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INTERNATIONAL PROTECTION OF GENETIC INFORMATION:

THE PROGRESSION OF THE HUMAN GENOME PROJECT AND THE CURRENT FRAMEWORK OF HUMAN RIGHTS DOCTRINES

Jennifer Elle Tauer[*]

INTRODUCTION

The Human Genome Project (HGP) is an international project to sequence and map the human genome as well as to document humanity's genetic resources.[1] It has the potential to impact human rights and public health by creating perpetual structural inequalities in society.[2] Yet despite this impact on society as a whole, legislation on the regulation of information gathered from the HGP is almost non-existent. The only current instrument in effect that discusses both the human genome and international human rights is the Universal Declaration on the Human Genome and Human Rights (Declaration).[3] The Declaration addresses research on the human genome, the rights of persons concerned, and the duties of states to advance the international dissemination of information on the genome. Since the Declaration deals with the issues of protecting genetic information that will possibly be revealed by the HGP, its implementation is essential to protect the individuals who risk the exposure of their genetic information. However, implementation depends on the will of states and it is up to

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[1] *See* Maha F. Munayyer, *Genetic Testing and Germ-Line Manipulation: Constructing a New Language for International Human Rights*, 12 AM. U.J. INT'L L. & POL'Y 687, 688 (1997).

[2] *See* Allyn L. Taylor, *Globalization and Biotechnology: UNESCO and an International Strategy to Advance Human Rights and Public Health*, 25 AM. J.L. & MED. 479, 479 (1999); *see also* Alastair T. Iles, *The Human Genome Project: A Challenge to the Human Rights Framework*, 9 HARV. HUM. RTS. J. 27, 27 (1996).

[3] G.A. Res. 152, U.N. GAOR, 53rd Sess., U.N. Doc. A/53/625/Add.2 (1998) (adopting the Universal Declaration on the Human Genome and Human Rights, *at* http://www.unesco.org/ibc/en/genome/project.index.html (visited Dec. 18, 2000) (hereinafter Human Genome Declaration).

them to incorporate the principles of the Declaration into their legislation where appropriate.[4] More importantly, the Declaration encourages states without any legislation to legislate within the boundaries established by the principles of the Declaration.[5]

A genome is an organism's entire genetic material[6] and the human genome is specifically all of the genetic information of the entire human race.[7] The HGP is therefore an effort to decode the entire genetic make-up of human beings. Once the HGP is complete and the genome is mapped, sequenced and identified, individual genetic compositions will be knowable. The questions then become: who is entitled to this information, how will this information be used against individuals, and most importantly, will the use of this information violate their human rights? In 1997 the United Nations Educational, Scientific, and Cultural Organization (UNESCO) enacted the Declaration, which takes steps to protect the human rights of individuals with specific regard to genetics as it relates to dignity, rights and research. This Declaration has been effectively adopted by the General Assembly of the United Nations.[8]

In order to properly understand the nature and breadth of this inquiry and what solutions may present themselves, a comprehensive understanding of the HGP is required. This article will discuss the legal and ethical issues surrounding the HGP as well as the shortcomings of traditional international human rights law on this particular issue, including the Declaration and how its implementation will protect the human rights concerns of individuals.

The Declaration needs effective implementation on a state-by-state basis to protect the privacy, autonomy and dignity of individual human rights. However, there is a significant lack of current and uniform legislation throughout the world protecting these rights in local governments.[9] Although there is some national legislation in a few industrialized countries, there are inconsistencies and other countries that have no legislation are being exploited due to their lack of safeguards.[10] Such loopholes encourage international regulation of

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[4] *See* Noelle Lenoir, *Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level*, 30 COLUM. HUM. RTS. L. REV. 537, 575 (1999).

[5] *See* Noelle Lenoir, *Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level*, 30 COLUM. HUM. RTS. L. REV. 537, 575 (1999).

[6] Anne Lawton, *Regulating Genetic Destiny: A Comparative Study of Legal Constraints in Europe and the United States*, 11 EMORY INT'L L. REV. 365, 369 (1997).

[7] *See* Taylor, *supra* note 2, at 484.

[8] This Declaration was adopted by the U.N. on December 9, 1998. G.A. Res. 152, U.N. GAOR, 53rd Sess., U.N. Doc. A/53/625/Add.2 (1998).

[9] *See* Lenoir, *supra* note 4, at 537.

[10] *See id.*

bioethics by effective implementation of the Human Genome Declaration.

I. THE HUMAN GENOME PROJECT

Before understanding how this issue will exist within the legal framework of international human rights, one must first comprehend the background of the HGP. The HGP is an international collaboration of the world's best scientific minds created to identify the form and content of the human genome.[11] The HGP began in 1988 and is the result of three individuals who independently and publicly proposed to sequence the entire human genome.[12] Robert Sinsheimer, the Chancellor of the University of California of Santa Cruz (UCSC), planted the idea of sequencing the human genome, although it did not succeed in attracting money for a genome research institute on the campus of UCSC.[13] Renato Dulbecco of the Salk Institute, a Nobel Prize winning molecular biologist, was the first to expose his ideas publicly and gave impetus to the idea's third independent origin.[14] Charles DeLisi, who knew of neither the Santa Cruz workshop nor Dulbecco's lectures, conceived of a concerted effort to sequence the human genome under the aegis of the Department of Energy (DOE).[15]

A. Mapping the Human Genome

The HGP will result in information in the format of high-resolution genetic linkage and physical maps of all the human chromosomes as well as human deoxyribonucleic acid (DNA) sequence data, which scientists will then be able to use as a resource for studies of gene structure and function. Many see this completion of the HGP, and the fruits that it will bear for the field of genetics, as tantamount to the power of understanding "ourselves."[16] Such profound understanding is

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[11] *See* James D. Watson and Eric T. Juengst, *Foreward, Doing Science in the Real World: The Role of Ethics, Law, and the Social Sciences in the Human Genome Project, in* GENE MAPPING: USING LAW AND ETHICS AS GUIDES XV (George J. Annas and Sherman Elias, eds., 1992).

[12] *See* Robert Mullan Cook-Deegan, *Origins of the Genome Project, in* 5 RISK: HEALH SAFETY & ENV'T 97, 108 (1994).

[13] *See id* at 102.

[14] *See id.*

[15] *Id.*

[16] Allison Morse, *Searching for the Holy Grail: The Human Genome Project and Its Implications*, 13 J.L. & HEALTH 219, 230. Allison Morse emphasizes that the theory that human behavior can be understood through our genes is reductionist by its nature and such claims go beyond what science can support. She asserts that genetics and molecular biology can tell us about our genes and not all that much about people. To fully understand the nature of human behavior, it is essential to go beyond the genetic compositions and pre-dispositions of individuals and look at their surrounding environments. *Id.* at 231.

anticipated to be available after the genome is completely "mapped." To those for whom the HGP has become the "Holy Grail of Biology" and a quest for the all-revealing "Book of Man"[17] the results of the HGP will include a complete set of genetic instructions. Such details will give researchers basic information about how human cells work as a system, such as how the cells of the brain or heart work together or how a single fertilized cell develops into a fully formed baby.[18]

The HGP began as a scientific endeavor to attempt to discover the roughly four thousand known diseases.[19] Scientists are now able to predict those diseases that are caused by a single genetic defect through genetic technology.[20] One of the main objectives of the HGP is the promotion of medicine through three stages.[21] First, the ability to screen for genetic disorders; second to provide possible predictions of the onset of certain diseases or behavioral disorders; finally to be able to eventually eradicate unwanted genetic disorders through the use of gene therapies.[22]

The scientific community has determined that the goal of identifying genes that cause defects will be best advanced through procedures known as gene mapping and gene sequencing. Gene mapping assigns genes to specific chromosomes.[23] Once researchers are aware of where the genes are located, they are able to tell when certain traits are being inherited together.[24] Next, gene sequencing informs researchers where genes are located and how they are ordered with in the DNA double helix.[25] Finally, gene identification offers researchers insight as to which gene is actually responsible for the disease.[26] Often these three stages get lumped together under the title of "gene

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[17] *See* Report of the Secretary to the President, Health Insurance in the Age of Genetics in PRIVACY, CONFIDENTIALITY AND DISCRIMINATION IN GENETICS 11 (Comm. Print 1997). (Hereinafter Health Insurance in the Age of Genetics); *see also* ROBERT COOK-DEEGAN, THE GENE WARS: SCIENCE, POLITICS AND THE HUMAN GENOME 9 (1994) (Hereinafter, COOK-DEEGAN, GENE WARS).

[18] *See* Health Insurance in the Age of Genetics, *supra* note 17, at 11.

[19] *See* Iles, *supra* note 2, at 27.

[20] Michael R. Costa, *Genetic Testing: International Strategies to Prevent Potential Discrimination in Insurance Risk Classification*, 20 SUFFOLK TRANSNAT'L L. REV. 109, 109 (1996).

[21] *See* Morse, *supra* note 16, at 232-33.

[22] *Id.*

[23] *See* Costa, *supra* note 20, at 111-12.; *see also* COOK-DEEGAN, GENE WARS, *supra* note 17, at 34-35 (explaining how the physical mapping of chromosomal DNA is complete through seven separate stages, which are a combination of fragmentation and cloning).

[24] *See* Costa, *supra* note 20, at 111-12.

[25] *See* Lawton, *supra* note 6, at 376.

[26] *Id.* "To date, more than 60 genes that lead to disease have been identified, including genes for early-onset breast and ovarian cancer, cystic fibrosis, Huntington's disease, hereditary colon cancer, and the most common form of skin cancer." Beverly Merz, *Reading the Human Blueprint: The Human Genome Project*, *at* http://www.hhmi.org/genetictrail/reading/read.htm.

mapping."[27]

The HGP began with efforts to produce a complete physical map of the human genome. By the late 1980's, the Department of Energy (DOE) and the National Institute of Health (NIH) emerged as the leaders in the quest to complete the map of the human genome.[28] The Howard Hughes Medical Institute joins these two United States federal agencies as the major fundraisers for the HGP in the United States to form the overall "initiative" on genome mapping.[29] According to James Watson, the co-discoverer of DNA and head of the National Institute of Health Human Genome Initiative, the Human Genome Project has four phases:

> One, we map all the genes; two, we sequence all the genes, or break them down into their chemical components, which is the ultimate map; three, we distribute this information to scientists around the world through 'in-formatics' that are easily understood and useful; and fourth, we build in ethical safeguards so that the information is properly used and not exploited to discriminate against anyone.[30]

A physical genetic map is useful because it provides the necessary information regarding the relative location of genes along the 46 human chromosomes.[31] Once a gene has been located and isolated, researchers sequence the base pairs of the DNA to understand the nature of the protein codes and to identify mutations that are related to diseases.[32] The further goal of dissemination and the requirement to build in ethical safeguards are given recognition in the Declaration.[33]

Gene mapping is achieved through gene linkage and physical maps of the genome.[34] Physical mapping of DNA is completed through a

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[27] *See* Costa, *supra* note 20, at 112.

[28] COOK-DEEGAN, GENE WARS, *supra* note 17, at 167. "NIH and DOE signed a memorandum of understanding in the fall of 1988, to avoid the threatened Chiles-Kennedy-Domenici bill. The memorandum ratified an existing informal arrangement, but grew into substantially more, as bona fide joint planning came to seem advantageous to both agencies." *Id.*

[29] George J. Annas, *Mapping the Human Genome and the Meaning of Monster Mythology*, 39 EMORY L.J. 629, 637 (1990). (Hereinafter Annas, *Monster Mythology*).

[30] *Id.*, at 638;

> James D. Watson set in motion the whole chain of events that led to the Human Genome Project when he and Francis Crick discovered the double-helical structure of DNA in 1953. The longtime director of Cold Springs Harbor Laboratory, he served as the first head of the NIH human genome program from October 1988 to April 1992.

COOK-DEEGAN, GENE WARS, *supra* note 17, at 162.

[31] *See* Lawton, *supra* note 6, at 375-76; *see also* COOK-DEEGAN, GENE WARS, *supra* note 17, at 34-35.

[32] *See* Merz, *supra* note 26.

[33] *See* Human Genome Declaration, *supra* note 3, articles 9 & 23.

[34] *See* Lawton, *supra* note 6, at 374.

series of seven stages, which may be summarized as three more general steps.[35] The DNA is cleaved into chromosomal fragments, which are cloned, and then cleaved again.[36] According to the International Human Mapping Consortium, this clone-based approach to mapping will eventually produce a series of overlapping clones and these overlapping clones will create a map of the entire genome.[37] Researchers are able to reconstruct the order of DNA fragments by looking at the fragments from common clones.[38] Scientists will assemble a complete physical map by placing the DNA fragments in the correct order.[39] This stage of the HGP is essential because "roughly 50% of the human genome is repetitive. Some regions have DNA sequences that are ninety-eight percent identical to one another even though they are millions of base pairs apart or on different chromosomes."[40]

Gene sequencing is the process by which scientists determine the order of the nucleotides that comprise double stranded DNA.[41] The sequencing of three billion base pairs of nucleotides that comprise the human genome is a monumental endeavor.[42] The Office of Technology Assessment of the United States Congress argues five points in favor of the sequencing of the human genome.[43] They are as follows:

> [1)] The information in a genome is the fundamental description of a living system . . . and so is of fundamental concern to biologists.
>
> [2)] Genome sequences provide a conceptual framework within which much future research in biology will be structured [such as] . . . control of gene expression.
>
> [3)] [N]early 90 percent of total DNA content [is likely to have no function] . . . Without a complete DNA sequence of several genomes, it will be impossible to determine whether such sequences have meaning or are "ancestral" junk sequences.
>
> [4)] Genome sequences are important for addressing questions concerning evolutionary biology. The reconstruction of the history of life on this planet, the definition of gene families . . . and the search for

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[35] *See* COOK-DEEGAN, GENE WARS, *supra* note 17, at 34.

[36] *See id.* at 34-35.

[37] International Human Genome Mapping Consortium, *A Physical Map of the Human Genome*, 409 NATURE 934 (Feb. 15, 2001), *at* http://www.nature.com.

[38] *See* COOK-DEEGAN, GENE WARS, *supra* note 17, at 34-35.

[39] *See id.*

[40] Geoff Spencer, *International Human Genome Mapping Consortium Publishes Physical Map of the Human Genome*, *at* http://www.nhgri.nih.gov/NEWS/physical_map.html.

[41] Lawton, *supra* note 6, at 376.

[42] *See id.*

[43] *See* Annas, *Monster Mythology*, *supra* note 29, at 638.

> a universal ancestor all require an understanding of the organization of genomes.
>
> [5)] Genomes are natural information storage and processing systems; unraveling them may be of general interest to computer and physical scientists.[44]

The human genome is 25 times larger than any other genome sequenced to date, and is the first vertebrate to be sequenced fully.[45]

B. Possible Uses for Information Provided by the HGP

A complete map of the human genome will allow interested parties eventually to be able to discover whether or not an individual has a predisposition to one disease or another.[46] However, the tests that would discern such genetic information cannot reveal the extent to which a disease may manifest itself in one patient versus another.[47] Even though vast amounts of information will be supplied through "gene mapping," genes do not operate in a vacuum, but instead, they interact with the environment surrounding each individual. Inevitably, every person's habitat will have an influence on the expression of specific genetic traits within each human being and these facts must be remembered when examining genetic make-up and an individual's genetic predisposition.[48]

1. Therapies for Genetic Disorders

The HGP is targeted towards helping the treatment of genetic disorders, such as spontaneous genetic mutations in the germ cell[49] and inherited genetic anomalies. Every person has an estimated five to thirty serious "misspellings," or alterations, in his or her DNA, which means that every individual may be subject to some form of "genetic" discrimination if there is not adequate protection of genetic information.[50] The roughly thirty genetic mutations, which are not

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[44] *Id.*

[45] International Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, *available at* http://www.nature.com.

[46] *See id.*

[47] *See* Munayyer, *supra* note 1, at 691.

[48] *See infra* text accompanying notes 145 to 150.

[49] A Germ cell is either a Sperm or egg cell or their precursors. Germ cells are haploid and have only one set of chromosomes (23 in all), while all other cells have two copies (46 in all). *Genome Glossary*, *at* http://www.ornl.gov/TechResources/Human_Genome/glossary/glossary_g.html.

[50] Prepared Statement of Francis S. Collins, *in* PRIVACY, CONFIDENTIALITY AND DISCRIMINATION AND GENETICS 17 (Comm. Print 1997), *supra* note 17.

inherited, occur due to mistakes in DNA copying or cell division or environmental damage.[51] "A significant number of genetic disorders, approximately 1,050 as of 1995, have been correlated with specific chromosomes and even particular genes."[52]

Each human cell, with the exception of red blood cells, contains genetic data in its DNA.[53] Genes are stretches of DNA that produce something and often contain instructions to make a biological molecule, usually a protein.[54] There are roughly six feet of DNA tightly coiled in every one of the trillions of cells in the human body, with the exception of red blood cells.[55] However, a gene is not some "master molecule" sending out orders to be completed by the rest of the body.[56]

There are currently two types of therapies available for such genetic disorders, somatic and germ line, both of which can be developed in response to genes that contribute to disorders.[57] Somatic cell therapy allows for the alteration of cells that make up a person's tissues and organs, known as somatic cells, and results in changes to only that individual.[58] Germ-line manipulation (GLM) replaces missing or defective genes with perfect normal copies of the same genes by inserting them into the sex cells of the patient or the undeveloped cells of an early embryo that is fertilized in vitro.[59] Inserting the missing or defective genes in this manner either cures the defect entirely or alleviates the effects of a genetic disease.[60] While somatic cell therapy

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[51] Maya Pines, *Why So Many Error in Our DNA? 30 New Mutations per Lifetime*, *available at* http://www.hhmi.org/GeneticTrail/errors/wyso.htm.

[52] Iles, *supra* note 2, at 30.

[53] Honourable Justice Michael Kirby, *The Human Genome Project – Promise and Problems*, 11 J. CONTEMP. HEALTH L. & POL'Y 1, 8. Egg and sperm cells, as germ or sex cells, are different from other types of cells because they carry one copy of each gene of twenty-three single chromosomes.

[54] Pines, *supra* note 51.

[55] *Id.*

[56] Morse, *supra* note 16, at 230.

> DNA, in order to send a message for the production of a certain protein replicates itself onto RNA. RNA then transports this message of the DNA to another part of the cell, the ribosomes, where the production of the protein occurs. This message system, however, does not go only one way. It has been discovered that enzymes, called reverse transriptase, can copy the message of the RNA and send it back to the DNA. Furthermore, this entire process can be quickened or stopped by other proteins. *Id.*

[57] *See* Taylor, *supra* note 2, at 487.

[58] Jason T. Corsover, *The Logical Next Step? An International Perspective on the Issues of Human Cloning and Genetic Technology*, 4 ILSA J. INT'L & COMP. L. 697, 710 (1998); *see also* Munayyer, *supra* note 1, at 692-93.

[59] *See* Munayyer, *supra* note 1, at 692-93.

[60] *See* Corsover, *supra* note 58, at 710. The ideas of what constitute health and disease are generally determined by society and should not be manipulated for future generations on this basis alone. For a further discussion of the ethical issues involved in this debate, *see infra* notes 81 to 90 and accompanying text.

has this effect for the individual whose genes are altered, GLM prevents passing the same genetic disease on to future offspring.[61] Germ-line manipulation raises issues of informed consent because the embryo and future progeny, for obvious reasons, are not available to consent to this procedure.[62] Furthermore, the issue of eugenics[63] comes to the forefront. If the procedure of simply changing a known gene can be performed, then it likewise becomes possible to do the same procedure for a gene that merely needs to be improved, such as altering the gene in a child to cause him to be born with blue eyes inside of brown or vice versa.

2. Potential Social Ramifications for Application of Information Provided by the HGP

The availability of this genetic information has potential to affect the lives of individuals in a variety of meaningful ways and for this reason should not be overlooked. For example, a successful HGP purportedly could supply predictive and socially usable information in the following four areas:

1. Individual propensities to contract diseases, with varying degrees of medical · therapy available to moderate or overcome any such disease,

2. An individual's status as a carrier of harmful or defective genes, even though not personally affected,

3. An individual's propensity to engage in anti-social behavior, based on theories of inherited characteristics having effects independent of nurture or environment,

4. An individual's likelihood of having various exceptional abilities based on theories of superior inherited mental or artistic talents.[64]

Once this information is made available, there are both legal and ethical implications as to how it may be used. The overarching legal

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[61] *Id.*

[62] *See* Munayyer, *supra* note 1, at 698. The issue of informed consent and "genetic" discrimination for the embryo – or unborn fetus – leads into a human rights argument under traditional human rights instruments of the International Bill of Rights; (UDHR) (ICCPR) & (ICESCR). *See generally id.* at 698-700.

[63] "A science that deals with the improvement (as by control of human mating) of herediatary qualities of a race or breed." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY (Merriam Webster, Inc., Electronic Dictionary Version 1.5, 1994-96).

[64] Alan Westin, *Privacy and Genetic Information: A Sociopolitical Analysis, in* THE GENETIC FRONTIER: ETHICS, LAW AND POLICY 53, 66 (Mark S. Frankel and Albert Teich eds., 1994).

concern is the individual's right to privacy concerning genetic information. In the event that the knowledge is not kept private, the specter of possible "genetic" discrimination arises. The ethical concerns are more numerous because they deal with questions of screening and counseling, eugenics, reductionism and determinism. There are also privacy issues associated with possible policies such as mandatory genetic testing in the interest of public health.

The availability of this information raises significant concerns regarding who will have access to the information and how they will use it. Five major stakeholders have been identified with regard to this process: individuals, employers and insurers, researchers and scientists, business corporations, and governments.[65] All of these parties will place an economic value on this information and the main question is whether they will have equal rights to access the information given the wide-ranging impact it may have.

II. THE IMPLICATIONS OF THE HUMAN GENOME PROJECT

A. The Legal Issues

Once the mapping, sequencing and identification process of the HGP is completed, inquiry on the legal implications of how the information is to be used will develop. As one scholar has noted, "the revolution in molecular biology that is producing a human DNA map and sequence of genetic material is fundamentally a scientific information revolution in the arena of personal identity."[66] Information is rapidly becoming available through the mapping and sequencing of the genome and this increases awareness of certain genes and the resulting characteristics that individuals may manifest as a result. For example, there is now an increasing ability to test for genes that indicate the presence of seriously debilitating ailments such as Alzheimer's and Huntington's disease.[67] Now that the ability to access this type of information is becoming more available, the implications to individual privacy are severe. In addition, the ability to examine DNA for genetic alterations that may indicate the presence of diseases and on the basis of this knowledge people may make different decisions than they would have otherwise. In this manner the new information

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[65] *See* Iles, *supra* note 2, at 32.

[66] Philip R. Reily, *Introduction: Reading the Human Genome: Gothic Tale or Happy Ending?* 26 J.L. MED. & ETHICS 181, 182 (1998).

[67] For instance, it is now known that Alzheimer's disease type 3 is located on chromosome 14, while Alzheimer's disease type 4 is sited on chromosome 1 and Huntington's disease is on chromosome 4. *Available at* http://www.ncbunlm.nih.gov/c/s.dll/ SCIENCE96/genelist.

provided by the HGP may allow for a new twist on an old injustice by creating "genetic discrimination."[68] People, as groups or as individuals, may be treated unfairly based on the different content of their DNA.[69] The application of human rights principles to these legal issues will help to shield genetic information from inquisitive third parties.

"Information privacy" is an individual's right to determine what information about him or her should be shared with others.[70] Objectively, a society should respect individual privacy rights because a violation of privacy rights may cause harm to the person.[71] So long as the culture as a whole esteems the principle of individual privacy, then members of society are wronged by any invasion of their privacy, even if no actual harm results from the intrusion.[72] The United States has historically looked at privacy in four ways: private information, private relationships, private decisions, and private places.[73] The personal knowledge that will become available upon a successful completion of the HGP will cross all four of these areas. Genetic information is inherently private since it is distinctly individual and disclosure may harm a person. These highly sensitive facts are often revealed in trust to physicians or health care providers or to intimate friends and family members. The results of genetic testing are often revealed in private places, such as a doctor's office, and will lead to personal decisions on the part of the individual.

A successful genome project may produce usable information with regard to an individual's ability to contract disease as well as his or her status as a carrier of harmful or defective genes.[74] Regulations need to be established to protect individual privacy rights regarding the most personal information and to keep the decisions about this information

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[68] *See* Health Insurance in the Age of Genetics, *supra* note 17, at 11.

[69] *Id.*

[70] *See* Westin, *supra* note 64, at 54. JAMES MICHAEL, PRIVACY AND HUMAN RIGHTS, 3 (1994).

[71] *See* Ruth Macklain, *Privacy and Control of Genetic Information, in* GENE MAPPING: USING LAW AND ETHICS AS GUIDES 157, 159 (George J. Annas and Sheman Elias, eds., 1992).

[72] *See* Macklain, *supra* note 71, at 159.

[73] *See* Westin, *supra* note 64, at 54. However, not every culture considers privacy with such deference.

> When Victor Sidel, a physician well known for his national and international work in public health visited the People's Republic of China some years ago, he encountered common public-health practices that required people to reveal highly personal information, which was then posted in a public place. Sidel asked, "Don't people consider this an invasion of their privacy?" and his Chinese interpreter could not translate the question. The Chinese language apparently lacked a concept of privacy in the sense that makes it an ethical value in Western society. Macklain, *supra* note 71, at 157.

[74] Westin, *supra* note 64, at 66. *See also* Macklain, *supra* note 71, at 159-60.

in the hands of the individual rather than other interested third parties. An absence of appropriate protection would allow outcomes that challenge existing ideas of privacy in five areas.[75] First, in the management of intra-personal boundaries, an individual makes decisions concerning what to know or not know about him or herself.[76] Will individuals retain their right to expand or limit the knowledge of their own selves? Second, in the setting of intimate relationships, the genetic testing of one family member may reveal a condition that will have potentially limiting effects on the life opportunities of other family members.[77] Does the family member have a right to reveal that information? Third, in confidential communications individuals reveal aspects of their private genetic information and other personal facts to providers of medical and health services.[78] Who is to be bound by the confidence and trust of their patients to keep such data confidential? Fourth, regarding qualifications for social benefits, the availability of genetic information may restructure qualification systems, and key benefits or opportunities in society may become conditioned upon obtaining or providing new genetic information about individuals.[79] Who will have access to information and on what basis will individuals be required to grant releases of this information? Fifth, in the realm of social control and public policy, with the advent of genetic technology, the standards for government programs and operations will change since such information may aid with disease control and criminal justice programs.[80] Should the government be allowed to keep DNA data banks on convicts, as proposed by the FBI in the United States and the federal government of Canada, or is this a violation of inherent privacy rights?

In conjunction with the possible breaches of individual privacy rights, there exists the more insidious dilemma of "genetic

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[75] Westin, *supra* note 64, at 66.

[76] *Id.*

[77] *Id.*

[78] *Id.*

[79] Westin, *supra* note 64, at 66.

[80] *Id.* at 68. The FBI has proposed to create a national database for the purpose of law enforcement which includes the following types of indices: a statistical DNA population database, devoid of any personal identifiers; open-case DNA profiles obtained from body fluid stains found on evidentiary materials recovered from violent crime cases having no suspects; convicted violent offender DNA profiles; and missing persons/unidentified bodies DNA profiles. Macklain, *supra* note 71, at 166. The federal government of Canada has also proposed that a genetic data bank of serious offenders, particularly dangerous sexual offenders, be established, in order that repeat offenders more promptly be identified by genetic testing of tissue samples such as blood and semen found at the sites of serious crimes and recoverable from the bodies of victims. Bernard Dickens, *Choices, Control, Access – The Canadian Position, in* HUMAN DNA: LAW AND POLICY: INTERNATIONAL AND COMPARATIVE PERSPECTIVES, at 73 (Bartha Maria Knoppers, ed., 1997).

discrimination." The possibility for this discrimination is given force by the reverence with which society regards health. "Much of what we expect, aspire to, need or choose is seen as dependent on our state of health, however defined."[81] The HGP will yield tremendous benefits in the advancements of health by allowing for disease detection through screening, which may then be treated with currently available medicine or possible gene therapies.[82] The British Medical Association (BMA) has offered estimates that "Genetic and pre-genetic diseases affect one in every twenty people by the age of 25 and perhaps as many as two in three people in their lifetime."[83] While the BMA asserts that these statistics are morally neutral, the numbers and their applications may be manipulated and, therefore, the holding of such knowledge becomes an ethical as well as a legal concern.[84]

Genetic facts may be complicated and confusing to the average person, thereby making him or her highly amenable to misinterpretation and abuse.[85] Linking a high rate of disease to a race or a class may further entrench social disparities and create a "biological underclass."[86] Although it is widely believed by the scientific community that the expression of genetic traits involve many factors,[87] the danger exists that greater attention will be paid to the genetic explanation than to the more complex environmental factors.[88] Such an approach will further serve to the impairment of the vulnerable and disadvantaged groups.[89] Regulation of the application of HGP outputs is essential because, "(h)istory teaches that one must be wary of a nation's institutions and social strategies when it comes to situations when genetic information is linked with racial, ethnic and class differences."[90]

Governments play a key role in the legislative and regulatory framework of the HGP by restricting the uses of genetic information, the marketing of genetic tests, and the dissemination of genetic information by private entities.[91] However, one of the largest problems surrounding the privacy implications of the HGP is the different

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[81] SHEILA MCLEAN, OLD LAW, NEW MEDICINE, MEDICAL ETHICS AND HUMAN RIGHTS, 9 (1999).

[82] *See supra* section B 1, "Therapies for Gene Disorders", and accompanying notes 50 to 62.

[83] MCLEAN, *supra* note 81, at 166.

[84] *See id.* at 167.

[85] *See* Patricia King, *The Past as Prologue: Race, Class and Gene Discrimination, in* GENE MAPPING: USING LAW AND ETHICS AS GUIDES 95, 99 (George J. Annas and Sheman Elias, eds., 1992).

[86] *See id.* at 99-100.

[87] MCLEAN, *supra* note 81, at 178.

[88] *See id.*, at 102.

[89] *See id.*

[90] *See id.* at 95.

[91] *See* Iles, *supra* note 2, at 34.

viewpoints adopted by individual countries on how to handle the interplay between privacy rights and newly discovered genetic information. In the United States, the assumption exists that people possess the freedom to act absent any specific and justifiable prohibition against such action.[92] Therefore, in order to protect the genetic information that will be available after the mapping of the human genome, protection must be statutory.[93] The Human Genome Privacy Act was introduced to the United States Congress with a broad safeguard of the privacy of genetic information against misuse by agencies maintaining records for the purpose of research, diagnosis, treatment, or identification of genetic disorders.[94] The Act was referred to the House Judiciary Committee, but never enacted.[95] Unfortunately, federal legislation on this issue is necessary for the protection of genetic privacy. Although 19 states have enacted legislation protecting genetic privacy through restricting the use of genetic information in insurance, and another 31 states prohibit genetic discrimination in insurance policies, this will not safeguard genetic privacy rights for two reasons.[96] First, health plans are often exempt from state legislation under the Employment Retirement Income Security Act (ERISA).[97] Second, the laws are narrowly focused on genetic tests rather than on genetic information generated by family history, physical examination, or medical records.[98]

Similarly, Canadian law does not have any legislation that is specifically designed to protect genetic material or information.[99] The Canadian concepts of privacy include an individual's right to limit other people's access to personal health information.[100] However, privacy is considered voluntarily surrendered if the patient reveals information to health care professionals, discusses conditions with family members or others, and when health care professionals are under legal duties to

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[92] *See* Corsover, *supra* note 58, at 744-45.

[93] George J. Annas, *Genetic Privacy: There Ought to be a Law*, 4 TEX. REV. L. & POL. 9, 9 (1999).

[94] *See* Costa, *supra* note 20, at 121-22. The overarching premise of the Genetic Privacy Act is that:

> [N]o stranger should have or control identifiable DNA samples or genetic information about an individual unless that individual specifically authorizes the collection of DNA samples for the purpose of genetic analysis, authorizes the creation of that private information, and has access to and control over the dissemination of that information.

R. Weir, *Differing Perspectives on Consent, Choice and Control, in* HUMAN DNA: LAW AND POLICY: INTERNATIONAL AND COMPARATIVE PERSPECTIVES, at 94 (Bartha Maria Knoppers, ed., 1997).

[95] *See* Costa, *supra* note 20, at 122.

[96] *See* Health Insurance in the Age of Genetics, *supra* note 17, at 11.

[97] *See id.* at 14.

[98] *See id.*

[99] Dickens, *supra* note 80, at 71.

[100] *See id.* at 75.

make patient's health information known.[101] This concept of privacy does not seem to assure much protection for Canadian citizens. In 1983 the federal government of Canada enacted the Privacy Act, which has given effect to "international standards that regulate the collection, use and disclosure of personal information by governments and governmental agencies."[102] In addition, under §28 of the Act, the head of a government institution may refuse to disclose any personal information relating to the physical or mental health of an individual when such a declaration would be contrary to the best interests of the individual.[103] Finally, the Privacy Commission of Canada published a report in 1992 recommending that there be no mandatory genetic testing at the behest of the state and no denial of services or benefits to people who refuse to submit to genetic testing for the purpose of acquiring benefits or services.[104]

Human rights regulation is the proper approach because, as a control technique, human rights ensures that all the interests of those involved will be factored into the decisions of the development of the law. Furthermore, the introduction of human rights methodology will ensure that the uses of the genetic information will not be left solely to the governments and private corporations that are funding most of the research and development of the HGP. Since the HGP is primarily a quest of science, those entities currently wielding power have an additional basis of legitimacy.[105] Consideration of human rights laws will augment peripheral voices and make other control techniques more responsive through time, and will also be able to counter social problems before they materialize.[106] Human rights laws protect the interests of the individuals whose privacy is at stake and ensure that their concerns will be heard and dealt with rather than simply ignored in favor of those concerns of larger and more prominent figures.

This debate makes evident the fact that the current legal structure in which the genetic developments are occurring is too slow to absorb the scope and speed at which this technology is advancing.[107] Therefore,

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[101] *See id.*

[102] *See id.* at 76. The eight principal elements of the Act require that: only personal information can be collected that directly relates to the institution, the institution must collect the information directly from the individual, the institution must inform the individual, the institution cannot use information except for authorized purpose, the institution cannot disclose information except in accordance with the Act, the information must be accurate, the individual must have access to the information and the individual must be able to obtain the information upon request and be able to make necessary changes. *See id.*

[103] *See id.* at 77.

[104] Dickens, *supra* note 80, at 78.

[105] *See* MCLEAN, *supra* note 81, at 15.

[106] *See* Iles, *supra* note 2, at 34-35.

[107] *See* Taylor, *supra* note 2, at 500.

institutions of bioethics have been established to deal with the growth, and have developed both a statutory and practical independence from the existing administrative structures.[108] These bioethical institutions are confronted with issues of informed consent and the rejection of eugenics.[109] They also hold true to the ideals of respect for the individual and the dignity of human beings.[110] These bioethical institutions should not be expected to function in this manner indefinitely. A uniform set of international guidelines is necessary to provide for explicit content and process regarding the protection of the specific human rights that are likely to be affected by the outputs of the HGP.

B. The Ethical Issues

Early on in the HGP, the ethical considerations became impossible to ignore and five percent of NIH's annual budget is devoted to the study of these inherent ethical issues.[111] Concerns such as the lack of respect towards individual autonomy and uniqueness as well as the decrease in bio-diversity once people are able to choose to enhance the traits they desire in their offspring are only the beginning. An international study in 19 nations has shown that human geneticists and their patients in many nations frequently face a set of eight ethical problems.[112] These areas include: fairness of access to genetic services, abortion choices, confidentiality problems when other family members' interests are involved, protection of privacy from institutional third parties, disclosure dilemmas in counseling, indications for prenatal diagnosis, voluntary or mandatory screening policies, and counseling of incapacitated patients.[113] While all of these are substantial interests, the shadow looms largest over uncertainties for the futures of individuality and human dignity.[114]

Currently, issues of common identity are not a societal concern because identical twins are such a rarity.[115] The advantages of modern

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[108] *Id.* at 501.

[109] *Id.*

[110] *See id.*

[111] *See* Reily, *supra* note 66, at 182.

[112] *See* John Fletcher, *Ethics and Human Genetics Once the Human Genome Has Been Mapped, in* HUMAN GENOME PROJECT: ETHICS 265, 268 (1990).

[113] *See generally id.* Many of these issues cross over into the legal question of privacy rights and genetic discrimination. With respect to access to genetic services, Patricia King suggests that it is imperative to make sure institutions that will be responsible for providing medical services are established and operated to fairly distribute benefits so that vulnerable and disadvantaged groups are not displaced. *See* King, *supra* note 85, at 102. She also discusses the fact that poor women receiving Medicaid are already suffering disadvantages with regard to abortion choices and prenatal diagnosis. *See id.* at 103.

[114] *See* Corsover, *supra* note 58, at 748.

[115] *Id.* at 749.

genetics will change the proportionality of individuals with the same genetics because there will be the possibility of an infinite number of identical embryos that can be manufactured at will.[116] Legislation must be enacted to stop this from occurring.[117] When Aldous Huxley wrote BRAVE NEW WORLD, he expressed the horror of selective genetic engineering while describing the process of manufacturing lives to become members of a society in which individuals were classified by their inherent genetic characteristics.[118] Huxley's social structure reinforced genetically engineered traits to the disadvantage of biodiversity and individuality. Modern genetic technology will be able to go even further because once an "ideal" individual is born or created, the genetic information may be replicated an infinite number of times. Utilization of splitting techniques to create multiple clones of a particular embryo will lower feelings of self-worth because an individual may know he or she was artificially manufactured and not only that an identical copy exists, but that there are multiple copies.[119] This concept raises issues of whether or not there is an inherent right to individuality and if such a right would deserve specific governmental or international protection against the copying of genetic compositions.[120] In addition, if such a right is found to exist, will it belong to the parent or to the child whose genetic make-up is being exploited?[121] Since cloning human beings is an issue that is no longer science fiction but real science,[122] whether the parents will have this fundamental right is most definitely an ethical one worth considering.

Germ line manipulation and cloning are both processes that are viewed negatively because of their wide-ranging implications for society

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[116] *Id.*

[117] *Id.*

[118] ALDOUS HUXLEY, BRAVE NEW WORLD, 5-6 (1932).

> [O]ne by one the eggs were transferred from their test-tubes to the larger containers; deftly the peritoneal lining was slit, the morula was dropped into place, the saline solution poured in . . . and already the bottle had passed, and it was the turn of the labellers. Heredity, date of fertilization, membership of the Bokanovsky Group – details were transferred from test-tube to bottle. No longer anonymous, but names, identified, the procession marched slowly on; on through an opening in the wall, slowly on into the Social Predestination Room. *Id.*

[119] *See* Corsover, *supra* note 58, at 749.

[120] *See id.*

[121] *See id.* In turn, what about the child who will be born as a copy? Although the genetic material will be identical to another person's the expression of genetic traits and life experiences will belong entirely to the new embryo.

[122] Corsover, *supra* note 58, at 703. Dr. Ian Wilmut at the Roslin Institute in Scotland led a research team to the first successful cloning of an adult mammal in 1997. This process resulted in the birth of Dolly, a sheep that "contained genetic material of only one parent and is basically a delayed twin of the adult sheep that donated the material." *Id.*

as a whole. As human beings, it would seem as if we are "playing God" to change what is the common heritage of mankind. While cloning merely copies genetic information to create a new life, germ-line manipulations have an even more sinister effect because they alter the genetic line of a family without the informed consent of the progeny whose genetics are also being altered.[123] While the trait being altered in a germ-line manipulation may initially be considered to be in the best interests of all parties concerned, there is simply no way to know how such a manipulation will affect other genes given each individual's environment. The use of genetic testing to discover abnormalities and germ-line manipulation to make genetic conditions avoidable may encourage narrow, socially determined standards of "health" and "normality."[124] Such narrow standards can also generate social animosity towards parents who allow their children to be born "defective" despite knowledge of a potential genetic condition.[125] This may lead to discrimination on many levels, beginning with the economics of being able to afford the initial genetic testing and gene therapies and progressing to "genetic discrimination" for being considered unhealthy or not normal.[126]

There are three different sets of issues to be considered when discussing the ethical implications of the Human Genome Project: those that pertain to the individual, to society, and to the species.[127] On the individual level, the main concerns are issues of genetic screening and counseling.[128] At the societal level, the focus shifts to population-based genetic screening, resource allocation and commercialization, and eugenics.[129] The species level issues are related to determinism, reductionism, normalcy and the meaning of health and disease.[130]

At the individual level, the modern advances in gene screening technology inherently raise other issues concerning genetic discrimination and public health concerns. Genetic screening will allow parents to evaluate their future children in their embryonic state for genetic defects and disease.[131] The results of such a screening may indicate a predisposition for a condition that will onset later in life, but does not indicate when the onset will occur.[132] If the gene is for a late onset condition and the embryo is prematurely aborted, the embryo has

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[123] *See* Munayyer, *supra* note 1, at 698.

[124] *See id.* at 698-99.

[125] *Id.* at 699.

[126] There may be situations when public policy requires a minimum level of genetic health.

[127] Annas, *Monster Mythology, supra* note 29, at 639.

[128] Annas, *Monster Mythology, supra* note 29, at 639.

[129] *Id.*

[130] *Id.* at 640.

[131] Corsover, *supra* note 58, at 710.

[132] MCLEAN, *supra* note 81, at 173.

been denied the potential for life based solely on the indicated "defect."[133] Genetic screening is also a public health interest because the ability to seek out asymptomatic people in this manner, many of whom would not otherwise be aware of their condition, means that genetic screening bridges the individual and societal levels.[134] The idea of counseling follows from the effects that the screening will have on the individual once the results of the tests become known.[135] The Stamatoyannopoulous study in Greece suggested that knowledge of carrier status had a stigmatizing effect when provided to families in that culture and this was enough to keep families from sharing the information with other families in order to avoid disrupting the mate selection process.[136] This reinforces an individual's right to privacy regarding genetic information as well as an individual's right "not to know."[137] People are currently being protected by bioethics legislation that establishes the right "not to know" if they chose to not be "haunted by the prospect of a predisposition to grave or even fatal biological conditions."[138]

At the societal level, eugenics becomes an issue and can be a positive or negative process that may be used to improve the human species as a whole.[139] "Negative eugenics" eliminates the weaker genetics of a society through processes such as sterilization. This renders a *Buck v. Bell* type of reasoning upon an entire society.[140] "Positive eugenics" promotes the fit and healthy through possibly offering financial incentive programs.[141] Eugenics may eventually lead parents to desire to design "ideal" children, which would lead to a

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[133] *Id.* She also mentions the judgments made about pre-implanted embryos and how this enhances discrimination.

> If we are unconcerned about the embryo before implantation, then we may chose to screen for, then screen out, a whole range of conditions which might – were the embryo already implanted – be regarded as inappropriate to look for or insufficiently serious to merit a pregnancy termination, thus reinforcing discrimination against others who suffer from the same condition.

Id. at 172.

[134] Annas, *Monster Mythology, supra* note 29, at 640.

[135] Morse, *supra* note 16, at 241.

[136] James Sorenson, *What We Still Don't Know About Genetic Screening and Counseling, in* GENE MAPPING: USING LAW AND ETHICS AS GUIDES 210 (George J. Annas and Sheman Elias, eds., 1992).

[137] Madison Powers, *Privacy and the Control of Genetic Information, in* THE GENETIC FRONTIER: ETHICS, LAW AND POLICY 53, 66 (Mark S. Frankel and Albert Teich eds., 1994).

[138] Lenoir, *supra* note 4, at 564.

[139] Corsover, *supra* note 58, at 711.

[140] Buck v. Bell, 274 U.S. 200, 207 (1927). Justice Holmes justified the sterilization of institutionalized mental defectives with the remark that "three generations of imbeciles are enough."

[141] Robert N. Proctor, *Genomics and Eugenics: How Fair is the Comparison?, in* GENE MAPPING 57, 60.

socially created homogeneity, which would in turn be based on current societal definitions of normalcy.[142] What constitutes an "undesirable" trait has traditionally been determined by cultures and society. Eugenics then places the determination of genetic make up in the hands of the social system rather than the natural system. In addition, eugenics supports the notion that biology determines individual talent and disability.[143] Eugenics "presents a dramatic case of how genetic knowledge (and genetic ignorance!) can be coupled with repressive state policy to deprive individuals of rights and liberties."[144] Striving for such homogeneity obviously defeats the goals of bio-diversity, but more importantly, may also violate human rights if extended too far. The idea that genetics is somehow more pure than other forms of information leads to greater justification for discrimination. The contravention of fundamental freedoms may be hidden from view in the guise of public health policies or the like. This impels a need for universal protection of genetic information so that it may not be used against people in such a manner.

Finally at the species level, the HGP by definition brings with it the notions of reductionism and determinism because it breaks human beings down into their most basic elements. James Watson has characterized the Project as the search for "ultimate answers to the chemical underpinnings of human existence," and he has also stated "our fate is in our genes."[145] However, the idea that human beings may be broken down into parts like machines is not entirely accepted within the medical field. "The reduction of all of biology, all of behavior characteristics and 'fundamental living things' to molecular mechanisms of life betrays a metaphysical ambition to demonstrate that organisms really *are* machines, and that all of life may be accounted for in this way."[146] "Genes have become the near universal scapegoat for all that ails the human species."[147] Human beings are complex organisms internally and they also must interact with their external environments. Therefore genetic conditions must be viewed as the result of an unpredictable interplay of many factors and processes.[148] Genetic predisposition studies can do little to explain epidemiological patterns for increases in lung and breast cancer.[149] Such failure challenges the view of biological determinism that to a large extent

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[142] Morse, *supra* note 16, at 243.

[143] Proctor, *supra* note 141, at 60.

[144] *Id.* at 61.

[145] Evelyne Shuster, *Determinism and Reductionism: A Greater Threat Because of the Human Genome Project?*, *in* GENE MAPPING: USING LAW AND ETHICS AS GUIDES 115, 115 (George J. Annas and Sherman Elias, eds., 1992). *See also* Morse, *supra* note 16, at 230.

[146] Shuster, *supra* note 145, at 115.

[147] Proctor, *supra* note 141, at 76.

[148] MCLEAN, *supra* note 81, at 178.

[149] Proctor, *supra* note 141, 77-78.

human talents and disabilities are written in genetics.[150] Although the final mapping of the genome will operate as a blueprint of the human race, there is no real way to know how genes will actually manifest themselves in any single human being.[151] For this reason as well, individual genetic information must be fully protected. Geneetic information may not be understood in the abstract, when it appears as a person's genetic blueprint of predispositions for disease or other physical characteristics, but must be seen as it manifests itself in the actual environment.

III. THE DECLARATION AND INTERNATIONAL HUMAN RIGHTS

There is no current international legal framework in which to set the HGP because the scientific developments have moved much more rapidly than the legal system in which it exists.[152] There are a number of international instruments that deal with international human rights generally in which the international legal debate for the protection of an individual's genetic information sits uneasily. These international instruments are the International Bill of Rights, which contains within it the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights (ICESCR), and the International Covenant on Civil and Political Rights (ICCPR).[153] When taken together these instruments are still too vague to ensure the protection of human rights and the promotion of public heath with specific regard to personal genetic information.

Although the ICCPR and ICESR documents are vague, they do guarantee individuals the right to "enjoy . . . fully and freely their natural wealth and resources."[154] The human genome is undoubtedly a natural resource that, while it is shared by the entire race, deserves the protection of these international instruments. The ICCPR, Article 12, recognizes the right to "the enjoyment of the highest attainable standard of physical and mental health."[155] Under this standard, people are entitled to the benefits of the HGP because the outputs of the project will eventually lead to advancements in human health. Now that research has located genes that carry harmful diseases, such as

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[150] *Id.* at 76.

[151] Shuster, *supra* note 145, at 123.

[152] Taylor, *supra* note 2, at 500.

[153] Universal Declaration on Human Rights, G.A. Res. 217 A(III), U.N. GAOR, 3rd Sess., 67th plen. mtg. at 1, U.N. Doc. A/810, at 71 (1948) (hereinafter Universal Declaration); International Covenant on Economic Social and Cultural Rights, G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doc A/6316 (1966) (hereinafter ICESCR); International Covenant on Civil and Political Rights, G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No 16, at 52, U.N. Doc. A/6316 (1966) (hereinafter ICCPR).

[154] Munayyer, *supra* note 1, at 703.

[155] ICCPR, *supra* note 153, art. 12

Huntington's and Alzheimer's, people can be screened and treated much earlier. ICCPR Article 15 further recognizes the right to "enjoy the benefits of scientific progress and its applications."[156] When viewed at the most basic level, the HGP is the result of scientific progress, and the data it yields produces benefits through application in both health and medicine. For example, one possible benefit of the HGP is that it may become possible to produce any human protein and new molecules may be designed specifically to block biochemical pathways that lead to disease.[157] The information that will be available as a result of the HGP is such a benefit of scientific progress that it would be entitled to protection under this provision.

As of 1994, there was a Draft Convention for the Protection of Human Rights and the Dignity of the Human Being with regard to the Application of Biology and Medicine.[158] This Convention is not limited to the genetics issue but also addresses a range of biomedical problems.[159] The Convention's single largest problem is that it focuses on individual rights and disregards the impact on social inequalities as well as the overall social effect of personal decisions regarding genetic technology.[160] The Convention addresses only the most direct and visible consequences of technological innovations and does not deal with the full range of implications stemming from the HGP.[161] An instrument that is more specifically targeted at the HGP with a broader impact is necessary.

Article 2 of the Universal Declaration of Human Rights states, "Everyone is entitled to the rights and freedoms set forth in this declaration, without distinction of any kind, such as race, colour, sex, language, religion, political, or other opinion, national or social origin, property, birth or other status."[162]

A distinction made based on genetics, even though it is not specifically listed in the article, falls within the other category of "other status" and should be condemned. Individual rights and protection of genetic information must be protected under a human rights framework on an international level. Results of the HGP have already identified more than 60 genes that lead to disease.[163] Human beings inherit genetic mutations and DNA undergo an estimated additional 30 mutations during an individual's life span.[164] The HGP will make

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[156] *Id*, art. 15.

[157] Merz, *supra* note 26.

[158] 36 I.L.M. 817 (1997); *see also* Iles, *supra* note 2, at 42.

[159] Iles, *supra* note 2, at 42.

[160] *Id.*

[161] *Id.*

[162] Universal Declaration, *supra* note 153, art. 2.

[163] Merz, *supra* note 26.

[164] Pines, *supra* note 51.

available this most profoundly personal information about an individual's genetic make-up, including whether or not he or she possesses an abnormal gene or one that indicates a disease. The possibility for the abuse of such knowledge is endless. Therefore, the HGP does not raise new issues in medicine and human rights, but exacerbates old ones, especially regarding privacy, disclosure of personal information, and freedom of reproductive choices.[165]

UNESCO was established in 1945 and has the primary constitutional directive of promoting collaboration among nations in education, science, and culture. In 1993, UNESCO formed the International Bioethics Committee (IBC) to respond to ethical concerns raised by progress in genetic science and to promote international debate and worldwide dialogue.[166] In determining what type of instrument would best serve the interests of individuals and science regarding the Human Genome Project, the IBC determined that there was:

> [A] need to establish general principles and to assert the ineluctable respect for dignity, freedom and human rights, while remaining flexible in order not to interfere with scientific progress but respecting ethics and responsibilities which· come with it. Therefore it is necessary to conceive of a document which can remain timely and in accordance with progress and scientific changes in the future.[167]

The IBC finally decided that a declaration was the most appropriate form of document because this format would take into account the evolution of the actual state of practice and would have immediate applicability, binding legal effect and a procedure to verify its use and its efficiency.[168] The Declaration was therefore drafted, focusing on the needs of the individual while being sufficiently specific with regard to individual dignity, rights and research. It also takes into account the rapid rate at which biotechnology in this area is developing.

The main idea that fuels the Declaration is that there is inherent dignity, and equal and inalienable rights bestowed in all members of the human family.[169] The Declaration also recognizes that research, which keeps open the "vast prospects for progress in improving the health of individuals and of humankind as a whole," must be balanced against the possibility that further understanding of genetics may lead to "discrimination based on genetic characteristics."[170]

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[165] Taylor, *supra* note 2, at 490.

[166] *Id.* at 507.

[167] Hector Gros Espeil, *Project of an International Instrument for the Protection of the Human Genome*, *at* http://www.unesco.org/ibc/uk/genome/juridique/instrument/html.

[168] *Id.*

[169] Human Genome Declaration, *supra* note 3.

[170] *Id.*

In Articles 1 through 3, the Declaration discusses the dignity of the individual and holds that the genome is the heritage of humanity and out of the respect for human dignity, individuals should not be reduced to their genetic characteristics.[171] In addition, the Declaration recognizes that genetic potentialities are expressed differently based on varying states of health, living conditions, nutrition and education.[172] These holdings are important because they offer broader protections for the individual than one may currently possess. Under current scientific theories, individuals are the sum of their genetic parts.[173] The Declaration denies this genetic reductionalism and reinforces the dignity of the individual. Article 3 further protects the individual from discrimination for being merely a carrier of a gene by recognizing that external conditions will have an effect on genetic expression.

Articles 5 through 9 focus on the rights of the individual. Article 5 specifically deals with the right to grant the use of genetic information for research, the necessity to deliver prior, free and informed consent, the right of each individual to decide to be fully informed, the necessary protocols required for research, and the requirement that when there is no capacity to consent, the research will only be allowed for the direct health benefit of the individual.[174] Each one of these aspects of consent and use of genetic information specifically protects the rights of the individual because they must be informed of the procedures ahead of time and then they have the choice to consent or refuse to consent. Article 6 requires that no discrimination infringe upon human rights or fundamental freedoms of human dignity. Article 7 requires that genetic data for identifiable people must be kept confidential. This is a key aspect of the Declaration because it would protect people from having their employers and insurers look into their genetic information without their express consent. Article 8 offers reparations for damages to individuals.

Article 9 is perhaps the most important of these five articles because it deals with changes that may be advanced by local governments. It states that "limitations to the principles of consent and confidentiality may only be prescribed by law for compelling reasons within bounds of public international law and international law of human rights."[175] This wording allows room for states to legislate on this issue as they see fit, so long as they are not in direct conflict with public international law or the international law of human rights and they show compelling reasons. Although it is necessary to allow states to retain some control over this issue, the boundaries here are very easy

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[171] *Id.*, arts. 1 & 2a, b.

[172] *Id.*, art. 3.

[173] Morse, *supra* note 16, at 230.

[174] Human Genome Declaration, *supra* note 3, art. 5.

[175] Human Genome Declaration, *supra* note 3, art. 9.

to push.

IV. IMPLEMENTATION OF THE DECLARATION AND THE PROTECTION OF HUMAN RIGHTS

International human rights laws assert direct access onto the international legal system.[176] Traditional international human rights laws posit that an individual will need protection of their rights against the abuses of the government. The current situation resulting from the HGP outputs will require that groups of people, the "genetic underclass," who are discriminated against, be protected both from their governments as well as from private agencies. [177] Since international human rights law is only made effective by each nation enacting rules and adopting the instrument as part of its own democratic legal system, the Declaration will need an implementation device stronger than the one currently in place.

International human rights law is a relatively recent development, having truly come to the fore since World War II to replace the idea of natural rights.[178] Traditionally, human rights were within the realm of the domestic countries to determine when wrongs occurred and to decide how to handle them, with some minor exceptions.[179] International human rights law can be made effective only if each nation chooses to adopt the rules as part of its own domestic legal system.[180] The content of international law comes from five sources, one of which is an international declaration.[181] Since the Declaration is an international declaration, it qualifies as a source of international law. Furthermore, based on the basic operating principles of international law, implementation is essential to the survival of the principles that it purports. If the Declaration is not implemented and enforced at local levels, the human rights it attempts to protect will go unguarded and the tool will become virtually useless.

Sometimes the domestic implementation of human rights norms may be achieved by pressuring and embarrassing governments.[182] There are four ways to domestically implement human rights law: constitutionalism, treaty application, domestic judicial enforcement,

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[176] MARK W. JANIS, AN INTRODUCTION TO INTERNATIONAL LAW 249 (3rd edition, Aspen) (1999).

[177] Costa, *supra* note 20, at 110.

[178] Weston, *Human Rights, in* INTERNATIONAL LAW 862, 862 (Barry Carter and Phillip Trimble, eds., 1999).

[179] Hurst Hannum, *Guide to International Human Rights, in* INTERNATIONAL LAW 844, 845 (Barry Carter and Phillip Trimble, eds., 1999).

[180] *Id.* at 844.

[181] *Id.* at 847.

[182] Hannum, *supra* note 179, at 880.

and diplomacy.[183] The theory of constitutionalism suggests that a nation's constitution traditionally guarantees to some extent the rights covered by the international instruments.[184] Treaty application looks to the terms of a treaty to see whether or not each one is self-executing or not.[185] An example of domestic judicial enforcement is the *Filartiga* case.[186] *Filartiga* strengthens the movement for human rights in the countries where the abuses take place and in the United States by strengthening and expanding international human rights law.[187] Since the Declaration has been adopted in the form of an international declaration, the main question is now one of how the individual states will choose to implement it domestically. UNESCO and other non-governmental organizations have tremendous influence, however, through both empowering and exclusionary effects.[188] Although the non-governmental organizations (NGOs) raise consciousness about the issue, the fear is that they will not be as effective for prevention and treatment.[189]

The enforcement of international obligations is a concern for any issue in the arena of human rights.[190] Implementation of human rights may present a jurisdictional problem if the states involved in a dispute have not properly consented to the authority of the court asserting the power to decide the case.[191] The international courts are open only to nations and not to individuals, and with the HGP it will be the genetic information of the individual that will need the protection.[192] Finally, there is no international police force to effectively enforce the decisions of an international court, but the parties must rely on voluntary compliance.[193] If a decision is implemented, there are three possible levels of implementation. First, the decision may be implemented only within the national system of the state concerned. Second, a determination may be implemented by other states in the course of

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[183] *Id.*

[184] *Id.* at 881.

[185] *Id.* at 882.

[186] Filartiga v. Pena-Irala, 630 F.2d 876, (2nd Cir. 1980). The United States court recognized a cause of action for "wrongful death" even though the victim and the defendant were both citizens of Paraguay based on the U.N. Charter, the Universal Declaration on Human Rights; the U.N. Declaration Against Torture; the American Declaration of the Rights and Duties of Man; and other pertinent declarations, documents and practiced constituting the customary international law of human rights and the law of nations.

[187] INTERNATIONAL LAW at 885-87 (Barry Carter and Phillip Trimble, eds., 1999).

[188] Sikkink, *Transnational Advocacy Networks and the Social Construction of Legal Rules, in* INTERNATIONAL LAW 853, 861 (Barry Carter and Phillip Trimble, eds., 1999).

[189] *Id.*

[190] Hannum, *supra* note 179, at 849.

[191] *Id.*

[192] *Id.*

[193] *Id.* at 850.

international relations. Finally, international bodies may implement the judgment.

HGP is a human rights topic because the information that will be available once the genome is finally mapped and sequenced will relate to all human beings, since the genome is the collective heritage of the human race. The new information will also allow for special considerations in reproductive choices that must be made in light of the new technology and therefore raises concerns of human rights.[194] Most significant are the following questions: what information should be released, how is it to be collected, by whom should it be collected, on whose authority should it be collected, to what purpose may it be collected, and how and to whom is the information to be disclosed?[195] Issues including autonomy, privacy and informed consent are raised by these sorts of questions and will be borne out through the improper use of genetic information.[196] Third parties such as insurers, employers, private corporations, governments and individuals may desire to gain access to this information and may use it in a discriminatory fashion.[197] This would then be the first step to creating a "genetic underclass" through group classification based on common ties of heredity and disease. This process of classifying could redefine groups that are already marginalized by society because of other characteristics.[198] These groups must be protected from discrimination in the same way that an individual receives protection under the traditional human rights paradigm. They risk the same types of discrimination based on their genetic heritage and the new technology that is developing. All individuals will be at risk of discrimination if the Declaration is not properly implemented. The Declaration is the only international document of its kind that protects individual privacy with respect to genetic information.

The basis for human rights laws is the concept that every nation has an obligation to respect the human rights of its citizens and other nations. The international community bears both a right and responsibility to protest this when countries that profess to uphold the values of human rights are not upholding this obligation.[199] It is an inherent right of people that they should not be discriminated against on the basis of their genetic compositions. Therefore, human rights laws should necessarily protect the issues raised by the HGP.

International human rights law can be made effective in practice only if each nation makes these rules part of its own domestic legal

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[194] Taylor, *supra* note 2, at 490.

[195] *Id.* at 491.

[196] *Id.*

[197] *Id.*

[198] *Id.* at 493-94.

[199] Hannum, *supra* note 179, at 845.

system, which is why there needs to be state by state implementation of the Declaration. UNESCO needs to set up an effective mechanism for the implementation of the Declaration. The IBC recognizes their role in promoting the broadest possible dissemination of information about fields covered by the Declaration.[200] However, in order to effectively take action and move from a rhetorical promotion to authentic advancement of international norms, UNESCO must develop a supervisory system by which they can monitor the advancement of the goals detailed in the Declaration.[201]

CONCLUSION

> So the Genome Project I think deserves its current status as perhaps the most important organized scientific effort humankind has ever mounted. When you think about it, this is an adventure into ourselves. This is learning about our biology, reading our own blueprint, and its potential to transform medicine for the better is enormous.
>
> - Francis S. Collins, Dir. National Human Genome Research Institute[202]

The HGP is making significant advances in the biological world to the benefit of the entire human race. How we choose to use the information is crucial and we cannot leave this area entirely unregulated. Genetic information will hold the blueprint to individuals. Whether or not each individual will manifest each genetic predisposition is impossible to know, but to allow dissemination of this information into the wrong hands would be catastrophic. There must be safeguards on the privacy rights of individuals to protect them from wrongful discrimination and this should start at the international level with effective implementation of the Declaration.

The HGP has developed into a worldwide effort to map, sequence and identify the entire human genome. As of February 13, 2001, the entire genetic sequence was made public and placed online. Although the human genome contains more than 3 billion letters, the genome itself is composed of only roughly 30,000 genes and not the originally estimated 100,000. Despite the lower number of genes present in the genome, the legal and ethical implications do not diminish. The legal

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[200] Report by the Director General on the Implementation of the Universal Declaration on the Human Genome and Human Rights, UNESCO, Doc. 154 EX/41 (1998).

[201] Taylor, *supra* note 2, at 524.

[202] COMMITTEE ON COMMERCE U.S. HOUSE OF REPRESENTATIVES, 105TH CONG., *in* PRIVACY, CONFIDENTIALITY AND DISCRIMINATION IN GENETICS (Comm. Print. 1997), *supra* note 17.

concerns of privacy and "genetic discrimination" make the results of the HGP issues for human rights. The ethical concerns with respect to individuality and human dignity are also within the traditional arena of human rights. However, the International Bill of Human Rights does not offer adequate protection for these new and difficult situations.

The Declaration is the only international instrument with the force of law that would protect people worldwide from some of the legal and ethical violations that are possible. The Declaration, however, has not yet been implemented and the effects of the protection offered cannot be realized. An international agreement of this sort is appropriate because it will serve to protect human rights on a worldwide scale. Once the Declaration is implemented, it will become difficult to discriminate or violate human rights on a genetic basis because there will not be any way to effectively shift from one country where regulations on genetic privacy exist to another where they don't. The same idea would apply to the ethical safeguard against reductionalism within the Declaration. The implementation of the Declaration is of the utmost importance and needs to be inaugurated as early as possible.