

NOTE

COMMERCIALIZED GENETIC TESTING: THE ROLE OF CORPORATE BIOTECHNOLOGY IN THE NEW GENETIC AGE

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I.	INTRODUCTION	
II.	PRIMER ON THE STATE OF THE ART: THE BIOTECHNOLOGY INDUSTRY IN THE 21ST CENTURY	
	A. <i>DNA – The Building Block of Life</i>	
	B. <i>Human Genetics</i>	
III.	PATENT PROTECTION NOW AND TOMORROW: THE BACKDROP FOR COMMERCIAL GENETIC TESTING	
	A. <i>The Current Status of Human Genetic Patents</i>	
	B. <i>Interpretation of the Patent Statute by the Courts</i>	
	C. <i>Calls for Prohibition or Proscriptive Narrowing on Human Genetic Patents</i>	
IV.	REDEFINING THE PRACTICE OF MEDICINE: GENETIC TESTING, MEDICAL LICENSURE, AND THE CORPORATE PRACTICE OF MEDICINE PROHIBITION	
	A. <i>Medical Licensure Requirements</i>	
	B. <i>The Corporate Practice of Medicine Prohibition: HMOs as a Model for Non-Medical Practice</i>	
	C. <i>Application of the Corporate Prohibition to Commercial Genetic Testing: Policy for the New Genetic Age</i>	
V.	A PROPOSED REGULATORY FRAMEWORK FOR GENETIC TESTING: RECOMMENDATIONS FROM THE SECRETARY’S ADVISORY COMMITTEE ON GENETIC TESTING	
VI.	RECOMMENDATIONS.....	
	A. <i>Preservation of Patent Protection</i>	

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B. *Non-Application of Medical Licensure Requirements and Corporate Practice of Medicine Prohibition*.....
C. *FDA Regulation of the Commercial Genetic Testing Industry*.....
D. *Genetic Counseling and Physician Intermediaries*.....
VII. CONCLUSION.....

I. INTRODUCTION

With the sequencing of the human genome nearing completion,¹ biotechnology, genomics, and pharmaceutical companies are filing thousands upon thousands of patent applications on human genetic material.² Encouraged by the prospect of winning potentially lucrative patents on genes and associated gene markers³ relating to genetic disorders, disease susceptibilities, and drug sensitivities, corporate entities are scrambling in their research efforts to discover and patent important pieces of the human genetic code.⁴ Genes related to maladies such as cancer, cardiovascular disease, obesity, and osteoporosis have already been sought, discovered, and patented,⁵ providing their patent holders exclusive use and licensing rights. Much of the value contemplated in discovering and protecting these sequences is their potential to be used in diagnostic testing for genetically induced disorders, disease susceptibility, and individual responsiveness to particular drug treatments linked to them.⁶ In combination with technologies that allow samples of a person's own genetic makeup to be easily extracted from blood samples or tissue swabs, the discovery of indicia for various diseases and drug

¹ See generally J. Craig Venter et al., *The Sequence of the Human Genome*, SCIENCE, Feb. 16, 2001, at 1304 (describing the initial findings of Celera's sequencing of the human genome); International Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, NATURE, Feb. 15, 2001, at 860 (describing the initial findings of the International Human Genome Sequencing Consortium's sequencing of the human genome); see also KEVIN DAVIES, CRACKING THE GENOME 236 (The Free Press 2001). As of December 31, 2001, 63.0% of the genome was in complete form and 34.8% was at a draft stage, with 2.2% remaining to be sequenced. See National Center for Biotechnology Information, *Human Genome Sequencing*, at <http://www.ncbi.nlm.nih.gov/genome/seq> (last visited Jan. 5, 2002).

² See DAVIES, *supra* note 1, at 159-61.

³ Gene markers are genetic sequences that mark the presence of genes. See *id.* at 219-20.

⁴ See *id.* at 160, 219-20.

⁵ For example, Myriad Genetics, Inc., a pioneer in the field of disease gene research, has discovered and patented the well-known BRCA1 and BRCA2 disease genes implicated in breast and ovarian cancers and now commercially markets genetic tests for these disorders as well as colorectal cancer. See *Myriad Genetics*, at <http://www.myriad.com> (last modified Nov. 11, 2001). Myriad has also discovered genes implicated in heart disease, prostate cancer, and obesity, among other disorders. See *Myriad Gene Discovery*, at <http://www.myriad.com/research/genomics.html> (last modified Nov. 11, 2001).

⁶ See DAVIES, *supra* note 1, at 219-21.

sensitivities creates enormous potential for diagnostic genetic testing.⁷ Such testing would make possible screening for disease predisposition, provide for pre-symptomatic warnings, and allow for more effective, personalized medical treatment and even prophylaxis against the onset of disease.⁸

With the vast potential for genetic testing, however, comes a multitude of problems. Foremost is that the intellectual property protection that underlies potential corporate involvement in diagnostic genetic testing is a matter of extreme controversy. Many contend that genetic sequences, as part of our naturally occurring human heritage, should not be afforded patent protection at all.⁹ Still others are critical of the impact such monopolies on gene sequences have on affordable access for medical purposes.¹⁰ Another issue is that genetic testing skirts the boundaries of medical practice, calling into question the propriety of corporate involvement. Where diagnostic genetic testing service is deemed medical practice, medical licensure statutes and the long-standing Corporate Practice of Medicine Prohibition, which has served over time to protect the public from improper medical practice by for-profit entities whose interests conflict with those of patients, could be implicated. Yet a third problem is that regulations are not currently in place for genetic testing, and their absence poses significant opportunity for negligence, abuse, and danger to the public. The information imparted through genetic testing would impact those receiving its results both medically and psychologically and could also have significant insurance and financial consequences. Disseminating genetic information must be undertaken in accord with strict standards. Though the manner in which genetic testing should be regulated is an open question, some level of oversight is an absolute necessity.

The resolution of each of these issues will determine how and to what extent the vast potential locked in commercial genetic testing may be extracted and realized. This note will review the prominent problems that underlie commercialized genetic testing¹¹ and develop a recommended legal model for the juggernaut that diagnostic genetic testing, now in its infancy, promises to

⁷ *See id.*

⁸ *See id.*

⁹ *See* Charles W. Schmidt, *Cashing in on Gene Sequences*, MODERN DRUG DISCOVERY, May 2001, at 73 (quoting Massachusetts Institute of Technology professor Jonathan King, stating that “[g]enes derive from millions of years of evolution and are, in the deepest sense, products of nature. . . . They are not the inventions of individuals, corporations, or institutions.”).

¹⁰ *See* AMERICAN MEDICAL ASSOCIATION, REPORT 9 OF THE COUNCIL ON SCIENTIFIC AFFAIRS (I-00): PATENTING OF GENES AND THEIR MUTATIONS (2000), *available at* <http://www.ama-assn.org/ama/pub/article/2036-3603.html> (last modified July 5, 2001) (conditioning support of genetic patents on affordable licensing access for medical professionals) [hereinafter AMA REPORT].

¹¹ One such problem, whose treatment will be conspicuously absent from this note, is genetic privacy. Controversy surrounding disclosure of genetic information is a vast and much-debated topic unto itself and could not be adequately treated here.

become if permitted. Part II begins by providing a lay person's introduction to the science germane to genetic testing. Part III discusses the current intellectual property framework that shapes genetic patents and changes proposed to prohibit such patents or narrow the scope of their protection in the dawning age of genetic medicine. Moving past the threshold issue of patent protection, Part IV then addresses how medical licensure laws and the Corporate Practice of Medicine Prohibition may impact corporate involvement in diagnostic genetic testing as a derivative product of proprietary genetic information. Part V next reviews a proposed administrative framework for the genetic testing regulation. Finally, Part VI offers recommendations for commercialized diagnostic genetic testing, suggesting that under the current patent regime and with appropriate regulation within the proposed administrative framework, corporate involvement in the quasi-medical endeavor of genetic testing is not only appropriate but desirable. This note concludes that corporate involvement in the genetic testing industry will effect the most efficient and far-reaching biomedical advancement for the benefit of humankind.

II. PRIMER ON THE STATE OF THE ART: THE BIOTECHNOLOGY INDUSTRY IN THE 21ST CENTURY

On Monday, June 26, 2000, from the White House, the "rough draft" of the sequencing of the human genome¹² was announced.¹³ On that historic date, J. Craig Venter, pioneering founder of Celera Genomics, and Francis Collins, head of the public Human Genome Project, proudly announced that the genome had been all but fully sequenced.¹⁴ While some controversy surrounded the peculiar timing of the announcement that the major endeavor had been completed when it had actually been completely finished, the substantive impact of the announcement was enormously significant nonetheless.¹⁵ Finally, the race between the publicly funded Human Genome Project ("HGP") (a joint effort by the National Institutes of Health ("NIH") and Department of Energy ("DOE")) and the private upstart, Celera, to sequence the genome was declared politically both a tie and a victory for all of

¹² The human genome, or genetic blueprint of humanity, is comprised of a DNA sequence of billions of nucleotide "letters" which is overwhelmingly similar among each member of the human species. Estimates on the homology of the genetic makeup between any two individuals range from 99.996% to 99.999%. See CHARLES R. CANTOR & CASSANDRA L. SMITH, *GENOMICS: THE SCIENCE AND TECHNOLOGY BEHIND THE HUMAN GENOME PROJECT* 564, (John Wiley & Sons, Inc. 1999); DAVIES, *supra* note 1, at 41. Efforts to determine the predominantly common or consensus sequence, known generally as 'the human genome,' have been underway since 1990. See DAVIES, *supra* note 1, at 3.

¹³ See DAVIES, *supra* note 1, at 236.

¹⁴ See *id.* at 239-40.

¹⁵ See *id.* at 241-42.

humanity.¹⁶ Another sentiment rang even more clearly, however: The true race in the area of genetics has just begun.

Roy Whitfield, President and CEO of Incyte Genomics, described the sequencing of the genome as “the beginning of a thousand races. . . .”¹⁷ Steve Holtzman, Chief Financial Officer of Millennium Pharmaceuticals, stated, “The race at this point is not for the DNA The race is in assigning to genes and to variations in genes a role in disease initiation and progression and drug response.”¹⁸ This statement perhaps best encapsulates the current state of affairs in the world of biotechnology and genomics. Determining the roles genes play in giving rise to important proteins that carry out essential life functions is the next great task in the area of biotechnology. The sequencing of the human genome, while a monumental first step in a long process, merely represents the acquisition of raw data reflecting the chemical structure for the blueprint of the living organism. This blueprint is DNA.

A. DNA – *The Building Block of Life*

DNA, or deoxyribonucleic acid, is the building block of all living organisms, serving as a hereditary blueprint for biological structure and function.¹⁹ Every cell in an organism (with the exception of the germ cells and cells of haploid organisms²⁰) contains the DNA-based master plan for the entire organism.²¹ DNA, complexed with accompanying structural proteins,

¹⁶ *See id.* at 236-39.

¹⁷ *Id.* at 242.

¹⁸ *Id.*

¹⁹ Organisms, including many viruses, use RNA, or ribonucleic acid, a single-stranded, molecule closely related to DNA (but containing an additional hydroxyl group in its chemical structure) as their genetic blueprint. *See WILLIAM PURVES ET AL., LIFE: THE SCIENCE OF BIOLOGY* 258-59 (Sinauer Associates, Inc. 1995). All viruses, however, are vastly different from other types of organisms as they are non-cellular and do not display the life processes of independent cells found in other organisms. *See id.* at 87. Among non-viral organisms, DNA is the universal building block. *See id.* at 258-59.

²⁰ *See id.* at 202-03 (discussing haploidy, diploidy, and reproduction). Germ cells, or gametes, contain half of an organism’s genetic material (one set of chromosomes) and are the cells involved in fertilization when an organism reproduces. *See id.* During fertilization, germ cells containing genetic material from each parent combine to form a zygote containing a full complement of the organism’s genetic material (two sets of chromosomes). *See id.* Cells containing two sets of chromosomes are called diploid cells, and germ cells, which contain only one set of chromosomes, are known as haploid cells. *See id.* In haploid organisms, all of the organisms’ cells contain only one set of chromosomes. *See id.* Germ cells in a haploid organism combine with germ cells of another haploid organism of the same species during reproduction to form a diploid zygote, which undergoes immediate meiotic division to achieve cells in a haploid state in the offspring. *See id.* at 202-04.

²¹ *See id.* at 191.

comprises an organism's chromosomes.²² A piece of DNA lies in each chromosome and is further divided into genes, which each occupy a particular locus within that chromosome.²³ A gene is defined as a unit of genetic function that carries the information for construction of a polypeptide, or protein, and each protein encoded by a gene serves a particular biological function.²⁴

Chemically, DNA is comprised of two strands of sugar-phosphate backbone linked to nitrogenous bases of four varieties – adenine (“A”), cytosine (“C”), guanine (“G”), and thymine (“T”).²⁵ Each one of the four “letters” of the genetic code along with its accompanying share of deoxyribose-phosphate backbone is called a nucleotide.²⁶ The two strands of a DNA molecule constitute long chains of nucleotides and are coupled together by hydrogen bonds between the nitrogenous bases of each strand in a helical structure.²⁷ The strands of a DNA molecule are complementary.²⁸ That is, where adenine forms hydrogen bonds specifically with thymine, and cytosine with guanine, each “A” in a single strand of DNA will correspond to a “T” in the complementary strand, and each “C” will correspond to a “G.”²⁹ Each complementary set of nucleotides in a genetic sequence comprises a base pair.³⁰ Before cells divide in the growth process, the two strands of DNA may be separated and used as templates for the faithful synthesis of new complementary strands, resulting in two new and complete, double-stranded DNA molecules for allocation to each of the new cells.³¹ This process is called replication, and it is the mechanism by which the genetic blueprint is accurately maintained throughout all the newly created cells in an organism.³²

In accord with a doctrine known as the “central dogma of molecular biology,” genetic information contained in DNA is “transcribed” into RNA, an intermediate molecule in the process of gene expression, which is in turn “translated” into a polypeptide product or protein.³³ Proteins are the unit of

²² See *id.* at 69, 203.

²³ See *id.* at 218.

²⁴ See D. PETER SNUSTAD ET AL., PRINCIPLES OF GENETICS 350-352 (John Wiley & Sons, Inc. 1997) (discussing the concept of the gene and the manner in which it encodes for protein products). Note that some genes encode no protein at all but serve only as a template for RNA molecules essential in protein synthesis. See PURVES ET AL., *supra* note 19, at 259-64 (discussing how RNA molecules are derived from DNA and how various RNA molecules are involved in the process of making proteins).

²⁵ See PURVES ET AL., *supra* note 19, at 245 (discussing the chemical structure of DNA).

²⁶ See *id.* at G22.

²⁷ See *id.* at 245.

²⁸ See *id.* at 57 (explaining complementary base pairing).

²⁹ See *id.* at 57-58.

³⁰ See *id.* at G7.

³¹ See *id.* at 248-54 (explaining replication of DNA).

³² See *id.*

³³ See SNUSTAD ET AL., *supra* note 24, at 250.

functional utility in an organism, as they are responsible for carrying out an organism's various life functions and are the main constituents in structures throughout an organism.³⁴ The integrity of the DNA's progression from master blueprint to final functional protein product is thus of critical import to the life of an organism.

Should an error occur during the replication of DNA or should DNA be damaged in some way, the protein products produced from that DNA may have limited function or be rendered non-functional all together.³⁵ These errors are called mutations.³⁶ Such errors will also be passed on to the descendant cells within that organism in the case of mutation within somatic (body) cells and to the organism's offspring if the error occurs in the organism's germinal (reproductive) cells.³⁷ While there are proofreading mechanisms in higher organisms that help ensure that the process of DNA replication is carried out accurately and precisely, occasionally these proofreading mechanisms are overcome, and mutations result.³⁸

Mutations vary in the significance of their impact on life function.³⁹ Some mutations may have no impact at all; others may have dire or, more rarely, beneficial consequences.⁴⁰ One reason for the variability in a mutation's effect is that not all of an organism's genetic code is implicated in giving rise to proteins. Eukaryotic organisms (of which human beings are one type) carry

³⁴ See PURVES ET AL., *supra* note 19, at 47-49.

³⁵ See *id.* at 268-70 (discussing the manner in which mutations in DNA may give rise to malformed proteins of diminished or no function).

³⁶ See *id.* at 268 (explaining the concept of genetic mutation).

³⁷ An error occurring in a somatic, or 'body' cell, will be passed on only to other descendant somatic cells within the organism. However, if such an error occurs in a germinal cell, it may be passed on to the progeny of the organism. See SNUSTAD ET AL., *supra* note 24, at 313 (discussing the difference between germinal and somatic mutations).

³⁸ See PURVES ET AL., *supra* note 19, at 252-54; SNUSTAD ET AL., *supra* note 24, at 336-40. The frequency of spontaneous mutation in eukaryotic organisms is roughly between one per 10^7 and one per 10^9 base pairs replicated. See *id.* at 314. In human beings, this rate is roughly one mutation per 10^7 base pairs replicated. See DAVIES, *supra* note 1, at 44.

³⁹ See PURVES ET AL., *supra* note 19, at 270.

⁴⁰ See *id.* One example of a genetic mutation that has had both detrimental and beneficial consequences is the mutation giving rise to sickle-cell anemia. See *id.* at 335, 337. At some point during the course of human history, the sickle mutation developed in the germinal cells of some person or persons and was passed on in the process of sexual reproduction. See SNUSTAD ET AL., *supra* note 24, at 726-27. Those inheriting the mutant sickle cell gene from one parent benefited from increased resistance to malaria, a substantial genetic fitness advantage in tropical areas, where malaria is very common. See *id.* at 727; PURVES ET AL., *supra* note 19, at 337. Unfortunately, if a child inherited a copy of the mutant gene from both of its parents, the offspring will develop sickle cell anemia, a potentially fatal illness, characterized by red blood cells that collapse into a sickle shape. See PURVES ET AL., *supra* note 19, at 256-57; 337. The sickle mutant gene persists today, conferring resistance to malaria in individuals who carry a copy of the gene and causing sickle cell anemia in individuals who have two copies. See *id.* at 337.

portions of DNA called introns that are not involved in making protein products.⁴¹ These introns, or non-coding regions, are interspersed among exons, the regions of the genome that actually code for proteins in eukaryotic organisms.⁴² Introns do not directly influence biological function or gene expression, and a mutation to an intron region would generally have no observable effect on the organism.⁴³ When a mutation occurs in the coding region of a gene, however, some observable effect may manifest itself in the organism. A change of even just one letter in a critical region of an organism's genome can alter the structure or chemical properties of the final protein product, thereby altering the manner in which it functions.⁴⁴ Such a departure may diminish or enhance the efficacy of the protein in carrying out its function. While beneficial mutations can give rise to more resilient organisms with better functioning proteins for an organism in given environmental conditions (the hallmark of Darwin's theory of natural selection⁴⁵), the obvious converse and the event that occurs with far greater frequency is detrimental mutation.⁴⁶ In any case, mutation to the coding regions of the genome is an essential process in evolution, for it is what has given rise to genetic variants better adapted to changing environments over time.⁴⁷

Somatic mutations may give rise to some observable effect on biological function such as an uncontrolled growth of mutated cells (cancer) or by some means of altered protein production in the descendent cells of the somatic cell in which the mutation occurs.⁴⁸ A germinal mutation, however, does not affect an organism itself, but rather its progeny.⁴⁹ When an organism reproduces sexually, a germ cell from each parent containing one-half of each of the parent's paired chromosomes is combined to form a zygote containing a full set of chromosomes.⁵⁰ In this way, an offspring contains half of the genetic material from each parent.⁵¹ If a parent sustains a germinal mutation, the genetic material from affected germ cells it contributes to its progeny, and from which all of the progeny's somatic and germinal cells in turn arise, will

⁴¹ See SNUSTAD ET AL., *supra* note 24, at 268-73 (explaining the concept of introns and exons).

⁴² *See id.*

⁴³ *See id.*

⁴⁴ See PURVES ET AL., *supra* note 19, at 268 (discussing point mutations and their effects).

⁴⁵ See SNUSTAD ET AL., *supra* note 24, at 724-25 (explaining the process of natural selection postulated by Charles Darwin).

⁴⁶ See PURVES ET AL., *supra* note 19, at 270.

⁴⁷ See SNUSTAD ET AL., *supra* note 24, at 312-13; DAVIES, *supra* note 1, at 42.

⁴⁸ See SNUSTAD ET AL., *supra* note 24, at 313-14 (distinguishing somatic mutations from germinal mutations).

⁴⁹ *See id.*

⁵⁰ See PURVES ET AL., *supra* note 19, at 202-03 (explaining the genetics of sexual reproduction).

⁵¹ *See id.*

carry the mutation.⁵²

If the deleterious effect of the mutation that has been passed on to the offspring manifests itself and kills the offspring before that offspring can reproduce or prevents the offspring from reproducing the mutation will “die” with the offspring. Such mutations are in this way “selected out” of the gene pool in Darwin’s process of natural selection and will not be passed on through heredity.⁵³ If, however, the offspring is able to reproduce before any deleterious effect of a dominant mutation it carries from one of its parents results in death, or if the mutation is recessive, then the offspring may pass that very same mutation on to its own progeny.⁵⁴ In this way genetic disorders have developed over the course of the evolution of organisms. Mutant genes that do not prevent an organism from reproducing before its death are not eradicated from the “gene pool” and remain within a given population at some frequency determined by selective pressures.⁵⁵ Mutations are an important consideration in the field of human genetics, as new technologies will increasingly be able to detect, and eventually treat, the genetic roots of these heritable disorders.⁵⁶

B. *Human Genetics*

The human genome sequence is estimated to comprise between 3.12 and 3.15 billion base pairs,⁵⁷ and it is thought that human beings have between 26,000 and 40,000 genes within this vast sequence.⁵⁸ In the wake of the

⁵² See SNUSTAD ET AL., *supra* note 24, at 313 (discussing how germinal mutations may be passed to offspring and the perpetuation of such mutations as new alleles in a population).

⁵³ See *id.* at 65 (discussing lethal mutations); SNUSTAD ET AL., *supra* note 24, at 724-36 (discussing the process of natural selection).

⁵⁴ An offspring’s homologous chromosome pairs are comprised of one chromosome from each parent, and chromosomes from each parent contain corresponding genes. See PURVES ET AL., *supra* note 19, at 218. Different forms of each of these genes are called alleles. See *id.* at 217; SNUSTAD ET AL., *supra* note 24, at 43. Mutant gene forms, or mutant alleles, may be termed dominant or recessive. See SNUSTAD ET AL., *supra* note 24, at 66. In the case of a dominant mutation, the effect of the alteration in one gene of the chromosome pair gives rise to a phenotypic (observable) effect despite the normalcy of the unaltered, or wild-type, gene in the other chromosome. See *id.* In the case of a recessive mutation, the normalcy of the wild-type gene from one chromosome provides sufficient functionality to render the mutated state of the gene in the other chromosome moot. See *id.* Most mutations are in fact recessive and only manifest themselves in the form of some phenotypic effect when both parents contribute a chromosome containing the same mutant allele and are said to be homozygous for that allele. See *id.* at 316-18 (discussing recessive mutations and the reasons for their prevalence).

⁵⁵ See *id.* at 724-36 (discussing natural selection, population genetics, and mutation).

⁵⁶ See DAVIES, *supra* note 1, at 216-29 (discussing developing technologies of disease gene detection and gene therapy).

⁵⁷ See *id.* at 239-41.

⁵⁸ Compare International Human Genome Sequencing Consortium, *supra* note 1, at 860

sequencing of the human genome, scientists will face the challenge of identifying these genes from among the over three billion base pairs and deciphering the exact function of each gene, namely to determine the protein or proteins each gene encodes. Understanding the function of each human protein will allow scientists to understand better human biological function, and identifying the gene sources of these proteins and how the expression of these genes is controlled will greatly further the cause of this understanding.

By coming to comprehend normal protein production and function in healthy human beings, scientists will develop a much deeper understanding of heritable disorders for which previous understanding came only from an approach retrospective and reactive to symptomatic diagnosis. Rather than diagnosing an abnormal condition by the recognition of symptoms and, in turn, discovering its cause in a deductive manner, advances in genetics will allow scientists to gain a broader understanding of how malfunctions associated with heritable disorders are linked to underlying genetic abnormalities which exist pre-symptomatically. An understanding of the genetic roots of disease and the ability to test for them can ultimately lead to the development of prophylactic measures against heritable pathologies – a giant leap forward in medicine. Detecting the genetic source of such maladies in the hope that such prophylactic measures may be developed is a primary goal of genetic testing.

In mapping and deciphering the human genome for indicia of heritable disorders, two phenomena are of particular import: “mutant” or “disease” genes and single nucleotide polymorphisms (“SNPs”), which are a type of gene marker. Genes containing portions of sequences that have been mutated from their normal (“wild-type”) form to the detriment of an individual are termed mutant genes.⁵⁹ While the technical meaning of the term mutant is reserved for genetic alterations occurring with a frequency of less than two percent in a given population, the term is used more loosely and commonly as a pejorative term indicating deleterious impact to the individual.⁶⁰ For purposes of this paper, any altered gene that gives rise to a genetic disorder will be termed generally a mutant or disease gene. Disease genes that have been identified include those responsible for Huntington’s disease, cystic fibrosis, Duchenne muscular dystrophy, Lou Gehrig’s disease, retinitis pigmentosa, spinal muscular atrophy, polycystic kidney disease, and breast cancer.⁶¹ Of the more than 5,000 genetic disorders that have been discovered to date, the responsible genes or mutations for the maladies have been discovered in more than 1,000 cases.⁶²

(suggesting that there are between 30,000 and 40,000 genes) *with Venter et al., supra* note 1, at 1346 (postulating that there are 26,000 to 38,000).

⁵⁹ *See PURVES ET AL., supra* note 19, at 224 (explaining the origin of mutant alleles from wild-type forms).

⁶⁰ *See id.*

⁶¹ *See DAVIES, supra* note 1, at 71-86.

⁶² *See id.* at 43.

Other variant genetic forms with a higher rate of occurrence are termed polymorphisms, of which SNPs are an extremely important type.⁶³ Constituting mere single base pair variations from the normal consensus genetic sequence, SNPs are the most common points of departure between individuals' genomes with more than 1.4 million currently identified,⁶⁴ and their role in the future of medicine will be critical.⁶⁵ SNPs within genes themselves may have a direct effect on the protein production that is biologically benign, such as with the effect of certain SNPs on skin pigmentation, or profoundly negative, such as in causing the disease cystic fibrosis.⁶⁶ Alternatively, SNPs may mark the presence of disease-causing genes, indicate susceptibility to disease, or possibly even signal sensitivity to certain drug treatments.⁶⁷

Where SNPs are proximate to disease genes on the chromosomes, they are often inherited from one's parents along with the genes that actually give rise to a disease, disease susceptibility, or drug sensitivity.⁶⁸ Scrutiny of inheritance patterns of SNPs in families afflicted with genetic disorders has revealed links to unknown disease genes in close proximity within afflicted individuals' genomes.⁶⁹ In this way, SNPs can demarcate errant disease genes, thereby facilitating the tracking and identification of the disease genes themselves.⁷⁰ SNPs may likewise signal the presence of drug-responsiveness genes or give rise to differential drug responsiveness, providing the potential for individualization of drug treatment on the basis of genetics.⁷¹ Single

⁶³ *See id.*

⁶⁴ *See* International Human Genome Sequencing Consortium, *supra* note 1, at 860.

⁶⁵ *See* DAVIES, *supra* note 1, at 41.

⁶⁶ SNPs within the gene encoding a protein involved in the synthesis of melanin diminish the protein's activity, leading to lower melanin levels and lighter skin color. *See id.* at 41-42. The altered gene form that gives rise to cystic fibrosis is technically a polymorphic, not mutant, form as the recessive allele occurs in one of 25 persons of European descent. *See id.* at 43. Likewise, the variant gene responsible for hemochromatosis, a less serious iron overload disorder, is estimated to occur in one of ten Europeans and is therefore technically not a "mutant" gene but a polymorphism. *See id.*

⁶⁷ *See id.* at 219-20.

⁶⁸ *See id.*

⁶⁹ *See id.* at 128-29.

⁷⁰ *See id.* at 41-42, 128-29.

⁷¹ Research in this area is known as pharmacogenomics. *See id.* at 220. Millennium Pharmaceuticals, Inc. is one significant corporation in the field of pharmacogenomics. Its wholly owned subsidiary, Millennium Predictive Medicine, is employing pharmacogenomic and Diagnomic™ strategies to "shift medical care from merely addressing symptoms to tackling the root causes of disease." *Millennium Pharmaceuticals, Science and Technology: Predictive Initiative, Moving from Gene to Patient*, at <http://www.mlnm.com/scitech/pred.html> (last visited Dec. 26, 2001). Millennium believes that identifying the genetic basis for disease will, with the use of the strategies it employs, lead to individualized and thus more effective treatment. *See id.*

nucleotide variations within actual genes themselves could theoretically instigate deleterious effects or differential drug responsiveness in an individual, or they may merely serve as markers for the genes responsible for these phenomena. In any case, SNPs will generally be referenced throughout this paper for their role in tracking and cataloguing disease genes and their future potential to indicate drug responsiveness.

An individual's own genome may be tested to check for the presence of particular genes or SNPs that cause or predict the future onset of a disease state.⁷² If an individual's genome is found to contain the disease gene or marker in question, the individual may then be informed and advised to take prophylactic actions to help prevent future onset of the given disease state.⁷³ In many instances, lifestyle changes and even medical therapeutic measures may be taken to combat the onset of the disease or at least ameliorate its negative impact on the patient.⁷⁴ Today, gene therapy technologies are being developed to treat such irregularities at the genetic level by inducing production of normal proteins through the infusion of normal copies of genes into individuals' genomes.⁷⁵ Similarly, the identification of genes and markers that indicate individuals' sensitivity to various drug treatments could provide for the positive outcome of personalized drug treatments of maximum efficacy in individuals.⁷⁶

III. PATENT PROTECTION NOW AND TOMORROW: THE BACKDROP FOR COMMERCIAL GENETIC TESTING

A. *The Current Status of Human Genetic Patents*

An essential foundation for the biological research community is the patent system.⁷⁷ Through patent protection, those spending extraordinary amounts of money on research and development endeavors are able to recoup costs and turn profits by benefiting from limited monopolies on their discoveries.

⁷² See DAVIES, *supra* note 1, at 216-21 (discussing technologies to identify the presence of disease genes and SNPs); SNUSTAD ET AL., *supra* note 24, at 517-18 (describing the molecular diagnosis of human genetic diseases by testing for disease genes using polymerase chain reaction (PCR) processing).

⁷³ See DAVIES, *supra* note 1, at 220-21 (discussing possible prophylactic actions to take in response to discovery of disease genes or gene markers).

⁷⁴ See *id.*

⁷⁵ See SNUSTAD ET AL., *supra* note 24, at 519-22 (describing the promising technology of human gene therapy); DAVIES, *supra* note 1, at 221-25 (discussing the current state and future potential of gene therapy).

⁷⁶ See DAVIES, *supra* note 1, at 219-20.

⁷⁷ See F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691, 692 (2001).

In exchange for public disclosure of an invention⁷⁸ and the societal benefits derived therefrom, a patent holder is granted exclusive rights to make, use, and sell the invention, and the right to exclude all others from the same⁷⁹ for a period of twenty years.⁸⁰ Under the Patent and Trademark Office's ("PTO") current interpretation of the United States patent laws, individuals or entities may patent specific genes and gene markers, such as SNPs, discovered in the course of their work, though the issue of DNA sequence patenting remains highly controversial.⁸¹

As with any application, to obtain a patent on a gene or other genetic component such as an SNP, the applicant must demonstrate utility,⁸² novelty,⁸³ and non-obviousness⁸⁴ and supply a written description of the subject of the proposed patent that is sufficient in detail to enable one skilled in the pertinent art to make use of the subject matter.⁸⁵ Applying these traditional patent requirements to genetic material in the new age of biotechnological discovery has engendered substantial debate over the propriety of granting limited monopolies on the building blocks of life. To clarify its position on the utility requirement of the patent statute in light of the advent of new biotechnological innovation, the PTO published a revised version of its guidelines concerning utility, which clearly reflects the position of the PTO as supporting the patenting of human genetic material.⁸⁶ Therein, the PTO explicitly rejects public comments suggesting that genes and other genetic components should be unpatentable because they are naturally occurring phenomena and not new compositions of matter, and that DNA should be viewed as the constitutionally protected and fundamental core of humanity, not a marketable invention.⁸⁷ In

⁷⁸ See 35 U.S.C. § 112 (2000) (detailing the requirement for enabling disclosure).

⁷⁹ See *id.* § 271 (describing patent infringement).

⁸⁰ See *id.* § 154(a)(2).

⁸¹ See generally John Murray, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 CHL.-KENT L. REV. 231 (1999). Compare Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 151-52 (1999) (arguing that patent protection is often too broad and that information-sharing norms should also be utilized to optimally promote invention) and Arti K. Rai, *Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff*, 95 NW. U. L. REV. 707, 711-13 (2001) (emphasizing that a combination of private intellectual property rights and information sharing in the public domain best promote innovation) with Kieff, *supra* note 77, at 704 (contending that strong patent protection should be preserved as it "increase[s] community output . . . by increasing input . . . [and] by improving efficiency" in what would be an otherwise selfish and secretive environment).

⁸² See 35 U.S.C. § 101.

⁸³ See *id.* § 102.

⁸⁴ See *id.* § 103.

⁸⁵ See *id.* § 112.

⁸⁶ See Utility Examination Guidelines, 66 Fed. Reg. 1092 (2001), available at <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>.

⁸⁷ See *id.* at 1092-94.

response to the assertion that DNA has little utility, the PTO unequivocally states that a “purified DNA molecule may meet the statutory utility requirement if, *e.g.*, it can be used to produce a useful protein or if it hybridizes⁸⁸ near and serves as a marker for a disease gene.”⁸⁹ Likewise, in response to the suggestion that only whole genes with known, functional protein products ought to be patentable, the PTO maintains, “the utility of a claimed DNA does not necessarily depend on the function of the encoded gene product. A claimed DNA may have a specific and substantial utility because, *e.g.*, it hybridizes near a disease-associated gene. . . .”⁹⁰

The PTO’s statements in this clarification clearly evince its support for the patenting of human genes and gene markers, such as SNPs, that meet the utility and other statutory requirements. As the PTO asserts, genes encoding both normal proteins (encoded by wild-type genes) and defective, disease-causing proteins (encoded by mutant genes) are indubitably useful. Sequences marking disease genes or drug responsiveness also carry the requisite utility.⁹¹ In its revised guidelines, the PTO made an affirmative indication that useful SNPs, like whole genes of known function express sequence tags (“ESTs”) ⁹² with sufficiently demonstrated utility, are patentable subject matter.⁹³ The impact of SNP patentability may be mitigated, however, by efforts of the SNP Consortium, a partnership of leading pharmaceutical and technological companies collaborating to construct a map of all human SNPs in the genome that will be made available to the public without intellectual property

⁸⁸ Nucleic acid hybridization is the process by which single-stranded nucleic acid fragments join together to form doubled-stranded molecules based on their complementary sequences and following nitrogenous base pairing rules. *See* PURVES ET AL., *supra* note 19, at 294. Nucleic acid hybridization is often used to probe for known gene or other sequences in given nucleic acid samples by cutting the long chains into fragments, rendering them single-stranded, fixing the fragments to a sheet, and washing the surface with an indicator probe of the sequence of interest under conditions optimal for hybridization. Should the indicator probe bind the fixed fragments, a match is demonstrated. *See id.* at 321 (describing the method of detecting specific DNA fragments using a nucleic acid probe).

⁸⁹ Utility Examination Guidelines, 66 Fed. Reg. at 1094.

⁹⁰ *Id.* at 1095.

⁹¹ *See id.* at 1094-95.

⁹² An express sequence tag, or EST, is a sequence fragment obtained from identified genes of known sequence in one species of organism that may be used to identify or “tag” a whole gene in another species. *See* DAVIES, *supra* note 1, at 57-61. ESTs were used, initially and notably by Craig Venter and his research associate Mark Adams, to identify many human genes. *See id.* at 57-58. The process relies on the strong conservatism of gene sequences across species and hundreds of millions of years of evolution to use gene sequences from other organisms’ known genes to find analogous genes in human beings. *See id.* at 59. The PTO declared ESTs patentable in 1997. *See* Leora Ben-Ami et al., *Biotech Patent Law Developments*, 573 PLL/PAT. 555, 558-61 (1999) (discussing the patentability of ESTs).

⁹³ *See* Utility Examination Guidelines, 66 Fed. Reg. at 1094.

restrictions.⁹⁴ The consortium was formed with the collective goal of making an accurate and complete SNP map available to researchers as quickly as possible using economies of scale and without wasting resources on duplicative efforts.⁹⁵ Information about the loci of single nucleotide variations provided by an SNP map will both foster the most efficient research and development by scientists in discovering important genes and their variations and also help drive genetic-based diagnostic testing.⁹⁶ While the SNP consortium is a cooperative endeavor, it should not be construed as a signal that those in the biotechnology industry are prepared to forego the benefit of patent protection on genetic discoveries.⁹⁷ Rather, the consortium members are merely collaborating to assemble a raw map, much like that of the human genome, which will aid in making subsequent discoveries for which patent protection will be sought.

Given the exclusive rights that genetic patents confer, coupled with the enormous predictive medical value inherent to such genetic components, it comes as no surprise that such patents are hotly contested⁹⁸ and that their protection so profoundly influences the biotechnology industry.⁹⁹ In light of

⁹⁴ See *SNP Consortium*, at <http://snp.cshl.org> (last visited Dec. 26, 2001) (outlining the mission goal of the consortium). Members of the SNP Consortium include APBitech, AstraZeneca, Aventis, Bayer, Bristol-Myers Squibb, F.Hoffman-La Roche, Glaxo-Wellcome, IBM, Motorola, Novartis, Pfizer, Searle, SmithKline Beecham, and the Wellcome Trust. See *SNP Consortium, Members*, at <http://snp.cshl.org/about/members.html> (last visited Dec. 26, 2001).

⁹⁵ See *The Wellcome Trust, Frequently Asked Questions about the SNP Consortium*, at <http://www.wellcome.ac.uk/en/1/biovensnpfaq.html> (last modified Feb. 21, 2000).

⁹⁶ See Leslie Versweyveld, *IBM Participates in SNP Consortium to Construct Map of Genetic Diversity*, VIRTUAL MEDICAL WORLD, March 2000, available at <http://www.hoise.com/vmw/00/articles/vmw/LV-VM-03-00-11.html> (last visited Dec. 26, 2001).

⁹⁷ See *infra* discussion in Part III-C explaining the importance of patent protection to the biotechnology industry.

⁹⁸ A fine example of the stakes involved in these patents is the ongoing controversy between Amgen, Inc. and its competitors over patents on the erythropoietin gene, which protect its best-selling drug, EPOGEN®, for use in kidney dysfunction among other medical problems. See, e.g., *Amgen, Inc. v. Genetics Inst.*, 98 F.3d 1328, 1330-32 (Fed. Cir. 1997); *Ortho Pharm. Corp. v. Amgen, Inc.*, 882 F.2d 806, 808-15 (3d Cir. 1989); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 57 U.S.P.Q.2D (BNA) 1449, 1515-19 (D. Mass. 2001); *Amgen, Inc. v. Elanex Pharm.*, 160 F.R.D. 134, 136-41 (W. D. Wash. 1994); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 808 F. Supp. 894, 898-904 (D. Mass. 1992).

⁹⁹ Strong evidence that the status of gene patents influences the biotechnology industry was demonstrated in March of 2000 when President Clinton and British Prime Minister Tony Blair issued a joint statement regarding the human genome stating that its information “should be made freely available to scientists everywhere.” See DAVIES, *supra* note 1, at 205. Despite the explicit statement two sentences later that, “[i]ntellectual property protection for gene-based inventions will also play an important role in stimulating the development of important new health care products,” the technology sector of the U.S. took

the utility of these genetic components as predictors of disease, disease susceptibility, and drug sensitivity, the PTO's decision to extend protection for genetic patents and maintain the innovation impetus is understandable. The proprietary value of genetic patents is enormous to patent holders, and biotechnology companies are making tremendous capital and research investments in the area of genetic research.¹⁰⁰ If more restrictive limitations are to be imposed on patents for genetic material, they are unlikely to come from the PTO barring radical departure from recent policy under the PTO's patent utility clarification.

B. *Interpretation of the Patent Statute by the Courts*

The leading case in paving the way for the patenting of genetic material is *Diamond v. Chakrabarty*.¹⁰¹ In *Chakrabarty*, the Supreme Court ruled that claims did not fall outside the purview of patent protection merely because they pertained to living organisms, finding that a genetically engineered microorganism of sufficient utility brought into existence as the product of human ingenuity was plainly patentable.¹⁰² The Supreme Court's approval of patents on living organisms under the patent statute signaled a call for the lesser-included pieces of life – DNA sequences – to be patented as well. Since *Chakrabarty*, the Federal Circuit has ruled that, under the patent statute, DNA is a chemical composition to be held to the same non-obviousness standard as other standard chemicals in patent cases.¹⁰³ As with other chemical compositions, to satisfy the written description requirement, the applicant must produce the chemical structure of the specific DNA molecule; describing functional utility is not sufficient.¹⁰⁴ Thus, when a previously undiscovered gene (satisfying the novelty requirement) encoding for a given protein with a given function (satisfying the utility requirement) is discovered, its discoverers may satisfy the written description requirement by providing a written description of the gene sequence and the protein function in the patent application. Assuming the discovery was not obvious based on the prior art, the patent will be issued, granting the discoverers a limited monopoly over the use of that particular gene.

Mutant gene forms are one major subject of interest for patents relating to commercial genetic testing. When a gene's sequence varies from the normal gene, the protein product encoded by that variant gene may be abnormal and give rise to a disease state.¹⁰⁵ Even small variations in the genetic sequence

a major downturn, with share prices of biotech companies' stock plunging. *See id.* at 205-07. Such effects will be discussed more thoroughly *infra* Parts VI and VII.

¹⁰⁰ *See* DAVIES, *supra* note 1, at 61-64, 159-61, 217-21.

¹⁰¹ 447 U.S. 303 (1980).

¹⁰² *See id.* at 309-310.

¹⁰³ *See* Amgen v. Chugai Pharm. Co., 927 F.2d 1200, 1207-09 (Fed. Cir. 1991).

¹⁰⁴ *See* Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993).

¹⁰⁵ *See* SNUSTAD ET AL., *supra* note 24, at 316-17 (describing the phenotypic effects of

may have an enormous impact on the function of the protein that the gene encodes.¹⁰⁶ While a mutant gene form that differs from a previously patented wild-type form by only a few nucleotides might normally be considered prima facie obvious, a showing of unexpected properties of the mutant gene form not present in the previously patented form, such as correlation to disease, will satisfy the non-obvious standard.¹⁰⁷ Case law in the Federal Circuit clearly allows for more than one sequence to be patented on variations (different mutations or mutant vs. wild-type) of the same gene in such instances.¹⁰⁸ By the same reasoning, particular SNPs, representing variations in the human genome, would be held patentable by the courts where a relationship between the presence of that SNP in individuals' genomes and the onset of or susceptibility to a disease or responsiveness to a drug is demonstrated.¹⁰⁹

Genetic discoveries have enjoyed substantial patent protection under current interpretations of the patent statute. To conclude that genetic discoveries will continue to enjoy comparable patent protection in the future presupposes, among other things, that the current applicable statutory provisions will remain substantially intact. Such a presupposition, however, is a precarious one.

C. *Calls for Prohibition or Proscriptive Narrowing on Human Genetic Patents*

Critics of genetic patents often bemoan high price tags associated with genetic tests and licensing fees resulting from the monopolistic rights awarded by patents.¹¹⁰ Many contend that the \$2,580 cost of Myriad's breast cancer test, centered around patents on the BRCA1 cancer gene, is unjustifiably high.¹¹¹ The limited access and high prices patients face in seeking genetic testing for Canavan disease, which most commonly afflicts those of Eastern European Ashkenazic Jewish descent,¹¹² also draw criticism.¹¹³ The latter test, utilizing the patented Canavan disease gene, is only licensed to a select dozen

mutation).

¹⁰⁶ See PURVES ET AL., *supra* note 19, at 268-69 (describing the effects of point mutations).

¹⁰⁷ See Murray, *supra* note 81, at 250.

¹⁰⁸ See *id.* at 250-51.

¹⁰⁹ See *id.* at 253.

¹¹⁰ Peter G. Gosselin & Paul Jacobs, *Patent Office Now at Heart of Gene Debate*, L.A. TIMES, Feb. 7, 2000, at 1.

¹¹¹ See *id.*

¹¹² About one in forty Ashkenazi Jews is a carrier of the recessive allele for the disease, and if two carriers have children, they face a 25 percent risk of having a child afflicted with Canavan Disease with each pregnancy. See *University of Pittsburgh Department of Human Genetics, Canavan Disease*, at <http://www.pitt.edu/~edugene/Canavan.html> (last modified Oct. 9, 2001). Most children afflicted with this neurological disorder die before the age of five. See *id.*

¹¹³ See Richard Saltus, *Critics Claim Patents Stifle Gene Testing*, BOSTON GLOBE, Dec. 20, 1999, at C1.

labs by the patent holder, Miami Children's Hospital, and licensing fees may cost patients or their insurers anywhere from \$60 to \$300.¹¹⁴ Physicians bristle at the thought of having to pay licensing fees to conduct genetic tests on their patients for diseases implicating known gene or marker sequences.¹¹⁵

Massachusetts Institute of Technology professor Jonathan King decries the human genetic patenting underlying such tests as per se wrongful, stating that "Genes derive from millions of years of evolution and are, in the deepest sense, products of nature . . . not the inventions of individuals, corporations, or institutions."¹¹⁶ Likewise, both the American College of Medical Genetics and the College of American Pathologists have made position statements condemning human genetic patents.¹¹⁷ Dr. Aubrey Milunsky, director of the Center for Human Genetics at the Boston University School of Medicine, expresses concern that high licensing fees for use of patented genetic material could "ultimately exclude [everyone but the patent holder] from working on [a particular] gene," inhibiting potentially invaluable research contributions from the medical research community.¹¹⁸ Critics in the medical community contend that protecting the use of such genetic material only inhibits discovery of patient maladies while increasing patient costs.¹¹⁹

The issue of human genetic patenting is not an uncomplicated one, however. In defense of the cost of its breast cancer test, a Myriad spokesman cites the \$10 million the company spent in development.¹²⁰ Industry experts such as Jack Douglas, Chief General Counsel of Millennium Pharmaceuticals, contend that patents are essential for biotech companies, noting that without patent protection, such companies could not recoup the vast capital resources invested in research and development.¹²¹ According to Douglas, "Patents provide the incentive. They promise a company a period of exclusivity, and without it companies wouldn't make the investment. There's still healthy competition, and it's resulting in companies investing a lot of resources in what we all hope

¹¹⁴ See *id.*

¹¹⁵ See Karen Rafinski, *Hospital's Patent Stokes Debate on Human Genes*, SEATTLE TIMES, Nov. 14, 1999, at 1A.

¹¹⁶ See Schmidt, *supra* note 9, at 73 (quoting Professor King).

¹¹⁷ See AMERICAN COLLEGE OF MEDICAL GENETICS, POSITION STATEMENT ON GENE PATENTS AND ACCESSIBILITY OF GENE TESTING, Aug. 2, 1999, available at <http://www.faseb.org/genetics/acmg/pol-34.htm> (last visited Dec. 26, 2001); COLLEGE OF AMERICAN PATHOLOGISTS, GENES PATENTS DETRIMENTAL TO CARE, TRAINING, RESEARCH, July 5, 2000, available at <http://www.cap.org/html/advocacy/issues/genetalk.html> (last modified July 5, 2000).

¹¹⁸ Naomi Aoki, *Patent Applications Booming in Biotech*, BOSTON GLOBE, Aug. 30, 2000, at D1 (quoting Milunsky).

¹¹⁹ See Jon Merz, *A Patently Bad Prescription*, MSNBC ONLINE, Aug. 30, 2000 (on file with author).

¹²⁰ Gosselin & Jacobs, *supra* note 110, at 1.

¹²¹ See Aoki, *supra* note 118, at D1.

will be cures for diseases.”¹²² Douglas also points out that patents actually promote the free exchange of knowledge since they explain an invention or discovery in sufficient detail to be understood and used by others, and that researchers are permitted to use the information, provided that they do not profit from that use.¹²³ The danger for companies engaging in costly research and development is that without patent protection, competitors would be free to sell products or services derived from the another’s labor without having incurred the high costs of making the initial discovery and developing technology to use it.¹²⁴ While prohibiting human genetic patents may hold simplistic humanitarian appeal, the practical effects on genetic medical advancement would be severe and far-reaching.

The reliance of biotechnology on patent protection is perhaps best evidenced by an incident in which the mere public perception of a departure from the current status quo sent the United States biotechnology market sector into a tailspin.¹²⁵ In March of 2000, President Clinton and British Prime Minister Tony Blair made a brief joint announcement regarding the Human Genome Project that stated, “the human DNA sequence and its variations, should be made freely available to scientists everywhere.”¹²⁶ The statement read further, not two lines later, that “[i]ntellectual property protection for gene-base inventions will also play an important role in stimulating the development of important new health care products.”¹²⁷ In the aftermath of this announcement, public confusion and panic ensued. The announcement seemed to the uninitiated to constitute a doomsday statement. Investors perceived the joint statement to foreshadow a narrowing of the patent protection afforded to industry innovators, foreshadowing an imminent industry downturn. The resultant sell-off saw biotechnology stocks lose a tremendous percentage of their value.¹²⁸ Celera’s stock dropped from a previous apex of \$290 a share to \$100, and \$50 billion in value was drained from the leading American biotechnology companies within two weeks.¹²⁹ The public terribly misperceived the message of the announcement; proprietary innovations of biotechnology companies in the area of genetics were, in fact, safe. Nonetheless, the market felt staggering effects as investors withdrew on the perception that such companies would flounder without the protection of patents for their genetic advances.

Short of an outright ban on genetic patenting, a statutory amendment could also narrow the scope of protection. In 1995, Senator Ganske (R-IA), a

¹²² *Id.* (quoting Douglas).

¹²³ *See id.*

¹²⁴ *See id.*

¹²⁵ *Id.* at 205-07.

¹²⁶ DAVIES, *supra* note 1, at 205.

¹²⁷ *Id.*

¹²⁸ *See id.*

¹²⁹ *See id.* at 205-07.

medical doctor, introduced the Medical Procedures Innovation and Affordability Act, which sought to institute a moratorium on the patenting of medical procedures.¹³⁰ Though Congress did not adopt into law a full-blown prohibition on medical procedure patents, parties on both sides of the issue ultimately reached a compromise whereby licensed medical practitioners were exempted from patent infringement for use of patent-protected medical procedures.¹³¹ Patented genetic test procedures and laboratory test kits utilizing patented genes or markers, of course, do not fall within the purview of this medical procedure exemption. The genetic patents that underlie testing services rest at present securely under the penumbra of patent protection, but an exemption similar to that afforded medical practitioners with patented medical procedures could follow in the area of human genetic patents.

The American Medical Association (“AMA”) has taken a stance on human genetic patents that suggests the imposition of special standards for medical practitioners. In its report on genetic patents, the AMA calls for “equitable access to licenses . . . of gene patents for diagnostic genetic tests to any Clinical Laboratory Improvement Act (CLIA)-certified laboratory^[132] at a reasonable royalty . . . development of special guidelines for . . . promoting research and other benefits,” and careful monitoring of the “impact of gene patenting and licensing agreements on access to relevant medical care.”¹³³ The AMA concluded in its report that an important goal of “genetic research is to achieve better medical treatments and technologies. Granting patent protection should not hinder this goal. Individuals or entities holding patents on genetic material should not allow patents to languish and should negotiate and structure licensing agreements in such a way as to encourage the development of better medical technology.”¹³⁴ Policy makers on Capitol Hill are certain to consider such concerns from the medical community. Given the medical community’s posture, and the presence of physicians sitting in Congress who have previously moved to preserve the freedom of medical practitioners to perform procedures, the legislature may well take action to promote free or broader access to patented genetic innovations for physicians in practice and research.

IV. REDEFINING THE PRACTICE OF MEDICINE: GENETIC TESTING, MEDICAL LICENSURE, AND THE CORPORATE PRACTICE OF MEDICINE PROHIBITION

The medical community’s objection to the monopolistic rights genetic patents provide, allegedly limiting optimal medical practice and research,

¹³⁰ H.R. 1127, 104th Cong. (1997).

¹³¹ See Omnibus Consolidated Appropriations Act of 1996, Pub. L. No. 104-208, § 616, 110 Stat. 3009-67-68 (1997) (codified as amended at 35 U.S.C. § 287(c)(1) (2000)).

¹³² Laboratories in which human medical tests are conducted are regulated under the Clinical Laboratory Improvement Act. See 42 C.F.R. 493.1 (1996).

¹³³ AMA REPORT, *supra* note 10.

¹³⁴ *Id.*

brings into focus the ties of genetic testing to medicine. Insofar as genetic testing may be conceptualized as a form of medical practice, corporate entities enter perilous territory by undertaking in such activity, as only licensed medical practitioners may engage in medical practice.¹³⁵ Further, where an activity undertaken by a corporation smacks of medical practice, common law doctrine proscribing medical practice by corporate entities, known as the Corporate Practice of Medicine Prohibition (“CPMP”), is implicated.¹³⁶ In examining the issue of genetic testing as commercial enterprise, it is instructive to contemplate how medical licensure laws and CPMP doctrine have been construed for application to corporate entities that have previously skirted the boundaries of medical practice. Reasoning by analogy, or distinguishing important points of difference, between what has been construed medical practice and diagnostic genetic testing lends invaluable perspective to the present genetic testing dilemma in our changing health care environment.

A. *Medical Licensure Requirements*

The regulation of medical practice is an exercise left to the plenary powers of the states, and each state has its own licensure requirements for such practice. In no state may medicine be practiced without a license.¹³⁷ Many states have, in fact, set forth formal definitions for medical practice under their licensure laws, among which there is also little variation. Florida’s definition of medical practice is representative, defining the term as “the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.”¹³⁸ Similarly, a Washington, D.C. statute defines the term as “the application of scientific principles to prevent, diagnose, and treat physical and mental diseases, disorders, and conditions”¹³⁹ Texas uses similar language, defining the term as “the diagnosis, treatment, or offer to treat a mental or physical disease or disorder . . . by any system or method”¹⁴⁰ Even the most recent iterations of state statutes, however, do not contemplate diagnostic genetic testing for the potential onset of genetic disorders at a pre-symptomatic stage. Hence, determination of whether genetic testing constitutes medical practice is a matter of interpretation that has not yet come before the courts.

Intuitively, genetic testing might appear to fall within the scope of medical

¹³⁵ See Tom J. Manos, Comment, *Take Half an Aspirin and Call Your HMO in the Morning—Medical Malpractice in Managed Care: Are HMOs Practicing Medicine Without a License?*, 53 U. MIAMI L. REV. 195, 197-98 (1998) (noting that under the laws of all states, a license is required to engage in the practice of medicine).

¹³⁶ See *Berlin v. Sarah Bush Lincoln Health Center*, 688 N.E.2d 106, 110 (Ill. 1997).

¹³⁷ See *id.* at 231 (describing the development and universal adoption of physician licensure statutes).

¹³⁸ Fla. Stat. § 458.305 (1999).

¹³⁹ D.C. Code § 2-3301.2 (2000).

¹⁴⁰ Tex. Occ. Code § 151.002 (2000).

practice under the statutory definition of “diagnosis” set forth in medical licensure laws. However, diagnosis, as it is used in the state statutes, refers to diagnosis of a disease or illness, not determination that a patient carries a gene indicating future onset of or predisposition toward a genetic disorder. To equate the mere discovery of a sequence within an individual’s chromosomes that may indicate future development of a disorder with the diagnosis of a disease from which an individual is suffering and exhibiting symptoms seems to be an unfair conflation. Nonetheless, at least one high court did not find such an interpretation so unreasonable under different circumstances. In *Katskee v. Blue Cross Blue Shield of Nebraska*, the Supreme Court of Nebraska found that the plaintiff’s genetic predisposition, based on the presence of an indicative marker sequence, toward breast and ovarian cancer constituted an illness within the meaning of her health insurance policy.¹⁴¹ The court held that a future risk assessment of greater than 85% and a genetic diagnosis of “breast-ovarian carcinoma syndrome” by the plaintiff’s physician was sufficient to constitute an illness meriting prophylactic surgery under the plan’s benefits.¹⁴²

This construction of a genetic predisposition as illness or disease here comes under very different circumstances of determining insurance benefits. It seems probable that the *Katskee* case would be distinguished in determining whether a commercial entity is practicing medicine by simply administering diagnostic genetic tests. That a high court would categorize genetic testing as a diagnosis of illness under any conditions, however, merits attention. Also, since diagnostic genetic testing may lead to determinations on courses of medical treatment, some might contend that the testing itself constitutes medical practice. If positive identification of predisposition toward a disease is indeed construed as a disease state in and of itself or if the testing alone is otherwise deemed medical practice, the genetic testing industry could become subject to strict prohibition against medical practice under state medical licensure requirements.

One potential solution to this problem for corporate entities wishing to offer genetic testing services might be to hire physicians to administer and conduct such testing and thus avoid proscription under state licensure requirements. However, this remedy is in itself problematic under the CPMP, a doctrine that has historically combated abuse and indiscretion by doctors under the control of profit-driven corporate influence by prohibiting practice by physicians so situated.¹⁴³ A closer look at CPMP doctrine and its application throughout history illustrates how the doctrine may apply to commercial genetic testing.

¹⁴¹ 515 N.W.2d 645, 653 (Neb. 1994).

¹⁴² *See id.*

¹⁴³ *See Berlin v. Sarah Bush Lincoln Health Center*, 688 N.E.2d 106, 110 (Ill. 1997).

B. *The Corporate Practice of Medicine Prohibition: HMOs as a Model for Non-Medical Practice*

The Corporate Practice of Medicine Prohibition originated around the turn of the century in response to what were known as contract and corporate practice arrangements.¹⁴⁴ Contract practice consisted of physicians being hired by such entities as lumber and mining companies to care for employees, especially in areas such as the Pacific Northwest where doctors were then scarce.¹⁴⁵ These types of arrangements were problematic, even where they provided workers better access to care, in that the employers controlled the doctors and with them the quality of the care their workers received – a troublesome conflict of interest. In corporate practice, doctors were employed by corporate entities that marketed the physicians' services to the public as brand names, a franchise-type arrangement presenting similar conflicts.¹⁴⁶

At least two prominent problems existed with such relationships. First, physicians were being employed and thus controlled by for-profit corporations directed by lay persons interested in maintaining a full work force at all times and having their sick and injured employees return to work as soon as possible.¹⁴⁷ Such pressure threatened the physician's professional discretion, an absolutely essential component of good patient care.¹⁴⁸ This undermining of the physician's independent judgment was deemed grossly inappropriate.¹⁴⁹ Furthermore, this sort of relationship was found to divide the physician's loyalty between his corporate employer and his patients, an unacceptable conflict in the field of health care in which loyalty must lie with the patient to ensure the utmost medical integrity.¹⁵⁰

By the 1930s, state courts, pointing to medical practice statutes, ruled that only individuals, not corporate entities, could be licensed to practice medicine.¹⁵¹ Thus, in the climate of such policy concerns and borrowing from existing medical licensure norms, the corporate medical practice prohibition was born. This strict proscription, however, eventually became outmoded as managed care organizations became a dominant force in the health care industry beginning in the 1970s.

For all its early protection in the development of health care, today, in an enormously different health care environment, the CPMP has had seemingly

¹⁴⁴ E. Haavi Morreim, *Playing Doctor: Corporate Medical Practice and Medical Malpractice*, 32 U. MICH. J.L. REF. 939, 945 (1999).

¹⁴⁵ *See id.* at 945.

¹⁴⁶ *See id.*

¹⁴⁷ *See id.* at 946.

¹⁴⁸ *See id.*

¹⁴⁹ *See id.* at 947.

¹⁵⁰ *See id.*

¹⁵¹ *See id.* at 945; Jessica A. Axelrod, *The Future of the Corporate Practice of Medicine Doctrine Following Berlin v. Sarah Bush Lincoln Health Center*, 2 DEPAUL J. HEALTH CARE L. 103, 106 (1997).

little prohibitive impact on one important facet of corporate involvement in medicine: managed care. Despite the fact that managed care is driven by cost-containment, which poses some of the same threats as those feared in health care with corporate medical practice in the early 1900s, the managed care industry has flourished virtually unfettered. Health maintenance organizations (“HMOs”) are not subjected to CPMP proscription, even though many argue that HMOs intervene in the practitioner’s medical judgment, or substitute for it, affecting the outcome of patient care and thus practicing medicine inappropriately.

While courts in the 1930s envisioned the threat such corporate medical practice posed to the integrity of health care and physicians’ unfettered good judgment, changing times have brought changing policy. In the 1970s, with the protection of the Employee Retirement Income Security Act of 1974 (“ERISA”),¹⁵² managed care organizations, or HMOs, were spawned in an attempt to manage rapidly increasing medical costs by instituting competitive bargaining in the health care industry between health providers and insurers. In their normal operating function, HMOs are an accepted facet of the health care system designed to provide health care benefits to a greater number of persons at a lower cost. As a business model, HMOs aim to turn a profit through a process of close utilization management¹⁵³ in coverage and by negotiating competitive prices from physicians and hospitals, using a large volume patient base as leverage.

HMOs predefine the terms of their care coverage. In the case of ERISA-qualifying plans,¹⁵⁴ these organizations cannot, under the federal ERISA statute, be held liable for medical malpractice on the basis of denying benefits not included under the predefined coverage terms.¹⁵⁵ On the other hand, where

¹⁵² 29 U.S.C. §§ 1001, et seq. (2000). ERISA has broadly preempted state regulation of health care financing in employer-provided health benefit plans and provides for exclusive federal court jurisdiction over claims by pertaining to such health coverage relationships. *See* BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS, AND PROBLEMS*, THIRD ED. 780, 808 (West Group 1997). Unlike state insurance regulation, which is typically driven by concerns over rights, the federal law that underpins ERISA is classical contract and trust law. *See id.* at 815-16. This is more favorable to HMOs providing health insurance coverage to the employees of a given employer in that the terms of the contract, rather than the abstract health rights of the employee are what govern. *See id.* at 816.

¹⁵³ Utilization management or review is a cost-containment mechanism in which third party payers make case-by-case evaluations to determine the necessity and propriety of the health care service in question. *See id.* at 795. Those who actually conduct the utilization review are often physicians themselves operating in what is deemed a business capacity. *See* Manos, *supra* note 135, at 198.

¹⁵⁴ It is estimated that between 65 and 75 percent of all managed care plans are ERISA-qualified. *See id.* at 304.

¹⁵⁵ Any state claim “that relate[s] to any employee benefit plan” is preempted under ERISA. 29 U.S.C. § 1144(a) (2000). In claims brought under or preempted under ERISA, the statute permits recovery for “benefits due . . . under [the] terms of the plan, to enforce . . . rights under the terms of the plan, or to clarify . . . rights to future benefits under

a plaintiff alleges malpractice on the basis of an improper determination of necessary medical procedures or the quality of care in the exercise of a covered benefit, claims against HMOs are not preempted, and the entities may be subjected to malpractice liability.¹⁵⁶ In order to prove malpractice, however, the plaintiff must demonstrate that an HMO actually engaged in medical practice in the first place, and whether HMOs do so in conducting their normal business function has been a hotly contested issue in health care.¹⁵⁷ The presumption, and indeed why CPMP doctrine is not applied to managed care, is that HMOs do not engage in the practice of medicine.¹⁵⁸

Managed care organizations often escape malpractice liability under ERISA preemption and subsequent dismissal of the malpractice claims in federal court.¹⁵⁹ HMOs may also escape liability where they are deemed not to practice medicine in their normal operating capacity as a matter of policy, even where trained physicians make utilization management decisions, albeit in a “business function” outside the walls of hospitals or clinics.¹⁶⁰ Some critics find the suggestion that HMOs do not practice medicine preposterous, citing the exercise of medical judgments in determining the necessity of medical procedures as definite medical practice that should subject such actors to all malpractice claims.¹⁶¹

That there is serious debate as to whether corporate HMOs engage in the practice of medicine raises the question of whether CPMP doctrine should prohibit some of the practices of managed care. There has been no serious prohibitive hindrance to the development of HMOs, however, as these entities have been protected by special exemption under federal statutory mandate as

the terms of the plan.” *Id.* § 1132(a)(1)(B). The scope of preemption and the “relate to” language of the ERISA statute has been a matter of great controversy in the area of malpractice. *See* FURROW ET AL., *supra* note 150, at 298-306.

¹⁵⁶ *See* FURROW ET AL., *supra* note 150, at 298-306; *Dukes v. U.S. Healthcare*, 57 F.3d 350, 355-57 (3d Cir. 1995) (holding that claims speaking to the quality of care are not properly preempted under ERISA).

¹⁵⁷ *See* Morreim, *supra* note 144, at 950-62 (outlining the debate over whether HMOs conduct business in such a way as to fairly be regarded as practicing medicine and subjecting themselves to malpractice liability).

¹⁵⁸ *See* Axelrod, *supra* note 151, at 107-09. It is important to note here that CPMP doctrine is designed as a proscriptive measure to prevent establishment of corporate medical practice or practice by physicians under corporate control. *See supra* notes 143-149 and accompanying text. It is exceptional for HMOs to be found to practice medicine and thus meet this threshold for malpractice. Medical practice by HMOs, in this way, carries a pejorative connotation since HMOs will generally only be found to be practicing medicine where they have done so negligently and have been sued for medical malpractice. A finding of malpractice presupposes a violation of CPMP doctrine, and the concepts dovetail into one another.

¹⁵⁹ *See* FURROW ET AL., *supra* note 150, at 780, 808.

¹⁶⁰ *See* Manos, *supra* note 135, at 197-98.

¹⁶¹ *See* Morreim, *supra* note 144, at 961.

well as under state statutory exemptions enabling their existence for policy reasons, including reducing health care costs to the public.¹⁶² The managed care industry is able to avoid limitations CPMP doctrine might otherwise impose on the manner in which HMOs conduct business in several ways. Some states provide HMOs explicit statutory exceptions to common law CPMP doctrine that are read not to limit their function even where the line of medical practice is arguably crossed.¹⁶³ Other states without such statutes do not apply CPMP doctrine to HMOs because the organizations, in their normal and accepted operating function of hiring doctors as independent contractors rather than physician-employees, are not deemed to practice medicine.¹⁶⁴ Other states simply do not enforce the corporate prohibition or have never recognized the doctrine.¹⁶⁵

Whatever the formal legal reasoning, the ostensible policy reasons for shielding the managed care system from the corporate practice prohibition are not difficult to understand. In a nation without universal health insurance such as the United States, non-senior citizens not qualifying for Medicaid must insure ever-increasing health costs privately. With rapid advances in medical technology the cost of health care has increased sharply, in turn driving up the cost of insurance.¹⁶⁶ HMOs, by using large enrollment to bargain with physicians, infuse competitive prices into a market formerly unchecked under the previous regime of fee-for-service insurance. Helped further by careful utilization management, HMOs are able to offer lower cost health plans to their members. Policy-makers supported the rise of the newly developing managed care industry in the 1970s as a movement popular with constituents for providing an affordable health care option.¹⁶⁷ To clear a path for managed care, the corporate practice prohibition was either not applied to HMOs, or the entities were specifically exempted to the extent that they served their legitimate business function without making actual medical judgments. Likewise, diagnostic genetic testing by corporate entities may not be subjected to CPMP doctrine as a matter of policy, where the benefits of corporate participation – cutting edge research and development and high capacities and outputs derived from enormous capital investment – are so favorable.

Despite favorable policy resulting from their attractive affordability,

¹⁶² See 42 U.S.C. § 300e-10 (2000) (enabling development of HMOs by exempting them from prohibitive state laws); Axelrod, *supra* note 151, at 107; Sara Mars, Note, *The Corporate Practice of Medicine: A Call for Action*, 7 HEALTH MATRIX 241, 259-60 (1997).

¹⁶³ See Axelrod, *supra* note 151, at 107.

¹⁶⁴ See *id.* at 107-08.

¹⁶⁵ See *id.* at 109.

¹⁶⁶ Health care costs increased 9.7 percent in 2000, compared with 7.5 percent increases in 1998 and 1999. See Kent Hoover, *Employers See 9.7% jump in Healthcare Costs*, THE BUSINESS JOURNAL, March 31, 2000, at 30.

¹⁶⁷ See Arnold J. Rosoff, *Phase Two of the Federal HMO Development Program: New Directions After a Shaky Start*, 1 AM. J.L. & MED. 209 (1975) (describing the development and passage of the Health Maintenance Act of 1973).

however, HMOs are not universally popular. Critics argue that the managed care industry renders questionable decisions regarding coverage and medically necessary treatment that have a deleterious impact on their patients, yet HMOs often manage to escape malpractice liability. Some HMOs have asserted perverse but successful defenses to malpractice suits brought by aggrieved subscribers against their health care organizations by using the corporate practice doctrine to their advantage.¹⁶⁸ Other managed care organizations have refuted allegations of malpractice, in essence, by asserting that since they are not and cannot be licensed to practice medicine under the CPMP doctrine, they are “incapable” of medical practice and cannot therefore be held liable for medical malpractice.¹⁶⁹ Such obviously irrational arguments improperly equate a prohibited behavior with one that is impossible to perform. The prohibition against medical practice by corporations does not prevent such prohibition from being violated; rather the prohibition serves as the basis for sanctions when the prohibited behavior is performed. Despite the flawed logic, many courts have accepted the HMOs’ dubious contentions.¹⁷⁰ Legislation in some states supports the HMOs’ unsound reasoning, deeming HMOs not to be practicing medicine through their operations *per se* under statute.¹⁷¹

Managed care corporations have exploited policy exceptions to the Corporate Practice of Medicine Prohibition afforded to them for the purpose of promoting more affordable health care to a greater number of people. Such abuses certainly do not create the most hospitable atmosphere for other corporate entities seeking involvement in health care, even where the involvement sought may be further upstream from the actual practice of medicine and the “pseudo-practice” that HMOs undertake. In light of negative attitudes associated with HMO behavior,¹⁷² the public and policy makers may be wary of commercial attempts to market health care services such as diagnostic genetic testing. Critics of commercial genetic testing might warn that providing the same latitude to another “quasi-medical” entity and allowing escape from CPMP doctrine would result in similar abuse. Potential reluctance of policy makers to create a favorable climate for commercial genetic testing is a concern for the nascent industry.

Beyond economic policy arguments, however, at least some of the reasoning for the non-application of CPMP doctrine to HMOs, and part of the rationale for not applying CPMP doctrine against genetic testing, stems from how medical practice is conceptualized. Such normative views are crucial in determining whether an HMO operates outside its permitted function by practicing medicine and, in doing so, violates CPMP doctrine or is subject to malpractice liability for negligent medical practice. Likewise, the question of

¹⁶⁸ See Manos, *supra* note 135, at 229-30.

¹⁶⁹ See *id.* at 230.

¹⁷⁰ See *id.*

¹⁷¹ See *id.* at 229.

¹⁷² See *id.* at 198 (noting the public disapproval associated with HMO practices).

whether diagnostic genetic testing functionally constitutes medical practice will be critical in assessing how the corporate prohibition may affect the genetic testing industry. Analysis of how CPMP doctrine impacts HMOs serves as an excellent predictive model for the genetic testing industry.

The development of more reasonable standards for HMO behavior may promote a positive outcome for new ventures that approach the boundaries of medical practice, such as genetic testing. HMOs have certainly not been broadly held to practice medicine and subjected to malpractice claims. However, a reasonable standard that strikes a better balance between unbending accountability and a *per se* policy that HMOs do not practice medicine, which brings with it the maximum cost reduction of strict utilization management, is taking root in application to managed care organizations.¹⁷³ One commentator suggests that to be liable for malpractice, an HMO must first exercise medical judgment, which may be defined as the “formulation of opinions based on the esoteric, highly technical knowledge base that is distinctive to medicine as a profession.”¹⁷⁴ Second, this medical judgment must significantly impact the patient’s actual care – the “substantial factor” test of classic torts liability.¹⁷⁵ This sort of test is more logical for the present health care environment. Legislatures have already begun to amend statutory language that better serves the reality of medical care today. A South Dakota statute, adopted in 1993, demonstrates such change:

[I]t is the public policy of this state that a corporation may not practice medicine [A] corporation is not engaged in the practice of medicine or osteopathy and is not in violation of [this section] by entering into an employment agreement with a physician licensed pursuant to this chapter if the agreement or the relationship it creates does not . . . in any manner, directly or indirectly, supplant, diminish or regulate the physician’s independent judgment concerning the practice of medicine or the diagnosis and treatment of any patient.¹⁷⁶

Under such law, managed care organizations are allowed to operate reasonably and are able to offer affordable health care without exercising unethical and ill-advised medical judgments to cut costs. Such models strike an ideal balance between the threat of profit-driven, cost-containing corporate practice and the unchecked costs that are associated with fee-for-service insurance plans. In examining how and why HMOs are regarded as outside the purview of corporate practice prohibitions, and to what extent this is proper,

¹⁷³ See *id.* (noting that some HMO practices are being regarded by the courts as “crossing the line” of medical practice); Morreim, *supra* note 144, at 962-66 (noting that courts are beginning to “embrac[e] the notion that judgment is the central element of practicing medicine” and suggesting exercise of a medical judgment-based standard for evaluating HMO conduct).

¹⁷⁴ Morreim, *supra* note 144, at 963.

¹⁷⁵ See *id.* at 963-66.

¹⁷⁶ S.D. Codified Laws Ann. § 36-4-8.1 (Supp. 1995).

we can better understand the ways in which such a doctrine or its underlying policy might be applied to emerging health care endeavors such as diagnostic genetic testing.

C. *Application of the Corporate Prohibition to Commercial Genetic Testing: Policy for the New Genetic Age*

Standards for what constitutes prohibited medical practice by corporate entities such as HMOs could serve as policy a model applicable to the commercial genetic testing industry now being born. By analogy to managed care, corporate entities offering diagnostic genetic testing might not be held to exercise medical judgment if they do not render advice based on test results. Under a “medical judgment” standard, corporate entities engaged in genetic testing would merely need to avoid exercising undue influence on health care decisions for consumers. For example, the dispensation by a corporate entity of information about possible lifestyle changes or treatment options tailored to genetic test results would run afoul of such a policy. Dispensing test results could quickly slip from an acceptable diagnostic service into a form of “medical practice” if information that may be construed as medical advice were disseminated to patients. The execution of genetic testing services in itself, however, would not be construed as medical practice under such a standard.

Testing alone rests on one end of a continuum of potential activity, while on the other end rests offering highly technical advice about particular drugs to take or gene therapies to undergo given a patient’s genetic profile. The latter activity is much more likely to be considered the exercise of medical judgment that impacts the individual’s course of treatment substantially and directly, thus constituting prohibited medical practice. So long as commercial entities do not unduly influence the decision making of consumers or the consumers’ medical caregivers and insurers, it seems unlikely that they would violate the CPMP doctrine or any similar public policy designed to maintain the integrity of medical care. Determining where the locus along the continuum at which a diagnostic testing service crosses over into medical practice may lie is a thorny issue, but a safe region seems to exist, the outer boundaries of which must be established as the genetic testing industry develops.

In any case, such diagnostic genetic testing, as at least a “quasi-medical” undertaking, necessitates regulation. As genetic innovation continues to push the envelope of bringing more testing services to the marketplace, policy makers have carefully contemplated oversight mechanisms. Establishing the appropriate regulatory framework is a critical step if corporate involvement in genetic diagnostic testing is to be allowed.

V. A PROPOSED REGULATORY FRAMEWORK FOR GENETIC TESTING:
RECOMMENDATIONS FROM THE SECRETARY’S ADVISORY COMMITTEE ON
GENETIC TESTING

Genetic testing still lingers in its infancy, and such diagnostic procedures do

not currently fall within the purview of particular regulatory mandates. At present, only more general regulations apply to the type of commercialized genetic testing that is becoming available. Laboratory tests on human samples are currently regulated in two ways. Tests that involve commercially prepared, analyte-specific reagents in diagnostic kits are regulated by the FDA and must satisfy the rigors of an approval process demanding clinical validity and utility.¹⁷⁷ Generic lab tests, or “home brews,” which do not employ the use of prepared kits, are regulated solely on the basis of analytic validity by the Clinical Laboratory Improvement Amendments (“CLIA”).¹⁷⁸ The latter variety of tests avoids the more extensive rigors of the FDA approval process.¹⁷⁹ Though regulations specific to the genetic tests beginning to be offered by biotechnology and genomics companies and other commercial entities do not yet exist, critics demand that regulatory action be taken immediately. These demands stem in large part from the fear that corporate entities might irresponsibly disseminate information in the interest of recouping development costs and turning profits as quickly as possible.¹⁸⁰ Notable pitfalls include “misinformation, insufficient or unreliable information, and information with low predictive value.”¹⁸¹ The difficulty of preventing such transgressions in the context of free market enterprise is a conundrum that draws the attention of critics who oppose corporate involvement in genetic testing.¹⁸² Others who support a reasonably regulated commercial enterprise deem prohibiting participation by corporate entities far too draconian.¹⁸³ Regulation for a genetic testing industry is already being contemplated.

Recommendations recently made by the Secretary’s Advisory Committee on Genetic Testing (“SACGT”) indicate that diagnostic genetic testing will soon fall within the purview of FDA regulation.¹⁸⁴ The SACGT was chartered in

¹⁷⁷ See Michael J. Malinowski & Robin J.R. Blatt, *Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards*, 71 TUL. L. REV. 1211, 1229 (1997). Diagnostic kits constitute medical devices that fall within the purview of the Medical Device Amendments Act of 1976. See 21 U.S.C. § 360k(a) (2000).

¹⁷⁸ See 42 C.F.R. 493.1 (1996).

¹⁷⁹ See Malinowski & Blatt, *supra* note 177, at 1230. The CLIA analytical validity requirement is satisfied by a mere showing that a test demonstrates a genetic alteration accurately without regard to clinical predictability. No showing that there is an impact on health is necessary. See *id.* at 1231-32.

¹⁸⁰ See Anny Huang, *FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship*, 53 FOOD DRUG L. J. 555, 586-87 (1998).

¹⁸¹ *Id.* at 586.

¹⁸² See *id.*

¹⁸³ See Huang, *supra* note 183, at 580-89; Bryn Williams-Jones, *Re-framing the Discussion: Commercial Genetic Testing in Canada*, 7 HEALTH L. J. 49, 59-61 (1999).

¹⁸⁴ See SECRETARY’S ADVISORY COMMITTEE ON GENETIC TESTING, ENHANCING THE OVERSIGHT OF GENETIC TESTS: RECOMMENDATIONS OF THE SACGT, at 27 (2000), available at <http://www4.od.nih.gov/oba/sacgt/reports/sacgtfinal.pdf> (last visited Dec. 26, 2001) [hereinafter SACGT REPORT].

1998 by Department of Health and Human Services (“HHS”) Secretary Donna Shalala in response to the need for policy development to address new scientific, medical, social, and ethical issues concomitant with the development of pioneering genetic technologies.¹⁸⁵ From June 1999 through June 2000, the SACGT gathered background information and, in consultation with the public, drafted recommendations, which were finalized during the summer of 2000.¹⁸⁶ The Committee addressed options for oversight of genetic tests and the relative benefits and disadvantages of the various options. It concluded that “based on the rapidly evolving nature of genetic tests, their anticipated widespread use, and extensive concerns expressed by the public about their potential misuse or misinterpretation, additional oversight is warranted . . .”¹⁸⁷ The SACGT first suggested the augmentation of CLIA, which presently requires laboratories offering tests to determine the analytical validity of tests before they are employed clinically and to provide genetic test-specific quality requirements.¹⁸⁸ More importantly, the Committee recommended that the FDA be charged with the “review, approval, and labeling of all new genetic tests that have moved beyond the basic research phase.”¹⁸⁹ As the federal agency already charged with the review and approval power over all drugs and biologics,¹⁹⁰ the FDA’s model seems to offer an ideal platform for genetic testing regulation.

This model did not enjoy universal support, however. Those from biotechnology industry groups and professional organizations expressed concern about the potential detriment additional regulation might have on the development, availability, and accessibility of genetic tests.¹⁹¹ While the SACGT weighted concerns about the traditional heavy-handedness of the FDA, the committee found that the potential of biotechnology corporations to commercialize genetic testing on a massive scale necessitated regulatory safeguards.¹⁹² Recognizing the need for experience and expertise in evaluating analytical validity, clinical validity and utility, as well as conducting pre- and post-market surveillance, the Committee found the FDA to be the most qualified administrative agency to handle these duties.¹⁹³ Many outside commentators also agree that regulation is necessary and that the FDA seems

¹⁸⁵ See *Secretary’s Advisory Committee on Genetic Testing, About SACGT*, at <http://www4.od.nih.gov/oba/aboutsacgt.htm> (last modified Nov. 19, 1999).

¹⁸⁶ See SACGT REPORT, *supra* note 184, at vi.

¹⁸⁷ *Id.* at 26.

¹⁸⁸ See *id.* at 28.

¹⁸⁹ *Id.* at 27.

¹⁹⁰ See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (2000); 21 C.F.R. § 5.10 (2000).

¹⁹¹ See SACGT REPORT, *supra* note 184, at 26.

¹⁹² See *id.*

¹⁹³ See *id.* at 27.

to be the agency most fit for the task.¹⁹⁴ Mindful, however, of the concerns expressed about overly restrictive regulation, the SACGT duly notes that “[t]he review process must minimize the time and cost of review without compromising the quality of the assessment of test validity.”¹⁹⁵ FDA regulation of genetic testing, if implemented, is thus likely to be more streamlined than the drug review process.¹⁹⁶

With the recent administration change, the level of impact the SACGT’s recommendations will have under President George W. Bush’s new choice for HHS Secretary, Tommy Thompson, is unclear. The Committee’s thoughts, however, will probably be taken under serious advisement, and some action is likely to begin in the near future. Those interested in the industry will surely keep abreast of political movements and lobby to prevent overly restrictive regulatory mechanisms from being implemented. Meanwhile, those who fear lax regulation in the face of the industry’s boom will make efforts to protect their interests accordingly as well. In any case, the public image of genetic testing is critical in determining the operating climate for commercial genetic testing services. It will most certainly be shaped by the events in the days to come as well as the spin placed on the issues by supporters and skeptics of the genetic testing industry, in its formative stages.

VI. RECOMMENDATIONS

Resolving the difficulties of the rapid growth of the biotechnology industry, and the issue of commercial genetic testing in particular, is a complex task, rife with conflicts the likes of which have not been addressed previously in history. The genetic innovations in development that are beginning to take root in the biotechnology and biomedical industries offer remarkable benefits but are laden with confounding problems. While some bristle at the ethical and policy challenges presented, such advances promise uncharted health gains too important to retard or derail. Policy makers must rise to the occasion of managing the pains of growth in this area.

In consideration of the sophisticated issues presented, several models for commercial genetic testing may be envisioned along a wide spectrum. At one end stands full and unregulated participation by corporate entities in the

¹⁹⁴ See, e.g., Huang, *supra* note 183, at 558 (suggesting broad FDA regulation of genetic testing); Kerry Burke, Note, *Loose-Fitting Genes: The Inadequacies in Federal Regulation of Institutional Review Boards*, 3 B.U. J. SCI. & TECH. L. 10 (1997) (recommending FDA overview and guidelines for institutional review boards).

¹⁹⁵ SACGT REPORT, *supra* note 184, at 27.

¹⁹⁶ The drug development and approval process generally spans twelve to fifteen years given the stringent mandates imposed by the FDA to ensure that the benefits of drugs reaching the market outweigh their risks. See PHARMACEUTICAL RESEARCHERS AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL INDUSTRY PROFILE 2000: REGULATORY AND LEGAL ASPECTS OF DRUG DEVELOPMENT (2000), available at <http://www.phrma.org/publications/publications/profile00/chap3.phtml> (last visited Dec. 26, 2001) [hereinafter PHARMACEUTICAL INDUSTRY PROFILE].

genetic testing practice and, at the other, total prohibition of corporate involvement. The scenario that seems to strike the ideal balance would protect the individual interests of consumers impacted by the genetic technologies and preserve the greater good that such advance can provide to all humanity. Such an ideal tracks a model of patient choice, neutral genetic counseling, physician involvement, and regulation of process and information management. With these points of control, law and policy makers should allow commercial genetic testing to proceed. Corporate participation, given current levels of patent protection and the implementation of the appropriate regulatory mechanisms, will lead to the optimal rate of biomedical advancement and the greatest societal good.

A. *Preservation of Patent Protection*

Our patent system is founded upon the premise that granting an inventor a limited monopoly on his or her invention in exchange for public disclosure of that invention will inspire innovation and effect a greater public good. In no industry could the driving motivation of this limited monopoly be more important than in the area of biotechnology. Research and development costs in a field so technology-intensive are extremely high.¹⁹⁷ To attract sufficient capital for endeavors on the cutting edge of genetics, companies working in this must seek public financing and are, therefore, for-profit entities. Biotechnology companies must be afforded protection to market the fruits of their research, without infringement by poaching competitors, in order to vindicate the investments made by the public and increase share value.¹⁹⁸ When such companies are able to develop useful and marketable products through the success of their business model, they are able to increase the attractiveness to investors. Investors, in turn, invest in these successful companies who have proven the quality of their work product. Such an efficient market ensures the greatest investment in those companies that are able to effect the greatest innovations most efficiently and thus enhance the public good.

Indeed, experts admonish against removal of patent protection for genetic discovery. Interleukin Genetics CEO, Philip Reilly, contends that the billions spent annually by biotechnology and pharmaceutical companies would disappear without patent rights, stating that such corporations' "success depends entirely on the ability to tell our partners that we have patent protection on the products they invest in."¹⁹⁹ The intellectual property

¹⁹⁷ See Aoki, *supra* note 118, at D1 (citing the years of work and millions of dollars spent in development); Sara Dastgheib-Vinarov, Comment, *A Higher Non-Obviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, 143 ; Gosselin & Jacobs, *supra* note 110, at 1 (citing the \$10 million cost to develop Myriad's breast cancer test).

¹⁹⁸ See *id.*

¹⁹⁹ Schmidt, *supra* note 9, at 73.

portfolio of a biotechnology company largely dictates its ability – or inability – to obtain capital backing. Says one general partner of a venture capital firm outside Boston, a major center for biotechnology firms, “We do not do a deal before we look closely at the intellectual property.”²⁰⁰ Without patents to guarantee returns on research and development, investors will not provide financial backing to biotechnology companies, most of which are not profitable until years after working with the subjects of their patents.²⁰¹ For biotechnology firms, patents are invaluable capital assets.²⁰²

An amendment to the patent statute that narrows the scope of protection, rather than abolishing it all together, is an alternative possibility, having been undertaken with respect to patents in the area of medical procedures.²⁰³ Exemption for medical practitioners from patent infringement in the use of patented gene sequences or testing methods is not a perfect analogue to the medical procedure exemption, however. Conducting medical procedures is clearly the exclusive province of medical practitioners who perform such protocols in the treatment of their patients in the event of medical problems. A patient in need of a medical procedure has reached a threshold of imminence in his or her medical need, and a physician performs a medical operation to ameliorate the condition that has manifested itself in the patient. In the case of diagnostic genetic testing, the issue is not one of imminent threat to the patient’s health requiring a medical procedure, but rather a test to determine if a patient is predisposed to future manifestation of illness. When these predispositions are discovered, an individual’s physician may recommend or administer prophylactic actions if appropriate. In this sense, restrictions on use of genetic sequences for purposes of diagnostic testing procedures do not directly intervene in the physician’s performance of his or her medical duties. A complete medical practitioner exemption is probably not justified on such grounds, nor is it generally advisable.

If provided an exemption from infringement, physicians might attempt to offer diagnostic genetic screening to their patients in conjunction with their affiliated hospitals and clinical laboratories. The resources of doctors, hospitals, and contracting clinical labs, however, would be grossly inadequate to carry out such testing on a large diagnostic screening scale. Facilities at hospitals and clinical labs are only equipped to handle the demand for testing for patients who are already ill, not for large factions of the population seeking diagnostic screening for genetic disorders. Allowing medical practitioners a complete exemption from patent infringement for use of the patented genes and markers underlying diagnostic genetic testing would be an unproductive measure, only serving to foment confusion over the appropriate roles of

²⁰⁰ Aoki, *supra* note 118, at D1 (quoting Michael Carusi, general partner of Advanced Technology Ventures, a Waltham, MA venture capital firm).

²⁰¹ *See id.*

²⁰² *See id.*

²⁰³ *See supra* notes 130-31 and accompanying text.

various players in the evolving health care environment. Exempting medical practitioners unilaterally would allow for doctors to offer genetic tests using the discoveries of biotechnology companies as a complete gratuity. Without having made any investment in the innovation itself, physicians could co-opt the fruits of biotechnology companies' labors and theoretically "undersell" services these companies offer as part of the course of their routine medical care. While such an arrangement may appeal to some innate sense of justice from a patient perspective, this scenario is problematic both for its impracticality and the detrimental net impact its mere possibility would have on innovation in biotechnology.

A perceived departure from the thrust of patent protection, such as offering exemption from infringement on genetic patents for medical practitioners, would threaten to greatly retard further breakthroughs in biotechnology and genetics by undercutting the major power source driving the industry – capital investment. Where investors believe, whether correctly or not, that the intellectual property upon which biotechnology companies are founded is not protected from unfettered use, they will not offer financial backing, and given the average level of sophistication of investors, panic responses founded in misunderstanding are not uncommon. Such a reality is evident from the effect the Clinton-Blair announcement, which was hardly even suggestive of a threat to genetic patent protection, had on the public markets.²⁰⁴ Concerns over access for physicians engaging in research or the actual course of patient treatment requiring use of patented genes or markers are fathomable. The AMA makes valid arguments that equitable access for medical practitioners at reasonable and affordable licensing cost should be preserved.²⁰⁵ However, despite high profile cases like those of the Canavan gene²⁰⁶ and the BRCA1 and BRCA2 cancer genes,²⁰⁷ industry experts maintain that "[m]ost patent holders are eager to see research done on their gene. . . . They will let academics use it . . ."²⁰⁸

While there is a compelling need for licensing arrangements under which physicians conducting meaningful medical research or treating patients are able to use patented genes or markers, contrary to public fears, corporate entities already enter into such agreements with academic medical researchers.²⁰⁹ Exempting medical practitioners unilaterally is an overbroad solution that does not offer a positive net effect on biomedical advancement for societal good. Policy or legislation that narrowly provides for affordable use

²⁰⁴ See *supra* notes 125-29 and accompanying text.

²⁰⁵ See *supra* notes 132-34 and accompanying text.

²⁰⁶ See *supra* notes 112-14 and accompanying text (discussing the limited licensing Miami Children's Hospital allows for use of its test for the Canavan gene).

²⁰⁷ See Schmidt, *supra* note 9, at 73 (discussing Myriad's order to the University of Pennsylvania to pay for use of the BRCA genes in performing diagnostic tests in research).

²⁰⁸ See *id.* (quoting Interleukin CEO Philip Reilly).

²⁰⁹ See *id.*

or compulsory licensing for medical research or courses of treatment for patients already suffering from an illness, as distinguished from use for broad screening services, may be in order. Measures suggestive of limitation on patent protection for biotechnology companies must be taken with the utmost caution, however, so as to avoid a market panic and preserve the impetus to invest in the biotechnology industry.

Though the nuances of the standards for non-obviousness, utility, and novelty continue to be topics of ongoing debate,²¹⁰ the current disposition of the PTO and the courts under the patent statute generally serves to protect biotechnology corporations in an appropriate manner that does not damage competition.²¹¹ Moreover, by protecting innovators' work from opportunists who would co-opt it without providing any form of compensation, patents increase contribution to the community knowledge, and, in turn, increase the output of the community.²¹² While it is important to preserve important contributions from the medical research community, mechanisms of such preservation must not overreach or suggest a fundamental departure from current norms. Should the patent system become less protective of innovation, or should such a perception be needlessly propagated, the result would severely hinder the progress into the vast new frontiers currently being explored with aplomb. Without the labor- and capital-intensive research to discover new genes and markers currently undertaken by large, public corporations, development of diagnostic genetic testing would come to a grinding halt. To maintain and foster rapid advance in the area of biotechnology and genetics, the integrity of the patent system as today constructed must be maintained.

B. Non-Application of Medical Licensure Requirements and Corporate Practice of Medicine Prohibition

As we enter an era of genetic-based medicine, we are challenged to rethink just what constitutes medical practice. Traditional norms suggest that diagnosis of an illness is a form of medical practice to be undertaken only by licensed physicians.²¹³ In question, however, is whether identifying an underlying genetic element that may at some undisclosed time lead to the manifestation of illness, in itself, constitutes a medical diagnosis, and if so, whether this identification should be considered actual medical practice in our new age. The short answer is that such genetic testing should not be held to constitute the practice of medicine subject to policy prohibition against

²¹⁰ See generally *id.*; Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827 (1999) (arguing that the courts' application of patent law to biotechnology has led to non-uniform patent protection in this field, overprotecting in some instances and underprotecting in others).

²¹¹ See Kieff, *supra* note 77, at 704.

²¹² See *id.*

²¹³ See *supra* discussion in Part IV-A.

corporate entities. There are several reasons for such a conclusion.

First, and most simple, is the character of the genetic testing process. Without the manifestation of some health deficiency or actual pathology, there is, by definition, no illness to diagnose. Even disorders identified in the traditional medical context prior to any functional health detriment are diagnosed because of physiologically discernable, pathological phenomena taking place within the body. To contend that an eighteen-year-old individual carrying a gene implicated in heart disease has been affirmatively *diagnosed* with heart disease is inaccurate. This individual may never develop heart disease if the proper lifestyle precautions are undertaken or some other prophylactic remedy, such as gene therapy, is administered, and it is the administration of health care advice and prophylactic treatment, *not* the identification of a gene's presence, that constitutes medical practice. So long as commercial entities do not endeavor to provide health care advice to those individuals tested or attempt to pedal therapeutic products that such entities commercially market, they should not be held to be practicing medicine. Rather, these entities would merely be conducting a laboratory testing service, to which individuals should have the freedom to submit themselves.

Second, and more persuasive is that prohibiting commercial participation in genetic testing does not reflect the policy goals of any sort of corporate medical practice prohibition. The Corporate Practice of Medicine Prohibition was established to shield patients from substandard medical care and to prevent profit-driven interests from interfering with the quality of that care.²¹⁴ Corporate entities will certainly be motivated to administer as many genetic tests as they possibly can to increase profits. So long as the proper intervening measures – neutral pre-test counseling and regulated release of information through consumers' own physicians – are administered,²¹⁵ however, there is not a threat to those seeking out the tests that outweighs the interests of increased health awareness and individual autonomy. Widespread genetic screening and the prophylactic treatments developed in response to the discovery of the genetic markers used in such tests would confer enormous benefit to the overall health of the population. It is an individual's right to seek information about his or her own genetic makeup. The attitudes of consumers and medical professionals alike reflect such a concept of autonomy, with overwhelming majorities of consumers and doctors supporting an individual's right to undertake any testing service he or she can pay for out-of-pocket and to obtain any necessary referral from his or her physician.²¹⁶ Beyond the

²¹⁴ See *supra* notes 144-50 and accompanying text.

²¹⁵ See *infra* discussion in Part VI-D.

²¹⁶ See Williams-Jones, *supra* note 183, at 54. It is also important to note that as genetic testing becomes a more recognized and widely used diagnostic tool, it may become a benefit covered under medical insurance. Such pre-symptomatic "diagnoses" of genetic conditions, in fact, may be the ultimate cost containment tool for the insurance industry, where genetic disorders may be treated in the future with gene therapy at lower cost. Of course, not every detectable disorder may have a cost-effective treatment, and such genetic information could

import of this right of autonomy, it should be a policy imperative not to impede the medical progress that will derive from responsible use of genetic technologies commercially.

With the proper framework and safeguards in place for commercial genetic testing, application of the Corporate Practice of Medicine Prohibition would be inappropriate and run counter to the policy goals it embraces. To enhance the quality of individuals' health by allowing for a full appraisal of future health problems before they strike constitutes a health benefit, not a threat or detriment. Furthermore, promoting individual autonomy is also consistent with goals of prohibiting the corporate medical practices that threatened to limit patient options at the time the doctrine was conceived. So long as lawmakers establish the proper mechanisms to prevent corporate entities from taking on the role of medical practitioners situated to exploit consumers, application of CPMP doctrine is not warranted. Diagnostic genetic testing by corporate entities should play an invaluable role in a new health care environment, given the correct regulatory framework and appropriate intervening mechanisms.

C. FDA Regulation of the Commercial Genetic Testing Industry

It is uncontroverted that the commercial genetic testing industry must be regulated in some fashion. Commentators, as well as the SACGT, have stated that regulation of the industry is necessary.²¹⁷ Although genetic testing does not pose the same direct and affirmative harm that consumption of tainted or harmful food or drugs does, many of the same commentators and the SACGT believe that the FDA is most fit for the task of regulating genetic testing.²¹⁸ A critical point in regulating the commercial genetic testing industry is ensuring the validity and accuracy of the results provided to consumers. In this regard, FDA regulation would serve to protect against the psychological damage of inaccurate results of genetic tests and also potential physical harm that could result from subsequent courses of treatment carried out upon recommendation by physicians in reliance on erroneous test information.²¹⁹ The need for regulating and evaluating analytical and clinical validity of medical test results as well as monitoring products, including test kits, in the pre- and post-market stages, is one the FDA already fulfills in the drug and food markets.²²⁰

also be used against consumers in denying policies. Issues of genetic privacy abound and must certainly be resolved, but that is a matter for separate discussion.

²¹⁷ See *id.* at 66; Huang, *supra* note 183, at 591; Burke, *supra* note 194, ¶ 37; SACGT REPORT, *supra* note 184, at 13-32.

²¹⁸ See Huang, *supra* note 183, at 591; Burke, *supra* note 194, ¶ 47; SACGT REPORT *supra* note 184, at 27.

²¹⁹ A physician should not, of course, rely solely upon results of a single commercial test without corroborating data to suggest that some prophylactic measure is medically advisable.

²²⁰ See SACGT REPORT, *supra* note 184, at 27.

Having claimed statutory authority over all gene therapy products in 1993,²²¹ the FDA has clearly asserted an understanding of the relevant technologies and has the administrative experience and capacity to carry out this duty. Regulation of accuracy of testing methods and level of predictive value by the FDA would address major concerns posed by genetic testing and the inherent dangerousness of the information it provides if not properly controlled.²²² It is clear that the reliability of such tests cannot be judged by the corporate entities themselves, as they maintain a powerful interest in extolling the virtues of their own services.²²³ By holding for-profit entities accountable to a regulatory agency such as the FDA, the quality and integrity of their testing is better ensured. Likewise, while direct consumer marketing should be permissible, regulations mandating disclosure of pertinent information regarding predictive value and accuracy in testing, as well as the requirement that consumers seek physician referral to genetic counselors before testing, must be implemented.²²⁴ Such marketing regulations would be analogous to requirements in drug advertising that mandate both disclosure of risks of side effects and the physician advice.

The major concern with FDA regulation of the genetic testing industry is the agency's traditional heavy-handedness, most noted in the drug industry.²²⁵ Those in the corporate biotechnology field fear the chilling effect that overly burdensome regulation would have on the development, availability, and accessibility of genetic tests.²²⁶ The concern is a legitimate one, as over-regulating the industry would undoubtedly lead to escalating research and development costs, which would undermine the motivation to innovate and also drive up consumer cost of tests pushed through the development and regulatory pipeline. Given that genetic testing offers such enormous potential in the health care arena and that there is a far lower risk than with the direct physical harms of unregulated drugs and food products, somewhat lower regulatory standards than those imposed on drugs and food are in order. The SACGT's recommendations reflect fears of potential heavy-handedness in suggesting an approval process that minimizes time and cost while establishing reasonable criteria for clinical validity.²²⁷ Such a regime would maximize public health benefits while maintaining the strong motivation for research and development in the biotechnology industry so essential to this type of advance.

²²¹ See Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53,248 (1993).

²²² See Huang, *supra* note 183, at 586, 591.

²²³ See *id.* at 587.

²²⁴ See *infra* discussion in Part VI-D recommending mandatory physician reference and genetic counseling.

²²⁵ See PHARMACEUTICAL INDUSTRY PROFILE, *supra* note 196; SACGT REPORT, *supra* note 184, at 27.

²²⁶ See SACGT REPORT, *supra* note 184, at 27.

²²⁷ See *id.*

B.U. J. SCI. & TECH. L.

While such a regulatory framework addresses many concerns associated with the manner in which corporate entities would offer genetic testing services to the public, additional protection should be provided to consumers in the dissemination of such critical and sensitive health information. FDA regulation of tests should be augmented by genetic counseling and intermediary roles by physicians.

D. Genetic Counseling and Physician Intermediaries

The final piece of the puzzle in creating an appropriately balanced framework for commercial genetic testing is establishing the proper process for genetic information to be evaluated and disseminated to consumers. Releasing test results to lay consumers, who are not educated in such matters as genetic testing or qualified to understand the information contained therein, poses inherent psychological dangers. It is therefore essential that third party professionals participate as neutral intermediaries to inform and advise consumers in seeking tests and receiving their results. In order to ensure the proper neutrality, these mechanisms must operate wholly outside of the for-profit corporate sphere. Both formally trained and licensed genetic counselors (qualified physicians or separately trained professionals) and the consumers' own physicians should be involved. Under such a scheme, a consumer wishing to undergo genetic testing for general or particular disorders would contact his or her own physician to obtain a referral to a genetic counselor. After a discussion with a qualified counselor, in which the consumer was properly educated and informed about the testing and its psychological and medical ramifications, he or she could then proceed to submit him- or herself to testing by a commercial service. The results would then be released to the consumer's physician and genetic counselor. The licensed physician or counselor would release and explain the results to the consumer. In turn, the physician would be able to give his or her qualified medical opinion about the appropriate courses of action, and the counselor would be able to provide post-testing support.

This model provides an ideal balance. By vitiating the potential for abuse by commercial entities against consumers with the separation provided by neutral physician and counselor intervention, the patient is buffered from harm while still enjoying autonomous decision-making. The physicians and counselors would not enjoy any power of refusal when approached by consumers, but rather would inform the consumers about the endeavor they wished to undertake. Though the decision would rest with the consumer, no individual would be allowed to forego referral to a genetic counselor by the consumer's own physician, who would be involved with any subsequent medical advice.

VII. CONCLUSION

Corporate involvement in genetic testing offers great promise in advancing the state of genetic knowledge and health care and is far too valuable to be

stymied by overwrought concerns raised by critics of commercialization in health care. Although careful oversight of the commercialization of genetic testing is warranted, to preclude corporate involvement all together would unjustifiably impede important biomedical discovery and derail the most able delivery vehicle of this costly and highly technical service. Patent protection of genes and gene markers of known utility should continue so as to foster these important genetic innovations and discoveries. The role that corporate entities will play in harnessing their intellectual property to provide large-scale diagnostic screening to consumers should not be construed as medical practice or invoke medical licensure laws and CPMP doctrine. This new function in an evolving health care environment is a "pre-medical" one uniquely suited to corporate biotechnology companies. Diagnostic genetic testing is, in fact, not a service that would be practically available through traditional modes of health care given the resource- and capital-intensive nature of large scale, diagnostic genetic screening. With a regulatory framework in which the FDA monitors clinical validity and qualified counselors and physicians serve as intermediate advisors to lay consumers, corporate involvement would bring ground-breaking genetic testing services and foster significant advancement in genetics and medical care. Lawmakers and those close to the burgeoning biotechnology industry will grapple with the issues presented here as the era of personalized genetic medicine dawns.