Regulating Risk: Defining Genetic Privacy in the United States and Britain

Shobita Parthasarathy
Northwestern University

The availability of new genetic testing technologies to identify individuals as at risk for a particular disease has inspired tremendous concern that individuals with gene mutations will soon be universally identified, for both insurance and employment purposes, as a genetic underclass. Scholarship in science and technology studies, however, suggests that understandings of genetic knowledge might be locally contingent, while research in comparative politics helps us understand how national context might play an important role in framing approaches to the regulation of genetic information. What role does national context play in defining genetic risk and shaping approaches to the privacy of genetic information? Using data from interviews, document analysis, and ethnographic observation, the author follows debates among advocacy groups, insurers, and governments in the United States and Britain about the appropriate use of genetic information in insurance underwriting to understand how national context frames the definition of genetic risk as well as its regulation.

Keywords: *genetics; insurance; discrimination; comparative politics; activism*

This article explores recent debates about the use of genetic information in insurance underwriting in the United States and Britain.[1] The mapping and sequencing of the human genome and discoveries of genes linked to a variety of diseases has stimulated discussion worldwide about how advances in genomics will predict future disease incidence and influence our understandings of ourselves and each other. In particular, whether and how genetic information should be used for insurance or employment purposes is one of the most contentious areas of debate in the genomic age, and discussions about whether and how genetic information should be regulated have taken place in the media, academic scholarship, and government (Rothstein 1999;

Science, Technology, & Human Values, Vol. 29 No. 3, Summer 2004 332-352
DOI: 10.1177/0162243904264485

Kass 1992; Murray 1992). Here, I analyze discussions about the use of insurance underwriting in the United States and Britain to understand the role that national political styles play in framing understandings of genetic risk, as well as its regulation.

Throughout the 1980s and 1990s, scholars, scientists, and advocacy groups worried that individuals found to have genetic mutations through newly available testing technologies would be defined as "at risk"—discriminated against in both insurance and employment and dismissed as part of a new "genetic underclass" (Duster 1990). Meanwhile, insurers argued that access to genetic information would ensure a level playing field in the provision of health care, not only helping insurers better target preventive care to their clients but also dissuading clients from overbuying insurance in anticipation of future morbidity. Debates among these groups were quite vigorous, as they issued press releases and position papers on the subject, testified at government hearings, and sat on government advisory committees. In this article, I explore these discussions among advocacy groups, insurers, scholars, and governments regarding the development of regulation regarding genetic discrimination in insurance in the United States and Britain.[2] In analyzing these processes, I am particularly concerned with the following questions. First, How was genetic information and risk defined? Second, What roles did the actors involved in these debates play and how did they influence the development of regulation? Third, Was the way genetic information was defined and regulated contingent on national context?

Through study of debates over issues such as the regulation of the environment and toxic chemicals, scholars of comparative politics have demonstrated that the United States and Britain exhibit distinct styles of politics; politics in the United States are often quite adversarial while similar interactions in Britain have a more conciliatory and cooperative tone (Vogel 1986; Jasanoff 1991, 1995). As I will demonstrate below, debates about the use of genetic information in insurance underwriting appeared to adopt these national styles as well. While these politics involved the same types of actors in the two countries—advocacy groups, insurers, and government committees—interactions in the United States were quite polarized, while British actors tried to work together to develop a cooperative framework. Using insight from science and technology studies that has focused on the importance of local context in the construction of scientific and medical knowledge (Fujimura 1997; Haraway 1991; Latour and Woolgar 1986; Rabinow 1999), I will show how these national differences in the process of politics had important consequences for the definition of genetic risk as well as the regulation of genetic information. Despite worries among many scholars and

other commentators that a universal process of "geneticization" will take place (Lippman 1998), understandings of genetic risk and regulatory approaches appear mediated by national context in very important ways.

This article is divided into two sections: the first section examines the American case, while the second section explores the British case. In each section, I describe the politics among advocacy groups, insurance lobbies, and the government, as well as the resolution of debate in each country. For each case, I demonstrate how a national style of politics influenced the definition of genetic risk as it framed the terms of the debate and helped to shape a regulatory approach to the use of genetic information.[3]

United States

Advocacy Groups Fight to Define Genetic Information as Unique

Debates over the use of genetic information in insurance underwriting began as early as the 1980s in the United States, in anticipation of widespread availability of genetic testing and increased understanding of the makeup of the human genome. A 1983 report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research, for example, expressed concern that "genetic information should not be given to unrelated third parties, such as insurers or employers, without the explicit and informed consent of the person screened or a surrogate for that person" (President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research 1983, 6). As we shall see, this apprehension toward the use of genetic information for insurance purposes continued and grew in subsequent years. In a policy context that is famously adversarial, activist groups, government advisory committees, and even elected officials advocated that molecular information generated by new developments in genomics was qualitatively different from other types of medical information and should be protected as private to avoid misuse by health insurance companies. Meanwhile, insurance companies fought back against both the definition of genetic information as distinct from other types of medical information as well as the prospects of additional regulation.

By the early 1990s, a number of advocacy groups had taken up the charge to define genetic information as distinct and private. The most vocal among these was the Council for Responsible Genetics (CRG), based in Cambridge, Massachusetts, which began to lobby federal and state legislators to develop

laws regulating the use of genetic information to prevent health insurers and employers from access to genetic information when making decisions (Council for Responsible Genetics, pers. comm., April 20, 2000). It argued that specific legislation should be enacted to prevent genetic discrimination because public excitement and attention to genomics had led to misinformation about the power of DNA and incorrect expectations among insurers about the relationship between genetic information and disease incidence. Because society viewed genetic information as distinct from other types of medical information, CRG argued, it should be specially protected. In a position paper, it stated, "As genetic tests become simpler to administer and their use expands, a growing number of individuals are being stigmatized on the basis of their genetic makeup. Employers and insurers are using the results of genetic tests to discriminate based on perceptions of long-term health risks and possible future disabilities. Not only is this discrimination unjust, it is scientifically inaccurate" (Council for Responsible Genetics 1997, 1). Like the earlier President's commission, CRG not only argued that genetic information was private and distinct from other types of medical information but also focused on the results of genetic testing as the main indicator of genetic risk.

It is important to note that the molecular information generated through genetic testing is not the only indicator of genetic risk. While the mutation information identified through genetic testing is usually a primary indicator of genetic risk for Mendelian diseases (in which a gene mutation predicts certain future disease incidence), family history can also be an important indicator of genetic risk. In fact, as more and more susceptibility genes are discovered in which the mutation is incompletely penetrant (a gene mutation does not signify certain future disease incidence), family history is increasingly considered an important predictor of future disease incidence. As CRG and other groups sought to define all aspects of genetic risk as part of a protected category, however, most of them focused on the information generated by genetic testing as the main indicator of genetic risk in political discussions about the topic. Why did they choose to focus on the results of genetic testing as the primary indicator of genetic risk? Perhaps they thought it would be easier, particularly considering the adversarial political environment of the United States, to control the definition of this newly available genetic information that had not yet established a stable role in medicine or society, rather than to try to include other indicators of genetic risk such as family history, which was already available to insurers and in medical records. These other indicators already had established roles, and to try to recategorize them as part of a protected group might be far more politically risky. In addition, the

new technology of genetic testing had already raised public concern about its social implications. As a result, trying to protect the information generated by this new technology would be much more likely to encourage public support.

CRG advocated its position not only through position papers but also by assisting states and the federal government in developing legislation preventing genetic discrimination. State legislatures took action first. In 1994, Colorado passed specific legislation to regulate the use of genetic data, limiting its collection and use. By doing so, the law constructed genetic information as uniquely "confidential" and "privileged" (Colorado Rev. Stat. Ann. 1996). The law further noted that genetic information was the "unique property" of the individual to whom it pertains. Other states, such as California, followed suit to forbid certain uses of genetic information by insurers. By 1994, many states were considering the implementation of legislation to prevent insurance discrimination on the basis of genetic information.

The discoveries of a number of genes linked to common diseases such as breast cancer in the mid-1990s provided a significant boost to attempts to secure genetic discrimination legislation at the state and federal levels. Suddenly, efforts to protect individuals with rare genetic disorders had transformed into a movement to protect relatives, friends, and neighbors who might have a mutation to a very common disease. This urgency inspired many powerful advocacy groups, including the National Breast Cancer Coalition (NBCC), to get involved in the discussions.[4] In addition, the Hereditary Susceptibility Working Group of the National Action Plan on Breast Cancer (NAPBC), a public-private organization funded by the National Institutes of Health (NIH) that was intended to bring together activists and scientists, quickly began to review the issue of genetic discrimination in health and life insurance, particularly as it related to hereditary susceptibility to breast or ovarian cancer (National Action Plan on Breast Cancer 1999). The NAPBC Working Group included very high-profile members of the scientific and advocacy communities. Cochaired by Mary Jo Ellis Kahn (NBCC) and Francis Collins, the head of the Human Genome Project, it convened a workshop on genetic discrimination in July 1995 and reported its recommendations in an article in *Science* magazine in October 1995 (Hudson et al. 1995).

In the workshop report, NAPBC highlighted the unique nature of genetic information. It argued, "Genetic information is distinct from other types of medical information because it provides information about an individual's predisposition to future disease. In addition, genetic information can provide clues to the future health risks for an individual's family members" (Hudson et al. 1995, 392). It also reinforced the definition of genetic information as

private by recommending that insurers be prohibited from using genetic information to limit or deny coverage or increase premiums, and that all holders of genetic information should be prohibited from releasing genetic information "without prior written authorization of the individual" (Hudson et al. 1995, 393). Overall, the NAPBC working group reiterated what the Colorado legislature had codified into law: that genetic information was the private property of the individual alone. The authors even stated in the *Science* article, "The ability to obtain sensitive genetic information about individuals, families, and even populations raises profound and troubling questions about who will have access to this information and how it will be used" (p. 393). Coupled with its definition of genetic information as distinct from other types of medical information was an understanding of genetic information as inherently private.

The involvement of actors such as Francis Collins and the National Breast Cancer Coalition in the NAPBC working group and publication of their perspectives in America's leading scientific journal kept the issue of genetic discrimination on the public stage. This consistent visibility led to action on both the state and federal level and by March 1995, 118 bills to protect the privacy of genetic information were making their way through state legislatures (Reilly 1997). At the same time, fears of genetic discrimination were also working their way into broader federal legislation on health insurance. In legislation designed to increase the security of health insurance coverage, Senators Edward Kennedy (D-MA) and Nancy Kassebaum (R-KS) sought to include genetic information within a protected category.

Kennedy and Kassebaum's Health Insurance Portability and Accountability Act (HIPAA) of 1996, as it was called, was designed to improve coverage for individuals who change jobs and decrease discrimination against individuals with so-called preexisting conditions. It also incorporated the definition of genetic risk that had been proposed by advocacy groups. Genetic information was specified as a particular type of medical information that was private (HIPAA 1996). It was included in the definition of preexisting conditions, and therefore coverage could not be limited or denied nor premiums increased on the basis of genetic information. While HIPAA used the broad and inclusive definition of genetic information that might have been interpreted to include family history information ("information about genes, gene products, or inherited characteristics that may derive from the individual or a family member") that had been recommended by the NAPBC in the *Science* magazine article, it did not explicitly include family history information within the protected category of genetic information (Hudson et al. 1995, 393).[5] Congressional staff involved in drafting the legis-

lation noted that this was, in part, because family history information was already available to insurers through the medical record, and it would be much more difficult to reclassify existing medical information than to influence the definition of newly available genetic information (U.S. Senate staff member, pers. comm., June 8, 2000). This focus on genetic testing as the primary source of genetic information was evident in discussions about the legislation. Representative Rick Lazio (R-NY) noted, for example,

> An important feature of H.R. 3103 [HIPAA] will eliminate discrimination based on genetic information. This will allow thousands of men and women to undergo genetic testing needed to preserve their health without fear of losing their health insurance or not being able to acquire it. This protection is essential for the women of Long Island, where instances of breast cancer are among the highest in the country. With H.R. 3103 in place, these women can be tested for BRCA1, a gene linked to the disease, without fear of losing the insurance needed to meet their medical needs. (U.S. House of Representatives 1996)

Here, Lazio emphasized that it was particularly important to keep mutation information private in order for individuals to feel free to use new genetic testing technologies. HIPAA, as the first major federal effort to protect individuals from genetic discrimination, affirmed the construction of genetic information as both private and distinct from other types of medical information. It also privileged the individual's right to determine the meaning of genetic risk while de-emphasizing the insurers' right to control the use and meaning of genetic information.

Many Washington advocacy groups, however, were not satisfied with the protections of genetic information set forth in HIPAA because it covered only those enrolled in group insurance plans rather than people in employer-insured plans. In addition, many groups argued that protecting individuals with genetic conditions by including them as part of a broader group of individuals with preexisting conditions was inadequate; they felt that individuals who used genetic testing would be best protected if there were targeted legislation specifically written to prevent genetic discrimination. The National Breast Cancer Coalition continued its vigorous advocacy and noted, "While the passage of the Kassebaum-Kennedy Health Insurance Reform Act (1996) was an important first step, improvements must be made to close loopholes and provide comprehensive protection against genetic discrimination to all Americans" (National Breast Cancer Coalition 1999b, 1). The coalition continued to identify genetic discrimination as a major legislative priority, arguing, "As mapping of the human genome continues to progress and new genetic tests are developed, legislative and regulatory strategies

must be established to address the issue of how to protect individuals from the misuse of their genetic information. Genetic information is uniquely private information that should not be disclosed without authorization by the individual" (National Breast Cancer Coalition 1999a, 1).

Advocacy groups kept working with government officials to develop targeted legislation at both federal and state levels. For individual states, it developed model antidiscrimination legislation "to protect the confidentiality of genetic information" and encouraged its members to use it to lobby state legislatures (National Breast Cancer Coalition 1999b). At the federal level, it worked with Representative Louise Slaughter (D-NY) to develop H.R. 306, the Genetic Information Nondiscrimination in Health Insurance Act of 1999. This bill, as well as a number of other related attempts, was introduced in Congress in 1997. By May 1998, the issue had gained enough profile to warrant a Senate hearing on "Genetic Information and Health Care." Senators invited the vice president of National Breast Cancer Coalition as well as representatives of other advocacy groups such as Jewish women's group Hadassah to testify at the hearing (U.S. Senate 1998).

By the end of the 1990s, advocacy groups in the United States had taken advantage of public concern about the new technology of genetic testing and become quite successful in defining genetic information as both private and different from other types of medical information. This definition was codified in both the HIPAA regulations as well as many state laws, and both federal and state governments continued to explore the issue to see whether additional legislation was warranted.

Health Insurers Argue That Genetic Information Is Not Different

Meanwhile, insurers were not pleased with attempts to enact genetic antidiscrimination legislation that would further regulate their underwriting practices. They fought back through press releases and testimony at Congressional hearings, challenging the special attention paid to genetic information and arguing that new laws were unnecessary. The Health Insurance Association of America (HIAA), for example, submitted testimony to the May 1998 Senate hearing described above that stated, "HIAA believes that federal legislation intended to prohibit discrimination based on the use of genetic testing or genetic information is entirely unnecessary, ill-conceived, and ill-considered. . . . Existing state and federal laws already provide significant protections against discrimination and loss of insurance to consumers. Finally, in a misguided effort to fix a problem that does not exist, Congress may

in fact be stifling innovation and improvements in health care quality—against the best interests of millions of American patients" (Health Insurance Association of American 1998, 1). Other insurance lobby groups, such as the National Association of Health Underwriters (NAHU), echoed these sentiments. All of these groups argued that developing targeted genetic anti-discrimination legislation would be particularly damaging to them because individuals who had information about their risk of future disease incidence through genetic testing would be able to buy additional insurance to protect themselves, while insurers would not have access to this information and would therefore be unable to protect themselves from attempts to overbuy insurance (called adverse selection). While these groups acknowledged that some attention should be paid to preventing genetic discrimination, they strongly opposed both the characterization of genetic information as somehow different than other types of medical information as well as classification of its status as inherently private.

Although efforts to pass targeted federal legislation have been unsuccessful thus far, patient and consumer advocates have added to their success in enacting HIPAA by helping to enact specific legislation protecting genetic privacy and prohibiting genetic discrimination in over forty-two states (Council for Responsible Genetics 2000).[6] In addition, the Department of Health and Human Services recently issued regulations to ensure privacy of all individually identifiable health information. According to an HHS press release, "The new standards: limit the non-consensual use and release of private health information; give patients new rights to access their medical records and to know who else has accessed them; restrict most disclosure of health information to the minimum needed for the intended purpose; establish new criminal and civil sanctions for improper use or disclosure; and establish new requirements for access to records by researchers and others" (U.S. Department of Health and Human Services 2000, 1). While the new regulations do not address issues of insurance or employment discrimination, they do support the norms of individual privacy championed by advocates.

In the United States, advocacy groups worked hard to define genetic information as private and subject to government protection. In this notoriously adversarial context marked by battles among lobbyists in the halls of Congress, these groups tried to identify a new biotechnological entity—molecular information generated by genetic testing—and control its definition. In the American system, understanding genetic information as a new entity was coupled with its definition as distinct and inherently private.

Britain

Insurers and Advocacy Groups Try to Develop a Cooperative Framework

The status of genetic information was also debated in Britain among patient advocacy groups, insurers, and the government as many worried about the implications of genetic testing for the provision of life insurance. While using genetic information to discriminate in the area of health care was not a significant concern in Britain because of the existence of the government-run National Health Service (NHS), many individuals in Britain worried that private life insurance companies would use genetic information to set policies and premiums. This was a very important issue for much of the population as many individuals in Britain bought life insurance to secure mortgages on their homes.

Discussions about the use of genetic information in life insurance began in earnest in 1995, when the Science and Technology Select Committee (STC) of the House of Commons, inspired by increasing media attention to genetics across the country and reports by various scholars and independent organizations (Nuffield Council on Bioethics 1993), held hearings on the future promise and pitfalls of human genetics. It invited comment from interested parties, including scholars, patient advocates, and trade associations, and the possibility of insurance discrimination on the basis of genetic information played a significant role in these discussions. The STC, which was made up of eleven members of Parliament, finally issued a report titled *Human Genetics: The Science and Its Consequences* (U.K. House of Commons 1995). The report demonstrated a clear interest in developing a policy for the use of genetic information in insurance underwriting that would protect both the citizenry and insurance companies through an equitable policy. It noted, "it would be possible to find ways to regulate the use of genetic information in insurance which would protect the interests of society in enabling as many people as possible to obtain insurance and protect the insurance companies themselves" (U.K. House of Commons 1995, 5). The STC was interested in finding a solution that would be agreeable to both insurers and the public. Unlike in the United States, where legislators were keen to emphasize the privacy of risk information generated by the new technology of genetic testing, the STC did not want to assume that genetic information was inherently private. It recommended the formation of a government advisory body to study genetics issues and allowed the insurance industry one year to develop a solu-

tion to the dilemma of genetic information that was acceptable to Parliament or risk losing control to legislation. In a country that was reluctant to develop formal and binding legislation on most subjects, this was clearly a major step.

The insurance industry quickly sprang into action. The Association of British Insurers (ABI), which represents over 400 insurance companies and over 95 percent of the British insurance industry, appointed a genetics advisor and a genetics committee in 1996. The committee included geneticists, representatives of patient advocacy groups, and members of insurance companies, and was tasked with developing a framework to deal with the results of genetic testing. The appointment of outside experts, such as patient representatives from the Genetic Interest Group (GIG), to an internal decision-making body was unprecendented at the ABI. An ABI representative noted in an interview, "The issues here were different from elsewhere because the MPs [members of Parliament], the geneticists, and GIG had made genetics an issue and they had raised their profile, and they had raised the patient's profile in this issue, and so if we as the insurance industry were going to get a sustainable, defensible position on genetic testing for insurance, we wanted to consult the stakeholders" (Association of British Insurers representative, pers. comm., October 12, 1999). The British insurance lobby, in contrast to their American counterparts, adopted a conciliatory tone toward both government and advocacy groups. Rather than simply voicing their opposition to regulation in this area, it convened an expert committee that included patient representatives to address the issue. If they developed a framework in cooperation with these disparate groups, it might be more acceptable to the government and therefore more successful in the long run.

In February 1997, the ABI issued a policy statement announcing that insurers would continue to not require genetic testing as a precondition for insurance coverage and would temporarily place a voluntary two-year moratorium on the use of genetic information in developing premiums for mortgage-related life insurance contracts (Association of British Insurers 1997a). This moratorium would hold until the ABI Genetics Committee had an opportunity to study the issue in detail. The ABI's statement marked a major attempt to comply with the wishes of the government and the public. Indeed, it was under no obligation to heed the government's cautionary warnings or attempts to protect the interests of society. The ABI controlled over 95 percent of the British insurance industry. However, their cooperative efforts, which were compatible with the form that British politics traditionally took, could help establish trust among insurers, advocacy groups, and government and possibly encourage attempts to find a commonly agreeable position.

In addition to its participation in the ABI genetics committee, patient advocacy group GIG also developed its own position on the use of genetic

information in insurance and wrote a response to the House of Commons STC report. One of the most highly visible patient advocacy groups in Britain, GIG represented over 100 organizations for individuals affected by "genetic disorders" (Genetic Interest Group 1997, 1). Its opinions were widely respected and it was generally considered the primary source when gauging the opinion of patients and users of genetic services, as evidenced by invitations to provide testimony to the STC and have a representative sit on the ABI's genetic committee. Thus, its opinions were widely noted in the debate about genetic discrimination. Interestingly, GIG's statement on the issue staked out a very different position than that taken by American advocacy groups. GIG was reluctant to characterize genetic information as inherently private or distinct from medical information. It noted, "GIG does not agree with the more general case for strict privacy. In particular, GIG does not seek to make the argument that insurance companies cannot have access to information about the genetic status of individuals if this is already known to the individual concerned. To do so, it would be necessary to make the argument that genetic information is inherently different from other medical information. And this, GIG feels, is an untenable argument" (Genetic Interest Group 1995, 1). GIG opposed the specific categorization of genetic information for two reasons. First, it argued that genetic information simply could not be separated from other kinds of medical information, such as family history, which were already available in the medical record. By explicitly including family histories within its definition of genetic information, GIG made it hard to distinguish between genetic and other types of medical information. (By contrast, their American counterparts had emphasized the distinctiveness of genetic information by focusing on genetic test results rather than family history information.) Second, GIG simply disagreed with American advocacy groups who argued that labeling genetic information as private would be beneficial to individuals with genetic conditions. It worried that distinguishing genetic information from other types of medical information would actually encourage rather than diminish discrimination because calling attention to genetic information by creating a specially protected category would actually be more problematic in the long run.

GIG's approach facilitated cooperation with the insurance industry to develop an acceptable policy. It noted, "There is no point in trying to get insurance companies to be something they are not; insurers are not a part of the welfare state, and cannot be expected to operate on anything other than commercial principles." Rather than fighting them, it adopted a cooperative approach, stating, "if they choose to take account of genetic information, they need to show they are competent to do so" (Genetic Interest Group 1995, 2). It argued that a more "practicable" approach could be developed if insur-

ance companies knew enough about the meaning of genetic information to use it properly. To GIG, individuals possessed no fundamental right to define the meaning of information derived from their genomes. Unlike the American activists who had an adversarial relationship with insurers as they constructed genetic information as novel and private, GIG suggested that the meaning of risk and genetic information should be developed in consultation with all parties.

Meanwhile, the government's newly formed Human Genetics Advisory Commission (HGAC) was tasked to follow up on the STC report and deal with the appropriate use of genetic test results for insurance underwriting purposes. The commission, which included eminent scholars, a pharmaceutical industry representative, and a journalist, deliberated throughout 1997, inviting comment from insurance industry representatives, patient groups, policy analysts, clinicians, and scholars. Its final report, titled *The Implications of Genetic Testing for Insurance*, was issued in December 1997. While the commission acknowledged in its report that genetic information might be considered unique because of its predictive capacity, it echoed GIG's reluctance to distinguish genetic from other medical conditions. Categorically banning the use of information derived from genetic tests, it argued, would create problems for the use of certain types of information already used in underwriting, such as family histories. The commission stated, "Although the implications of hereditary disease for family members may become much more apparent using genetic tests, some conclusions of this sort may be drawn from more conventional family histories. We did not consider that a permanent ban on the use of genetic tests in insurance would be appropriate" (Human Genetics Advisory Commission 1997, 29). HGAC was not only reluctant to distinguish genetic from other types of medical information, but it argued that the previous use of family history information in underwriting suggested that genetic test results did not provide significantly different information. In essence, there really was not much that was "new" about the availability of new genetic tests.

Unlike American government advisory committees like NAPBC who adopted a strict approach to the privacy of genetic information, HGAC also concluded, "the evidence we collected did not support the argument that there should be an absolute right to privacy for knowledge of genetic test results" (Human Genetics Advisory Commission 1997, 10). The commission argued that within a commercial insurance system that was based on choice and optional purchase, both insurers and individuals had the right to use their own discretion and refuse unacceptable policy terms. In addition, it argued that the insurance industry routinely discriminated in setting premiums. The commission stated, "It has also been argued to us that it would be

unethical to discriminate on the basis of any factor which individuals cannot control, which would include their genetic status. However, we note that the long standing use of differences in age, sex, and medical history to set premiums also relies on risk factors which individuals cannot control" (Human Genetics Advisory Commission 1997, 15). It was quite clear that not only did the HGAC not construct genetic information or risk as inherently different from other types of risk, but it also felt that it was not fundamentally private. Instead, the HGAC characterized the meaning and use of genetic information within a social system, where the government was responsible both for the protection of the insurance industry and the public. The individual's right to privacy, HGAC implicitly argued, needed to be weighed against the insurance company's right to make decisions based on adequate information. This contrasted with the approach taken by both federal and state governments in the United States who decided that the individual's right to privacy outweighed the insurance companies' right to have access to genetic information.

The commission eventually recommended that in the short term, the life insurance industry should adopt a voluntary temporary moratorium on requiring disclosure of genetic tests. Like GIG, it argued that this moratorium should only be lifted in specific cases where adequate actuarial and scientific evidence suggested that "health and life-span estimates can be inferred from a given test result" (Human Genetics Advisory Commission 1997, 31). The HGAC also offered to work with government and the entire insurance industry in the long term to develop a cooperative mechanism to evaluate the actuarial importance of specific genetic tests through assessment of scientific evidence.

On the same day as the release of the HGAC report, the genetics committee that had been convened by the ABI issued its Code of Practice on the appropriate use of genetic testing for insurance purposes (Association of British Insurers 1997b). Although it had only had limited interaction with HGAC during its deliberations, the ABI genetics committee's recommendations were very similar to HGAC's. The ABI would not require individuals to take genetic tests to obtain insurance, but it reserved the right to use genetic test information for life assurance schemes over £100,000. Use of these genetic test results, the ABI promised, would be based on "reliable and relevant" evidence. The main difference between the HGAC and ABI reports was that the ABI did not agree with the two-year moratorium suggested by the HGAC. Instead, the ABI Genetics Committee would rely on the recommendations of its specially appointed Genetics Advisor and, specifically, his assessment of the actuarial and scientific evidence available regarding genetic testing, to immediately determine how to use genetic test results.

With the Code of Practice, the ABI Genetics Advisor issued a matrix of seven genetic conditions for which "tests which might have been carried out would be highly relevant to individual insurance proposals." The ABI permitted insurers to use information from these seven genetic tests when setting premiums. In the case of hereditary breast and/or ovarian cancer (i.e., that could be identified through BRCA1 or BRCA2 testing), the advisor noted, "In the small number of families in which there is a known mutation in the BRCA1 or BRCA2 genes, any genetic test result available from an at risk relative would have a high bearing on underwriting for several types of insurance. Thus, a woman aged 30 with a known BRCA1 mutation (and a positive family history for breast cancer) would have around 7 years reduction in life expectancy. This would place her in an insurance pool which required a higher premium than standard, 'whole life' policies" (Association of British Insurers 1997c, 1). The association would provide these recommendations of its Genetics Advisor and committee to its member companies, advising them to make individual decisions based on the information provided by the ABI, in addition to "fact, expert medical and genetic opinion and on his/her own judgment based on experience" (Association of British Insurers 1997a, 6). The ABI argued that scientific and actuarial evidence, as interpreted by its Genetics Advisor, should determine the meaning and importance of genetic information. The association considered each condition separately, however, implicitly rejecting the suggestion that all genetics conditions shared enough distinguishing characteristics to be considered separately.

Meanwhile, the HGAC was alarmed by ABI's attempt to immediately begin using genetic test results in underwriting decisions. It soon began informal negotiations with the ABI to develop a mutually agreeable solution. Around this time, the government (Department of Trade and Industry) also responded to HGAC's recommendations and suggested that instead of a two-year moratorium an independent evaluation mechanism be immediately formed "so that those test results which meet appropriate criteria of reliability and relevance to insurance risk assessment can be approved for use by insurers" (U.K. Department of Trade and Industry and Department of Health 1998, 1).

A National Framework for the Use of Genetic Information in Insurance

After months of negotiating with HGAC and ABI, the British government announced the formation of the Genetics and Insurance Committee (GAIC), a new "independent" advisory body under the Department of Health that was designed to evaluate applications by the insurance industry to use specific

genetic test results (e.g., BRCA1 and BRCA2) for underwriting purposes. Membership of the advisory body included two actuarial representatives of the insurance industry, a geneticist nominated by the government's Chief Medical Officer, a genetic epidemiologist nominated by the Department of Health, and patient representatives nominated by the GIG. The varied membership of the GAIC suggests not only an attempt to validate the opinions of the major stakeholders but also to ensure legitimacy of the decision-making body through a cooperative approach, an established form in the British political context.

GAIC would review genetic tests individually to assess their appropriate use in insurance underwriting. For each test, insurance companies would, and did, submit an "Application for Approval to Use Genetic Test Results for Insurance Risk Assessment" (Genetics and Insurance Committee 2000a). The application requested information, including peer-reviewed evidence, about the medical condition, its genetic basis, test accuracy and validity, and insurance and actuarial relevance. After initial review by the GAIC Secretariat, applications were circulated to external "experts" to assess the genetic and actuarial evidence, as well as patient support groups and medical charities. After all external opinions were gathered, the GAIC reviewed the materials and made a decision.

Soon after the GAIC was formed and application procedures established, the ABI issued a revised Code of Practice in August 1999. The new Code of Practice seamlessly incorporated the authority of the GAIC into its procedures, reflecting the "transfer of role from the Genetics Advisor to the independent Genetics and Insurance Committee in evaluating the validity of genetic test results for insurance use" (Association of British Insurers 1999, 2). While decision making about the validity of genetic testing for use in underwriting had previously been in the domain of the ABI Genetics Advisor, this responsibility shifted to the GAIC. While the Genetics Advisor was still responsible for advising the ABI and insurance industry on matters related to genetics, the ABI committed itself to adhering to the recommendations of the GAIC. As the GAIC made recommendations about the use of genetic tests in underwriting, insurance companies would adjust its policies accordingly. The ABI also requested insurers to review the terms of past policies if the GAIC made recommendations that differed from the previous matrix of the Genetics Advisor. In the meantime, the ABI advised its member companies to continue to adhere to the criteria for testing previously outlined by the Genetics Advisor. Thus, insurance companies would continue to use the results of seven genetics tests (including BRCA testing) in underwriting until the GAIC recommended otherwise.

The ABI's immediate acceptance of the government and GAIC's terms is quite striking. Because the GAIC was a nonstatutory advisory body, the ABI and its member companies were under no obligation to follow its recommendations. However, the inclusion of insurance company and actuarial representatives, as well as the ABI Genetics Advisor, on GAIC probably served to reinforce the trusting relationship between the government, patient advocacy community, and insurers. In addition, as mentioned earlier, the ABI felt that it gained significant legitimacy by working to build bridges with government, scientists, and patients.

The first condition for which the GAIC assessed the importance of genetic testing for insurance was Huntington's Disease (HD). After gathering external comment from independent geneticists, actuaries, and patient groups, the committee issued its recommendations in October 2000. It recommended that insurers be allowed to use results from HD genetic testing, but only to classify individuals as either normal or abnormal and not to use information about mutations to further specify premiums. It suggested there was not adequate data to refine underwriting to suggest specific correlations between mutation incidence and age of disease onset or death. The committee argued that it made its decision on the basis of "test accuracy," "clinical relevance," and "actuarial relevance" (Genetics and Insurance Committee 2000b). The GAIC decision, coupled with the previous policies of the ABI, served to construct genetic risk very specifically, according to condition. Unlike the American case, which considered genetic risk for all conditions collectively and distinguished it from other types of medical information, the British did not accord any special significance to information constructed by new understandings about the genome. Rather, the genetic basis of each condition was considered separately and assessed in the context of information about the disease itself.

In the British context, significant and repeated efforts were made to develop cooperative relationships among participants in debates about insurance underwriting. Most groups developed their perspectives with explicit attention to the dynamics of the larger social system. Even patient advocacy organizations, such as the GIG, advocated a need to work with the corporate sector rather than simply positioning itself against industry. The ABI Genetics Committee and HGAC were deliberately composed of multiple perspectives to develop a consensus that would be perceived by all actors as balanced and legitimate. The clearest articulation of these cooperative efforts was the composition of the GAIC, which included representatives from all major stakeholders and invited comment from organizations that might be specifically affected by the use of a particular genetic test in underwriting. Despite the GAIC's lack of statutory authority, the ABI quickly accepted the new

body's authority as the ultimate decision-making body with respect to genetics and insurance. In this context, genetic information was not identified as a new biotechnological entity that should be considered distinct from other types of medical information. Rather, it was understood in the context of the disease and family history, and decisions about its status as public or private were based on its accuracy as an indicator of future incidence of a specific disease.

Conclusion

In both the United States and Britain, national political styles framed both the definition of genetic information as well as its regulation. In the United States, where patient advocacy groups and insurers engaged in adversarial politics, advocacy groups defined the results of genetic testing as new products of biotechnology that needed to be protected in direct opposition to the views of insurers. They argued that genetic information constituted a novel and distinct category that was inherently private, and fought to develop legislation at both state and federal levels that reflected this understanding. Government officials seemed sympathetic, accepting that genetic information occupied a distinct category of protected information and placing greater weight on the individual's right to privacy than the insurer's right to access genetic information. In Britain, participants in biomedical politics instituted several cooperative forums—the ABI Genetics Committee, HGAC, and finally, the GAIC—to develop a mutually acceptable approach before any of the participants could develop opposing positions. The definition of genetic risk and its regulation reflected this cooperative style, as understandings of genetic information as distinct and private were explicitly rejected. Rather, genetic conditions were assessed on an individual basis, understood in the context of medical information such as family history and disease progression. This comparative case demonstrates how national political cultures not only shape the conduct of politics but influence the way biotechnological entities are defined and regulated. National styles of politics not only lead to very different approaches to regulation, but also very specific understandings of our bodies and ourselves.

Notes

1. This article is a result of fieldwork that I conducted while doing dissertation research on the development of genetic testing for breast cancer in the United States and Britain. This fieldwork included over 100 interviews with individuals involved in the development and regulation

of genetic testing for breast cancer in the two countries, document analysis, and ethnographic observation. For this particular part of the story on the regulation of genetic privacy in the United States and Britain, I interviewed representatives of advocacy groups, insurance companies, members of government advisory committees, and government officials involved in these debates in both countries. I also collected and reviewed documents that had been circulated and published by these actors. Finally, I conducted some ethnographic work, attending advocacy group conferences as well as meetings of the U.K. Forum on Genetics and Insurance (Parthasarathy 2003).

2. While some scholars may argue that the United States and Britain are not comparable because political debates and policy decisions focus on health insurance in the United State and life and disability insurance in Britain, each of these subindustries are interested in the use of risk information to ensure appropriate loading of premiums and company profit. In addition, debates about health insurance in the United States and life insurance in Britain were not only equally high profile but involved negotiations of the meaning of genetic risk and the actors who had the power to define it. This article focuses on very similar discussions in the two countries: What is genetic risk? How should risk be defined? Who gets to decide the meaning of genetic risk? Tom Wilkie, for example, argues that insurance policies in the United States and Britain are not comparable (Wilkie 1998).

3. The article adopts a coproductionist approach, which encourages a balanced approach to the relationships among science, technology, and society. It emphasizes attention to the simultaneous production of knowledge and political order. For more information on this new literature, which focuses on the coproduction of knowledge and political order, in the field of science and technology studies, please see Shapin and Schaffer (1984) and Jasanoff (forthcoming).

4. The National Breast Cancer Coalition became particularly visible and powerful when, in the early 1990s, it was successful in lobbying Congress to increase federal funding for breast cancer research sixfold to approximately $600 million (National Breast Cancer Coalition 2000; National Breast Cancer Coalition 1996).

5. This usage was confirmed in the May 1998 hearing by NBCC Vice President Brunswick and Francis Collins (U.S. Senate, Committee on Labor and Human Resources 1998).

6. Representative Louise Slaughter's bill continues to make its way through Congress, and while fourteen bills regarding discrimination on the basis of genetic information have been proposed since 1995, none have been successful (U.S. Congress 2001).

References

Association of British Insurers. 1997a. ABI issues policy statement on life insurance and genetics. Press release. London: Author.

———. 1997b. *Genetic testing: ABI Code of Practice*. London: Author.

———. 1997c. Professor Raeburn's criteria for testing: Specific diseases. http://www.geneticsinsuranceform.org.uk/Criteria/bcancer.asp (accessed February 13, 2001).

———. 1999. *Genetic testing: ABI Code of Practice*. London: Author.

Colorado Rev. Stat. Ann. S10-3-1104.7 (West 1994 & Suppl. 1996).

Council for Responsible Genetics. 1997. Genetic discrimination: A position paper presented by the Council for Responsible Genetics. Press release. Cambridge, MA: Author.

———. 2000. Genetic discrimination legislation in the United States. http://www.gene-watch.org/programs/GD_onepage_00.html (accessed March 11, 2000).

Duster, T. 1990. *Backdoor to eugenics*. New York: Routledge.

Fujimura, J. 1997. *Crafting science: A sociohistory of the quest for the genetics of cancer.* Cambridge, MA: Harvard University Press.

Genetic Interest Group. 1995. GIG position paper on genetic information, insurance companies, employer and trends in social policy, with regard to the approach recommended by the House of Commons Science and Technology Committee in its report on human genetics. Press release. London: Author.

———. 1997. *Annual report 1996/1997: Achieving change*. London: Author.

Genetics and Insurance Committee. 2000a. Application for approval to use genetic test results for insurance risk assessment. London: Department of Health.

———. 2000b. Decision of the Genetics and Insurance Committee (GAIC) concerning the application for approval to use genetic test results for life insurance risk assessment in Huntington's Disease. London: Department of Health.

Haraway, D. 1991. Situated knowledges: The science question in feminisim and the privilege of partial perspective. In *Simians, cyborgs, and women: The reinvention of nature*. New York: Routledge.

Health Insurance Association of America. 1998. Health insurance and genetic information: Just the facts, please. Press release. Washington, DC: Author.

Health Insurance Portability and Accountability Act of 1996. Pub. L. No. 104-191, 104th Congress ed. (1996).

Hudson, K. L., et al. 1995. Genetic discrimination and health insurance: An urgent need for reform. *Science* 270:391-93.

Human Genetics Advisory Commission. 1997. *The implications of genetic testing for insurance.* London: Author.

Jasanoff, S. 1991. Acceptable evidence in a pluralistic society. In *Acceptable evidence: Science and values in risk management*, edited by Rachelle D. Hollander and Deborah G. Mayo. New York: Oxford University Press.

———. 1995. Product, process, or programme: Three cultures and the regulation of biotechnology. In *Resistance to new technology*, edited by Martin Bauer, 311-31. New York: Cambridge University Press.

———. Forthcoming. *States of knowledge: Science, Power, and political culture*.

Kass, N. E. 1992. Insurance for the insurers: The use of genetic tests. Hastings Center Report 22. Garrison, NY: Hastings Center.

Latour, B., and Woolgar, S. 1986. *Laboratory life: The construction of scientific facts*. Princeton, NJ: Princeton University Press.

Lippman, A. 1998. The politics of health: Geneticization versus health promotion. In *The politics of women's health: Exploring agency and autonomy.* Philadelphia: Temple University Press.

Murray, T. 1992. Genetics and the moral mission of health insurance. Hastings Center Report 22. Garrison, NY: Hastings Center.

National Action Plan on Breast Cancer. 1999. Hereditary susceptibility workshop group sunset report. Fairfax, VA: Author.

National Breast Cancer Coalition. 1996. *Genetic testing for heritable breast cancer risk*. Washington, DC: Author.

———. 1999a. *A proposed model law to prevent genetic discrimination in health insurance.* Washington, DC: Author.

———. 1999b. Legislation prohibiting health insurance and employment discrimination based on genetic information. http://www.natlbcc.org/agenda/brief/p5.asp (accessed cited October 18, 1999).

———. 2000. *National Breast Cancer Coalition: History, goals, accomplishments.* Washington, DC: National Breast Cancer Coalition.

Nuffield Council on Bioethics. 1993. *Genetic screening: Ethical issues.* London: Author.
Parthasarathy, S. 2003. A global genome? Governing genetic testing for breast cancer in the United States and Britain. Ph.D. diss., Cornell University.
President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research. 1983. *Screening and counseling for genetic conditions: The ethical, social, and legal implications of genetic screening, counseling, and education programs*. Washington DC: Government Printing Office.
Rabinow, P. 1999. *French DNA: Trouble in purgatory.* Chicago: University of Chicago Press.
Reilly, P. 1997. Laws to regulate the use of genetic information. In *Genetic secrets: Protecting privacy and confidentiality in the genetic era*, edited by Mark A. Rothstein. New Haven, CT: Yale University Press.
Rothstein, M., ed. 1999. *Genetic secrets: Protecting privacy and confidentiality in the genetic era*. New Haven, CT: Yale University Press.
Shapin, S., and Shaffer, S. 1984. *Leviathan and the air-pump: Hobbes, Boyle, and the experimental life*. New York: Cambridge University Press.
U.K. Department of Trade and Industry and Department of Health. 1998. *The implications of genetic testing for insurance.* London: HMSO.
U.K. House of Commons Science and Technology Committee. 1995. Human genetics: The science and its consequences. HC231. London: HMSO.
U.S. Congress. 2001. Thomas: Legislative information on the Internet. http://thomas.loc.gov (accessed February 28, 2001).
U.S. Department of Health and Human Services. 2000. DHHS press release on final privacy rule. Bethesda, MD: Government Printing Office.
U.S. House of Representatives. 1996. Health Coverage Availability and Affordability Act of 1996, 104th Congress. Washington, DC: Government Printing Office.
U.S. Senate, Committee on Labor and Human Resources. 1998. Genetic information and health care, 105th Congress. Washington, DC: Government Printing Office.
Vogel, D. 1986. *National styles of regulation: Environmental policy in Great Britain and the United States*. Ithaca, NY: Cornell University Press.
Wilkie, T. 1998. Genetics and insurance in Britain: Why more than just the Atlantic divides the English-speaking nations. *Nature Genetics* 20:119-21.

Shobita Parthasarathy is a postdoctoral fellow in the Science in Human Culture Program and Department of Sociology at Northwestern University. She recently completed her Ph.D. in Science and Technology Studies at Cornell University, where her dissertation compared the politics of developing genetic testing for breast cancer in the United States and Britain.