

Linking the Public Voice with the Genetic Policy Process: A Case Study

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Abstract

The application of genetic information will shape economies and lives throughout the next century and beyond. At the current pace of discovery, genetic research will bring advances in pharmaceuticals and therapeutic treatments that not only serve to reduce human suffering, but also offer people new choices and greater control over their lives. But, what humanity will do with this new technology and knowledge remains to be seen. Current thinking on our genetic future ranges from fearful predictions of dire consequences to bold visions of disease-free existence. Should citizens play a role in deciding how this new genetic information and technology will be used? And what strategies should be developed to achieve that goal? Geneforum, a new non-profit organization that works to incorporate public ethics and values into the genetic science policy making process through grassroots education and Internet dialogue, believes that citizens should be informed and active participants in the Gene Age. Geneforum creates environments for learning, facilitates forums for discussion and provides input to policy makers. Classroom workshops, Town Hall Meetings, public opinion research, publications, an interactive Web site, and talk-radio programming are all used to achieve these ends. Geneforum's experience in employing these communication strategies to help guide genetic privacy policy development in Oregon is the focus of this paper.

Confronting the Gene Age

Today, many people understand that genes are the elements of heredity that specify the design and functioning of an organism. People also generally understand that the transmission of the intact comple-

ment of genes from parent to offspring is the way in which the organism's design plan is preserved and propagated. Increasingly, new techniques in the area of genetics are providing unprecedented ways to diagnose and treat disease and to manipulate the genome. The increasing availability of such tools and information is enhancing the practice of medicine and promises to improve the quality of life and increase life expectancy. However, the picture is not altogether rosy.

Our experience shows that advances in technology, no matter how benignly intended and applied, always have unintended consequences. Given the complexity of the genetic code and our relative unfamiliarity with the intricacies of genetic function, what are the potential unintended consequences in the application of genomic science and the information it reveals? What will it mean to substantially alter our biological inheritance in a single step—making changes that heretofore have arisen and been integrated into the genome over many generations? Do we want to undertake such experiments using humans as our test subjects? How do we evaluate the risk? What protections should we put in place? Who should make these decisions? How do we arrive at a consensus as a nation, a global society, and as members of the human community? Because these are issues that impact our future economic and physical well being, challenge deeply held values and beliefs, and call into question the very nature of what it means to be human, they are steeped in controversy and demand the most profound consideration by an informed citizenry.

Our genome future

President Clinton held a press conference in June, 2000, to mark what was billed as one of the most important scientific milestones of the century—the worldwide effort to spell out the 3 billion letters of the human genome, the biochemical messages encoded in our DNA for manufacturing and operating a complete human being. The fact that science is on its way to deciphering the blueprint for what makes us human is at once wondrous and worrisome. Wondrous because of the possibilities for fighting genetically triggered disease. Worrisome because some feel scientists are making it possible to look through the blinds of our private domain, enabling them to uncover secrets that many of us would rather keep to ourselves.

Francis Collins, head of the U.S. National Institutes of Health's National Human Genome Research Institute, predicts that by the year 2040, comprehensive genomics-based health care will be the norm, disease predisposition will be determined at birth, individualized preventive medicine will be available and largely effective, illnesses will be detected early by molecular surveillance, gene therapy and gene-based drug therapy will be available for most diseases, and the average human life span will reach 90 years.

With the growing power of genome science to obtain accurate genetic information about individuals, to what degree should the public be actively involved in shaping the rules that govern the generation, use and disclosure of genetic information and personal privacy?

Managing genetic information

As the link between genetics and pathology comes to be better understood, more genetic testing options will become available; new labs will come into existence; more effective testing methods will be available and automated; and more genetic information will need to be managed. Protecting it from abuse will be no less a challenge.

Further, once diagnostic tests become widely available, how can a patient's privacy be protected in situations where the release of information regarding disease susceptibility might adversely affect the cost and/or continuity of medical insurance—as well as jeopardize a person's employability, employment status, social standing and personal relationships? Will the unceasing drive for low-cost care at all costs backfire, engendering a new wave of burdensome litigation? What is the responsibility of legislators to ensure the privacy of medical information?

Every human cell whether derived from hair follicles, blood, fingernail parings or body tissue carries a complete set of a person's genes. Consequently, genetic profiles won't be hard to come by.

In this environment of burgeoning genome research and market-driven diagnostics, genetic privacy is sure to become the major constitutional issue of the next century. Indeed, 80 percent of respondents to a national poll said the marriage of the Information Age (the 20th century) with the Age of Biology and Technology (the 21st century) signals the end of personal privacy.

The Oregon story

Oregon is the site of the most recent battle over genetic privacy and the rights to DNA. In 1994, a committee of physicians, lawyers, and concerned citizens proposed new legislation aimed at protecting the privacy of individuals in the context of genetic research and diagnostic studies. Three aspects of genetic information led the committee to conclude that special privacy protections needed to be developed.

First, genetic test results can be used to predict future health risks that might be of interest to insurers or employers. Second, genetic test results apply to a whole family and therefore are of interest to people other than the individual patient. Third, information from a genetic test can be kept in many different places and under many different sets of rules over which an individual has no control.

The statutory language of Oregon's 1995 Genetic Privacy Act addressed the rights of individuals in relation to three questions: Who can collect genetic information? Who can retain genetic information? Who can disclose it and under what conditions? As we turn Huxley's "Brave New World" into our own reality with the power to accurately identify a host of genetic conditions—many of which will have no treatment—the question we need to ask ourselves is: Who should have access to this information? And under what conditions?

In an era when the map of the human genome can be accessed by any professor with an Internet connection, finding answers to these questions become more crucial by the day. Courts and lawyers and legislatures wrestle with them; people who joined medical studies wonder just what their participation means.

Experts have tried to sort out the complexities of privacy policies for years. Last year, the federal government strengthened its regulations protecting human research subjects, hoping to make more explicit the process by which patients are told what a study will entail.

The National Bioethics Advisory Commission report—on which some of those recommendations were based—noted the difficulty in protecting subjects no longer physically involved in a study.

DNA as property

Oregon's 1995 Genetic Privacy Act contained a property clause unique to genetic privacy legislation enacted elsewhere in the country: "...An individual's genetic information and DNA sample are the property of the individual except when the information or sample is used in anonymous research." (The definition of "anonymous research" is that the identity of the person from whom the sample is derived cannot be determined.) The statute further required that whenever genetic information is generated for medical purposes, informed consent is required before a person's DNA sample can be used for any purpose whatsoever, including research.

Oregon's property clause was intended to provide a way for individuals and their families to retain some control over their genetic information. The property designation was intended to empower individuals and their families to enforce their privacy rights through court actions rooted in commonly understood property rights.

In the minds of the framers of the 1995 statute, three reasons supported the use of property as the mechanism for protecting privacy rights:

First, it is a simple concept widely used and easily understood by the general public. Second, it gives families ownership of the genetic material of a decedent. Third, it provides families with protection from discrimination by providing them with standing for legal action.

In 1999, critics of the existing law raised concerns about the property clause. They pointed out that since its enactment, there had been no attempts to use the property clause in court action to enforce genetic privacy rights, and it may be difficult to do in practice. In addition, they argued that the property clause makes genetic privacy an alienable right. That is, when one signs away one's property right to a DNA sample, a person also signs away his or her privacy rights.

These critics also expressed concern that the property clause might inhibit genetic research and the development of the biotechnology industry in Oregon as a consequence of confusion over whether researchers would have a right to the commercial benefits of their work. They argued further that complications from property relations might limit scientists' access to genetic information in the research setting without really protecting the privacy of individuals.

The 1999, Oregon Legislature created the Genetics Research Advisory Committee (GRAC)—a gubernatorially mandated group of Oregon health care professionals and policymakers—to explore these issues.

After several months of deliberation, the GRAC reported its opinion to the Legislature that it would not be essential for the protection of privacy to retain the property clause in the Oregon statute. However, the report states that it is "Critically important that the purposes intended to be served by the property clause be accomplished." Accordingly, a privacy right was asserted for individuals whose DNA is used to develop genetic information. The GRAC recommended that violations of this privacy right should be punished by both civil and criminal penalties.

The perceptions of Oregonians

Throughout its deliberations, the Genetics Research Advisory Committee had the benefit of input from Oregonians around the state generated from: 1) a series of focus groups; 2) a survey of

opinion leaders; and 3) responses to an Internet interactive scenario. All three approaches were developed by Geneforum.

Four conclusions emerge from the data collected from these sources. Each pertains to how people think about genetic tissue and whether or not they believe it should be thought of as a person's property.

First, it is the personal information contained within the genetic tissue that was found to be more valued than the tissue itself. It is the use of the idea of property as a means of protecting one's own privacy that struck most people as being of primary importance.

Second, while less important than the privacy matter, genetic tissue too has value because many people consider it to be "mine." A straightforward expression of the concept of private property comes easily to mind when people are asked about the use of genetic tissue in research and development.

Third, confidentiality (even when carefully protected by researchers) is not widely considered to be an adequate substitute for the informed consent of the individuals whose DNA tissue researchers wish to study. Informed consent is seen as a strong and important way for individuals to exercise their privacy rights. Data collected from focus group meetings and the surveys based at the Geneforum Web site clearly show that neither confidentiality (securely coded identifying information) nor anonymity (the absence of any identifying information whatsoever) is sufficient in the absence of informed consent.

Fourth, a recent survey of 30 opinion leaders conducted by Geneforum shows that more than 90 percent of them equate 1) the deliberate and accidental release of information about a person's identity; and 2) the accumulation and storage of tissue without informed consent, to behaviors Oregon law describes as *felonies*.

These findings stand in sharp contrast to the privacy recommendation shaped by GRAC and later incorporated into Senate Bill 114 (Oregon's new statute on genetic privacy), which defines "the crime of unlawfully obtaining, retaining or disclosing genetic information...knowingly, recklessly or with criminal negligence" as a *Class A misdemeanor*.

That is to say that in the view of Geneforum's sample of Oregonians, SB 114 does not go nearly far enough in establishing appropriate punishment for the crime of violating an individual's genetic privacy or property rights.

More generally, a subsequent and random, representative sampling of more than 300 Oregonians supports two further conclusions: 1) DNA is fundamentally important to an individual's sense of self and relationship with kin; and 2) Oregonians want to participate in the advancement of science (and medicine) but, at the same time, are deeply unsettled about the strategies in place for protecting their genetic privacy. In that context, the overarching policy question underlying the issue of genetic privacy presents us with a classic conundrum:

How do we make laws which assure health care consumers that their personal privacy will be maintained—and their own genetic information will not be used against them—while at the same time encouraging the advancement of genetic research designed to improve human health and enrich the quality of human life?

Fear and greed: It's not just on Wall Street

It's commonly believed that volatility in stock markets is due to the collective ebb and swell of investor emotions: fear of loss and greed for gain. Investors overreact to uncertainty, driving market valuations first one way and then the other.

A similar oscillation seems to permeate the public response to science and technology. For the most part, the public is not scientifically literate and so does not have the means to coolly assess and evaluate the cacophony of voices from various quarters, each driven by its own agenda.

We know that technology can be threatening and that old ways of life can often be crushed by its momentum. We're all aware of the devastating effects stemming from the mechanization of warfare, the development of weapons of mass destruction, the insidious effects of pesticides and toxic wastes, the destruction of the ozone shield, the revelation of the effects of tobacco, of radiation and on an on—the list is very long.

Human mechanisms for survival are proven and resilient. But many of the dangers represented by new technology defeat our native ability to scan, recognize and react defensively—and that naturally creates anxiety. Such is the case with products developed by manipulating the genome.

In Europe, the appearance of “Mad Cow” disease helped catalyze a more general underlying anxiety about the genetic alteration food supplies. This anxiety was manipulated, in part, by national agricultural interests seeking to protect a tariff regime that rewarded farmer interest groups in a number of European countries. Initially, the dispute centered on the safety of American beef containing detectable levels of certain hormonal additives, but after Mad Cow disease became a burning issue, certain groups fueled by a media frenzy playing on public fears and ignorance used this issue to spearhead a campaign against any sort of genetic manipulation of the food supply. This campaign has now grown to global proportions under the demonizing heading of “Frankenfoods.” Whether or not there is reason to impose greater controls on genetic experimentation in agriculture, activists seeking to ban this GMO technology (or to create a chilling atmosphere which would dissuade private research and food product development) could preclude significant improvements in the safety and adequacy of the food supply, not to mention in the new field of food-based therapeutics. Once again, fear crowds out dispassionate, rational, knowledge-based decision-making.

A new social contract

How do we bring a rational dialog to issues which are so exacerbated by public anxiety and a lack of trust in both government and professional elites? A new social contract must be formed with the public. Institutional means must be developed by which the biotechnology industry, medical practitioners and a broad range of technical professionals are involved in educating, enlightening and empowering people to make more informed decisions.

An example of how this might be accomplished is the recent Green Party-inspired Swiss referendum on the continuance of government funding of biotechnology R&D in that country. The biotechnology industry rose to the occasion and mounted an educational campaign to inform the public of the actual work of biotechnology, its promise, where concern was merited and inappropriate and where it was entirely inappropriate. In that case, the referendum was decided in favor of the industry, showing that the public can be reached through open dialog—providing an effort is made to endow people with the intellectual tools needed to understand and freely evaluate the complex issues at hand. And provid-

ing just that sort of education is one of Geneforum's primary missions.

Geneforum: the public voice

Reflecting its mission to “create an informed citizenry for the Gene Age,” Geneforum is committed to four goals: 1) promote and enhance wider public understanding of the science and social ramifications of genome science; 2) incorporate public ethics and values into the genetic policy-making process; 3) link the public voice with those of the science expert and the policy maker; and 4) strengthen public participation in genome science policy deliberations.

Geneforum's success depends on its ability to continue to foster the three requisites of civic education: 1) an opportunity for deliberation; 2) a separation of issues of fact from value judgments; and 3) an analysis of public opinions and values with reference to a given issue prepared for—and delivered to—an appropriate decision-making body. All of these approaches are operationalized through a unique marriage of the media, the Internet, and grassroots education. Throughout, there is partnership with the experts aimed at creating informed science policy that reflects community values.

Together, these strategies—like those of the health decisions model from which they arise—achieve the three main goals of public participation: 1) education; 2) the transfer of information to policy makers; and 3) building a sense of community.

The process works

Geneforum is predicated on the belief that the public can participate meaningfully in public policy development, even when the area under consideration is as scientifically complex as the Human Genome Project. Members of Oregon's Genetic Privacy Advisory Committee (GRAC) ultimately agreed.

Included in its final report to the state legislature about genetic privacy, the committee unanimously recommended the creation of a new, and ongoing, advisory committee to monitor genetic research and privacy throughout the state. The following language in SB 114 reflects the proposed role of the public in that process:

As part of its regular activities, the Advisory Committee on Genetic Privacy and Research shall create opportunities for public education on the scientific, legal, and ethical development within the fields of genetic privacy and research.

The committee shall also elicit public input on these matters. The committee's recommendations shall take into consideration public concerns and values related to these matters.

The committee should make reasonable efforts to insure that this public input is representative of the diversity of opinion in the Oregon population.

A new paradigm and a wakeup call

We live with the benefits and the curse of technology, often working

to produce further advances capable of remedying past mistakes. This ongoing process of inflicting damage and then playing “catch up” increasingly threatens the biogeochemical web upon which all humanity depends. Until now our technology has been focused on shaping our world. But even through all that, as a biological organism, the essence of our humanity has not been altered significantly.

The advent of Dolly, the cloned sheep, has changed all that. It is a wakeup call that signals a change in humanity's technological direction. For the first time, the biological determinants of humanity are now becoming subject to technological manipulation. What does the concept of progress, of enhancement mean, when applied to the human genome? Do we have the necessary expertise to proceed? Are we prepared to live with the unintended consequences? If the reaction of the public to other examples of genetic manipulation are any indication, the answer is "no." Yet the genomics revolution rolls on, promising tremendous improvements in our ability to secure a new level of physical well being while simultaneously making us very uneasy about the future. So, the question then becomes: If you can't stop the process—how do you guide it?

This is the challenge before us: How to bring forward the application of modern genetics without leaving behind the nonscientists who make up the vast majority of our population. And once we have a political consensus on how to proceed, how should we confront the mountain of ethical decision making that is sure to follow?