

## Genetic Services Policy Project Final Report

### Chapter 7: A Changing Health Care World

Genetic services are delivered within a continually changing health care system. There is a rich literature on the challenges and opportunities facing the health care system at the beginning of the 21<sup>st</sup> century, and the changing economic and political context in which they have evolved. Among the trends forecast by most observers are:

- increased consumer cost-sharing for health insurance as employers continue their retrenchment from broad-based coverage;
- increased enrollment in Health Savings Accounts (HSAs), both as consumers choose this option and as alternative options are removed;
- increased transparency of information, both about the business and the content of health care services, from the Internet and through multi-media advertising;
- increased presence of national and international corporations in health care markets;

Walk-in clinics—both freestanding and inside retail establishments such as Target and CVS—are proliferating. The Convenient Care Association reports that there were 800 retail clinics in November 2007, with that number projected to be 1500 by the end of 2008 (Wood, 2008).

- growth in the number and variety of venues outside a doctor's office where health care services can be obtained;
- increased attention to the needs and desires of consumers;
- growth in the variety of non-MD professionals offering health care services;
- increased use of electronic technology to provide both information and services, including by government agencies; and

- growth in medical outsourcing, including patient travel for treatment overseas.

Genetic services markets will be similarly affected by these trends—in some cases, disproportionately so.

An estimated 55,000 Americans were treated at Thailand's Bumrungrad Hospital in 2005, 83 percent of whom received non-cosmetic procedures (Kher, 2006).

### **Implications for Genetic Services**

Two powerful forces will affect developments in genetic science and their application to genetic medicine: evolving health care markets, and rapid advances in information technology (IT). These forces interact, particularly as health care facilities and professionals adopt IT advances such as electronic medical records and electronic billing. Recommendations about the appropriate role of government in guiding the translation and implementation of genetic

advances must have as their underpinning a very clear understanding of the implications of these forces for the financing and delivery of genetic services. As a starting point to develop these recommendations, we summarize the unique characteristics of genetic services.

### ***Unique characteristics of genetic services***

*Family Based.* While many medical conditions affect family members indirectly because of their concern for the patient and their potential role in caretaking, genetic conditions have a much more direct effect. Genetic conditions may ripple through families in increasingly predictable ways. A woman's knowledge about her susceptibility to breast cancer has implications for her sisters and her daughters. A couple's carrier status for sickle cell disease has implications for the health of the child it might wish to have. Genetic science is helping to identify the conditions that have an important genetic component, although specific genetic characteristics often interact with environmental factors in inducing illness.

*Information Heavy.* Information is at the core of genetic services. All genetic services provide information directly, and most of them (given the family connections) have implications for information that might affect the decisions of others. In some cases, most notably for indigenous populations, genetic information can have implications for an entire group.

*Social Effects.* Genetic information affects not only decisions about medical treatment, but also reproductive and other life decisions. Genetics, perhaps more than other areas, challenges our social beliefs. This is particularly true around issues that affect reproductive decisions. For example, genetic services such as pre-implantation genetic diagnosis (PGD) and prenatal testing, which offer women choices about their pregnancies, present ethical dilemmas that sometimes have to be settled in courtrooms after the expenditure of many resources and much angst.

*Privacy and Confidentiality.* Because of the family connections and predictive power of genetic information, privacy and confidentiality are even more critical in this area than for other forms of clinical information. Fear of insurance and employment discrimination has led many states to adopt anti-discrimination legislation. Congress is also struggling with this issue, as evidenced by the fact that anti-genetic discrimination legislation has been introduced, but not passed, in every Congress from 1996 until 2008, when the Genetic Information Nondiscrimination Act of 2007 was signed into law on May 21, 2008 (S.358; H.R.493). Providers have concerns about the legal implications of how genetic information is handled. Physicians may have a duty to warn family members of patients whose genetic test reveals a hereditary illness, compromising the expected confidentiality of the patient/provider relationship (Offit et al., 2004). In addition, providers may be subject to wrongful birth and other lawsuits for not offering genetic tests whose results might have changed patient decisions (Caulfield, 2001).

*Checkered Cultural History.* Genetic information takes on special meaning in some ethnic and cultural communities because of its previous misuses. The African American community's experience with the mishandling of sickle cell disease information affects its view of genetic information and genetic services (Tapper, 1999). Native American communities are often concerned about the impact of genetic information on their views of family connections,

legal status of tribal affiliation, and origin beliefs, in addition to worries about misuse and discrimination (Foster et al., 1999).

*Genetics in the Media.* As with many new technologies, genetics and genetic services are receiving a great deal of attention in a broad array of public media (Gilliam et al., 2006). Newspaper and magazine articles on various aspects of genetics abound, ranging from art and ancestry to new treatments for genetic conditions. Genetics, particularly in the areas of forensics and paternity, play a frequent role in the storylines of popular television programs. Advertising of genetic services targeted directly to consumers is increasing. Not surprisingly, the messages offered by the media vary in content, tone, and accuracy, and play into consumers' views of genetic services in as yet unknown ways (Conrad, 2001; Geller et al., 2003).

*Provider Issues.* Genetic conditions, perhaps more than many other medical conditions, involve providers in many specialties ranging from genetic counselors to board certified specialists. Communication across the different provider groups is essential to treatment quality and outcomes; however, it is challenged by differing professional cultures, differing levels of knowledge about genetic conditions (not always in proportion to years of formal training), and differing reimbursement methods and levels. Further, the distribution of genetic specialists is quite uneven geographically, increasing the difficulty of adequate communication.

### ***Implications for consumers of genetic services***

In the 21<sup>st</sup> century, consumers expect and will increasingly receive personal information that is digital, virtual, and mobile. Consumers will seek this information from an increasing array of sources—professional, commercial, public, and consumer-based (i.e., from other consumers), both domestic and international. As the number and type of information sources increase, so will the variability of the accuracy and applicability of the information. The availability of trusted “integrators” and interpreters of the information – such as genetic counselors – will be important. Consumers without access to this interpretive resource, either virtual or face-to-face, will be left to sift through and synthesize complex information on their own.

Although general medical information (facts about specific diseases and treatments) is now readily available on the Internet, personal medical information has been slower to emerge in an electronic format. However, increased penetration of the electronic medical record and increased use of electronic communication for patient/provider interactions will change that (Asbrand, 2007). As consumers become more adept at using electronic means of obtaining and interpreting information, they are likely to become more comfortable with seeking genetic services from electronic sources. Susceptibility testing, such as for the heritable breast cancer gene mutation BRCA1/2, is currently available online from a variety of vendors, some of whom also offer electronic or telephonic genetic counseling services. Myriad Genetics clearly believes in the power of direct to consumer messaging, having engaged in several advertising campaigns for its BRCA1/2 tests (Myriad Genetics, 2007). A recent and controversial entrant is a genetic test for bipolar disorder developed by a psychiatric geneticist at the University of California, San Diego, that retails for \$399 (Wohlsen, 2008). It adds to the more than 1,000 genetic tests that have become available to consumers over the Internet in recent years. In addition, companies like 23andMe offer to provide a complete sequencing service for individuals (23andMe website).

Some segments of the consumer population will be at a disadvantage in a world of electronic information, most notably those without convenient and affordable access to the Internet, those with language and literacy issues, and those for whom privacy and confidentiality issues make electronic communication of personal medical information uncomfortable or impossible.

### ***Implications for providers of genetic services***

Perhaps the most obvious implication of this future for medical providers will be the loss of relatively exclusive control of patient information. Patients will expect electronic access to their own medical records. In addition, traditional providers of genetic services will find themselves practicing in collaboration – or in competition – with a wider variety of providers across a larger geographic area.

Genetic conditions are currently treated by a diverse array of medical and genetic providers. However, the changing health care context suggests an increased presence of alternative care providers (e.g., naturopaths and midwives) in primary care. This development would add to professional culture differences, and increase training and knowledge differences.

A world of electronic information will change the impact of geographic imbalances in the supply of genetic services providers. In communities with appropriate infrastructure, electronic and virtual service delivery can afford consumers in isolated areas access to specialized genetic services providers. Telemedicine demonstration projects will provide useful evidence about the opportunities and challenges of this form of virtual delivery (Columbia University, 2000). Cross-state licensure issues are among the barriers that must be sorted out before telemedicine can reach its full potential. Finding mechanisms for provider reimbursement for virtual and electronic services is another challenge.

The growth of multi-specialty clinics located off the campuses of traditional hospitals may work well in genetic services markets. Existing multi-specialty clinics that treat genetic conditions may already fit this model.

### ***Implications for the financing of genetic services***

Increased availability of electronic information and increased comfort with electronic and international commerce in health care will interact with changes in health care financing. Although estimates of the pace of health savings account growth differ across analysts, there is little dispute that HSAs will be a rising force in the next decade. Approximately 4.5 million individuals are currently enrolled in HSAs, and most surveys report roughly 50 percent of employers are offering HSAs or are planning to offer them in the near future (Trapp, 2007). Federal legislation to increase the tax advantages of HSAs, coupled with many state and federal government initiatives to encourage HSA enrollment among government employees, provide evidence of the public sector's commitment to the concept.

The growth of HSAs will shift billions of dollars of health care spending into the hands of consumers. As a result, forces that directly affect consumer demand for genetic services will play an important role in determining which services are used, how often, and by whom. These forces include direct to consumer advertising and Internet-based information as well as the counsel of health care professionals. Recent gender and ethnicity-oriented advertising of

vitamins and other supplements suggests that advertisers may seek to segment product markets if this appears to increase product sales and revenue (Payne, 2006).

As consumer-controlled dollars increase as a percentage of health care spending, restrictions placed on the coverage of certain services by traditional insurance products will become less important. This has particular relevance to the area of genetic testing and counseling, and decisions of families to seek testing for heritable conditions. Existing insurance policies generally cover neither genetic testing nor counseling for family members of enrollees, nor services from retail genetic service providers; however, these restrictions will be less important to families with HSAs.

Another spillover effect of an increased percentage of consumer-financed care is that disparities in access to health care and consequent disparities in health will worsen unless there are adequately financed public programs to support lower income consumers. Public programs are typically more cautious in their coverage of non-essential services and technologies. Thus, the beneficiaries of these programs may be unlikely to have access to the full range of genetic services.

### ***Implications for research***

Most observers agree that the growth of HSAs will increase the already growing trend of “commodification” of health care (Geyman, 2004). The impact of increased reliance on economic markets to distribute services will have implications for medical research. In particular, investors are likely to be more interested in new technologies that have direct appeal to consumers with resources at their disposal. Experience with television advertising of certain prescription pharmaceuticals supports this notion. Empirical observation suggests that technologies aimed at reproductive decisions and outcomes will command significant researcher attention. Policy decisions regarding the design and funding of the catastrophic insurance policies that must accompany HSAs will affect investors’ interest in treatments for rare diseases and very expensive technologies. If coverage of these services is restricted – perhaps through a requirement of evidence of effectiveness – investment in these services may fall. The implications for research directed at particular sub-populations are not yet clear, but will likely have increasing importance.

### ***The role of government***

The role of government is generally to alter markets in which independent decisions of market players (e.g. consumers and suppliers) yield results that violate social values. Developing genetic services markets are likely to heighten a number of existing policy concerns and generate some new ones.

*Provide Essential Market Infrastructure.* A primary role of government is to provide the infrastructure that allows markets to function. The basic infrastructure components include transportation corridors (safe roads, shipping lanes, and airways), a stable currency, and a court system that upholds legal agreements. In the future, Internet access may be added to the necessary components of publicly provided market infrastructure—a new “corridor” across which significant levels of commerce take place. Supporters of bio-banking initiatives might add

appropriate access to genetic data as a necessary component of at least the research enterprise in this area.

Even (perhaps especially) markets that function well largely serve those with resources. A consequence of relying on markets to deliver genetic services will be to heighten existing disparities in access to these services between those who have resources and those who do not. Thus, it could be argued that a necessary component of market infrastructure is a mechanism to address these disparities to a degree that comports with social values. It falls to government to provide and monitor this mechanism.

*Provide Information.* A frequent objection to the use of markets to ration complex personal services is the difficulty that consumers often have in obtaining sufficient information to make informed decisions. This is true for most health care services; it certainly is true for genetic services. Our traditional approach in other health care markets is to substitute external standards (e.g., professional licensure and facility accreditation) for complete information.

An increasing amount of commerce will occur outside the boundaries of current government jurisdiction. This will happen for several reasons. First, technology is expanding at a more rapid pace than public policy. The unregulated “home brew” genetic tests are an example of a technology that appeared, probably purposefully, outside the lexicon of existing regulation of laboratory tests. We can expect other new technologies to push regulatory boundaries as well. Second, the evolution of the structure of genetic services markets (along with health care services markets in general) is reducing the role of the traditional physician provider. The provision of genetic tests through department stores and over the Internet, often without the involvement of a genetic counselor, provides an example in this area. While Congress is considering legislation that would insert some government oversight into retail genetic services markets, none currently exists (Javitt and Hudson, 2006). Finally, as international markets for health care services increase, we can expect that this will include genetic services. The “nighthawk” model for radiology services (remote reading of radiology images, usually done overseas) would apply well to the performance of genetic tests. Some international outsourcing already exists for reproductive and other genetic services whose use in the U.S. is restricted and/or expensive (South Asian Women’s Forum, 2006).

These changes in technology, market structure, and venue suggest that an increasing volume of genetic services will be provided without the customary protections of regulation, physician oversight, or U.S. authority. An important government role in a more *caveat emptor* world will be as purveyor of easily accessible, high quality, unbiased information about services and providers. Service providers, too, will have increasing information needs as both the science and the organization of markets becomes more complex. Both consumers and providers will need access to information about what government programs exist to assist them. Because government activity in the area of genetics spans many agencies and departments at both the state and federal levels, coordination and communication among relevant government bodies would improve their collective efforts.

Finally, government can play a role in speeding the translation of basic science discoveries into clinical applications and in mediating scientific controversies. Convening experts to create

evidence-based practice guidelines or to generate scientific consensus is a mechanism that the federal government has used for this purpose.

*Monitor the provision of information by private sector entities.* Participants in active markets generate large amounts of “information.” Much of this information is provided in the form of product and service advertising, some of which is regulated by the FTC. However, there are other more subtle (and less regulated) mechanisms to influence consumer and provider behavior, including the activities of pharmaceutical sales representatives and public statements by commercial entities and advocacy groups on the Internet, in public forums, and through news outlets. While the FTC’s ability to adequately monitor formal advertising is limited by resources and the lack of specialized expertise, no government agency has oversight authority over these other mechanisms of influence. Thus, government has an additional role in expanding its ability to monitor the information generated by an increasingly commercial genetic services sector.

Enforcing, and where necessary creating, regulations to ensure the confidentiality of genetic information (both publicly and privately generated) and preventing its use for insurance, employment, or other discrimination is also an important government activity. When individuals fear how their genetic information might be used against them, they are both less likely to seek genetic services and less likely to participate in genetics research.

*Promote balanced competition.* Commercialized genetic services markets will serve consumers best when productive competition is encouraged and destructive competition is limited. Productive competition can be fostered by removing inappropriate barriers to entry, preventing subsets of professionals or commercial entities from monopolizing information, and maintaining a level regulatory playing field. Destructive competition can be limited by assuring transparency, monitoring market outcomes, and constantly balancing the benefits of market barriers (e.g., regulation) with their costs and side effects.

*Encourage innovation.* Innovation in a market has the potential to create new value. In genetic services markets, this can mean improved health and increased access to information with which to make life decisions. Innovation is generally the result of investments in research.

The government can play multiple roles in fostering innovation. At the most basic level, appropriate patenting policies that balance positive incentives for private investors and researchers with the needs of those who use the outcomes of research are essential. Existing patent laws, for the most part, were created in the late 19<sup>th</sup> century in an entirely different scientific and market context. Updating patent laws to reflect the realities of the 21<sup>st</sup> century would likely improve this balancing.

Maximizing the value of innovation also involves appropriate application of scientific discovery. This is facilitated through appropriate and even-handed regulation of emerging technologies to assure their safety and provide information to guide their efficacious use.

Important innovation can occur in the delivery as well as the creation of genetic services. Government can foster market structure innovation through both regulations that do not restrict it

unduly and creative reimbursements that reward it. Pilot and demonstration projects are often used for this purpose, as well as evidence-based modification of public purchasing strategies.

Government funds a large share of medical and genetic science research. If publicly funded research is to produce the highest public value, funding policies must reflect social priorities.

*Provide a forum for discussions of social values.* Genetic services raise many ethical, social, and cultural issues. An important role of government is to facilitate public discourse about these issues. Because not all social values have equal voice in a market-oriented environment, it falls to government to assure that all voices are at the table and all values are considered. Finally, it is the responsibility of government to incorporate the social values that emerge from these conversations into public policy.

*Lead by example.* Government at all levels has an important influence on markets through its purchasing power. The coverage decisions of Medicare, Medicaid, public employee benefits, and other government programs have a substantial direct effect by increasing (or decreasing) demand for covered (or excluded) services in a large population. Public decisions often have the important secondary effect of establishing a standard of coverage for private insurers. This double impact applies not only to the list of covered services, but also to provider payment mechanisms (e.g., direct reimbursement of genetic counselors) and conditions of coverage (e.g., tiered pharmaceutical benefits).

State and federal governments can be cognizant of their significant influence on genetic services markets when they design public program benefits, both with regard to consumer incentives/requirements and provider incentives/requirements.

### ***Conclusion***

The changing organization and financing of the health care sector provides both opportunities and challenges for genetic services delivery in the next 20 years. Traditional means of guiding consumer decisions through professional and government oversight will be less available and therefore less relevant. Thus, government agencies at all levels must adapt their strategies to the evolving context to assure that public values continue to be served by genetic services markets.

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