

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



## 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 going to peer through the blinds of our private domains, perhaps uncovering 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 healthcare will be the norm, disease predisposition will be identified 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?

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% 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 may apply to a whole family and therefore are of interest to people in addition to 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?

For years, experts such as George Annas, one of the nation's foremost experts on genetic privacy, have tried to sort out the complexities of privacy policies. Earlier this year, the federal government strengthened its regulations protecting human research subjects, hoping to make more explicit the process that informs patients what a study entails.

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.

By Gregory Fowler, PhD

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### 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, biotechnology leaders voiced concerns that the property clause in the Oregon Genetic Privacy Act would inhibit industry efforts to collect the data required for disease association studies. They pointed out that since its enactment, the property clause has not been used in court action to enforce genetic privacy rights, and it may be difficult to do this 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 healthcare professionals and policymakers, to explore these issues.

After several months of deliberation, the GRAC reported to the Legislature that the property clause in the Oregon statute

is not essential for the protection of privacy. However, the GRAC stated 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.



## Healthcare

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, the personal information contained within the genetic tissue is more valued than the tissue itself. Identifying this information as protected personal property struck most people as being of primary importance.

Second, while less important than the privacy matter, genetic tissue itself 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.

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% of them equate 1) the deliberate and accidental release

tally 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 that assure healthcare 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 its momentum can often crush old ways of life. Many of the dangers represented by new technology defeat our native ability to scan, recognize, and react defensively—and that situation naturally creates anxiety. Such is the case

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and later incorporated into Senate Bill 114 (Oregon's current 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 (please see side bar) 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 fundamen-

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

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



## Genetic Privacy—International View

Since genetic testing began, there has always been the concern that results of such testing could be detrimental. Classic examples of genetic “diseases” that may lead to discrimination include hemophilia and Tay-Sachs disease. Now that DNA can be removed and analyzed, and the information stored (as DNA or data), the possibility that others may use a person’s genetic information inappropriately has led to international concern.

Britain’s government, for example, has endorsed a ban on genetic testing by insurance companies, hoping to prevent the emergence of a “genetic underclass” of people unable to buy health or life insurance. The government also fears that people may avoid valuable medical tests for fear of losing their life insurance, if risk for a particular disease is identified. Austria, Belgium, Denmark, France, Norway, and the Netherlands have followed the U.K. lead by either banning genetic tests outright or placing a moratorium on their use.

Genetic privacy has been on the agenda at meetings of the United Nations and World Health Organization, but so far only proposed guidelines have been formulated. While these groups agree that genetic data should not be collected, stored, or communicated for any purpose that is inconsistent with the principles set out in the Universal Declaration on the Human Genome and Human Rights, they concede that the use of such data for insurance or employment purposes is controversial and requires further consideration.

Meanwhile at least two major data-collecting projects are progressing: deCODE in Iceland and BioBank in the U.K. The former genetic database is a sweeping commercial project approved by the Icelandic parliament through the Icelandic Health Sector Database Act in 1998. In January 2000, parliament granted deCODE an exclusive license to the database for 12 years. A major concern is privacy. The database will contain the genetic information of practically all Icelanders. Citizens are assumed to have consented to participate unless they opt out. BioBank is the world’s largest study of the role of nature and nurture in health and disease; the project is funded by The Wellcome Trust, the Medical Research Council and the Department of Health. Groups such as GeneWatch UK claim that the BioBank research project is poorly designed, based on simplistic assumptions, and could lead to spurious links being identified between genes and diseases.

*G. Fowler and M. Godfrey for Oregon’s Future*

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 of food supplies. National agricultural interests, seeking to protect a tariff regime that rewarded farmer interest groups in a number of European countries, further manipulated this anxiety. Initially, the dispute centered on the safety of American beef containing detectable levels of certain hormonal additives. 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 that would discourage private research and food product development) could preclude significant-but as yet uncertain-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 that are so aggravated by public anxiety and a lack of trust in both government and professional elites? A new social contract must be formed with the public.

An example of how this might be accomplished is Switzerland’s Green Party-inspired 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 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 information they need in order to understand and evaluate the complex issues at hand.

### The Process Works

As a result of public input throughout its deliberations, Oregon’s Genetic Privacy Advisory Committee (GRAC) included in its final report to the state legislature a unanimous recommendation to create 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.



## Geneforum

Geneforum, a non-profit organization based in Portland, OR, works to enhance the public's understanding of genome science and its social and ethical ramifications. Through a unique marriage of the media, the Internet, and grassroots education, the organization hopes to strengthen public participation and incorporate public ethics and values into the genetic policy-making process.

Its three-pronged strategy is based on education (public forums, publications, classroom presentations), engagement (interactive website [www.geneforum.org](http://www.geneforum.org), talk radio shows, research), and consultation (transmitting public values, fears, and hopes to decision makers).

Geneforum played a key role in helping legislators update Oregon's genetic privacy law, mandating the creation of an advisory committee that will elicit public input on genetic privacy and research. In September Geneforum reported results of a statewide survey of 500 Oregon respondents, indi-

cating that approximately 70% of the state's citizens would like to retain control over the use of their genetic material, whether or not the information can be traced back to original donors. Nearly 60% wanted the opportunity to approve or refuse each potential research application of their blood or tissue samples.

Gregory Fowler, executive director, is currently involved in a Fred Friendly, Inc. project "Our Genes, Our Choices", a three-part Public Broadcasting System television series to be aired in January, 2003 and has been invited to participate in a Futurists' Conference in Bellevue, WA where he will present his vision of humans 1000 years from now.

*Marie Godfrey for Oregon's Future*

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 curses of technology, often working to remedy past mistakes through further advances. 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.

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 we can't stop the process—how do we guide it?



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