in which clinical trials to test the safety and efficacy of new drugs do not take into account the influence of individual genes on individual health and wellness. In contrast, a personalized medicine approach may well allow (perhaps in the not too distant future) every individual patient to receive the best in tailor-made, evidence-based pharmocogenomic medicine.

Similarly, research, development, and clinical care in our health care system merely ensure that medical treatments will work for most of the population most of the time. In fact, most drugs prescribed today only work in 60 percent of patients or less.[3] Personalized medicine promises that treatments will be tailored to individuals by researching the effects of specifically tailored treatments on genetic subpopulations. Since one size does not fit all, personalized medicine will represent a marked improvement over the current system where patients are left to travel down a winding path of physician-led trial and error.

Compounding the unwieldiness of today's haphazard clinical approach is the disjointed health care informatics system that prevents scientists and physicians from making the most of our

nation's personalized genomics research data. Our impersonal and uncoordinated approach to care costs lives and squanders billions of dollars that could go towards insuring the 45 million Americans who are without coverage while also bringing down costs.[4]

In short, we are awash in evidence that not all individuals will respond similarly to the same medical treatment. But we have not taken the steps to integrate personalized medicine fully into our health care system in order to benefit individuals and society alike.

Granted, there is still a lot we don't know, especially when it comes to genetics. Most of the genes that have been discovered only have small effects from a diagnostic perspective.[5] But, the bigger question is how can scientists who are eager to expedite the integration of personalized medicine into clinical practice efficiently gather and disseminate their discoveries? It is because of this question that we should look at personalized medicine as contributing to the ultimate goal of turning medical practice into a total learning environment. This means physicians would be able to apply the most recent findings about the efficacy of available treatments while also sharing the outcomes of their own treatment decisions with others so that all physicians can have better data the next time around. This information will also be available to academic scientists and industry researchers so that they can gear their research and product development in more patient-specific directions.

Of course, given the private interests of all the various stakeholders involved, it should be no surprise that bringing about the era of personalized medicine will be no easy task. Many lingering legal, political, and administrative questions remain about patient privacy and about the ownership, organization, and security of the data. And those are just the tip of the iceberg when one considers the vast technical difficulties that computer programmers and health technologists are trying to overcome.

In April, at the Bio-IT World Conference and Exposition in Boston, for example, Microsoft Corp. announced the coming release of Amalga Life Sciences, which promises to be a single platform for aggregating and modeling data from "basic research, clinical trials, health care delivery, and consumer health information needs."[6] Amalga will also be linked to Microsoft HealthVault so that patients can import their medical data generated at the hospital into their own personal health file.[7] This is an ambitious project that will need to be watched closely in action to see if it enhances or limits the ability of physicians, researchers, and patients to access the information they need in a way that is useful, understandable, and comfortable for them.

For now, though, the bottom line is that there definitely needs to be a strong public debate about what health information is going to look like and what it is going to do. The most promising way to begin this debate is to not get bogged down in the technical questions just yet. Instead, this is a ripe time for taking stock in what values should guide our vision of personalized medicine; what tools we already have available to bring it about; and how responsibilities should be divided up or combined by public and private stakeholders.

Some federal government entities have already started taking steps to answer these questions by moving ahead with initiatives that better streamline the data, technology, and research efforts that are already available. The National Institutes of Health, for example, announced in February that it is moving forward on a clinical trial that will test the effectiveness of integrating genetic data into the dosing protocol for the blood-thinning drug warfarin. This happened just weeks after then-acting Director of the Food and Drug Administration Frank Torti announced that the

WHAT IS PERSONALIZED MEDICINE AND WHAT'S SO GREAT ABOUT IT?

Personalized Medicine is a phrase that many would find redundant. Physicians have always strived to personalize their patients' care by taking into account as many relevant factors as possible. From this, physicians can develop a unique profile of their patients and give them the individual care that they need. No two patients are the same, but that does not mean each patient exists in a complete vacuum. Commonalities exist across patient populations and evidence needs to be gathered in order to find reliable, consistent patterns about human health.

Physicians attempt to apply their knowledge of these evidence-based patterns to an individual patient through personal one-on-one interaction. In this way, medicine is both a science and an art—it always has been and always will be. No matter how much closer we come to making medicine into a pure science, nothing will ever replace the sound judgment that a physician can only develop through years of personal experience with patients.

Nevertheless, we cannot deny that modern science—no matter how intimidating it might be for some of us—has enhanced human welfare beyond anything earlier physicians could have imagined. Far from turning doctors into automatons, today's promise is that new scientific advances in genetics, genomics, diagnostics, and treatments will one day provide doctors with a more sophisticated array of tools and techniques with which to practice their art.

Indeed, we must not look at these new scientific advances as a way of replacing the art of medicine with more science but as a way of more deeply intertwining science and art. The science will be more personal and the art will be more consistent.

The good news is that we are already on our way to this modern age of personalized medicine. Most of the scientists, physicians, and policymakers who are preparing America's biomedical infrastructure for personalized medicine define it as "the right treatment, for the right patient, at the right time." Again, this is something medicine has always tried to achieve, but today it involves emerging technologies that will one day give scientists, treatment-makers, and caregivers the ability to zero-in on highly specific biological factors.

One area where personalized medicine will be able to provide the most benefits to patients as well as to the health care system overall is in the management of diseases that tend to be chronic in nature such as diabetes, heart disease, Alzheimer's, and cancer. These diseases manifest themselves through a complex interplay of genes and environment. They are also extraordinarily expensive to manage, comprising more than 75 percent of our nation's healthcare costs.[1]

Hopefully, by utilizing the tools of personalized medicine, we can one day manage the detection, classification, and treatment of these diseases in a way that is preventative, specific, reliable, and efficient. This will not only improve patient well-being, it will also reduce the financial burden on patients and the healthcare system.

The major technological tool that will contribute to this new kind of medicine is genomics, the study of an individual's entire genome. But it is not just DNA that will tell physicians which diseases a patient is at risk for and which treatments will work best for a patient. There are other factors such as RNA, proteins, and metabolites that also reveal this information. Collectively these factors are called "molecular biomarkers" and they are more precise than the larger and more obvious symptoms that physicians currently use to diagnose and treat illnesses.

Molecular biomarkers will allow physicians to better classify different diseases and different manifestations of diseases. This stands in stark contrast to today where Americans are left to travel down a winding path of physician-led trial and error. Personalized medicine will help physicians to make better treatment decisions, which will reduce adverse drug reactions and reduce the amount of time it takes to find the ideal treatment.

But personalized medicine requires more than just physicians taking a different approach. Information about molecular biomarkers will need to be disseminated by researchers in a standardized way that physicians will find useful. Medical schools will need to train physicians to obtain, interpret, and utilize this information in a clinical setting. Biomarker tests will need to be better regulated. And the manufacturers of medical treatments will need to develop their products in a targeted fashion based on our knowledge of biomarkers.

Overall, personalized medicine should thus be anticipatory and preventative. And even though there are signs of technological promise today, we still have a long way to go with the implementation. This will require that America's biomedical enterprise become a total learning environment.

In a total learning environment, not only will physicians be able to apply the most recent findings about available treatments, they will also be able to record the real-world outcomes of those treatments so that researchers can then update the findings. This information will also be available to medical scientists so that they can gear their research and product development in more patient-specific directions. The hope is that everyone involved will make better decisions as the information gets better and better. Thus, the system keeps learning.

But many issues still remain up in the air and there are many large moving pieces of America's biomedical enterprise that need to get on the same page. Only then can we fully realize the promise of personalized medicine within a total learning environment.

1 Centers for Disease Control and Prevention, "Chronic Disease Overview" available at http://www.cdc.gov/NCCdphp/overview.htm

FDA created a new position in the Office of the Chief Scientist called Senior Genomics Advisor. This office has been filled by FDA veteran Dr. Liz Mansfield, whose job will be to provide "FDA physicians and scientists with tools and personnel capable of high-level analysis of complex genetic data."[8]

Taking a broader view, the Personalized Healthcare Initiative in the Department of Health and Human Service's Office of the Assistant Secretary for Planning and Evaluation has conducted reviews of current federal efforts in order to identify organizational challenges to achieving overarching goals. This PHC initiative highlights the need for connecting clinical records with genomic information, ensuring the integrity and privacy of genetic data, preventing discrimination, ensuring the accuracy and validity of genetic tests, and devising common access protocols for genomic databases.

The PHC initiative also highlights various tasks for many government agencies and programs to ensure that that they do their part to achieve these goals for the ethical and coordinated advancement of personalized healthcare. Some of these tasks include directing other agencies in Health and Human Services to devise ways for sharing their data so that the genomic, clinical, and public health aspects of personalized medicine can mutually reinforce one another rather than remain siloed and even redundant in their research and analyses. The PHC initiative also includes in its review the ethical analyses published by the HHS Secretary's Advisory Committee for Genetics, Health, and Society, or SACGHS, on large-population genetic studies and the bureaucratic logistics of pharmacogenomic research.[9]

Other principled concerns about personalized medicine have also been addressed in general terms through SACGHS, a permanent group that advises the secretary on, among other things, personalized medicine and occasionally releases reports on the issues at hand.[10] Yet the fine practical details of these concerns still need to be hashed out by multiple collaborators on a case-by-case basis.

These concerns have to do with the inclusion of private entities in data-sharing about the validity, utility, and effectiveness of various technologies. What should private biotech companies, pharmaceutical companies, or diagnostic companies be required to share with the federal government? A recent SACGHS report recommends:

> *In situations where tests are essential to clinical drug use, HHS should require its grantees and contractors to participate in FDA's Voluntary Genomic Data Submission Program during the exploratory phase of drug development and/or the review process for preinvestigational device exemption.*[11]

This FDA program is overseen by a body known as the Interdisciplinary Pharmacogenomics Review Group, which was charged in 2005 with collecting phramacogenomic data about drugs in the developmental stage. This program has made regulators more cognizant of genomics, has influenced discussions on clinical trial design, and has even led to the development of a pilot process for qualification of biomarkers for use in regulatory decisions.[12]

From the standpoint of trying to better integrate pharmacogenomic data into the drug development process, this is a great idea. And personalized medicine would advance even more rapidly if pharmaceutical companies could cost-effectively collect information from large-cohort genetic studies and use that information to design better-targeted and more information-rich

clinical trials. But companies are reluctant to invest more money in doing their own large-population-based genetic studies that may or may not help them to make a better product let alone recoup their investment.

So who pays for these large-population genetic studies? Usually, it is the NIH. But how can NIH orient its genetic research toward personalizing the drugs that the private sector is developing? SACGHS recommends that the recipients of NIH grants for research that "will be used to demonstrate safety and efficacy to support a [drug or device's] premarket review application" to the FDA should consult with FDA "early in the study design phase."[13] Again, this is a practical idea but there needs to be a concerted effort on the part of HHS to make this cooperation materialize on a case-by-case basis.

As pharmacogenomic research develops methodologically and as further evidence is gathered about the application of pharmacogenomic technologies in clinical practice, the policies and protocols for public/private collaboration will need to develop as well. For instance, the SACGHS report makes recommendations about stratifying subject populations based on their predispositions to adverse reactions as indicated by their biomarkers. These recommendations include having the FDA guide the collection of genetic and biological factors that are better predictors of drug responses than race, ethnicity, or gender; and having post-market follow up to find other biological, social, or environmental factors that influence drug response when there is a racial or ethnic disparity in drug response.[14]

Other examples include the plethora of recommendations that SACGHS makes concerning the increasingly controversial areas of insurance coverage and reimbursement, clinical practice guidelines, professional certification, and drug labeling.[15] What we know so far is that these are all relevant issues that can be dealt with by means of better coordination throughout the entire healthcare system.

Researchers need to be informed of all the relevant data collection initiatives. Regulators need to be better aware of the technologies that are coming down the pike. Corporations need to engage in partnerships with the public sector in order to share data for the public good and develop more personalized drugs. And, the FDA needs to encourage drug and device companies to do post-market follow up and coordinate it with the development of new products.

There also needs to be coordination between the genetic test manufacturers, the drug manufacturers, and the health care providers who need to gather evidence for them as they implement tests and therapies in the clinic. The problem, however, is that we do not have sufficient knowledge—both in terms of biomedical data and real-world policy experience—to set in stone any policies for systemic coordination on personalized medicine just yet.[16] Therefore, the best course of action for the time being is for HHS to emphasize better coordination in general, and to guide various coordinated projects by holding them accountable to the broad goals and values put forth in the SACGHS reports and in the work done by the PHC initiative.

This might be a job for HHS's Office of the Assistant Secretary for Planning and Evaluation, which could:

- Consult with various agencies, programs, and private entities
- Suggest opportunities for collaboration
- Help to iron the terms on which these entities do collaborate

As various personalized medicine initiatives are implemented, HHS can then look at the protocols and policies that do and do not work in terms of data sharing, research coordination, or product development.

This would create an iterative self-correcting process that would allow us to gather more data on personal genomics and conduct more research into the implementation of personalized medicine. Thus, the United States will rapidly build a knowledge base for the future of personalized medicine while it still takes the time to learn how to develop the right policies for shaping that future.

Indeed, all of the initiatives described above are promising steps toward the development of personalized medicine as a new paradigm for medical practice. Nevertheless, the United States still has a long way to go before personalized genomics becomes a standard part of medical practice. Implementation and evaluation must proceed aggressively in tandem in order for us to not only achieve a personalized medicine revolution speedily, but also achieve it efficiently and ethically. This is the essence of progressive innovation and pragmatic policy making. For personalized medicine to fully come to fruition with the fewest number of bumps in the road, we must learn valuable lessons from the current piece-by-piece process as we ramp up our efforts to build upon it.

Where We Stand with the Current Infrastructure

There already exist multiple agencies, offices, and protocols for gathering data on personalized medicine, analyzing it, devising regulations from it, and even putting it into practice. With the right coordination, these federal bodies could better compile and assess genomic data and use it to educate physicians or create clinical guidelines. Physicians could then put these guidelines into clinical practice by diagnosing, treating, and evaluating patients with increasing specificity.

Unfortunately, there are still many holes in the system as most of these endeavors remain inefficiently isolated. For instance, scientists from an National Institutes of Health-organized research consortium called the eMerge Network are devising a nomenclature that can link genome-wide association studies with electronic health records but so far has not collaborated with Health and Human Services's Health IT Standards Committee, or HITSC, which "is charged with making recommendations to the national coordinator for health information technology on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information." [17,18] This is tragic since the right kind of collaboration between the eMerge Network and HITSC could give rise to a robust and efficient personalized health care infrastructure across both the biomedical research and health care administrator communities.[19]

As the United States embarks on new health care reform efforts, it must be mindful of how it can eventually incorporate a new personalized medicine approach. In order for American healthcare to truly be innovative, our myriad unconnected research efforts need to be better organized and coordinated. Indeed, we have already made some great progress as innovative scientists and administrators have instituted various networks, offices, and initiatives that move us toward a personalized medicine paradigm.

The ultimate goal for any reformed health care system must be to better organize biomedical data so that caregivers have the resources and information to provide the most effective treatments to the individual patient. This is a bold objective, but given the progress of genomics and proteomics research today, it is also a very necessary objective.

Fortunately, ideas for better organizing personalized medicine research already exist due to the work of the Department of Health and Human Services' Personalized Health Care Initiative.[20] The PHC initiative's major goal was to devise ways to leverage advances in genetic research in order to improve individual clinical care.[21] It has done good work so far, but the time has come to decide how to build upon that work in order to institute more sustained coordination of this valuable research.

The Genomics and Personalized Medicine Acts of 2007 and 2008, (S. 976) and (H.R. 6498) respectively, both provide the framework for the establishment of a Personalized Medicine Interagency Working Group.[22, 23] This group would include the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, and other groups outside of the Department of Health and Human Services. Since the 2007 bill was sponsored by then-Senator Barack Obama of Illinois, it might now be possible for the president and the HHS secretary to better facilitate the development of personalized medicine research and application through a similar arrangement. Of course, it does not necessarily need to be exactly the same as the working group described in the legislation.

A robust set of major principles, goals, and guidelines can be speedily devised from the work of the PHC initiative as well as from the Secretary's Advisory Committee for Genetics, Health, and Society, or SACGHS, report on pharmacogenomics. But HHS might still want to dedicate some funds and personnel for this purpose since the six members from the PHC, who are already well versed in these issues, are employed and paid by a variety of HHS offices.

Granted, the mandate of the PHC initiative was simply to examine "the challenges and opportunities of personalized health care" from different viewpoints and compile reports, but the time has come to couple examination with facilitation. Few if any new positions are inherently necessary for the PHC initiative itself to act on its findings—it has the knowledge and expertise—yet it is essential for the initiative to be adequately funded and given the proper authority in order to sufficiently facilitate the development of personalized medicine and make recommendations to the various stakeholders.

The bottom line is that regardless of whether we end up with a reincarnated PHC initiative, there must be some form of authoritative guidance and facilitation from the top levels of HHS—preferably from the Office of the Assistant Secretary for Planning and Evaluation or even the Office of Biotechnology Activities. The duty of this authoritative group should be to get these isolated research projects to communicate with each other and better organize their efforts as more is learned about the research and practice of personalized medicine.

Further on down the road, HHS Secretary Kathleen Sebelius may need to grant this authoritative group administrative authority and contracting capabilities to develop and enact an interagency action plan. This may require Congress to pass legislation since some of the authority is statutory. Secretary Sebelius may also need to establish new agency regulations through the federal rulemaking process.

If, however, HHS stays on automatic pilot, all that will happen on the personalized medicine front is more behemoth reports. But instead of coming from the PHC initiative group, these reports will most likely come from SACGHS. These two groups have already done excellent and comprehensive work on multiple pieces of the personalized health care puzzle, but they are not charged with implementing policy changes.

FEDERAL AGENCIES NOW INVOLVED IN PERSONALIZED MEDICINE

An almost incomprehensible alphabet soup of federal agencies, advisory committees, and interagency working groups and initiatives are now involved in developing guidelines and standards for the new personalized medicine field. Not surprisingly, they are not working together in any real coordinated way. Bringing these efforts under one overarching roof should be the Obama administration's objective, as we explain in the main body of this report, but understanding what each of these groups does is important to understanding how to change the process.

Food and Drug Administration

The FDA boasts two key initiatives under its agency umbrella, both of which we argue in the main column should be central to any reform effort. They are the:

Interdisciplinary Pharmacogenomics Review Group

IPRG is charged with establishing a scientific and regulatory framework for reviewing genomic data. It is an agency-wide review group that acts as the primary review body for Voluntary Exploratory Data Submissions, or VXDS—formerly Voluntary Genomic Data Submissions, or VGDS.

Center for Drug Evaluation and Research

This is the FDA's branch that oversees clinical trials and drug development. It issued a white paper in 2004 about the potential for pharmacogenomic research and how it plans to incorporate pharmacogenomic evidence into the regulatory process.

Critical Path Initiative

The Critical Path Initiative is FDA's effort to stimulate and facilitate a national effort to modernize the scientific process through which a potential human drug, biological product, or medical device is transformed from a discovery or "proof of concept" into a medical product.

National Institutes of Health

NIH has two key groups who play a role in developing policy for personalized medicine. Their ambits range over basic research guidelines, ethics and protocol standards.

Office of Biotechnology Activities

This office convenes advisory and ethics panels which issue safety, ethical, technical, and administrative guidelines for NIH-funded research. It aims to develop sound policies and increase public understanding.

Secretary's Advisory Committee on Genetics, Health, and Society

SACGHS is one of the Office of Biotechnology Activities' advisory committees. It issues ethics and safety recommendations on genetic research, genetic testing, and the application of genetic technologies in the public health and clinical practice settings.

National Institute of General Medical Sciences

NIGMS presides over key patches of medical research. It has two networks that are directly engaged in personalized medicine policy.

Pharmacogenomics Research Network

PGRN is a group of 12 independently-funded interactive research groups, each with its own focus in an identified area of pharmacogenomic research. The goal of this network is to build a knowledge base of data on how variation in human genes relate to drug responses.

PharmGKB

This is the Pharmacogenomics Knowledge Base built by PGRN. It "contains both raw and curated information" and "presents data and information accumulated in the field and contributed by researchers both within and beyond the network."

Electronic Medical Records and Genomics Network

The eMERGE Network is a national consortium formed to develop, disseminate, and apply approaches to research that combine DNA biorepositories with electronic medical record (EMR) systems for large-scale, high-throughput genetic research.

Center for Disease Control and Prevention

The CDC has two projects involved in personalized medicine research and oversight, one examining genomics practices in general and the other specifically focused on the environmental aspects of genomics.

Evaluation of Genomic Applications in Practice and Prevention

EGAPP is a pilot project initiated by the CDC Office of Public Health Genomics. The project's goal is to establish and evaluate a systematic, evidence-based process for assessing genetic tests and other applications of genomic technology in transition from research to clinical and public health practice.

FEDERAL AGENCIES NOW INVOLVED IN PERSONALIZED MEDICINE *(continued)*

Human Genome Epidemiology Network

HuGENet is a project aimed at incorporating phramacogenomics into the practice of public health by assessing the impact of environmental factors on the genetic variations present in large populations. It is a global collaboration of individuals and organizations committed to the assessment of the human genome variation's impact on population health and how genetic information can be used to improve health and prevent disease.

Centers for Medicare and Medicaid Studies

CMS is involved in personalized medicine through its role in Medicare. Its Council on Technology and Innovation specifically oversees CMS's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies between CMS and other entities.

Medicare Evidence Development and Coverage Advisory Committee

MEDCAC provides independent guidance and expert advice to CMS on specific clinical topics. It is intended to supplement CMS's internal expertise and to allow an unbiased and current deliberation of "state of the art" technology and science. The MEDCAC reviews and evaluates medical literature, technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered under Medicare, or that may be eligible for coverage under Medicare. The MEDCAC judges the strength of the available evidence and makes recommendations to CMS based on that evidence.

MEDCAC held a meeting on February 25 to advise CMS on "the desirable characteristics of evidence that could be used by the Medicare program to determine whether genetic testing as a laboratory diagnostic service improves health outcomes." At this meeting AHRQ presented an assessment of three groups of genetic tests: those tests detecting genes related to warfarin response, statin response, and methotrexate metabolism. The CDC's EGAPP program also presented findings. Finally, a group of professional associations, labs, and private companies gave five-minute presentations sharing their perspectives.

American Medical Association*

The AMA oversees medical nomenclature critical to any field of medicine as it enters the marketplace. The AMA would be involved with personalized medicine through its Current Procedural Terminology codes. CPT codes are: "the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. CPT is maintained by the CPT Editorial Panel, which meets three times a year to discuss issues associated with new and emerging technologies as well as difficulties encountered with procedures and services and their relation to CPT codes."

Agency for Healthcare Research and Quality

AHRQ is a unit of the Department of Health and Human Services dedicated to advancing excellence in health care. The unit has two programs dedicated wholly or in part to personalized medicine.

Evidence-based Practice Centers

EPCs review all relevant scientific literature on clinical, behavioral, and organization and financing topics to produce evidence reports and technology assessments. These reports are used for informing and developing coverage decisions, quality measures, educational materials and tools, guidelines, and research agendas. EPCs also conduct research on methodology of systematic reviews. AHRQ awards five-year contracts to institutions in the United States and Canada to serve as EPCs.

Centers for Education and Research on Therapeutics

CERTs are part of a national initiative to conduct research and provide education that advances the optimal use of therapeutics (drugs, medical devices, and biological products). The program consists of 14 research centers and a coordinating center and is funded and run as a cooperative agreement by AHRQ in consultation with the FDA.

* Not a government agency.

These recommendations should be acted upon through coordinated efforts between multiple HHS agencies and then revised in light of the outcomes of the coordinated efforts. Even more importantly, these government efforts will require partnerships with the private sector as well. By having better coordination among all of these players, personalized medicine can finally be put into practice.

A promising example of a public-private partnership is the current partnership between the Food and Drug Administration and Medco Health Solutions Inc., a pharmaceutical benefits manager for more than one-fifth of the American population. Medco will give the FDA access to a plethora of de-identified patient information on tests, prescriptions, and clinical outcomes. The FDA can then analyze this information and assess which treatments are the most cost effective overall and for which subpopulations a treatment is most effective. These assessments will then lead to the FDA issuing label changes for drugs and devices so that doctors and patients can know under what circumstances a drug is most effective.[26]

The FDA also instituted its Critical Path Initiative, which aims to enhance the product development process by incorporating new tools for product evaluation. Among them are biomarker assessments that correlate the presence of certain genes or proteins to the likelihood that a patient will respond to a new medical product.[27]

Unfortunately, the broader potential of innovative partnerships and initiatives such as these will remain unrealized as long as the bureaucracy remains out of sync with the objectives of these efforts. Stakeholders ranging from patients, physicians, and pharmacists to drug companies, government regulators, and academic researchers—would all benefit from a small but authoritative body that is specifically devoted to guiding, advising, and evaluating the coordination of personalized medicine research and practice. Without someone taking a continuous big-picture view of personalized medicine, it will be impossible to fully realize the potential that has been left almost completely untapped by the lack of interagency coordination.

There are many barriers today to a streamlined genetic information-derived, evidence-based system that puts personalized medicine into practice. One is the lack of interoperable electronic medical records, which forces personalized medicine to rely upon its traditional method of research—large-scale clinical trials that collect genetic, phenotypic, and drug history of each subject. Sufficiently large clinical trials, however, are unsustainably expensive given the limited profitability of drugs and devices that would be tailored to smaller and smaller subpopulations.

Pharmaceutical benefits managers such as Medco offer an economical alternative to clinical trials as they can data mine reimbursement claims from very large, diverse, real world cohorts of patients. By data mining these reimbursement claims, Medco aims to infer the predictive power of genetic tests and identify dosing trends—knowledge extremely valuable to personalized medicine as a whole.

Unfortunately, Medco's data is imprecise, which is why any effort for personalized medicine guidance and coordination should prioritize the eventual standardization of medical terminology and so-called current procedural terminology, or CPT, reimbursement codes that uniquely identify each genetic test. This would streamline data mining and enhance the usability of the data for such tasks as the validation of genotyping platforms. Today, however, it is logistically difficult for the federal government to compel private bodies such as the American Medical Association, which devises the CPT reimbursement codes, to get on board with an entirely new federally coordinated system.

THE FUNCTION AND CONTENT OF AGENCIES INVOLVED IN PERSONALIZED MEDICINE

FUNCTION	AGENCY
DATA AGGREGATION	Center for Disease Control—Human Genome Epidemiology Network
	National Institute of General Medical Sciences—Pharmacogenomics Knowledge Base
BASIC RESEARCH	National Institutes of Health—Genes, Environment, and Health Initiatve
	National Institute of General Medical Sciences—Pharmacogenomics Research Network
REGULATION	Food and Drug Administration—Center for Drug Evaluation and Research
TECHNICAL INTEGRATION	National Institute of General Medical Sciences—Electronic Medical Records and Genomics Network
EVALUATION	Biomarkers Consortium*
	Center for Disease Control—Evaluation of Genomic Applications in Practice and Prevention
	Centers for Medicare and Medicaid Studies—Medicare Evidence Development and Coverage Advisory Committee
	Agency for Healthcare Research and Quality—Centers for Education and Research on Therapeutics
ADMINISTRATIVE OVERSIGHT/ COORDINATION/LEADERSHIP	Centers for Disease Control and Prevention—Office of Public Health Genomics
	Food and Drug Adminstration—Critical Path Initiative
	Centers for Medicare and Medicaid Studies—Council on Technology and Innovation
	American Medical Association**
	Assistant Secretary for Planning and Evaluation—Personalized Health Care Initiative
REVIEW AND RECOMMENDATION	National Committee on Vital and Health Statistics
	American Health Information Community—Personalized Health Care Workgroup***
	Agency for Health Research and Quality—Evidence-based Practice Centers
	Office of Biotechnology Activities—Secretary's Advisory Committee on Genetics, Health, and Society

CONTENT AREA KEY

Informatics Therapeutics/products Genetic/genomic data Policy/protocol/management Whole system

* Public–private biomedical research partnership.

** Not a government agency.

*** Disbanded November 2008.

Insurers, naturally, exert the most influence in the claims reimbursement process through their coverage decisions. SACGHS recommends that HHS compile scientific evidence and make it available to public and private insurers so that they can consider this evidence when they make coverage decisions about genetic tests. Coverage decisions would then give drug companies a better idea of whether they will be able to recoup their investments in personalized drugs. SACGHS also recommends that the Centers for Medicare and Medicaid Services, or CMS, which is the federal body that runs Medicare and Medicaid, ensure consistency in the coverage decisions of local Medicare administrative contractors and consider opening up coverage to preventative care measures such as genetic tests.[28]

Additionally, the NIH plays a role through its research efforts, which fall under its auspices of the Pharmacogenomic Research Network and the Pharmacogenomic Research Knowledge Base.[29, 30] These two research collaboration initiatives have been working toward incorporating genetic test results as criteria for physicians to use in prescription and dosage guidelines. This is a good step with regard to the coordination and packaging of academic research for clinical use; however, it cannot be implemented fully until physicians have sufficient incentives to incorporate this new information into their day-to-day work.

Also under the NIH is the eMerge Network, a group of biomedical research centers that are attempting to devise a consistent nomenclature by which to link genomic databases with electronic medical records. This, too, is a good idea, but once again is not tied to any incentives or regulations that would encourage the adoption of this nomenclature. Granted, the eMerge nomenclature may not even be ready for such formal adoption into HHS policy, but at this point it does not even seem to be on the radar screen of HHS policymakers. This shows how the broader potential of all these initiatives—including the Medco-FDA partnership—is thwarted by the lack of a coordinated guidance across these multiple bodies.

Coordinated guidance of personalized medicine would allow each initiative to acquire a greater awareness of what the other initiatives are doing so that they can plan their work accordingly. One example of such coordination is a recent decision by CMS to reimburse genetic tests that assess a patient's ability to metabolize the drug warfarin, but only if the tests are part of a specifically designed prospective clinical trial by the FDA to investigate the clinical utility of said genetic tests.[31] Initiatives such as this give drug developers a heads up about how insurers might evaluate data on genetic tests. This would allow drug developers to better anticipate which genetic subpopulations they should target their research, development, and marketing efforts towards. Eventually, this may lead drug companies away from the current business model where they spend billions of dollars to develop and market one-size-fits-all blockbuster drugs toward a more targeted and personalized approach.

Even better, coordinated guidance would help unlock several additional areas of personalized medicine's potential. For instance, the Centers for Disease Control and Prevention runs two initiatives called the Human Genome Epidemiology Network, or HuGENet, and the Evaluation of Genomic Applications in Practice and Prevention, or EGAPP. HuGENet is aimed at global-population-based epidemiological studies of genomic variations and interactions, the validity of gene tests, and the effectiveness of therapies and interventions.[32] EGAPP assesses the validity of gene tests in specific clinical settings by contracting out to review groups through HHS's Agency for Healthcare Research and Quality's evidence-based practice centers and then releases succinct recommendation statements for health care professionals.[33]

Both EGAPP and HuGENet seem intent on collaborating with multiple stakeholders such as the pharmaceutical and biotech industries, insurers, and health care providers. EGAPP has already formed a dedicated stakeholders group to gather feedback and assess the effectiveness of their recommendations when stakeholders implement them.

Indeed, these initiatives are all very promising in and of themselves, but frustratingly siloed as a whole.

Next Steps

One should think of HHS's current personalized health care infrastructure as an orchestra that contains many talented solo musicians but still needs a good conductor to harmonize them and maintain the tempo. This can be achieved by ensuring that the multiple agencies that have a stake in the development of personalized medicine are able to exchange information, share suggestions, and promote best practices. This is not necessarily another project that needs a czar or centralized committee, but it does require all contributors to commit to the values and principles of

pragmatic progressive innovation. Only then will the public and private biomedical communities be able to create an environment where doctors can eventually deliver personalized care based on transparent, high-quality evidence that is both gathered and disseminated ethically.

The HHS can learn many lessons from their own PHC initiative, since it exists in neutral territory between invested federal agencies that include the FDA, the NIH, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality. The PHC group essentially acts as a liaison between private and federal stakeholders to create a "network of networks."

What all of the relevant public and private stakeholders need to do is promote principled dialogue through guidelines, forums, meetings, and other vehicles for getting everyone on the same page. There is much to learn from the PHC group about fostering a streamlined agenda. For instance, the PHC outlined four goals:

- Link clinical and genomic information to support personalized health care.
- Protect individuals from discrimination based on unauthorized use of genetic information.
- Ensure the accuracy and clinical validity of genetic tests performed for medical applications purposes.
- Develop common policies for access to genomic databases for federally sponsored programs.[34]

Additionally, SACGHS has framed their recommendations within the context of larger goals and principles that should guide personalized medicine, such as improving the productivity of the new drug pipeline and reducing adverse drug reactions. Personalized medicine should also employ pharmacogenomics to serve people with rare conditions and other underserved populations.

The report also recognizes that while pharmacogenomics has the potential to cut down on healthcare costs by helping to manage chronic diseases, it can also raise costs by shrinking the market for a specific drug and making the research more intensive. This all depends on the drug research and development strategy put in place by the public and private sectors, which will include the sharing of basic research data and clinical data so that both prospective research and retrospective research can inform drug development and make it more efficient. Naturally, this entails the protection of patient/subject privacy and intellectual property; the design of health IT systems and the education of caregivers so that they know how to navigate, operate, and integrate into the entire personalized medicine infrastructure.[35]

Finally, the public needs to be informed and educated about personalized medicine through outreach efforts, opportunities for public comment or input, and most importantly through transparency. HHS needs to hold each of the stakeholders to appropriate standards of transparency both so that each knows what the other is doing and so that the public knows. HHS also should think about how to engage and inform the public as citizens, patients, and consumers.

Personalized medicine may seem like the ultimate chicken and egg problem. We don't want to go ahead with it until we know how to do it right, but we won't know how to do it right until we go ahead with it. That is why HHS needs to be diligent in articulating the goals and values of personalized medicine and proactive in asking stakeholders for input while also guiding them according to best practices.

WHY COMPARATIVE EFFECTIVENESS RESEARCH WILL ENHANCE PERSONALIZED MEDICINE

Previously featured on The Wonk Room

The roadmap for comparative effectiveness research has become much clearer and detailed these past few days with the release of two new reports. One comes from the Institute of Medicine at the National Academies and the other comes from HHS's Federal Coordinating Committee for Comparative Effectiveness Research. The IOM released a list of 100 health topics for the Obama administration to prioritize as it spends $1.1 billion in stimulus funds dedicated to CER. More importantly, the Federal Coordinating Committee itself has stated in its report to the president and Congress that comparative effectiveness research should "complement the trend in medicine to develop personalized medicine," and that it will be "an important partner in helping to bring about this new level of medical effectiveness, personalization, and innovation." This bold vision of personalized medical innovation based on "patient-centered, pragmatic, 'real world' research," clearly dwarfs the feeble criticisms of CER aired by conservatives in last week's HELP Committee markup of the "Affordable Health Choices Act."

While the act incorporates comparative effectiveness research as part of its health reform agenda, there is another piece of legislation that will establish a dedicated, rigorously organized federal institute for this kind of research.

Formerly known as the Patient-Centered Outcomes Research Institute, the creation of this federal body depends on the passage of the Patient-Centered Outcomes Research Act, (S. 1213) sponsored by Senators Max Baucus (D-MT) and Kent Conrad (D-ND). Upon a close reading of the bill, it is evident that the Patient-Centered Outcomes Research Institute will not just be another meaningless chunk of bureaucracy as its critics claim. The institute's goal will not be to simply spit out generic guidelines that your doctor must follow "or else." Rather, theinstitute has been designed to ramp up medical innovation for the common good by championing a new era of personalized medicine.

Taking a close look at the bill, there is plenty of language about "evaluating and comparing the clinical effectiveness, risks, and benefits" of various tests, treatments, and devices. More importantly, the bill upholds a commitment to doing the best kind of comparative effectiveness research by making it personalized and reaching out to subpopulations. The bill charges the institute with conducting "research and evidence synthesis that considers variations in patient subpopulations." The bill builds upon this by later explaining what "subpopulations" means, specifically:

"Racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular subtypes, or quality of life preferences." This also means that the institute will "include members of such subpopulations as subjects in the research as feasible and appropriate."

Even more impressively, the bill kicks biomedical innovation into high gear by explicitly infusing its research with personalized, real world considerations. The bill stipulates that comparative effectiveness research take into account "treatment modalities that may affect research outcomes, such as the phase of the treatment modality in the innovation cycle and the impact of the skill of the operator of the treatment modality." This basically means that the research will look at how far along a treatment is in the product development process and the skill level of those administering the treatment. Again, these are real world considerations that other forms of research like clinical trials often miss.

Additionally, subpopulations will not just be part of the subject pool; they will be part of the implementation process. Their representatives will be incorporated into the advisory group that will set the agenda of the institute's primary research. Another advisory group will devise research methodologies by including members who are experts on personalized medicine technologies like biostatistics and genomics. The dissemination of research findings will also "discuss findings and other considerations specific to certain subpopulations, risk factors, and comorbidities, as appropriate."

Finally, for those who might be concerned about the intrusiveness of such an institute, the bill also stipulates that the dissemination of research findings discuss "limitations of research;" "shall not include practice guidelines, coverage recommendations, or policy recommendations;" and would not "violate the privacy of research participants or violate any confidentiality agreements." Indeed, far from assuming that scientific data is the infallible final word, the institute knows its limitations, admits them, and stays within them.

Perhaps one of the most astute and intellectually honest provisions of the bill involves the usage of research findings by the secretary of HHS. Many have feared that comparative effectiveness research will be used to deny coverage or to tell your doctor what to do. It won't—this is made explicit multiple times in the bill. Of course, it would not make sense to just let comparative effectiveness research sit there when it comes time for HHS to make Medicare coverage decisions. Thus, there are concerns that comparative effectiveness research will be used to justify the enforcement of one-size-fits-all treatments. Once again, it won't, and the bill states this explicitly by requiring the secretary of HHS to consider:

"Evidence and research that demonstrates or suggests a benefit of coverage with respect to a specific subpopulation of individuals, even if the evidence and findings from the comparative effectiveness research demonstrates or suggests that, on average, with respect to the general population the benefits of coverage do not exceed the harm**."**

WHY COMPARATIVE EFFECTIVENESS RESEARCH WILL ENHANCE PERSONALIZED MEDICINE *(continued)*

On the whole, this bill is a prime example of robust, evidence-based, scientific policymaking. It incorporates the best attributes of the scientific method and the democratic process right into the implementation of public policy. The institute will constantly update its research in light of new methodologies and treatments; its research will be transparent; it will seek input from the public and a broad range of stakeholders like patient advocates; it will build upon existing research efforts to avoid redundancy; and it will submit its research to peer review. Most importantly, the institute will respect the rights of the individual person by taking a personalized approach to comparative effectiveness research.

As Alan Garber of Stanford University and Sean Tunis of the Center for Medical Technology Policy put in a recent New England Journal of Medicine article, "far from impeding personalized medicine, comparative effectiveness research offers a way to hasten the discovery of the best approaches to personalization, providing more and better information with which to craft a management strategy for each individual patient."

As for now, the PHC group and SACGHS have articulated excellent starting points for the FDA, CDC, NIH, CMS, AHRQ, and others to bear in mind as they embark on their own pieces of the personalized medicine agenda. As this information is shared and reviewed among the agencies, they can each revise and hone their agendas so that they do not end up setting their own incongruent agendas and sharing limited success in improving public health. Personalized medicine needs a cohesive yet flexible agenda and conscientious planning on the part of each agency to put it into action.

To oversee the ethics, values, and goals of a cohesive personalized medicine enterprise the HHS Office of the Assistant Secretary for Planning and Evaluation or the Office of Biotechnology Activities may need some administrative funds or statutory authority to devise and continually review guidelines for public and private personalized medicine efforts. They could also consult with various agencies and review their practices to ensure that they are living up to the guidelines. Within the ASPE, the Office of Science and Data Policy stands as a strong candidate to house a new body for facilitating coordination on personalized medicine since it has experience dealing with bioethics, human subject protections, and health information. Other ASPE offices such as the Office of Health Policy, the Office of Human Services Policy, or the Office of Planning and Policy Support could also contribute knowledge, input, and expertise on consumer protections, public health, evaluation methods, and other issues.

This is not a call for HHS to micromanage every stakeholder's part of the personalized medicine symphony. Indeed, a conductor does not write the music or play the instruments for the musicians. This is a call for the HHS to be the maestro who listens closely and guides the timing, intensity, and harmonization of the stakeholders.

The administrative cost of coordinating these efforts will be nominal as all the other agencies are already investing their own resources in their own mostly isolated efforts, though rearranging agency duties and partnerships could prove more difficult politically. That is why the HHS secretary with the support of the Obama administration should support an effort to get these various research initiatives on the same page under the streamlined guidance of the HHS.

Coordinated guidance of personalized medicine will help ensure that stakeholders ranging from academic researchers and federal regulators to pharmaceutical companies and insurers to doctors, pharmacists, and patients are maximizing the gains from their investments in personalized medicine research and health care. A failure to coordinate the personalization efforts of the American biomedical community will cause us to unnecessarily forgo the additional returns that our research dollars and health care dollars can bring us by investing them in an innovative era of individualized medical treatment.

Endnotes

1 "Virus-specific Drug Approved for HIV," *New Scientist*, August 11, 2007, available at http://www.newscientist.com/article/dn12456-virusspecific-drug-approved-for-hiv.html.

2 "Possible Drug Target Found For One Of The Most Aggressive Breast Cancers," Science Daily, July 9, 2009, available at http://www.sciencedaily.com/releases/2009/07/090708153238.htm.

3 Federal Coordinating Council for Comparative Effectiveness Research, *Report to the President and the Congress*, (Health and Human Services, 2009) available at http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf.

4 Paul Ginsberg, "Efficiency and Quality: The Role of Controlling Health Care Cost Growth in Health Care Reform," (Washington: Center for American Progress, 2009) available at http://www.americanprogress.org/issues/2009/06/payment_reform.html.

5 Alan M. Garber and Sean R. Tunis, "Does Comparative-Effectiveness Research Threaten Personalized Medicine?" *New England Journal of Medicine* 360 (19) (2009): 1925-1927.

6 John Russell, "Microsoft Launches Amalga Life Sciences," Bio-IT World, April 28, 2009, available at http://www.bio-itworld.com/news/2009/04/28/amalgals.html.

7 Microsoft, "Microsoft Introduces Next-Generation Amalga Unified Intelligence System," Press release, April 6, 2009, available at http://www.microsoft.com/presspass/press/2009/apr09/04-06AmalgaUISPR.mspx.

8 U.S. Food and Drug Administration, "Viewpoint: FDA and Genomics," February 2, 2009, available at http://www.fda.gov/AboutFDA/CommissionersPage/Viewpoint/Archives/ucm153614.htm.

9 Health and Human Services, "Personalized Health Care," available at http://www.hhs.gov/myhealthcare/

10 Office of Biotechnology Activities, "Secretary's Advisory Committee on Genetics, Health, and Society," available at http://oba.od.nih.gov/sacghs/sacghs_home.html.

11 Advisory Committee on Genetics, Health, and Society, "Realizing the Potential of Pharmacogenomics: Opportunities and Challenges; A Report of the Secretary's Advisory Committee on Genetics, Health, and Society," (Health and Human Services, 2008) p. 24, available at http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_PGx_report.pdf.

12 U.S. Food and Drug Administration, "Interdisciplinary Pharmacogenomics Review Group," available at http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083889.htm.

13 Advisory Committee on Genetics, Health, and Society, "Realizing the Potential of Pharmacogenomics: Opportunities and Challenges; A Report of the Secretary's Advisory Committee on Genetics, Health, and Society," (Health and Human Services, 2008) p. 24, available at http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_PGx_report.pdf.

14 Advisory Committee on Genetics, Health, and Society, "Realizing the Potential of Pharmacogenomics: Opportunities and Challenges; A Report of the Secretary's Advisory Committee on Genetics, Health, and Society," (Health and Human Services, 2008) p. 43, available at http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_PGx_report.pdf.

15 Advisory Committee on Genetics, Health, and Society, "Realizing the Potential of Pharmacogenomics: Opportunities and Challenges; A Report of the Secretary's Advisory Committee on Genetics, Health, and Society," (Health and Human Services, 2008) p. 4-8, available at http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_PGx_report.pdf.

16 Alan M. Garber and Sean R. Tunis "Does Comparative-Effectiveness Research Threaten Personalized Medicine?" *New England Journal of Medicine* 360 (19) (2009): 1925-1927.

17 "The eMERGE Network," available at https://www.mc.vanderbilt.edu/victr/dcc/projects/acc/index.php/About

18 Health and Human Services, "HIT Standards Committee Schedule for the Assessment of HIT Policy Committee Recommendations," available at http://healthit.hhs.gov/portal/server.pt?open=512&objID=1271&parentname=CommunityPage&parentid=19&mode=2&in_hi_userid=10741&cached=true#schedule.

19 Health and Human Services, " Federal Health IT Programs," available at http://healthit.hhs.gov/portal/server.pt?open=512&objID=1141&parentname=CommunityPage&parentid=6&mode=2&in_hi_userid=10741&cached=true.

20 Health and Human Services, "Personalized Health Care," available at http://www.hhs.gov/myhealthcare/.

21 Health and Human Services, "Personalized Health Care: Goals" available at http://www.hhs.gov/myhealthcare/goals/index.html#Goal1.

22 "S.976: Genomics and Personalized Medicine Act of 2007," GovTrack.us, available at http://www.govtrack.us/congress/bill.xpd?bill=s110-976.

23 "H.R. 6498: Genomics and Personalized Medicine Act of 2008," GovTrack.us, available at http://www.govtrack.us/congress/bill.xpd?bill=h110-6498.

24 Advisory Committee on Genetics, Health, and Society "Coverage and Reimbursement of Genetic Tests and Services: Report of the Secretary's Advisory Committee on Genetics, Health, and Society," (Health and Human Services, 2006) p. 3-7.

25 Health and Human Services, "American Health Information Community," available at http://healthit.hhs.gov/portal/server.pt?open=512&objID=1199&parentname=CommunityPage&parentid=3&mode=2&in_hi_userid=10741&cached=true.

26 Medco Health Solutions, Inc., "Medco Announces Research Collaboration with FDA Focused on Personalized Medicine," Press release, August 18, 2008, available at http://www.reuters.com/article/pressRelease/idUS187277+18-Aug-2008+PRN20080818.

27 U.S. Food and Drug Administration, "Critical Path Initiative," available at http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm.

28 Advisory Committee on Genetics, Health, and Society "Coverage and Reimbursement of Genetic Tests and Services: Report of the Secretary's Advisory Committee on Genetics, Health, and Society," (Health and Human Services, 2006) p. 4.

29 National Institute of General Medical Science, "Pharmacogenetics Research Network," available at http://www.nigms.nih.gov/Initiatives/PGRN.

30 The Pharmacogenomics Knowledge Base, available at http://www.pharmgkb.org/.

31 Health and Human Services "Centers for Medicare and Medicaid Services: Proposed Decision Memo for Pharmacogenomic Testing for Warfarin Response," available at http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?from2=viewdraftdecisionmemo.asp&id=224&.

32 Centers for Disease Control, "Population Research: Human Genome Epidemiology," available at http://www.cdc.gov/genomics/hugenet/default.htm.

33 "Evaluation of Genomic Applications in Practice and Prevention," available at http://www.egappreviews.org/default.htm.

34 Health and Human Services, "Personalized Health Care," available at http://www.hhs.gov/myhealthcare/.

35 Advisory Committee on Genetics, Health, and Society, "Realizing the Potential of Pharmacogenomics: Opportunities and Challenges; A Report of the Secretary's Advisory Committee on Genetics, Health, and Society," (Health and Human Services, 2008), available at http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_PGx_report.pdf .

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