Bridging the Gap Between Life Insurer and Consumer in the Genetic Testing Era: The RF Proposal

CHRISTOPHER M. KEEFER *

INTRODUCTION

The last ten years have proven to be significant for the world of science. Thousands of genes have been located on chromosomes by researchers from the Human Genome Project (“HGP”). Their research has led to the location of genes responsible for conditions including, but not limited to, cystic fibrosis, Huntington’s disease, some breast and ovarian cancers, and some forms of

---

*J.D. Candidate, 1999, Indiana University School of Law-Bloomington; B.B.A., 1996, University of Notre Dame. I would like to thank the following people/organizations who aided in developing this proposal: Midwest Alliance for Health Education; Barrett & McNagny, Attorneys at Law; Richard D. Robinson, Esq.; Eleni Z. Angelopoulos, Esq.; Patricia I. Bader, M.D.; Donald C. Chambers, M.D.; John P. Gerni; Professors Roger Dworkin and Susan Stuart; J. Michael Keefer, Esq.; William M. Daly; and Daniel F. McCarthy.

The HGP is a multibillion dollar initiative designed to map and sequence the genes in the human genome. See Heather McClure, The Insurance Industry’s Use of Genetic Information: Legal and Ethical Concerns, 28 J. HEALTH & HOSP. L. 231, 231 (1995); Lori Whittaker, Clinical Applications of Genetic Testing: Implications for the Family Physician, 53 AM. FAM. PHYSICIAN 2077, 2077 (1996), available in LEXIS, GENMED Library, AFP File. The genome of an organism consists of its haploid set of chromosomes. Humans have 23 pairs of chromosomes (or 46 total chromosomes). The 23 pairs of chromosomes are known as a diploid set of chromosomes. Each parent donates one set of chromosomes from the pair (known as a haploid set) to the offspring, giving it a diploid set (one haploid set from each parent). Genes are located on each haploid set and are responsible for bodily functions. The HGP is focused on finding the location of human genes on each chromosome in the haploid set. See JAMES W. FRISTROM & PHILIP T. SPIETH, PRINCIPLES OF GENETICS 47, 132-33 (1980); NATIONAL CANCER INST., U.S. DEP’T OF HEALTH AND HUMAN SERVS., UNDERSTANDING GENE TESTING 2 (1995).

Cystic fibrosis (“CF”) is one of the most common genetic disorders causing death in the white population. Pulmonary disease is responsible for 90% of CF-related deaths. Liver disease, trauma, and suicide are responsible for the other 5% of CF-related deaths. See generally Garry R. Cutting, Cystic Fibrosis, in 1 EMERY AND RIMOIN’S PRINCIPLES AND PRACTICE OF MEDICAL GENETICS 268 (David L. Rimoin et al. eds., 3d ed. 1997) [hereinafter MEDICAL GENETICS] (discussing symptoms, genetic structure, diagnosis, and management of CF).

Huntington’s disease (“HD”) causes a gradual deterioration of physical and mental capabilities around the age of 40 and lasts for about 15 years, until death. See generally Michael R. Hayden & Barry Kremer, Basal Ganglia Disorders, in 2 MEDICAL GENETICS, supra note 2, at 2197, 2203-09 (discussing symptoms, diagnosis, genetic counseling, and management of Huntington’s Disease).

Present studies have shown that, although the majority of breast and ovarian cancers develop sporadically, a small percentage (approximately 5-10%) of these cancers are genetically related. See generally C. Michael Steel, Cancer of the Breast and Female
Alzheimer’s disease. Tests for these, and many other genetic disorders, are becoming more readily available and could soon become inexpensive.

Questions arise as to whether employers, insurance companies, and the government may access an individual’s genetic information resulting from such tests. The insurers’ ability to access this information has received a great deal of attention. More specifically, may an insurance company classify its applicants based on their genetic makeup? Many different views have been expressed to answer this question. On one hand, insurance companies, particularly life insurers, believe that they should be entitled to genetic information if the risk classification process is to survive. Insurers believe that widespread fraud would result from the ability to withhold genetic information, raising the premiums for all policyholders.

Consumers, on the other hand, believe that allowing insurers’ access to genetic information would violate rights of privacy, prevent patients from getting needed help, and lead to widespread discrimination against applicants. These debates have resulted in legislative intervention at the state level. Federal legislation has also been proposed, however, no significant efforts have been passed directly relating to this issue.

Reproductive Tract, in 1 MEDICAL GENETICS, supra note 2, at 1501, 1501-23 (discussing the genetic mapping of heritable breast cancer).

Alzheimer’s disease is different from other genetically related diseases in that there are different copies of the same gene. If one of the copies of the gene is received from the parent, the process of Alzheimer’s is hastened. See generally Allen D. Roses & Margaret A. Pericak-Vance, Alzheimer Disease and Other Dementias, in 2 MEDICAL GENETICS, supra note 2, at 1807, 1807-20 (discussing symptoms, diagnosis, genetic counseling, and management of Alzheimer’s disease).

As of 1995, tests for cystic fibrosis, Duchenne/Becker muscular dystrophy, hemophilia, Gaucher’s disease, Huntington’s disease, Lou Gehrig’s disease, Tay Sachs disease, and thalassemia (among others) were available. See McClure, supra note 1, at 232-33. As of 1996, tests for the presence of the BRCA1 mutation, which predisposes a person to breast or ovarian cancer, were commercially available, and tests to determine the predisposition to Alzheimer’s were being developed. See PEOPLE’S MED. SOC’Y, INC., GENETIC TESTING: THE CONTROVERSIAL BACKGROUND CHECK 16 (1997).

Cystic fibrosis tests, which cost around $400 in 1993, cost around $125-$150 in 1995, and cost even less in 1997. (The Michigan State University Genetics Clinic quoted a price of $52 for a cystic fibrosis carrier screening test.) If this trend continues, it is predicted that these tests will cost five to ten dollars. See Alfred G. Haggerty, Genetic Advances Are Seen As Boon for Insurers, NAT’L UNDERWRITERS, Mar. 15, 1993, at 25, 25 (Life & Health–Financial Services ed.).

Many articles have been published dealing with this subject. For a comprehensive examination, see Eric Mills Holmes, Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project, 85 KY. L.J. 503 (1997).

See id. at 531-78.

See infra text accompanying notes 87-93.

See infra text accompanying notes 90-91.

Although many consumers side with insurers with regard to this issue, the insurers’ opposition will be referred to as “consumers” for purposes of objectivity.


See Holmes, supra note 8, at 629-44.

See infra text accompanying notes 123-34.
BRIDGING THE GAP

State legislators have addressed this issue by introducing and passing laws that define the rights of insurers and consumers. Some states narrowly define the protection insurers and consumers can expect to receive, focusing on specific types of insurance and genetic disorders. Other states have addressed the issue through broad legislation, covering all types of insurance and genetic disorders.

The states’ right to regulate the insurance industry was premised on public policy. However, public policy now calls for federal treatment of this social dilemma, as state regulation has provided little protection to the life insurer and consumer with regard to accessing genetic information. Therefore, this Comment calls for the establishment of a federal subagency to develop regulations, as well as to update those regulations when genetic research and advances deem it necessary.

15 See Holmes, supra note 8, at 629-44.
17 See infra text accompanying note 135.
18 The McCarran-Ferguson Act, which passed on March 9, 1945, declared that it was in the public’s interest for states to regulate the insurance industry, and therefore gave the states that power. 15 U.S.C. §§ 1011-1012 (1994).
This Comment will begin by introducing some of the basic concepts of genetics and insurance (particularly life insurance). Next, it will show how these concepts interrelate to affect both life insurers and consumers. The final focus of this effort is to demonstrate that developing and updating risk factors ("RFs") for each individual genetic disorder discovered, to be incorporated into each life insurer’s premium valuation process, is an ideal step toward alleviating the stresses between the life insurer and consumer with regard to accessing genetic information.

I. THE BASICS OF GENETICS

Genes exist in strands of DNA, which carry all the information about our bodies and how they function. There are forty-six molecules of DNA in each human cell which coil into the condensed “double helix” shape. These coiled DNA strands, or chromosomes, can be found in twenty-three pairs-twenty-two autosomes (non-sex determining chromosomes) and one pair of sex chromosomes which determines the sex of the individual. An individual receives one set of twenty-three chromosomes (twenty-two autosomes and one sex chromosome) from each parent.

The forty-six molecules of DNA contain between 50,000 and 100,000 genes, each of which provides instructions to the cells regarding bodily functions. Some genes instruct cells to produce proteins which aid in the development of the embryo, some are responsible for diversifying the cells (for example, making a bone cell and brain cell differ in characteristics), and some produce proteins necessary for everyday bodily functions.

Genetic disorders may occur when there is a mutated gene which leads the cell to produce aberrant proteins or other gene products which may obstruct efficient bodily performance. Sometimes full segments of DNA may be missing, multiplied, or transposed (found on a different segment of the chromosome), resulting in a missing gene, an extra gene, or a misplaced gene which alters the...
regular production of gene products that the cell needs. These mutations may be either inherited or acquired.

Inherited mutations arise when one parent (or both) donates an aberrant gene in the set of chromosomes passed on to the child. This mutation then replicates itself as the cell multiplies inside the embryo, resulting in millions of cells containing the flawed information. These mutations could then be passed down as the next generation receives its set of chromosomes from the parent with the mutation.

Such mutations may then lead to genetic disease. These disorders may be classified as either “multifactorial” or “single-gene” genetic conditions. Multifactorial conditions may never manifest themselves in the absence of certain other factors. These conditions rely on the “interaction of numerous genetic and environmental factors.” For example, a person may have a gene which makes him susceptible to lung cancer. If he avoids smoking, he might not develop lung cancer. In other words, by eliminating the environmental factors, the disease may not manifest itself.

In the case of single-gene diseases, such as cystic fibrosis and Huntington’s disease, the carrier received a gene in which the disease will manifest itself regardless of environmental factors. Hence, a single gene can cause the manifestation of the symptoms.

---

27 See id. at 5; see also Kowles, supra note 20, at 84 (describing how the nucleotide sequence of a gene can be altered); Snyder et al., supra note 23, at 353-89 (providing a more in-depth analysis of gene mutations).

28 See National Cancer Inst., supra note 1, at 5; see also Kowles, supra note 20, at 217-18 (suggesting the “nature versus nurture” approach to a person’s genotype (actual genetic makeup) and their phenotype (physical expression of their genetic makeup, or genotype)). Kowles instructs that a person’s genome (nature) reflects his “potential phenotype.” Id. at 218 (emphasis in original). However, environmental factors (nurture) can influence the degree to which the phenotype expresses itself. See id.

29 See National Cancer Inst., supra note 1, at 5.

30 See id.

31 See id.

32 Donald C. Chambers, Genetic Testing and Insurance in the United States, MED. RESOURCE (Lincoln Nat’l Reinsurance, Fort Wayne, Ind.), Oct. 1994, at 3; see also Snyder et al., supra note 23, at 566 (“Quantitative traits are often referred to as multifactorial traits in order to emphasize the many genetic and environmental factors in their determination.”) (emphasis in original).

33 See Kowles, supra note 20, at 233 (discussing oncogenes—genes which may cause cancer if activated by, among other things, environmental factors).

34 Parents pass on a particular copy of a gene to their offspring. As stated supra note 1, each parent donates a haploid number of chromosomes to the offspring, giving it a diploid number. In donating a haploid number of chromosomes, each parent donates one allele to the offspring. See Brian R. Gin, Genetic Discrimination: Huntington’s Disease and the Americans with Disabilities Act, 97 COLUM. L. REV. 1406, 1414 & n.45 (1997). The combination of the two alleles forms the particular gene. See id. Huntington’s disease only requires the presence of one allele in order for the disease to manifest itself. (The dominant allele must be present in the pair for manifestation of Huntington’s.) See id. Suppose the dominant Huntington’s allele will be represented by “H,” and the recessive allele (which does not cause Huntington’s), will be represented by “h.” If each parent donates h alleles, the offspring is considered homozygous recessive (hh) for Huntington’s and the disease will not manifest itself. See id. However, if one parent donates an H allele, and the other parent
At this point, it is important to distinguish between the terms “predisposed genetic condition” and “presymptomatic genetic condition.” People who are predisposed to a genetic disease do not have the disease. Rather, they have an increased likelihood that the disease will develop. The Equal Employment Opportunity Commission (“EEOC”) provides an excellent explanation of a predisposed genetic condition:

“If your grandmother had heart disease, you may have a predisposition to heart disease. And if your father has cancer, you may be predisposed to developing cancer. However, the presence of these genetic characteristics does not indicate that an individual has an impairment or a record of an impairment, or necessarily that the individual may develop an impairment in the future.”

Breast cancer, heart disease, lung cancer, alcoholism, and obesity are all examples of predisposed genetic conditions. There is a possibility that someone with a predisposition to one of the above conditions may never develop that condition. For example, the carrier of the BRCA1 gene, which predisposes an individual to breast cancer, has around an 85% chance of developing breast cancer. The carrier may never develop breast cancer, however the presence of the mutation indicates an increased risk for developing the disease.
On the other hand, people with presymptomatic genetic conditions will develop the disease if they live long enough. An example of such a condition is Huntington’s disease. Although the carrier of the Huntington’s mutation may not develop symptoms for the disease for the first forty years of his life, symptoms will eventually develop, regardless of outside factors. Once symptoms develop, the carrier can be classified as symptomatic for the disease.

Another aspect of genetic diseases is the gene’s penetrance and expressivity. Some diseases express themselves more consistently than others. For example, the BRCA1 gene results in breast cancer for 85% of the people who have it (predisposing them to breast cancer) while the Huntington’s gene manifests itself in nearly 100% of the people who have it (causing them to be presymptomatic for Huntington’s). The ability of a gene to express itself in a person is known as a gene’s penetrance. In the earlier example, the BRCA1 gene is 85% penetrant, while the Huntington’s gene is nearly 100% penetrant. The Huntington’s gene is so penetrant that people are considered presymptomatic for the disease if they have the gene. However, there are some cases where the Huntington’s gene does not express itself until very late in life. Expressivity deals with the degree and manner in which the gene manifests itself once it has penetrated. A gene may express itself differently in one individual relative to another, possibly leading to a more severe genetic condition in that individual.

The discussion thus far has focused on inherited genetic diseases. Another family of genetic diseases, “acquired” genetic diseases, arises from mutations that may form spontaneously from environmental or age-related factors. Spontaneous cancers are acquired genetic disorders. The inherited BRCA1 gene is responsible for approximately 5-10% of breast cancers, while 90-95% of breast cancers are spontaneous genetic disorders. These non-BRCA1-related breast cancers may occur when the cell is dividing itself and DNA is poorly transmitted to the sister cell, although environmental factors such as radiation may be responsible for spontaneously causing an error in the DNA.

The presence of these inherited and acquired genetic disorders can be determined by analyzing an individual’s DNA through genetic testing. The advent of genetic testing has provided valuable information for individuals and families affected by genetic conditions. It has also highlighted the importance of informed consent and genetic counseling in managing genetic information and the potential health risks associated with genetic diseases.
testing has made it possible to determine whether an individual possesses a particular genetic disorder, the nature and severity of that disorder, and the chances that the disorder will be passed to that individual’s offspring.\textsuperscript{52}

II. WHAT IS GENETIC TESTING?

Testing for the presence of genes involves taking a person’s cells and examining their DNA.\textsuperscript{53} Geneticists performing these tests focus on a particular segment of DNA in order to find missing information sequences, added sequences, or transposed sequences.\textsuperscript{54} Testing involves not only looking for altered genes, but also looking for gene products which could signal an aberrant gene.\textsuperscript{55}

Genetic testing is used to determine if a person is a carrier of a particular gene, which then may lead to a determination of whether the person is predisposed to a particular disease or presymptomatic for a particular disease. However, a person may be neither predisposed nor presymptomatic. In such a case, he or she is just a carrier of a particular allele, which is a different form of the same gene.\textsuperscript{56} Since some diseases, such as cystic fibrosis, require the presence of two of the same alleles in order for the diseases to manifest themselves, a person possessing only one of the requisite alleles is said to be a carrier of such a disease. Some diseases, such as Huntington’s disease, only require the presence of one particular allele for manifestation.\textsuperscript{57}

Tests can determine whether a person is a carrier of a dominant or recessive allele,\textsuperscript{58} and therefore can inform the patient whether he may be predisposed or presymptomatic for a particular disease. This kind of information helps the patient know what genetic information can possibly be passed down to the next generation.\textsuperscript{59} This information can also be used to determine the possibility of mutant alleles in parents and siblings. It can even be used to track the potential for a mutant gene in grandchildren.\textsuperscript{60}

Genetic tests can be expensive. A 1995 report found that a cystic fibrosis test cost between $125 and $150, a Huntington’s disease test cost between $250 and $300, and a Tay-Sachs test cost about $150.\textsuperscript{61} Commercial tests for breast and ovarian cancer are available, and tests for Alzheimer’s disease are being commercially developed.\textsuperscript{62} As technology advances and more information is acquired about genes and gene products, these tests could become less expensive.\textsuperscript{63}

\textsuperscript{52}See NATIONAL CANCER INST., supra note 1, at 9, 11-12.
\textsuperscript{53}See id. at 8.
\textsuperscript{54}See id.
\textsuperscript{55}See id.
\textsuperscript{56}See FRISTROM & SPIETH, supra note 1, at 156-57; see also KOWLES, supra note 20, at 4; SNYDER ET AL., supra note 23, at 8; supra note 34.
\textsuperscript{57}See Chambers, supra note 35, at 4; see also supra note 34 (discussing the required allele pairings for different diseases).
\textsuperscript{58}See NATIONAL CANCER INST., supra note 1, at 9.
\textsuperscript{59}See id.
\textsuperscript{60}These tests are known as predictive gene tests. See id. at 11.
\textsuperscript{61}See McClure, supra note 1, at 232-33.
\textsuperscript{62}See id.
\textsuperscript{63}See Haggerty, supra note 7, at 25.
III. THE BASICS OF INSURANCE

Before proceeding on to the fundamentals of insurance, it is important to note that the McCarran-Ferguson Act stated that it was in the public’s interest for states to regulate the insurance industry.\textsuperscript{64} As a result, “state laws enacted ‘for the purpose of regulating the business of insurance’ do not yield to conflicting federal statutes unless a federal statute specifically requires otherwise.”\textsuperscript{65} Congress has “explicitly reserved the power to enact legislation relating to the business of insurance.”\textsuperscript{66}

There are generally two types of insurance at issue with regard to the genetic testing conflict: health insurance and life insurance. Health insurance is designed to pay immediate medical costs, such as doctor and hospital bills,\textsuperscript{67} and can be packaged as an individual policy or a group policy. Under individual health insurance, the insured is personally purchasing the insurance, while in group health insurance, that person’s employer owns the policy and he, as well as the other employees, are covered as a group under the policy.\textsuperscript{68}

\textsuperscript{66}Holmes, \textit{supra} note 8, at 584.
\textsuperscript{67}Health insurance is generally defined as “insurance providing indemnification for losses caused by illness.” 1 \textsc{Lee R. Russ} \& \textsc{Thomas F. Segalla}, \textsc{Couch on Insurance} § 1:46 (3d ed, 1995).
\textsuperscript{68}See \textit{id.} § 1:2.
Life insurance is essentially a contract in which the insurer agrees, in exchange for a specified premium, to pay a determined amount of money to designated beneficiaries upon the death of the insured.\(^\text{69}\) Whereas most health care policies are group policies provided by employers, most life insurance policies are individual in nature.\(^\text{70}\) While health insurance may be considered a necessity, since it is the primary access to medical care for many individuals, life insurance is more of a property interest in that proceeds from the policy may be transferred to another individual.\(^\text{71}\) However, it is imperative not to underestimate the importance of life insurance, since it is the primary means of future financial planning for many individuals.\(^\text{72}\) Life insurance is generally regulated by the states as permitted by the McCarran-Ferguson Act.\(^\text{73}\) To date, there are no significant federal provisions designed to regulate life insurance.

A. Risk Classification and Its Role in Life Insurance

---

\(^{69}\) See id. § 1:39.


\(^{71}\) See id. at 6.


\(^{73}\) A life insurance policy “may, in the absence of contrary legislation or contract provision, be delivered and transferred as other personal property.” Russ & Segalla, supra note 67, § 1:39.

\(^{74}\) See NAIC, supra note 70, at 8.

BRIDGING THE GAP

Medical underwriting involves assessing the applicant’s risk of accident, sickness, or death, depending on the type of insurance policy for which the individual applied. Individuals applying for life insurance experience the full effects of medical underwriting and risk classification, since individual, and not group, insurance is involved. Individual insurance applicants (“applicants”), at the time they apply, are grouped together into risk classes and charged premiums relative to the risk class they belong in; a person in a higher risk class is charged a higher premium, while a person in a lower risk class is charged a lower premium. Applicants are classified as “standard,” “substandard,” or “declined” based on personal risk relative to the risks of other policyholders. A person with a standard rating may have a lower premium than a person with a substandard rating, who may be refused insurance altogether.

Once insured, persons who suffer a misfortune collect on their insurance; those who avoid misfortune do not collect. If a large number of people suffer misfortunes relative to the total number of people insured, overall premiums would have to rise in order to guarantee that the unhealthy policyholders could collect and the insurers could still stay in business. Premiums are part of an insurer’s revenue—if the insurance claims outweigh the revenues, the insurer might possibly become insolvent.

As stated earlier, the McCarran-Ferguson Act allows states to regulate the insurance industry. States have permitted insurers, through legislation, to “discriminate” among applicants through risk classification. In general, risk classification is considered “fair” discrimination. At this point, “fair” discrimination and “unfair” (or “invidious”) discrimination must be distinguished. The Massachusetts Supreme Judicial Court, in Telles v. Commissioner of Insurance (and most, if not all, courts in general) defined “unfair discrimination” in the context of insurance as “that which treats individuals of the same class and

---

76 See RUSS & SEGALLA, supra note 67, § 1:2.
77 An insurer agrees to assume the risk of an applicant individually, or as a member in a group of employees, in exchange for consideration from the individual. This consideration is known as a premium, and may fluctuate based on that individual’s personal level of risk, or on the risk within the insured group. See id. § 69:1.
78 Insurance underwriters divide applicants into various risk groups to determine the possibility and degree of loss that the groups might cause the insurers. Risk classification helps to clarify the rates insurers require to protect themselves from excessive losses and ensures that each applicant pays a premium relative to the risk he projects. See MICHAEL C. THOMSETT, INSURANCE DICTIONARY 186 (1989).
79 A person given a standard rating means that he is to be insured at the average rate. A person given a substandard rating means that he is not qualified for standard policy rates. This will lead the insurer to issue a higher premium, or deny the applicant altogether. See id. at 199, 201.
80 See id.
83 See RUSS & SEGALLA, supra note 67, § 69:38. “The basic principle underlying statutes governing underwriting practices is that insurers have the right to classify risks and to elect not to insure risks if the discrimination is fair.” Life Ins. Ass’n v. Commissioner of Ins., 530 N.E.2d 168, 171 (Mass. 1988).
equal expectation of life differently.” Converse, unequal treatment of insured who were of different risk classifications resulted in “fair” discrimination.

Discrimination in premium setting results from the theory that the insurer knows as much about the applicant’s risk as the applicant does. However, there are situations when there is an unlevel playing field, and the applicant knows more about his risk than the insurer does. An example of this occurs when a person checks the “nonsmoker” box on an application form when, in reality, he is a smoker. This can lead to the insurers’ inability to establish equitable premium rates since records reflect a decrease in average risk. Therefore, insurance becomes a bargain for those with greater risk, but it becomes a burden for those with lower risk. This phenomenon is also known as adverse selection, or antiselection.

Antiselection results in high-risk individuals purchasing more insurance than those with minimal risk exposure. This could lead to overall premiums increasing in order for insurers to protect themselves. Individuals with low risk exposure might then seek out other insurers willing to charge premiums relative to their low risk, leaving the initial insurer selling policies to high-risk individuals, who continue to find the higher premiums a bargain for their risk.

The existence of antiselection led to the development of the Medical Information Bureau (“MIB”), which alerts insurers to the possibility of antiselection. The MIB was designed to “protect the honest consumers against higher premiums which would be necessary if the forgetful or dishonest applicants were too often successful.” The underwriting process does limit the existence of antiselection, since underwriters access physicians, employers, the MIB, and all other sources relevant to the insurance contract, in order to classify risk accurately.

---

85 Id. at 361-62. 
86 See id. at 362.
87 The element of risk is not present when a party has knowledge of their medical future. See Russ & Segalla, supra note 67, § 101:2.
88 Of those who claim to be nonsmokers and thus stand to gain significantly in terms of lower rates for their insurance, at least six percent of those who say ‘I am a nonsmoker’ are in fact smokers.” Interview with Donald C. Chambers, M.D., Senior Vice President and Chief Medical Director, Lincoln National Corporation, in Fort Wayne, Ind. (June 9, 1997) [hereinafter Chambers Interview]. Dr. Chambers alluded to a test which measures the level of a metabolic byproduct of cigarette nicotine in urine. See id.
89 See Gibbons et al., supra note 81, at 69.
90 See id.
91 See id.
92 The MIB collects health-related information on those applying for health and life insurance. After receiving an application from an individual, the insurer may request information from MIB, to find any health conditions which were unreported by the applicant. See Thomsett, supra note 78, at 127.
The advent of genetic testing has created a situation which could harm both the life insurer and consumer. On the one hand, life insurers might use genetic information obtained from testing to practice unfair discrimination. On the other hand, consumers might withhold this genetic information from life insurers, resulting in antiselection.

IV. GENETIC TESTING AFFECTS LIFE INSURERS AND CONSUMERS

As technological advances make genetic testing more commercially available and accessible, there becomes a risk of an unlevel playing field. This occurs because those who are at risk for genetic disease and get tested have knowledge that they may possibly withhold from insurers. In other words, there is a potential for antiselection. If there is a chance that an applicant will be denied insurance because of testing results he obtained, it seems plausible that he might withhold those results from an insurer if the insurer might otherwise classify him as a substandard risk, or deny him insurance altogether.

As stated earlier, underwriting involves classifying applicants by risk. If there is a possibility that test results could be withheld, the underwriting process falters, since risk classification becomes less accurate. The underwriter, unable to see genetic test results, might place the applicant in a standard risk category (with a standard premium), when the applicant is in fact substandard. The average risk premium would be lower than normal, leading to more people who are at risk purchasing insurance. Life insurers believe that they, in particular, should have access to genetic information. They claim that life insurance is not as significant in society as health insurance—life insurance only provides a certain lifestyle for the beneficiary of a life insurance contract, while health insurance provides the more significant immediate medical care for the policyholder.

The life insurance industry could suffer if the issue of genetic testing is not handled properly. If a situation arises where no insurer is entitled to genetic information, antiselection may become more prevalent, premiums may rise, and existing policyholders may cancel their insurance. The healthy would refuse to buy insurance, while the unhealthy would purchase large amounts of insurance. The life insurers might then be forced to either increase the premiums to the point where each person subsidizes his own sickness or maintain the existing premiums and go out of business.

Insurers are not the only parties affected by the advent of genetic testing. Insurance applicants may also be affected since insurers may require genetic information when classifying applicants’ risk. Issues of privacy and discrimination fuel many of the arguments against insurers’ access to genetic information.

---

94 See GIBBONS ET AL., supra note 81, at 69.
95 See RUSS & SEGALLA, supra note 67, § 1:2.
96 See McClure, supra note 1, at 237.
97 See id.
98 See id.
99 See id.
Genetic information is the most private of information. Once an individual is tested, the result is a blueprint of that individual’s genetic makeup. This blueprint can be used to trace genes through past generations, predict the likelihood of the gene’s presence in present generations, and can be used to predict their presence in future generations. In other words, obtaining one person’s genetic information could lead to finding genetic disorders for that person’s parents, siblings, and children. This could become a concern if insurers discover a genetic disorder in one person, and they use that information to classify not only the person tested, but also that person’s family members.

Some commentators have suggested that a person’s autonomy must be taken into consideration when examining rights of privacy. With regard to requiring genetic testing and screening, commentators suggest that autonomy refers to individuals’ rights to make informed, independent decisions about whether they would like to be tested, and furthermore, whether they want to know the results of the testing. Once tested, they argue, privacy rights include making an informed, independent decision about whether others may access those results, and if so, who may access those results. Some have argued that if insurers are entitled to a person’s genetic information, there exists “a ‘big brother’ scenario where complete strangers know everything about you and are making decisions about your life.”

The issue of discrimination is another focus of commentators. As stated earlier, insurance, through the risk classification process, is discrimination. The key is determining whether the discrimination is fair or unfair (invidious). A study conducted by Dr. Paul Billings in 1996 illustrated isolated instances of invidious discrimination. One example listed in the study involved a mother who applied for life insurance for her two children. One of the children had Hurler syndrome, a genetic condition resulting in mental retardation by the age of ten. Both of the children were rejected. The rejection letter informed the mother that the one child was denied life insurance since Hurler’s syndrome is fatal (which is considered fair discrimination), but no reason was given for the other child’s rejection (which is considered arbitrary, or invidious, discrimination). She was later able to obtain insurance for the healthy child through another insurer. An additional study

---

100 See NATIONAL CANCER INST., supra note 1, at 10-11.
101 See id. at 9-16.
102 See id. at 14.
105 See INSTITUTE OF MED., ASSESSING GENETIC RISKS 248 (Lori B. Andrews et al. eds., 1994).
106 See id. at 249.
109 See id. at 76.
110 See KOWLES, supra note 20, at 151-52.
111 See Geller et al., supra note 108, at 76.
BRIDGING THE GAP

conducted at Georgetown University in 1997 was able to discover more instances of isolated invidious discrimination.\footnote{See Donald C. Chambers, Genetic Discrimination: Much Press, Little Substance, MED. RESOURCE (Lincoln Nat’l Reinsurance, Fort Wayne, Ind.), Jan./Feb. 1997, at 3, 3.}

As a result of the potential infringement upon rights of privacy and unequal treatment, commentators argue that some people are refusing to get tested to avoid losing their access to insurance. Dr. Billings’ study mentions cases in which people, who were at risk for genetic disease and were classified as standard risk, refused to get tested in order to avoid losing that standard rating.\footnote{See Geller et al., supra note 108, at 79.} These people believed that their insurance would be denied if they were tested, and the results came back positive for disease.\footnote{See id.} Policyholders and applicants may be denying themselves treatment which may alleviate the condition, and even if there is a treatment, insurers might not want to classify someone with a genetic disease as a standard risk. Moreover, there is little information available about many treatments, and insurers fear the effects of antiselection. For example, people with hemachromatosis\footnote{Hemachromatosis is a genetic disorder where iron accumulates in tissues, leading to heart and liver damage. Regular phlebotomies (withdrawals of blood) are performed in order to keep the iron level down and to prevent organ damage. See More Screening Needed for Hemachromatosis, GENESIS REP.–DX (Genesis Group Ass’n), Jan. 1, 1996, available in 1996 WL 9660649.} are generally denied life insurance unless they receive regular withdrawals of blood in order to keep the iron level down, thus reducing the potential for liver and heart damage. These withdrawals, or phlebotomies, cannot be administered unless the individual submits to a genetic test for the presence of hemachromatosis.\footnote{See Chambers Interview, supra note 88.}

A similar problem exists in individuals who have a family history of Marfan’s syndrome. Individuals with Marfan’s syndrome are often tall with long limbs and generally suffer from weaknesses in the eyes, bones, joints, and heart. Without proper treatment, an individual with Marfan’s could suffer a heart attack at an early age due to an enlarged aorta.\footnote{See Dorothy Nelkin & Lori Andrews, Do the Dead Have Interests? Policy Issues for Research After Life, 24 Am. J.L. & Med. 261, 268 (1998).} Again, proper treatment can be administered if the individual has submitted to a genetic test for Marfan’s. However, unlike individuals with hemachromatosis, where these individuals stand with regard to receiving life insurance is unclear.\footnote{See Chambers Interview, supra note 88.}

Very few courts have addressed the concerns facing insurers and consumers with regard to accessing genetic information. Justice Lederberg, Supreme Court of Rhode Island, has expressed his concerns over the potential issues of rights of privacy and equal treatment. He stated in his dissent in \textit{State v. Almonte}\footnote{644 A.2d 295 (R.I. 1994).} that

[privacy issues requiring constitutional protection will expand as discoveries from the Human Genome Project reveal the complete menu of each individual’s genetic components, including the flaws in one’s genetic makeup and the likely time and nature of one’s death. Information on whether an}
individual carries a gene for Alzheimer’s disease or early heart disease would be of interest to employers as well as insurance companies.\footnote{Id. at 306 (Lederberg, J. dissenting).}

Justice Lederberg furthered his concern over the potential misuse of genetic information in his holding in \textit{State v. Morel}.\footnote{676 A.2d 1347 (R.I. 1996).} Although that case dealt with DNA testing in the criminal area, Justice Lederberg stated,

\begin{quote}
This Court is aware of the great promise of DNA research in health care as well as the potential for abuse and misuse of genetic information. Legitimate privacy concerns continue to be raised, such as the dangers of unauthorized access to data banks that can lead to disclosure of genetic information and possible genetic discrimination by entities such as insurance companies and employers.\footnote{Id. at 1356.}
\end{quote}

However, aside from expressions of concern, there is little direction given by the courts on how to deal with this sensitive topic; few, if any, courts have decided the issue. Although the federal and state courts have rarely addressed the issue of genetic testing and insurance, federal and state legislatures have been busy developing legislation to deal with this issue.

\section*{V. Government Response to the Life Insurance/Genetic Testing Issue}

Eric Mills Holmes, in a comprehensive article on the subject, has addressed the question of whether the issue of insurers’ access to genetic information should be handled by Congress or each state legislature.\footnote{Holmes, \textit{supra} note 8, at 578.} He suggests that while the history of American insurance favors state legislation, genetic information is of national concern, and thus warrants a “nationally uniform and comprehensive approach,”\footnote{Id.} which would be permissible under the McCarran-Ferguson Act. As stated earlier, the McCarran-Ferguson Act provides that “[n]o Act of Congress shall be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance . . . unless such Act specifically relates to the business of insurance.”\footnote{15 U.S.C. § 1012(b) (1994); see also American Deposit Corp. v. Schacht, 84 F.3d 834, 838 (7th Cir. 1996).}

Nearly every state legislature has regulated insurers’ access to genetic information.\footnote{See Holmes, \textit{supra} note 8, at 629-44, for a list of the various state legislation regulating insurers’ access to genetic information.} However, Congress has been slow to pass such regulation.\footnote{See Bornstein, \textit{supra} note 72, at 579-88, for a list of \textit{proposed} federal legislation concerning insurers' access to genetic information.} The only federal legislation which deals with this issue directly is the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).\footnote{Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 26, 29 & 42 U.S.C.).} This legislation provides that genetic information cannot be used as a pre-existing condition by health
insurers. However, federal bills proposed by Senator Olympia Snowe and Representative Louise Slaughter have gained support in both the Senate and House of Representatives. These bills, which are nearly identical, are each called the “Genetic Information Nondiscrimination in Health Insurance Act of 1997,” and they generally provide group health care protection.

In the case of benefits consisting of medical care provided under a group health plan or in the case of group health insurance coverage offered by a health insurance issuer in connection with a group health plan, the plan or issuer may not deny, cancel, or refuse to renew such benefits or such coverage, or any participant or beneficiary under the plan on the basis of genetic information; or on the basis that the participant or beneficiary has requested or received genetic services.

For life insurers and consumers battling the issue of accessing genetic information, the proposed Snowe/Slaughter bills, the Americans with Disabilities Act of 1990 (“ADA”), the Employee Retirement Income Security Act of 1974 (“ERISA”), and HIPAA, seem to present the only available answers at the federal level. Unfortunately, these legislative responses to this highly sensitive issue are insufficient protections for both life insurers and consumers alike.

The one central problem with these regulations, as well as the proposed Snowe/Slaughter bills, is that they all deal with insurers’ access to genetic information with regard to health insurance. They do not deal with the potential for invidious discrimination with regard to life insurers’ access to genetic information when considering individual life insurance policies. However, many state legislatures have addressed this issue through varying legislation. Some states have passed legislation focusing on specific genetic diseases and types of insurance, while other states have opted for comprehensive legislation, focusing on all types of genetic conditions and insurance.

Holmes has expressed concern over the impracticability of the states’ approach to this issue. The states which have opted for narrow legislation must continually update their legislation as either advances in genetics reveal new genetic conditions or new forms of insurance develop. The cost to the public of updating legislation in each state due to genetic discoveries would be greater than costs imposed by an individual federal entity responsible for such updating, because that entity could spread such costs over the nation as a whole. This approach would produce fewer costs to citizens than individual states spreading the same costs of updating over its constituents.

Furthermore, states which have adopted more comprehensive genetic testing laws lack uniformity. “Some define genetic testing broadly, some narrowly. Some
provide explicit privacy protection, some do not. Some prove a private cause of action under the unfair trade practices law, civil penalties including attorney fees and costs, and criminal sanctions; others do not. Some states do not even mention life insurance with regard to genetic information but have rather adopted the provisions of HIPAA. As a result, a life insurance applicant in one state could be denied the same coverage that the same individual could have received in another state with differing legislation.

Holmes has suggested a potential solution of authorizing “fair insurance/genetic discrimination” for types of insurance purchased for financial protection, such as life insurance. He has also suggested that a more comprehensive ban on access to genetic information by insurance companies aimed at providing medical care, such as health insurance, might be more appropriate. In other words, public policy favors protecting individuals from losing their immediate medical coverage over those losing their future financial protection.

VI. PROPOSAL

Developing risk factors (“RFs”), assigned to each genetic condition discovered by the HGP and incorporated into each individual life insurer’s risk premium valuation techniques, would be a significant step toward alleviating the tension between the life insurer and consumer. These factors would be developed and passed by a federal agency (preferably the Department of Health and Human Services). Utilizing the agency as a vehicle for passing the RFs would benefit the general public, the consumer, and the life insurer. The public would benefit due to the efficient use of resources, the consumer would be assured of heightened privacy and autonomy as well as a decreased likelihood of unfair discrimination, and the life insurer would be assured of a decreased likelihood of antiselection.

A. Taking Holmes a Step Further

Holmes’s potential solution of a uniform federal legislation covering insurers access to genetic information is a valid approach, since the current federal and state laws are not entirely sufficient. The McCarran-Ferguson Act was premised on public policy—public interest favored state regulation of the private insurance industry. However, McCarran-Ferguson explicitly granted Congress the power to enact legislation pertaining to the business of insurance. The drafters of McCarran-Ferguson may have anticipated a situation where state regulation of insurance would be insufficient, and public policy would favor federal enactment of legislation regulating the business of insurance. The issue of genetic testing is such a situation.

---

138 Id. at 647.
140 Holmes, supra note 8, at 645-46.
141 See id. at 646.
142 See id. at 652-56.
143 See supra text accompanying notes 18, 64-66.
144 See supra text accompanying notes 65-66.
The Snowe/Slaughter bills, and in some ways HIPAA, have addressed Holmes’s potential solution of a comprehensive federal regulation for health insurance effectively by providing consumers greater access to immediate medical coverage. However, Holmes’s “fair insurance/genetic discrimination” federal regulation for life insurance, while valid, can be taken a step further in order to ensure that the risk classification practices of these insurers take the genetic conditions themselves into consideration. As a result, this proposal will focus on the risk classification and premium setting methods of life insurers.

The “step” referred to is developing risk factors assigned to each genetic condition discovered by the HGP and incorporating them into each individual insurer’s risk premium valuation techniques. The RFs would be calculated for every genetic condition discovered to date, and they would be updated as new advances in genetics provide more insights into these, as well as newly discovered, conditions. This procedure would be a time-consuming process, but it would be necessary to ensure that genetic conditions become a part of insurers’ risk classification practices. A question then arises as to who would develop the RFs.

The RFs might be developed by a task force composed of HGP representatives, insurers, insurance medical directors, law school professors, governmental representatives, and leaders of special interest groups. The reason for such a diverse task force would be to facilitate compromise through extensive discussions and debates concerning each party’s viewpoint regarding the RFs. Understanding and appreciating the arguments that each party makes would be essential to the creation of the RFs.

One attempt at such an understanding occurred at a roundtable meeting in 1995, held by the American Academy of Actuaries, designed to provide information on genetic testing. Participants included insurance company medical directors, geneticists, underwriters, a law school dean, and a spokesperson for the National Breast Cancer Coalition. “The participants shared information and opinions for more than eight hours. At the day’s conclusion, differences remained, but there was greater understanding and tolerance for others’ viewpoints as well.”

This understanding and respect for each others’ views could lead to more efficient dialogue which, in turn, could lead to balanced RFs, reflecting the expectations of all parties involved.

---

While perfect compromise through this task force approach is unrealistic, as one party may try to influence another to set the RFs more in their favor, a general understanding of each party’s point of view facilitates compromise, which is necessary in developing RFs which benefit both the insurer and consumer.

B. Why Choose the Department of Health and Human Services?

While the task force approach is beneficial in that it attempts compromise, the RF proposal would be best served by remitting it to a governmental administrative agency, preferably the Department of Health and Human Services (“HHS”). An agency is an attractive choice because of its flexibility—it permits the hiring of “people with whatever mix of talents, skills and experience it needs to get the job done.” Moreover, the purpose of creating administrative agencies is to address “current crises or to redress serious social problems.” The issue of insurers’ access to genetic information is certainly a serious social problem, and the needs of the insurers and consumers with regard to this potential crisis should be addressed.

The choice of the HHS is attractive due to its interest in health care reform with regard to genetic information. HHS Secretary Donna Shalala, on June 26, 1997, stated that “[p]reventing genetic discrimination by health insurers is an important step in making sure that no one is treated unfairly because of information contained in their genes.” The National Institute of Health, a subsidiary of the HHS, has also published a pamphlet on genetic testing. However, the HHS should not limit its concern to unfair treatment with regard to health insurance. The medical underwriting processes utilized by life insurers provide opportunities by the insurer to practice unfair discrimination. They also provide the consumer with opportunities to practice antiselection. The HHS could create a subdivision designed specifically for developing the respective RFs for each genetic condition discovered by the HGP. That subdivision (possibly consisting of the aforementioned HGP representatives, insurers, insurance medical directors, law school professors, governmental representatives, and leaders of special interest groups) would also be responsible for updating the RFs as new findings necessitate such changes. The RFs, developed by this subdivision of the HHS, might then become part of an administrative regulation mandating that life insurers incorporate the RFs into existing risk classification processes in order to ensure that instances of “unfair discrimination” are diminished, if not eliminated.

This approach is beneficial because the costs incurred as a result of a federal agency developing and updating these RFs could be spread across the nation as a whole, leading to lower costs for each citizen. If each state attempted to develop and update such factors, the citizens within each state would suffer high costs.

147 Id. at 1.
149 See generally NATIONAL CANCER INST., supra note 1.
BRIDGING THE GAP

Therefore, from a cost standpoint, RFs developed by the HHS would be in the best interests of the public.

The HHS would also have better access to resources than the individual states. The HHS could more efficiently obtain the aforementioned members necessary to develop a balanced RF, reflecting the needs of both the insurer and consumer. In other words, the HHS would be more capable of obtaining leaders in their respective fields than would an individual state agency.

C. What Factors Would the RFs Be Based On?

Once the decision to develop RFs has been made, the question becomes: What criteria will be taken into consideration when developing these RFs? Possible factors to be taken into consideration by the HHS subagency might be as follows:

1. The potential treatment and average success of treatment for the condition and the likelihood of death resulting from the disorder.
2. The average life expectancy of an individual with that particular genetic condition.
3. The average penetrance/expressivity of the gene (e.g., severity of gene’s expression, average age of onset, etc.).
4. The amount of the average insurance policy taken, or anticipated to be taken, by a person with that condition.
5. The average expenses incurred for treatment of the condition.
6. The amount that existing policyholders’ premiums would increase to make up for a particular applicant with a particular disorder obtaining insurance.
7. Whether the carrier of the particular gene is merely predisposed, in which case the average chance of becoming symptomatic is taken into consideration, or is presymptomatic for a particular genetic condition.
8. The potential effect of genetic testing for a particular condition on relatives and offspring of that individual.

For example, the RF for a genetic disease which has no treatment (which would result in higher premiums for policyholders if an individual with the disease was insured) would be different than the RF for a genetic disease that is treatable (in which no increase in premiums would occur). In other words, the RF values would reflect the benefit to the life insurance applicant as well as the cost to the life insurer for insuring that applicant.

As stated earlier, these RFs would be utilized with regard to the valuation of life insurance, as well as other insurance designed to protect an individual’s financial future. When insurance is purchased for financial reasons, an individual should have to pay a premium relative to the risk incurred by the insurer. The higher the risk incurred, the higher the premium. The presence of the RFs in valuing these premiums, however, would ensure that unfair discrimination would be mitigated.

However, with regard to health insurance, these RF values would not play as large a role, if any role at all. When an individual health insurer provides medical care protection to a person, it provides something much more important than the future financial well-being of the insured’s family—it provides medical care for the insured in the event of illness. Health insurers should not be entitled to engage in risk classification practices in the same was as life insurers. Health insurance is
a medical necessity, and a more comprehensive ban on genetic testing in this regard would be appropriate. Since health insurers should not be entitled to engage in these risk classification techniques, it would be inappropriate to suggest that the RFs should apply to health insurers. The RFs would also be less relevant in the valuation of group insurance premiums, since statistics from similar groups within the industry are utilized, and not the personal health history of the employee. In the event that such information is utilized by employers, the HIPAA and the passage of the Snowe/Slaughter bills would be effective means of quelling these practices.

D. The RFs Are Beneficial to Both the Life Insurer and the Consumer

The RF proposal is beneficial in that it lessens the likelihood that unfair discrimination will not be practiced by life insurers. These insurers would be forced, through the passage of an administrative regulation incorporating these RFs, to practice sound actuarial principles. However, the regulation would also give life insurers the ability to conduct their traditional business of “fair discrimination.” Some isolated insurers might arbitrarily deny an individual insurance due to a genetic predisposition or presymptomatic condition, without regard for the established RFs. As a result, the subagency might also be responsible for monitoring the practices of life insurers to ensure that bona fide risk classification processes are maintained.

A question arises as to whether life insurers should be able to mandate genetic testing for a particular condition. The answer, as alluded to earlier, is that since genetic information is the most private of information, neither mandatory genetic testing nor unwarranted access to genetic information should become steps in obtaining life insurance. In the spirit of an individual’s right to privacy, life insurers should not be entitled to genetic information absent the express consent of the applicant.

With regard to the issue of genetic autonomy, the incorporation of RFs into the underwriting process would help the applicant weigh the costs of being tested versus the costs of refusing testing. Individuals would gain general knowledge of how high their premiums would increase over standard risk premiums if the tests came back positive. This could be balanced against existing premiums paid as an “at risk” individual who has not been tested, but has rather submitted the standard family history forms. The RFs enhance applicants’ autonomy through heightened informed decisionmaking.

The RFs also enhance the autonomy of the life insurers because they could make more informed decisions about whether to grant or deny life insurance, as well as the level to set premiums. Just as applicants should not be obliged to provide their genetic information, life insurers should not be obliged to provide life insurance policies. Life insurance is a financial privilege, not a guaranteed right. As a result, the autonomy of the life insurers, as well as the consumers, should be maintained.

There may come a time, as stated earlier, when genetic testing equipment could be purchased inexpensively over the pharmacy counter. Life insurers should be entitled to the results of those tests if individuals would subsequently attempt to conceal that information when purchasing life insurance. Just as the subagency would be responsible for monitoring instances of unfair discrimination, it would
also be responsible for developing monitoring techniques to discover instances of antiselection. The subagency would also be responsible for taking steps to deter such behavior. The equal playing field theory, in order to flourish, involves monitoring both the life insurer and consumer.

The costs of establishing a subagency in order to develop and update RFs, as well as to monitor unfair discrimination and antiselection, could be steep. However, those costs seem more than reasonable when balanced against the costs of the potential flood of litigation in the aftermath of the HGP’s conclusion.

CONCLUSION

The McCarran-Ferguson act, which gave states the right to regulate insurance, was premised on public policy. However, Congress was granted explicit rights to enact legislation regarding the business of insurance. This clause appears to have been added to address situations in which public policy would demand a more uniform, federal legislation. Since the issue of genetic testing is of such national importance, public policy calls for federal legislation in this area.

Federal legislation, which would provide broad consumer protection with regard to health-based insurance and more narrow protections for insurance providing financial security, is a valid solution. On the one hand, health insurance provides a tremendous benefit to individuals requiring immediate medical attention, and as a result, broad legislation (such as the Snow/Slaughter bills) is an adequate means of protecting rights to this insurance.

On the other hand, future financial protection, such as that provided by life insurers, is not as pressing a concern as immediate medical care. However, risk classification methods of the life insurance industry which arbitrarily discriminate against individuals with genetic conditions, should not be tolerated. Equally important to this issue, the practice of antiselection by consumers should not be tolerated.

The incorporation of the RFs into the premium valuations of life and other financial-based insurance bridges the gap between the insurer and consumer by attempting to eliminate potential invidious discrimination from risk classification processes as well as potential antiselection. Although the costs of implementing the RF proposal could be steep (involving the establishment of a subagency of the HHS and the hiring of qualified individuals to develop and update the RFs, as well as to monitor unfair discrimination and antiselection), the costs of potential litigation in the aftermath of the HGP’s conclusion would far surpass the costs of implementing this proposal.