Personal Genomics and Human Society: Part II

So this week I picked up from where I left off on the issue of the genie being out of the bottle.

1. **The genie is out of the bottle (con't)**

Human genome sequencing has never been in a publicly funded "bottle" of course, given that many sequencing technologies and techniques were developed in privately funded laboratories.

But the extent to which human genome sequencing is already available to wider society is remarkable. Accessibility is increasing as costs fall, and this has raised some concerns about how private firms have moved ahead of the ethical, legal, and social debates about how the technology should be used, managed or regulated by government.

One example is direct-to-consumer testing. As a result of falling costs, the availability of full human genome sequencing has increased, but so have services like ancestry tracing and "predictive medicine" (a list of genetic variations that may put you at risk for certain diseases).

This genetic data and ancestry tracing is accomplished through spit or blood samples, and a search for a certain number of genetic traits in each sample. Costs vary by service.

The marketing is excellent!

There are a lot of concerns about these services, particularly the medical ones. Critics charge that these companies do not require high levels of consumer knowledge and awareness. When such tests are used for medical screenings, misinterpretations of test results can result in unnecessary stress and lead to misinformed decision-making.

The experience of the company 23 and Me is interesting. In November 2013, the company was ordered by the Food and Drug Administration (FDA) to halt the marketing and sale of its saliva collection kit and personal genome service test kit, because it was being sold "without

market approval." This is because the kit components fall under the category of a medical device and require FDA clearance.

In a statement, the FDA said: "FDA is concerned about the public health consequences of inaccurate results from the PGS [testing] device. The main purpose of compliance with FDA's regulatory requirements is to ensure that the tests work." It seems 23 and Me did not exactly work hard to comply with FDA requests. According to the FDA, over 14 meetings took place and extensive information was supplied to 23 and Me on achieving compliance. However, according to the FDA, "Even after these many interactions with 23 and Me, we still do not have any assurance that the firm has analytically or clinically validated the PGS for its intended uses, which have expanded from the uses that the firm identified in its submissions."

Undaunted, 23 and Me started new marketing campaigns and television ads, despite not having FDA clearance. Apparently, 23andMe did submit FDA applications in July and September of 2012 for two of its products, but the FDA said the company failed to address "the issues described during previous interactions."

And then there are the larger concerns about the accuracy of these tests. United Health Group Inc, the largest publicly traded health insurer in the United States, has warned of the dubious accuracy of the direct to consumer testing. Given that this industry could be values at $25 billion a year within the decade, testing accuracy is going to be a big public health issue.

In a New York Times article by Kira Peikoff in December 2013, the accuracy of the tests was questioned in an interesting experiment. As she recounts in the article, she requested three direct to consumer DNA screening service kits from three different companies, and sent all three off for assessment.

One company's report said her most elevated risks were for psoriasis and rheumatoid arthritis, with the lifetime odds of getting the diseases at 20.2 percent and 8.2 percent, respectively. But according to another of the three companies, her *lowest* risks were for psoriasis and rheumatoid arthritis at 2 percent and 2.6 percent, respectively!

For coronary heart disease, two companies agreed that she had a close-to-average risk, at 26 to 29 percent, but the third company listed her odds of getting coronary heart disease as “above average.”

For Type 2 diabetes, terminology seemed to be a problem: one company graded her risk as “medium” (10.3 percent), but another graded it as “decreased” (at 15.7 percent!).

The experiment exposed a number of issues. First, there are no agreed industry standards for evaluating risk factors or reporting language. Second, the tests these companies used are based on reading segments of DNA (the SNPs Dave talked about) and not the whole genome. Each test read about a million SNPs, but there are 10 million identified SNPs in the human genome and 3 billion nucleotides. So the amount of information being read is very small. Third, different companies choose different SNPs to read or interpret for the same condition. That can lead to different results. As J. Craig Venter (who was interviewed for the article) observed: “Your results are not the least bit surprising. Anything short of sequencing is going to be short on accuracy — and even then, there’s almost no comprehensive data sets to compare to.” Finally there is the stark reality that the causes of most common diseases remain unknown.

Debate has also arisen over fetal testing and the impact this might have on familial relations and public policy. Will spousal genomic testing impact decisions on procreation? Would prenatal testing impact decisions on procreation? Illumina's CEO, Jay Flatley, stated in February 2009 that "A complete DNA read-out for every newborn will be technically feasible and affordable in less than five years, promising a revolution in healthcare" and that "by 2019 it will have become routine to map infants' genes when they are born." This raises all kinds of questions!

Then there is the issue of the privacy of genomic information. In an article in Science, a researcher recounted how he could take the anonymously donated genome from an open-source site like 1000 Genomes Project, identify an inherited pattern (markers on the Y chromosome called Y-STR markers) in the genetic sequence of that genome, take the age and region of the donor which provided on the

website, match the pattern and age and location to the patterns and name information available on genealogy websites (which use the same genetic pattern along with surname to identify heredity for their customers), match individuals based on age and names, and then Google their names and their relatives names to discover information about them, including where they lived, where they worked, etc.

So the genie is out of the bottle. And the question is no longer whether it can be put back, but rather what kind of regulations should be put in place to manage or govern the activities of the private sector, which could have profound implications for individuals and society.

Currently, regulations in the US are mostly at the state level: 25 states permit direct-to-consumer genetic tests without restriction. The most common restrictions are the need for a permit (a state or federal clinical lab certification) and authorization from a physician. Many companies have been issued "cease and desist" orders based on a failure to comply. However, many companies argue their services are educational, not diagnostic, thus avoiding the more stringent regulations associated with diagnostic services.

There is no regulation of direct-to-consumer genetic testing in Canada under the Health Act (and very little anywhere else, for that matter). Studies of the habits of direct-to-consumer service providers suggest they fall well short of the recommendations of the Canadian College for Medical Geneticists, established in 2011.

Ethical Issue:

- Fairness in the use of genetic information by insurers, employers, courts, schools, universities, adoption agencies, and the military, among others.
    - *Who should have access to personal genetic information, and how will it be used?*

Ethical Issue:

- Reproductive issues include adequate informed consent for complex and potentially controversial procedures, use of genetic

information in reproductive decision-making, and reproductive rights.

- *Do healthcare personnel properly counsel parents about the risks and limitations of genetic technology?*
- *What are the larger societal issues raised by new reproductive technologies?*

Then, we moved on to examine just a few examples of how the complexity inherent in the relationship between genetics and human society can play itself out.

3. Human Evolution and Trait Variation

On February 12th 2009 (Darwin's birthday) a version of Neanderthal Man's DNA was assembled, by Svante Paabo (the inspiration for Michael Crichton's novel "Jurassic Park"). Finished in 2010, this discovery has enabled researchers to isolate differences between the genome of *Homo Sapiens* and Neanderthals: and therefore the basis of modern human distinctiveness.

Now, a comparison of the genomes of people alive today can reveal where natural selection has been most active in the recent past. This information provides new insights into the migration of *homo sapiens* throughout the world. As we migrated, we became more distant, and thus natural selection becomes more distinctive to "branches" of humanity as they developed (remember, we are still overwhelming alike in genomic terms).

But what if geographic differences or variations emerge in areas such as intelligence and behavior? Already, genetic studies are examining variations within populations on personality type, religiosity, the ability to make money, and intelligence. Has anything turned up? Should you rush out to get tested to see if you have the gene that expresses itself in the ability to make money (or at least find someone who does)? Or to find out how good your intelligence genes are?

Dr. Spencer Wells, head of the Genographic Project run by the National Geographic Society and IBM, would say no. In his project, volunteers from around the world (about half a million so far) give samples of

cheek cells for genetic analysis, and get a breakdown of their ancestral migration of the past 150,000 years. Some variations have turned up, and are not surprising: skin pigmentation and hair morphology (structure, shape, colour) for example.

Others are somewhat surprising: several genes associated with sensory perception (especially hearing and balance) have altered, and in particular have altered most in some branches of the peoples who migrated to what is now called Asia. Does this mean that some "Asian" branches of humanity hear differently? Possibly. But Dr. Well's project has not shown up any genes that encode traits such as intelligence, although that might mean they have not undergone recent change or selection, or the genes responsible have not been uncovered. Oh, and nothing has shown up on the making money piece either.

Others think a link between genetic trait variation and intelligence might be found. One project at the BGI (formerly the Beijing Genomics Institute) based in Shenzen, and led by Yang Huangming, is embarking on a search for the genetic foundations of intelligence. 2000 Chinese school children will have 2000 of their genes sampled, and these samples will be compared to test scores at school. Although not close to a comprehensive study of the complete genome and intelligence, this study will be largest of its kind yet attempted. What a discovery that would be, and imagine the potential for misrepresentation and abuse.

But even if such genes were found, remember the principle of controlling for variables. There is no doubt that intelligence has a hereditary aspect: studies of identical and non-identical twins have established that. Parenting and education and life experience matter as well. But it is also possible that each human brain develops differently, as neural pathways are strengthened and die in ways unique to each individual. So even if a gene for intelligence is uncovered, it may not mean as much as we might think (or will be portrayed in the media).

Nevertheless, this does raise interesting questions about the relationship between traits attributed to genetics and personal responsibility. The Nuffield Council on Bioethics has explored this in a number of studies, and has divided concerns about the relationship between genetics, trait variation, and human behavior into a number of

categories, including misuse of information, discrimination, changing and selecting traits, legal issues, understanding of free will, and a variety of others.

4. Genetic Testing and Medical Decisions

The relationship between genetics and individuals also emerges in the area of medical treatment. Consider the 2010 case of Claudine Wrighter, a 34-year old mother of two daughters from Pocasset, Cape Cod (this was all reported in a newspaper so we are not violating her privacy here!). Claudine's mother was diagnosed with breast cancer at age 71. Doctors were concerned about the family's history of cancer: Claudine's mother had a sister with ovarian cancer, and had four aunts die of breast and ovarian cancer. So Claudine's doctors recommended she undergo genetic testing at the Dana Farber Cancer Institute in Boston.

Claudine's test results showed she had inherited the BRCA1 gene mutation, known as breast cancer susceptibility gene 1, from her mother. BRCA1 and another mutation known as BRCA2 increase the lifetime risk of women getting breast cancer from 12 percent (or 120 out of 1,000) to about 60 percent and the risk of getting ovarian cancer from 1.4 percent to 15 to 40 percent, according to the National Cancer Institute. These genes, when they function correctly, are actually tumor suppressors, but one in 800 to 1,000 people carries the tumor-suppressant function of the gene: in Claudine's case, the BRCA1 gene mutation. "It was like someone had a crystal ball looking into your life," she said. "It was an emotional roller coaster."

Doctors at Dana Farber recommended the surgical removal of her ovaries and fallopian tubes. Removing the ovaries would virtually eliminate the chance of acquiring ovarian cancer, and would reduce the prospects of contracting breast cancer as well, as ovaries produce estrogen, which contributes to the development of many breast cancers. Remember, she was not diagnosed with cancer; she was tested for an inherited gene mutation. She also wants her three brothers to get tested for the gene mutation, because it increases their risk of male breast cancer and early prostate cancer. She also wants her daughters to get tested.

Claudine had the surgery, but this case raises so many questions about the doctor patient relationship, the question of appropriate treatment, the quality and equity of care provided, the role of education, and many other ethical questions that medicine, and many most of us, will have to grapple with. As for Claudine, she has no regrets: "It's been a long year, but I gave the gift to my husband and I gave the gift to my children by making this decision," she says.

Two examples, two sets of huge questions about individuals and genetics. Next, I turned to some of the implications of genetics for certain groups in society.

5. Religion and Genetics

Genetic research in general, and human genetic research in particular, has been a contentious subject for religion and their ethical systems. This was the basis for my little story about the Prince and Biologist!

On March 10, 2008 the Vatican issued an update to the "seven deadly sins" which now include: 1) genetic modification; 2) human experimentation, 3) polluting the environment; 4) social injustice; 5) causing poverty; 6) financial gluttony; and 7) taking drugs. Argues Monsignor Gianfranco Girotti, "You offend God not only by stealing, blaspheming or coveting your neighbor's wife, but also by ruining the environment, carrying out morally debatable scientific experiments, or allowing genetic manipulations which alter DNA or compromise embryos."

Christian ethicists believe that using genome-sequencing technology to determine behavioral choices should be the lowest priority in personal genetic research. The Judeo-Christian ethic promotes genetic research in guiding the care and management of patients and in developing new treatments. Behavioral genetics, it states, does not do these things.[1] Furthermore, using science in this way limits the ability to defend and

[1] Christian Medical Fellowship, "Submission from CMF to the Nuffield Council on Bioethics' Working Party on 'Genetics and Human behavior: The Ethical Context" (paper published July 1, 2001) accessed on August 22, 2010, http://www.cmf.org.uk/publicpolicy/submissions/?id=15

protect life, as it encourages a mentality of helplessness, instead of free will.[2]

In the Islamic world, the approach taken toward genetics is grounded in the decisions of The Islamic Jurisprudence Council of the Islamic World League (Organization of Islamic Countries). In its 15th session in October 1998, the IJC decided: 1) to permit use genetic of engineering for disease prevention, treatment, or amelioration on the condition that such use do not cause further damage; 2) to forbid the use of genetic engineering for evil and criminal uses or what is forbidden religiously; 3) to forbid using genetic engineering and its tools to change human personality and responsibility, or interfering with genes to improve the human race; 4) to forbid doing any research or therapy of human genes except in extreme need, after critical evaluation of its benefits and dangers and after an official consent of the concerned, respecting the extreme confidentiality of the information and human rights and dignity as dictated by Islamic Sharia'ha; 5) to allow the use of bio-engineering in the field of agriculture and animals, on the condition that precautions are taken not to inflict harm (even in the long term) on humans, animals or vegetation.

Religions, in the form of the political power of religious groups and organizations, are important influences over ethical and legal systems. Look no farther than debates over abortion. As a result, the nexus between genetics and religion is likely to be a hot one in the coming decades.

6. Group Identity

Human and personal genomics can have a profound impact on cultural, ethnic, linguistic, and indigenous groups. For example, genetic testing of indigenous groups makes it easier for researchers to identify genetic "peculiarities" as the gene pool is often relatively homogenous and

[2] Bishop Camillo Ballin, "Where the Catholic Church Stands on Genetic Issues: How and where do we draw the line?" Paper presented at the International Seminar on "Human Genetic and Reproductive Technologies: Comparing Religious and Secular Perspectives, Cairo, Egypt, February 6-9, 2006.

isolated from large-scale cross-breeding.[3] Studies on these isolated groups can focus on identifying gene indicators for diseases prevalent in the racial group or information that will uncover genetic ancestral links.

However, indigenous groups around the world have taken a defensive stance concerning the genetic testing of their populations.[4] This is not particularly surprising, given the historical experience of colonization, political and economic marginalization, and institutionalized repression that most such groups have endured. This treatment extends to a historical relationship with Western medicine that is ambivalent at best.[5] As in colonial times, indigenous groups see researchers and academics benefitting from their genetic studies of groups, yet see very few benefits for the populations who provided the genetic materials.[6]

Most importantly, indigenous groups worry about how the testing will be used and how it could hurt their cultural identity both mentally and legally. Most indigenous groups have a contrasting belief of community membership to most Western societies. The value of "common beliefs of origin, cultural affinities and linguistic characteristics" in identifying with a group transcends that of genetic information.[7] Thus, population genetics has the potential to confirm or refute long-held notions of common genetic and ancestral origins. This not only causes psychological damage for individuals, but also can seriously harm quests for self-determination.[8]

One such example of these fears being realized involves the Havasupai Indians in Arizona. As we saw in the video, the legal case involving Arizona State University and the Havasupai Indians demonstrated the consequences that genetic data can have when it conflicts with

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[3] Ikechi Mgbeoji, "Talking Past Each Other: Genetic Testing and Indigenous populations," *Actionbioscience.org,* September 2007, accessed August 19, 2010, http://www.actionbioscience.org/genomic/mgbeoji.html

[4] Sivaramjani Thambisetty, "Study Paper 10, Human Genome Patents and Developing Countries," Commission on Intellectual Property Rights, 2002, pg.21, http://www.iprcommission.org/papers/pdfs/study_papers/10_human_genome_patents.pdf

[5] Ikechi Mgbeoji, "Talking Past Each Other: Genetic Testing and Indigenous populations,"

[6] Ibid.

[7] Ibid.

[8] Ibid.

traditional beliefs.[9] Even more, the case raised debate on what fulfills the "informed consent" clause required by federally funded researchers and institutions.[10] Researchers at the Arizona State University received consent from the Havasupai Indians to gather genetic information regarding the high rate of diabetes diagnosed within their population. However, more conclusive data was found on the tribe's rate of mental illness and genetic information that contradicting traditional stories of their geographical origins.[11] The research article published on this research suggested that the Havasupai ancestors had crossed the Bering Sea to arrive in North America, both challenging the tribe's traditional stories and the basis of their sovereign rights to their canyon land.[12] Elders were devastated, the tribe felt manipulated and misused, and the Havasupai youth who had convinced the elders to partake in the study felt like they had betrayed their ancestry. The researchers claim that they received consent for wider-ranging genetic studies.[13] In response, the University paid out $700,000 to 41 members of the tribe and returned the blood samples. This case is a milestone in indigenous genetic testing, as the compensation implies that the rights of an individual can be violated when full information about how their DNA might be used is not given.[14]

7. Consent and Privacy Protection

Genomic services and DNA databases present a host of consent and privacy issues. Many, perhaps most, people want to keep their private lives private. There are good reasons for doing so. DNA information could contain (or might be believed to contain) information about susceptibility to disease, life expectancy, personality traits, intelligence, and criminal tendencies. Would you want that kind of information about you available to your family, friends, doctor, employer, the service industry (such as insurance companies), and the government?

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[9] Amy Harmon, "Indian Tribe Wins Fight to Limit Research of Its DNA," *The New York Times,* April 21, 2010, http://www.nytimes.com/2010/04/22/us/22dna.html
[10] Ibid.
[11] Amy Harmon, "Indian Tribe Wins Fight to Limit Research of Its DNA"
[12] Ibid.
[13] Ibid.
[14] Ibid.

Laws and regulations surrounding consent and privacy are still unclear. In the United States, despite various levels of state regulation and nation-wide protection offered by the Genetic Information Nondiscrimination Act (GINA), much is left unregulated and open to interpretation in the states and other countries. Currently, the outpacing of technological advances to social reform is crippling society's ability to understand and interpret the field of personal genomics and the rights citizens deserve within it.

In Canada, discrimination against individuals and groups with certain diseases has already occurred. A 2006 survey of Canadians at risk for Huntington disease found that 39.9% had experienced discrimination. Life and disability insurance companies were the main source of discrimination, with 29.2% of respondents reporting their applications for coverage were rejected, their premiums were increased, or they were forced to take a predictive test before they could obtain coverage.

Canadian law is rather silent on this matter. There are no specific laws on this matter, and although there are laws that might apply in oblique ways (see the slides) it is unclear just how much protection they provide. A Private Members Bill (C536), titled "An Act to Amend the Canadian Human Rights Act (genetic characteristics)" was introduced in parliament in April 2010. It did not become law.

8. Patent Law

As was the case with climate change, there is a close relationship between human and personal genomics and economics. Legal frameworks, especially rights and privacy legislation and patent law, also influence this nexus. So we have to explore the subject of human and personal genomics in the context of the economic and legal context.

This context is crucial because many of the concerns raised by critics of some human and personal genomics activities are connected to the emergence of these technologies and techniques into marketplace dominated by liberal economic principles and a general lack of regulation. As a result, motives such as profit, intellectual property rights, and ownership are driving the commercialization of research and the development of products and services without sufficient debate or

discussion of wider social impacts or potential negative consequences. Existing laws are insufficient to address individual and social concerns about the technologies, creating a vacuum that can be exploited by profit-driven actors.

As pharmaceutical manufacturers conduct research and development tailored to the marketplace, their patent applications are tailored to domestic patent law. In the United States, where most research takes place, the patent system happens to be the most favourable to potential patent holders in the world. US legislation allowing genotype sequences of all kinds to be patented has sparked many debates. Under US patent law, a person can patent anything that does not occur in nature, meaning it is new and invented. Discovering a new function of a known DNA sequence (for example, its association with a particular disease) requires a gene to be isolated and thus could be considered 'new'.[15] In this line of reasoning, these copies of genes are 'made by man' as they do not exist in nature prior to synthesis in a test tube by scientists.[16]

An opposing view argues that genes are discoveries, not inventions and that it is unethical to attempt to privately own a human gene.[17] The main debate themes center around whether or not genotype sequences are patentable under existing law, whether gene patents help or harm research, encourage biotechnological innovation or if they maintain public health and safety.[18] There is also widespread concern that current patent systems will become outdated very soon, if they are not already.

The legalities of patent law with respect to human genomics are continually evolving. A US District Court ruling in New York in March

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[15] Geoffrey Karny, "In Defense of Gene Patenting," *Genetic Engineering & Biotechnology News,* April 1, 2007, accessed August 15, 2010, http://www.genengnews.com/gen-articles/in-defense-of-gene-patenting/2052/

[16] Kevin E. Noonan, "Falsehoods, Distortions and Outright Lies in the Gene Patenting Debate," *Patent Docs,* June 15, 2009, accessed August 16, 2010, http://www.patentdocs.org/2009/06/falsehoods-distortions-and-outright-lies-in-the-gene-patenting-debate.html

[17] Michael Crichton, "Patenting Life," The New York Times, February 13, 2007, accessed August 18th, 2010, http://www.nytimes.com/2007/02/13/opinion/13crichton.html?ref=michael_crichton

[18] Ibid.

2010 flipped the pharmaceutical patent world on its head. In the case *Association for Molecular Pathology v Myriad Genetics and the University of Utah Research Foundation* the judge surprisingly ruled against precedence established in both European patent law (set in the European Patent Office) and in US Patent Law. The case involves Myriad's patents on the Breast Cancer genes BCRA 1 and BCRA 2, which grant them the exclusive right to perform diagnostic tests on these 2 genes. The judge ruled that patents on human genes violate patent law because genes are products of nature. Despite the decision, Myriad still has patents on 16 of the 23 BCRA genes.[19]

Another example of the nexus between genomics, economics, and patent law emerged on May 20th 2010, when Craig Venter announced the creation of the world's first living organism with a completely synthetic genome. The organism was created from the genome of a bacterium by dropping the genes out one by one to see which ones the bacterium could live without. The organism has been named JCVI-syn1.0. Dr. Venter has pursued a patent on JCVI-syn1.0. He has a case, if only because the organism is an artifact and is not human.

The idea that one can "own" an organism this way upsets many people. However, many companies currently hold patents on genetically modified organisms, especially crops. Also, we do own pets… and they can be genetically modified too. Like Glofish, for example!

Ethical Issue:

- Commercialization of products including property rights (patents, copyrights, and trade secrets) and accessibility of data and materials.
    - *Who owns genes and other pieces of DNA?*
    - *Will patenting DNA sequences limit their accessibility and development into useful products?*

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[19] Meredith Wadman, "Breast cancer gene patents judged invalid," *Nature news,* March 30, 2010, accessed on, August 20, 2010, http://www.nature.com/news/2010/100330/full/news.2010.160.html

9. Global Governance

In one sense human and personal genomics is an international enterprise by its very nature: the research into sequencing the genome took place in a number of countries. In another sense, the project has been very exclusive to a small set of countries and laboratories. However, this is changing rapidly.

In China, human and personal genomics is regarded as a key growth sector. The most prominent example of this is an organization I have mentioned above called BGI (formerly the Beijing Genomics Institute). Based in Shenzen, the BGI has opened a new sequencing facility in Hong Kong. This facility will allegedly have more sequencing capacity than exists in all of America. Yang Huangming, the head of the BGI, wants to make it the first truly global genomics operation. Hong Kong was chosen at least in part because its more reliable and function legal framework is more attractive to foreign investors, scientists, and customers. There are plans to expand into Europe and the United States.

So when it comes to human genomics research and related services and projects, we are already talking about a global enterprise. However, there is little in the way of global agreements governing the international dimensions of genomics. There are currently no institutions or international treaties solely responsible for the global governance of personal genomics. The WHO and UNESCO seem to be the only international organizations that address the issue, although what attention they do address to it fails to address any unique issues. In fact, no document discusses how states should cooperate to regulate genetic testing (for example). There are guidelines, but no binding rules.

Large research institutions like the National Human Genome Research Institute and the Genome Network Platform focus on either their development in a national context or on collaboration between institutions. These institutions do not seem to advocate policymaking in their field.

The one major international document on genetics is the Universal Declaration on the Human Genome and Human Rights (1997). However, the declaration does not bind states to specific action, although there

are suggestions for how states might proceed to do so. As one would expect, the Declaration calls for respect for the human dignity of each individual, and calls upon nation states to protect groups within their population that may be most vulnerable as a result of genetic testing.[20] However, there are no calls for specific policymaking or for advances in international governance of genetics.

Countries do not seem to have a general consensus on regulating genetic testing. In general, all states seem to be equally far behind in regulating and addressing the main issues arising in the field. An exception would be Switzerland, which held a referendum on banning genetic engineering (it failed to pass).[21] There also seems to be a general acknowledgement that educating consumers and research subjects is a crucial issue, but no one knows exactly how to do this.

Who will benefit most from the development of human and personal genomics research? The question should not be rhetorical, but it probably is. It is commonly known that the world's "most neglected" diseases are being largely ignored by the pharmaceutical industry.[22] 90% of health research dollars are currently being spent on health problems that affect only 10% of the world's population, and this has not been any different in the pharmacogenomics industry.[23] What little presence this industry has outside of North America and Western Europe is a result of the "boutique" style market developed by pharmacogenomics that has largely focused on specialized treatments for a minority of the population.[24]

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[20] UNESCO, "Universal Declaration on the Human Genome and Human Rights: from theory to practice: Article 14," February 3, 2000, accessed on http://unesdoc.unesco.org/images/0012/001229/122990eo.pdf

[21] WHO, "Education, Policy and Protecting Basic Rights," accessed on August 23, 2010, http://www.who.int/genomics/public/patientrights/en/index.html

[22] Yamey G., "The World's Most Neglected Diseases-Ignored by the pharmaceutical industry and by public-private partnerships," British Medical Journal, 325, (2002):176-177. Accessed on August 15, 2010 from http://www.msf.org/msfinternational/invoke.cfm?objectid=34BA82AD-853E-4476-B45F4BE4F349CA50&component=toolkit.article&method=full_html

[23] UNESCO, "Universal Declaration on the Human Genome and Human Rights: from theory to practice," pg. 145.

[24] Abdallah S. Daar and Peter A. Singer, "Pharmacogenetics and Geographical Ancestry: Implications for drug development and global health," pg. 78

Human and personal genomics techniques have resulted in some small public health gains in developing countries. The WHO cites a Malaria vaccine initiative in India, and another project in Nairobi that utilizes genetics in creating a vaccine for HIV by measuring the resistance of each strain in a group of sex workers. These are examples of the potential for personal genomics to enhance public health in developing countries.[25]

However, the use of developing world population groups for testing, which is predicted to be the biggest utility of developing countries in the field, is "fraught with ethical and social problems that will need to be addressed with interdisciplinary research."[26] On the other hand, genetic testing has the potential to address disease-related public health concerns in the developing world, and these will not occur until a significant market incentive is created for the private sector to invest in the health problems of the poor.

A movement that is gathering steam is something called genomic sovereignty. There are a number of aspects to this idea. First is the notion that a state should exercise control over the genetic material of their populations. The Mexican government passed a law in 2008 prohibiting genetic testing and the transport of genetic material outside Mexico. Another angle is the desire to develop national expertise and infrastructure in this area, to avoid dependence and domination by foreign science and expertise. In taking protective custody of a population's genetic heritage, the government in effect can champion the interests of the country and ensure that research is conducted for the benefit of that population. However, it is also the case that governments may be thinking of the genetic heritage of their populations as a resource, to be "mined" like any other. And many social groups in developing countries worry that governments will use genetic testing against them.

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[25] WHO, "Global applications of genomics in healthcare: Kenya," accessed on August 23, 2010, http://www.who.int/genomics/professionals/applications/africa/en/index.html

[26] Abdallah S. Daar and Peter A. Singer, "Pharmacogenetics and Geographical Ancestry: Implications for drug development and global health," pg. 94

Okay, so that is about it. Obviously there was a lot to talk about and we really only touched the surface. But I hope it is clear that of you want to understand climate change and human genomics, it is best to have knowledge from both the sciences and the arts. Whatever you go on to do, please hold on to that as the basic message of this course!