

**PRIVACY CONCERNS RAISED BY THE COLLECTION  
AND USE OF GENETIC INFORMATION BY EM-  
PLOYERS AND INSURERS**

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**HEARING**

BEFORE THE

SUBCOMMITTEE ON THE CONSTITUTION

OF THE

COMMITTEE ON THE JUDICIARY

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

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# PRIVACY CONCERNS RAISED BY THE COLLECTION AND USE OF GENETIC INFORMATION BY EMPLOYERS AND INSURERS

THURSDAY, SEPTEMBER 12, 2002

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON THE CONSTITUTION,  
COMMITTEE ON THE JUDICIARY,  
*Washington, DC.*

The Committee met, pursuant to call, at 10:03 a.m., in Room 2237, Rayburn House Office Building, Hon. Steve Chabot [Chairman of the Subcommittee] presiding.

Mr. CHABOT. The Committee be in order.

This morning the Subcommittee on the Constitution convenes to explore the privacy concerns raised by the collection, use, and exchange of genetic information by employers and insurers. As technology advances, scientists will be able to predict human susceptibility to disease with a high level of accuracy. While scientific developments and genomics will aid society in many ways, many fear the possibility of discrimination at the hands of employers and insurers.

Today, discrimination based on genetic information is highly speculative because the technology is new and still developing. However, as science continues to advance, genetic testing will become cheaper, more reliable, and more prevalent.

Genetic discrimination is the use of genetic information to judge an individual with a predisposition to a certain disease or condition, based on the possibility that he or she might, 1 day, develop that disease or condition.

If an employer would access information about an individual's susceptibility to disease, that employer might misuse the data to avoid expenses associated with absenteeism, health benefits, and risky occupational exposures. Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act of 1990, and various State laws may provide some protection to private employees from genetic discrimination.

Currently, 31 States have legislation prohibiting genetic discrimination in the workplace. Most States prohibit employers from requiring genetic testing as a condition of employment, unless the employer is conducting genetic monitoring.

However, existing State laws vary widely in coverage, with some of the earlier laws only protecting individuals with specific genetic characteristics for particular genetic disorders.

In the insurance industry, laws protecting individuals from discrimination based on genetic information focus mainly on health insurance. The Federal law prohibiting genetic discrimination in health insurance is the Health Insurance Portability and Accountability Act of 1996. As of April 2002, 41 States have enacted laws prohibiting insurers from using genetic information to discriminate against individuals.

Genetic discrimination by health insurers is very low or non-existent because insurance companies tend to look for medical expenses that can be predicted with more certainty in the near future, instead of focusing on long-term health problems.

Laws governing other types of insurance, such as life and disability insurance, only protect individuals from genetic discrimination in a few States. Since life insurance focuses on long-term risks, the interest in obtaining genetic information is much higher than in the health insurance industry.

The advance of technology increases the potential for discrimination at the hands of employers and insurers. In today's hearing, we hope to explore the privacy concerns raised by the collection, use, and exchange of genetic information by employers and insurers. I look forward to hearing from witnesses.

And with that, the Ranking Member is not here yet, but Mr. Scott, would you have an opening statement?

Mr. SCOTT. Thank you, Mr. Chairman.

Mr. Chairman, a lot of this information we're talking about could be embarrassing. It's very sensitive. It has, as you have indicated, significant implications about insurance, life and health particularly, and in employment. And, futuristically, they've got markers that could make you more susceptible to crime and everything else. We don't know where this thing is going.

I think most people would be shocked if they knew how this information is expected to be disseminated and how many people could have access to it.

I look forward to the testimony of the witnesses as we deal with this. Thank you for calling the hearing. I ask unanimous consent that the Ranking Member be able to give a statement when he arrives.

Mr. CHABOT. Without objection, we'll recognize him for that purpose, if he chooses to do so.

Mr. SCOTT. Thank you.

Mr. CHABOT. I would also ask unanimous consent that Representatives Connie Morella and Louise Slaughter may have 5 minutes in which to question the witnesses after all Members of this Subcommittee have had the opportunity to question the witnesses. Without objection, that will be so ordered.

At this time, I would like to recognize and introduce the panel here. And we thank them very much for being here this morning.

Our first witness today will be Tom Miller, director of health policy studies for the Cato Institute. Mr. Miller directs a research program that emphasizes expanded health care financing and purchasing options. His writings have appeared in the Los Angeles Times, USA TODAY, Wall Street Journal, Reader's Digest, Reason, and the American Spectator. Prior to joining Cato, Mr. Miller spent 14 years at the Competitive Enterprise Institute as director of eco-

conomic policy studies and as a senior policy analyst. Prior to that, he worked as a trial attorney, a broadcaster, and a journalist. Mr. Miller holds a law degree from Duke University.

We welcome you here this morning, Mr. Miller.

Mr. MILLER. Good morning, Mr. Chairman and Members of the Subcommittee.

Mr. CHABOT. I'll go ahead and introduce the other members. Thank you.

Our second witness will be Dr. John W. Rowe, chairman and CEO of Aetna, Inc., one of the Nation's leading health care organizations. Prior to joining Aetna, Dr. Rowe served as president and chief executive officer of Mt. Sinai NYU Health. Prior to the Mt. Sinai NYU Health merger, Dr. Rowe was president of the Mt. Sinai Hospital and the Mt. Sinai School of Medicine in New York City. He serves as clinical professor of medicine at the Mt. Sinai School of Medicine. Before joining Mt. Sinai in 1988, Dr. Rowe was a professor of medicine and the founding director of the division on aging at Harvard Medical School and chief of gerontology at Boston's Beth Israel Hospital. Dr. Rowe served on the board of governors of the American Board of Internal Medicine and as president of the Gerontological Society of America.

And we welcome you here this morning.

Our third witness will be Joanne L. Hustead, senior counsel for the Health Privacy Project and assistant research professor at Georgetown University's Institute for Health Care Research and Policy. Ms. Hustead's areas of expertise include medical privacy, genetic discrimination, and managed care reform, as well as ERISA and HIPAA and other Federal laws affecting the health care system. Prior to joining the Health Privacy Project in early 2001, Ms. Hustead spent 10 years at the National Partnership for Women and Families as director of legal and public policy, where she was involved in efforts to pass the 1996 Health Insurance Portability and Accountability Act, HIPAA. Between 1982 and 1990, she was an associate in private practice, focusing on employment discrimination and family law. Ms. Hustead holds J.D. from the University of Pennsylvania School of Law.

And we welcome you here this morning.

Ms. HUSTEAD. Thank you.

Mr. CHABOT. And our final witness today will be Dr. Deborah C. Peel, president of the Mental HealthCARE Foundation and co-chair of the Committee on Government Relations and Insurance for the American Psychoanalytic Association. She serves as a medical consultant to Time magazine and has made numerous appearances on the Today Show and Dateline NBC. Dr. Peel is the founding director of the Department of Psychiatric Education at the Central Texas Medical Foundation. From 1979 to 1990, she served as the chief of psychiatry at Breckenridge Hospital in Austin, Texas. Her writings have appeared in Congressional Quarterly Researcher, Psychiatric Times, and the Texas Journal of Medicine. Dr. Peel received her M.D. from the University of Texas Medical Branch at Galveston, where she also has completed her residency in general adult psychiatry.

And we welcome you here, as well, this morning.

We thank all the panel members for being here.

Mr. SCOTT. Mr. Chairman?

Mr. CHABOT. Yes.

Mr. SCOTT. I don't think the lights are working. I think there's a vote on, as we speak, with about 10 minutes left.

Mr. CHABOT. There's a vote on? How many minutes?

Mr. SCOTT. About 10 minutes left.

Mr. CHABOT. Okay, I've been instructed that our lights aren't working back here. We have a vote on the floor, so we're going to go into recess for just a moment, go over and vote, and be back in a few minutes, and then we'll start with the panel.

Mr. SCOTT. I think there may be more than one vote.

Mr. CHABOT. Two votes. Okay, well, we'll be more than just a few minutes, then. As soon as the two votes are over, we'll be back and get underway. Thank you.

[Recess.]

Mr. CHABOT. The Committee will be in order.

We have already introduced the panel. We're just getting ready to begin the testimony. And I was just going to remind the panel that we have a 5-minute rule, and we have a lighting system. When the yellow light comes on, that means that there's 1 minute of the 5 minutes left. And then the red light will come on, and that means that you should wrap up, please. And we may give a little leeway, but for the most part, we try to keep within that 5-minute rule, if at all possible.

So without further ado, Mr. Miller, you're recognized for 5 minutes.

**STATEMENT OF TOM MILLER, J.D., DIRECTOR OF HEALTH STUDIES, CATO INSTITUTE**

Mr. MILLER. Good morning, Mr. Chairman and Members of the Subcommittee. My name is Tom Miller. I'm director of health policy studies at the Cato Institute.

A little earlier, I may have jumped the gun in starting my testimony, but we may be at risk of doing the same thing in legislating to protect genetic privacy.

There's little, if any, evidence that health insurers are using or are likely to use pre-symptomatic genetic information in their medical underwriting. Evidence that employers try to obtain let alone use such information generally is limited to isolated anecdotes.

However, this topic usually is built on assumptions about the future and what some observers believe private insurers and employers might do in the event that genetic testing and genetic information eventually become more accurate and precise in revealing an individual's prospects for future disease, incapacity, and unusually high health care claims costs.

Now, as Yogi Berra once said, the future ain't what it used to be. So let's proceed by assuming that more accurate, comprehensive, and inexpensive genetic testing promises eventually to improve dramatically our ability to detect disease at an early stage and treat it more effectively or even prevent it.

The offsetting concern encompassed in the catchall desire to protect genetic privacy is that one's personal genetic information might be disclosed to others without one's consent and then used

to one's personal detriment. And without question, any information that can be used may also be used badly.

But consider the complications and complexities in crafting a unique brand of legal protection against the disclosure of personally identifiable genetic information in the name of "genetic privacy."

Any possible constitutional protections for genetic privacy would and should be limited to apply only against Government action. The only accurate way to frame the issue for statutory law affecting private parties is in terms of genetic nondiscrimination rather than genetic privacy.

This would narrow the focus to whether and how to protect consumers from harmful use of genetic information rather than whether and how to maximize consumers' legal control over that information per se.

Erecting legal barriers against discrimination based on genetic information would strain the limits of genetic exceptionalism, defy precise definition, pose serious threats to the functioning of private insurance and labor markets, and overlook more effective alternative remedies.

There is no clear line that separates genetic data from other kinds of personal health information. The sources of legally protected genetic information might be obtained from many current and commonly accepted medical practices that do not involve explicit tests of one's genetic material.

Overly broad legal claims to genetic privacy and genetic nondiscrimination often serve as a subterfuge for more fundamental opposition to various kinds of private health insurance underwriting based on individual health risk or to voluntary disclosure of sensitive personal health information to one's employer. One's right to privacy should not include the right to misrepresent oneself to the rest of the world or engage in unilateral strategic behavior to choose the time and scope and/or duration of the insurance coverage one purchases.

A broad prohibition on *any* disclosure of genetic information would prevent good health risks from obtaining positive genetic information on their behalf and then voluntarily disclosing it to potential health insurers.

The common practice of insurers is to rely on experience rating for all but the smallest employer-sponsored groups. The expense and administrative burden of more intensive underwriting simply outweighs the practical value of whatever limited and imprecise information about health risk that an insurer might obtain. Even medical underwriting in individual market tends to focus on medical costs that are likely to occur within the first few years after a policy is purchased.

Insurers also have no incentive to turn away apparently healthy customers or even somewhat less healthy ones, as long as they can adjust the premiums to reflect relative health risk, when it's based merely on possible long-term genetic risk that remain hard to measure.

Prohibiting the use of predictive genetic information would rather "indiscriminately" provide a hidden subsidy to any individual who might be discriminated against for genetic risk reasons regard-

less of their financial circumstances or particular needs. Yet we generally do not provide similar subsidies for other forms of bad luck in life's genetic lottery.

We first should consider other market-based, private-sector mechanisms or at least more explicit and overt public subsidies as alternatives to expanded regulatory cross-subsidies, as I've outlined in my written testimony.

Thank you.

[The prepared statement of Mr. Miller follows:]

PREPARED STATEMENT OF TOM MILLER

Good morning, Mr. Chairman and Members of the Subcommittee. My name is Tom Miller. I am director of health policy studies at the Cato Institute. It is a pleasure to appear before you today to examine privacy concerns raised by the possible collection and use of genetic information by employers and insurers.

I say "possible" because there is little, if any, evidence that health insurers are using or likely to use presymptomatic genetic information in their medical underwriting.<sup>1</sup> Evidence that employers try to obtain, let alone use, such information generally is limited to isolated anecdotes. One survey of human resources managers revealed that limited evidence of genetic testing actually reflected misunderstanding of what truly is genetic information, as opposed to routine blood tests or testing for the presence of a disease (rather than a genetic susceptibility to it).<sup>2</sup>

However, this topic usually is built on assumptions about the future and what some observers believe private insurers and employers might do in the event that genetic testing and genetic information eventually became more accurate and precise in revealing an individual's prospects for future disease, incapacity, and unusually high health care claims costs.

As Yogi Berra once said, or probably should have if he did not, "Predicting the future is hard, because it hasn't happened yet." Nevertheless, let's proceed by beginning with what we do know about how private insurance markets and labor markets operate.

It's reasonable to assume that more accurate, comprehensive, and inexpensive genetic testing will arrive one day; the question is more one of the pace at which this will take place. When combined with reliable evidence from epidemiology about the probability and magnitude of various maladies, the continuing genetic revolution promises to improve dramatically our ability to detect disease at an early stage, and treat it more effectively or even prevent it. Better, and earlier, knowledge about genetic predisposition to illness might help individuals take preventive measures to reduce the consequences of disease or even eliminate its onset. Enhanced use of more predictive genetic information may assist individuals in making lifestyle plans and choices. It also holds great promise in fine-tuning health care treatment, such as through more narrowly targeted "designer" drugs and gene therapy interventions.

But the offsetting concern encompassed in the catchall desire to protect "genetic privacy" is that one's personal genetic information might be disclosed to others without one's consent and then used to one's personal detriment.

Without question, any information that can be used may also be used badly. But a host of policy complications and administrative complexities arise if one attempts to craft a unique brand of legal protection against the disclosure of personally identifiable genetic information in the name of "genetic privacy."

First of all, any possible constitutional protections for genetic privacy would be limited to apply only against government action. The Fourth Amendment right of privacy (the right to be free from "unreasonable searches and seizures") and the more narrow right to "informational privacy" recognized in *Whalen v. Roe* do not apply to the private sector.<sup>3</sup>

Moreover, the more accurate way to frame the issue of whether statutory law should prohibit or limit disclosure and use of genetic information by private parties

<sup>1</sup>Mark A. Hall, "Legal Rules and Industry Norms: The Impact of Laws Restricting Health Insurers' Use of Genetic Information," 40 *Jurimetrics Journal* 93-122 (Fall 1999).

<sup>2</sup>Eric Greenberg, American Management Association. Testimony before the House Education and the Workforce Subcommittee on Employer-Employee Relations, 107th Cong. 1st Sess., July 24, 2001.

<sup>3</sup>Fred H. Cate, "Principles for Protecting Privacy," *Cato Journal* 22, no. 1 (Spring/Summer 2002): 54-56.

is in terms of genetic “nondiscrimination” rather than genetic privacy. It also would narrow the legislative and regulatory focus to consider whether and how to protect consumers from harmful use of genetic information, rather than whether and how to maximize consumers’ legal control over that information per se.

But even erecting legal barriers against discrimination based on genetic information would strain the limits of genetic exceptionalism, defy precise definition, pose serious threats to the functioning of private insurance and labor markets, and overlook more effective alternative remedies.

There is no clear line that separates genetic data from other kinds of personal health information.<sup>4</sup> Attempts to define “genetic” diseases must sort through a fuzzy mix of compulsive, addictive, and patterned behaviors, as well as characteristics like intelligence, aggressiveness, and obesity that have both genetic and environmental roots.<sup>5</sup>

Moreover, the sources of legally protected genetic information might be obtained from many current and commonly accepted medical practices that do not involve explicit “tests” of one’s genetic material. For example, personal medical histories, family medical histories, routine physical exams, and blood pressure tests all might convey predictive health information that could be linked to genetic factors.

In efforts to protect against genetic discrimination, how should policymakers deal with the “predictability” of medical conditions that are influenced by multiple genes that work in conjunction with environmental factors? Or with genetic predispositions that only increase the risk, rather than establish the certainty, of developing a disease? Or with genetic conditions that increase one’s probability of experiencing both adverse and beneficial outcomes? Should legal prohibitions apply only to uses of genetic information that disadvantage the protected party?

Overly broad legal claims to genetic privacy and genetic nondiscrimination often may serve as a subterfuge for more fundamental opposition to various kinds of private health insurance underwriting based on individual health risk or to voluntary disclosure of sensitive health information to one’s employer. As Richard Epstein observes, modern uses of privacy may be used to override freedom of contracts and even “act as a handmaiden to fraud.”<sup>6</sup> One’s right to privacy should not include the right to misrepresent oneself to the rest of the world, particularly in the case of making statements to one’s health insurer or employer that one knows to be false, material to the listener, and relied on to the listener’s detriment.<sup>7</sup> For example, individual insurance consumers who know or suspect their genetic risk factors should not be able to engage in unilateral strategic behavior to choose the timing, scope, and/or duration of the insurance coverage they purchase.<sup>8</sup>

A broad prohibition on any disclosure of genetic information would prevent good health risks from obtaining positive genetic information on their behalf and then voluntarily disclosing it to potential health insurers. Yet efforts to separate the treatment of predictive genetic information into prohibitive negative categories and permitted positive categories would defy administrative consistency and predictability. They would essentially lead to a regulatory regime of “Can’t ask, may tell, may lie” in which truth is discouraged and lies are protected, promoted and necessary.<sup>9</sup>

At this point of the discussion of genetic privacy and genetic discrimination, many private health insurance industry representatives begin to retreat behind the current wall of federal and state legislation that already prohibits or limits most forms of genetic discrimination, particularly in the employer-sponsored group insurance market. For example, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits discrimination against individual workers who are members of an employer group plan—either on the basis of their current health status or on the basis of their predisposition to a particular disease based on genetic information. They cannot be denied access to group health plan benefits or be required to pay higher premiums due to their individual health status. And, after they have satisfied HIPAA’s preexisting condition limitations once, they then may move to another employer’s group health plan without facing new limitations on coverage due to ad-

<sup>4</sup> Lawrence O. Gostin and James G. Hodge, Jr. “Genetic Privacy and the Law: An End to Genetics Exceptionalism,” 40 *Jurimetrics Journal* 21–58 (Fall 1999).

<sup>5</sup> Colin S. Diver and Jane M. Cohen. “Point/Counterpoint: Genophobia: What Is Wrong with Genetic Discrimination,” 149 *University of Pennsylvania Law Review* (May 2001): 1439–1479.

<sup>6</sup> Richard A. Epstein. “How Much Privacy Do We Really Want?” *Hoover Digest* No. 2 (2002) <http://www-hoover.stanford.edu/publications/digest/022/epstein.html>.

<sup>7</sup> Richard A. Epstein. “The Legal Regulation of Genetic Discrimination: Old Responses to New Technology,” 74 *Boston University Law Review* (January 1994): 1–23.

<sup>8</sup> See Diver and Cohen, op. cit., pp. 1456–1458, 1466–1467.

<sup>9</sup> Epstein, 1994, p. 14.

ditional information about their health status. Genetic information also is treated as protected personal health information under HIPAA's health privacy regulations.

However, HIPAA does not govern the use of genetic information in the individual health insurance market, which generally has more operating freedom in the underwriting process under the insurance rules of most states. Health insurers are more likely to oppose explicit prohibitions on use of genetic information in the individual market and to point out that tighter restrictions on underwriting and pricing in such a smaller and often transitory market are more likely to reduce rather than expand available coverage there.

But even medical underwriting in the individual market tends to focus on medical costs that are likely to occur within the first few years after a policy is purchased, and more expensive genetic screening tests to predict much longer range health risks would not be worthwhile to insurers, even if legally permitted. Yet insurance industry representatives generally will caution against outright bans on genetic testing in the individual market, essentially arguing, "We don't use it, we don't plan to use it, but don't prohibit us from using what we don't need to use." One might ask, why?

For one reason, first consider that, apart from HIPAA's legal prohibition on medical underwriting of individuals within employer group health plans, the common practice of insurers is to rely on experience rating for all but the smallest employer-sponsored groups. The expense and administrative burden of more intensive underwriting simply outweighs the practical value of whatever limited and imprecise information about health risk that an insurer might obtain. Insurers also have no incentive to turn away apparently healthy customers, or even somewhat less healthy ones (as long as rating flexibility permits some adjustments), based merely on possible long-term genetic risks that remain hard to measure.

However, it does remain possible that, as genetic testing and genetic information becomes more predictive much further down the road, and as private insurance coverage becomes more customized (such as through defined contribution plans and consumer-driven health care options), more private insurers eventually will face greater pressure either to sort high risks into high-premium and restricted coverage risk classifications or to increase premiums and restrict coverage further across the board. If individual customers become better armed with personal genetic information and can engage in behavior that increases the previously predictable range of insured claims, insurers will want to use, and they will need to use, such information to correlate more accurately those genetic characteristics with future costs and premiums. Otherwise, low-risk customers increasingly will exit voluntary private insurance markets and the overall supply of coverage will contract.

A good bit of this speculation about the future and the so-called "end of insurance" reflects the likely time lag we will experience in making a uneven transition from the first round of genetic information and biomedical research that is better able to detect and diagnose genetic problems than later rounds of scientific discovery will be able to cure or mitigate.<sup>10</sup> As Roberta Berry has observed, we should more carefully weigh the consequences of regulatory interventions that essentially are aimed at assuring that genetically high-risk individuals are able to obtain bargain premiums from and transfer their losses to a private pool of lower risk insurance customers or their employers.

Prohibiting use of predictive genetic information also rather "indiscriminately" provides a hidden subsidy to any individual who might be discriminated against for genetic risk reasons, regardless of their financial circumstances or particular needs. Yet we generally do not provide similar subsidies for other forms of "bad luck" in life's genetic lottery, such as less desirable levels of traits like intelligence, aggressiveness, or physical appearance that have at least some genetic roots. It would also seem odd if regulatory treatment were to become relatively more tolerant of adverse treatment of symptomatic individuals than for asymptomatic individuals who merely possess genetic risk factors.<sup>11</sup>

Broad federal regulatory prohibition against genetic discrimination in health insurance may shut off valuable flows of information and suppress financial incentives that could encourage individuals to make better decisions about the insurance coverage they buy, the investments they make in other health-promoting activities, and the behaviors in which they engage.

<sup>10</sup> See Roberta M. Berry, "The Human Genome Project and the End of Insurance," 7 *Florida Journal of Law and Public Policy* (Spring 1996): 205–256.

<sup>11</sup> See Diver and Cohen, p. 1452 (suggesting that HIPAA, the Americans with Disabilities Act, and President Clinton's February 2000 executive order prohibiting genetic discrimination in federal employment already essentially do this).

Not very far below the surface of claims that genetic discrimination in health insurance should be prohibited is the larger issue of whether risk classification based on health status is permissible within at least some private sector portions of our mixed system of voluntary private insurance and publicly financed health programs. Employer group health plans straddle the fence by moving risk classification to the firm, as opposed to individual, level. But private insurers still need to be able to predict the approximate level of health claims they are likely to pay if they are to set their premiums high enough to stay in business, yet assure lower risk customers that the coverage offered to them is worth the price charged.

As enhanced availability and use of more predictive genetic information strains the fault lines of our private health insurance system, we first should consider other market-based, private-sector mechanisms, or at least more explicit and overt public subsidies, as alternatives to expanded regulatory cross subsidies. Public policy might encourage the development of better voluntary pooling mechanisms outside of the employer-employee relationship. It could facilitate long-term health insurance contracts that offer guaranteed renewability options or other time-consistent insurance incentives such as second-tier savings components that would remain subject to illness-state-contingent “severance payments” for early departure from a particular insurance pool. Or consumers might consider purchasing “genetic test insurance” to insure themselves against any as-yet unknown risks before they took particular genetic tests.<sup>12</sup> More conventional approaches might include expansion of high-risk health insurance pools and greater incentives for charitable contributions to nonprofit intermediaries that organize and deliver safety net health care.<sup>13</sup>

I will touch more briefly on the issue of genetic information and genetic discrimination in employment settings (although the above health insurance issues also would come into play for employers that sponsor self-insured health plans). In general, I concur with Richard Epstein’s view that employers should be able to seek whatever information they might find relevant to their employee’s job performance. Prospective and current employees, of course, may refuse to supply information that is requested.<sup>14</sup> One might imagine some extreme circumstances that could necessitate the intervention of public authorities to do more than enforce employment contracts and prevent fraudulent misrepresentations, but that should be the narrow exception rather than the broad rule. Irrational prejudice and discrimination in labor markets may overwhelm economic logic on some occasions, but market forces also will impose significant costs on employers who persistently exclude productive workers who might happen to possess genetic risk factors. If employers are faced with prohibitions against using valuable genetic information, they are most likely to resort to other legal and second-best (or third-best) substitutes for forbidden information. Employers might restructure compensation packages to adjust for higher health benefits costs, substitute part-time labor and independent contractors for full-time jobs, rely more on capital investments or offshore operations, or hire younger and presumably healthier workers.<sup>15</sup>

If regulatory policy insists that employers should remain blind to the known costs of employing certain types of individuals, those employers will resort to coping mechanisms to cut their losses but leave us all a bit poorer and less efficient.

Rather than rely on greater regulation of information flows simply because they are labeled “genetic,” we should restore and renew our commitment to competitive markets, private property rights, and private contracts.

Mr. CHABOT. Thank you very much, Mr. Miller.  
Our next witness will be Dr. Rowe.

<sup>12</sup>See, e.g., Tom Miller. “A Regulatory Bypass Operation,” *Cato Journal* 22, no. 1 (Spring/Summer 2002): 88–91; Vip Patel and Mark V. Pauly. “Guaranteed Renewability and the Problems of Risk Variation in Individual Health Insurance Markets,” *Health Affairs*, August 28, 2002; John H. Cochrane. “Time Consistent Health Insurance,” 103 *Journal of Political Economy* (1995): 445–473; Alexander Tabarrok (ed.). *Entrepreneurial Economics: Bright Ideas from the Dismal Science* (New York: Oxford University Press, 2002).

<sup>13</sup>Tom Miller. “Improving Access to Health Care without Comprehensive Insurance Coverage,” In *Covering America: Real Remedies for the Uninsured*, Vol. 2. Elliot K. Wicks and Jack A. Meyer, eds. (Washington: Economic and Social Research Institute, forthcoming 2002).

<sup>14</sup>Epstein, 2002.

<sup>15</sup>Diver and Cohen, p. 1459, 1464.

**STATEMENT OF JOHN W. ROWE, M.D., CHAIRMAN AND CEO,  
AETNA, INC.**

Dr. ROWE. Thank you, Mr. Chairman. I'm Jack Rowe, chairman and CEO of Aetna, one of the Nation's leading providers of health care and related group benefits.

This is an exciting time in medicine. Predictive gene testing holds a promise of saving thousands, many thousands of lives, through prevention and early detection.

Unfortunately, with this progress, we have developed some myths. One myth relates to the prevalence of discrimination, as commented on by Mr. Miller. There is strong public concern regarding the use of genetic information to disadvantage individuals for health insurance.

But there is a difference between perception and reality. The record does not appear to include identifiable cases in which individuals have been discriminated against in group health insurance, based on genetic information.

Professors Hall and Rich at Wake Forest University, in a paper in the American Journal of Human Genetics, evaluated the effect of State laws in reducing the extent of genetic discrimination by health insurers. Their findings, and I quote, "There are almost no well-documented cases of health insurers either asking for or using pre-symptomatic genetic test results in their underwriting decisions either (a) before or after these laws have been enacted or (b) in States with or without these laws—that a person with a serious genetic condition who is pre-symptomatic faces little or no difficulty in obtaining health insurance. Furthermore, there are few indications that the degree of difficulty varies according to whether or not a State regulates the use of genetic information," unquote.

A second myth is that health insurance coverage decisions are arbitrary. At Aetna, we've developed a comprehensive process for deciding whether or not a specific test should be covered. Our analysis begins with a review of the peer-reviewed medical literature, consultation with organizations such as the American College of Medical Genetics, CMS, and other Government agencies about whether they believe a test should be covered.

We then next turn to a review by expert physicians in our network. Then we go to participant provider reviews. We then disseminate the finalized guidelines for wide review and publish coverage policy bulletins on our Web site.

Some individuals feel the safest way to assure that health insurers do not use genetic information to disadvantage members will be to prevent insurers from having the information. This approach is unnecessary and counterproductive. It will impair insurers' capacity to provide appropriate service to our members.

Let me give you two quick examples.

For individuals known to have the gene for a familial form of colorectal cancer, their best interest, in terms of early detection and prevention, is to have frequent screenings via colonoscopy, every 6 months instead of every 3 to 5 years. We can only approve payment for those 6-monthly tests if we know that the individual has the colorectal cancer gene. If we don't have access to that information, the person doesn't have access to that treatment.

Another example has to do with medication side effects. There's a very effective medication for AIDS but a small number of individuals have fatal reactions to the medicine. One can predict the likelihood of a fatal reaction through a gene test. If the health plan has the information that these individuals are positive for this gene, we can provide busy physicians running around with many patients and many demands with a list of the members of their practice who are positive for that test and alert them to the fact that this individual should not be given X prescription.

We also have results of the prescriptions that are given because we pay for those, and we can set up an alert mechanism if a physician happens to prescribe such a drug for somebody, with this information.

So these are ways that we think our having the information can be helpful.

With these considerations in mind, Aetna has recently suggested—and with appreciation of the fact that HIPAA already provides substantial protection relative to individual privacy, we have suggested some guidelines for the industry, and I'd like to end by just iterating those briefly.

We feel that it is not just a series of things we should not do. There are things that we should do, and we believe that health plans should make available products to their self-insured plan sponsors and their fully insured customers that, one, cover genetic testing in individuals shown to be at risk where results will vary the course of treatment. Number two, we think we should cover genetic testing for a family member where the family member is not otherwise insured and that the results will affect the course of treatment of an Aetna member. Three, we think we should cover consultation with qualified counselors and physicians to facilitate the appropriate interpretation; to just cover genetic testing and not provide consultation and advice about the implications of the testing is inappropriate. Four, we support physician education in this area, including guidance in selection of medications, as I mentioned. And fifth, we will work with physicians to promote confidentiality and to use genetic information for the maximum benefits of the members.

And lastly, there are a number of things that we think health plans should not do. They should not establish rules for health coverage eligibility based on genetic testing. We at Aetna feel very strongly about that. They should not request or require genetic testing results as a condition to providing group health insurance coverage. They should not use genetic testing for risk selection or risk classification purposes in providing health coverage. And we should not disclose genetic testing results that may come into our possession without the authorization of our members.

We believe genetic testing should be seen an effective tool to enhance the health status of individuals and are working hard to accomplish that goal. Thank you very much.

[The prepared statement of Dr. Rowe follows:]

PREPARED STATEMENT OF JOHN W. ROWE

Thank you for inviting me to testify today on this important issue. I am John W. Rowe, Chairman and CEO of Aetna, one of the nation's leading providers of health care and related group benefits with 2001 revenue of \$25.2 billion, serving approxi-

mately 14.4 million health care members, 11.9 million dental members and 12.0 million group insurance customers as of June 30, 2002. The company has an expansive nationwide network of more than 527,000 health care services providers, including approximately 321,000 primary care and specialist physicians and 3,300 hospitals. Aetna provides health care and related benefits to employer and plan sponsor customers in all 50 states.

I appreciate the opportunity to speak with you about genetic testing, privacy of genetic information and the role of health plans which are providing coverage for members at high risk for certain treatable diseases. We are in an exciting period in medicine. New techniques have allowed scientists to learn a great deal about how genes work and how genes are linked to disease. Tests for gene mutations have made it possible not only to detect disease, but predictive gene testing holds the promise of saving thousands of lives through prevention or early detection. With these advancements, it also is critically important to assure the public that their confidential information will be protected.

I will review the current status of genetic testing as I see it, including some facts and myths regarding the insurance industry, and finish by iterating the guidelines that Aetna recently proposed as a standard for the industry in this area.

There are two distinct issues here. One is assuring that genetic information is not used for discriminatory purposes in insurance. The second is the use of genetic information as part of a benefit covered by health insurance, the issue of medical management.

#### CURRENT STATUS OF GENETIC TESTING

As for the facts, the current situation can be defined with five general statements.

**1) Medical science can detect the presence of a growing inventory of genes that influence either the development of a disease or the effectiveness and/or safety of a specific treatment.**

There are basically two kinds of disease related genes. In one case, if you have the gene, you get the disease 100% of the time. One such example is Huntington's Disease. If you have an identical twin with Huntington's Disease, you're going to get Huntington's Disease. A second category of genes are susceptibility genes. These genes increase the likelihood of developing a given disease, but don't make it a certainty. This is true of the commonly discussed breast cancer genes—BRCA 1 and 2. As a result of the human genome project, the repertoire of susceptibility genes that we can now measure has increased dramatically.

**2) Health plans can play an important role in providing access to clinically useful testing and the proper interpretation of tests results.**

**3) There is substantial public interest in genetic testing as well as concern regarding the potential for the inappropriate use of genetic testing.**

**4) Legislation specifically prohibiting health plan's discriminatory use of genetic information is present in most states but varies considerably from state to state.**

**5) There is a pressing need for the health insurance industry to establish guidelines for covering genetic testing and the interpretation of the test results.**

#### MYTHS

Unfortunately, with progress often comes misconception which frequently turns into myth. One myth relates to the prevalence of discrimination. Regarding the strong public concern regarding privacy and the potential use of information to disadvantage individuals for health insurance, there is a difference between the perception of how medical information is used and reality. The record does not appear to include any identifiable cases in which people have been discriminated against in health insurance based on genetic information. Professors Hall and Rich from Wake Forest University in a paper in the *American Journal of Human Genetics* evaluated the effect of state laws in reducing the extent of genetic discrimination by health insurers (Hall, Mark A; Rich, Stephen S: Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination. *American Journal of Human Genetics*, 66:293–307, 2000). They found, and I quote:

“. . . that there are almost no well-documented cases of health insurers either asking for or using presymptomatic genetic test results in their underwriting decisions, either (a) before or after these laws have been enacted or (b) in states with or without these laws. . . . that a person with a serious genetic condition who is presymptomatic faces little or no difficulty in obtaining health insurance. Furthermore, there are few indications that the

degree of difficulty varies according to whether a state regulates the use of genetic information.”

Another myth is that our health insurance coverage decisions are arbitrary. At Aetna, we've developed a comprehensive process for deciding whether or not a specific genetic test should be covered. Our policies are based on the assumption that use of the genetic information will positively affect the course of treatment of our member. The coverage policy analysis begins with a review of the peer reviewed medical literature and the formal opinions of national professional organizations such as the American College of Medical Genetics, American College of OB/GYN, and government agencies such as Medicare on whether they believe a given genetic test should be covered. After these nationally accepted professional sources, we turn next to a review by expert physicians in our network. Then we go to a participant provider review, of how, for instance, do the practicing obstetricians and gynecologists feel about it rather than just the experts in breast cancer or ovarian cancer. We then disseminate the finalized guidelines for wide review and publish a coverage policy bulletin—we have about 150 or 160 of these available on our website.

Another myth is that genetic testing will break the bank. The reality is, I believe, that genetic testing of individuals with pronounced susceptibility to a treatable or preventable disease is cost effective.

A good example is breast cancer. In screening for the breast cancer genes (BRCA 1 and 2) in carefully selected patients, the cost is low, and the risk of misinterpretation is much less and potential clinical benefits are more certain than in lower risk groups. In a study by Eccles et al in the *British Journal of Cancer* in '98 (Eccles, DM; Englefield, P; Souly, MA; Campbell, IG: BRCA1 Mutations in Southern England. *British Journal of Cancer*, 1998; 77(12), 2199–2203), the cost per gene mutation detected, if screening every woman, is \$170,000. If screening just women under 40 who are already diagnosed with breast cancer to see if their cancer is this genetic variant, the cost is \$1,700. And if testing women who have a strong family history, the cost was \$489 per detected gene mutation. And if a woman has BRCA 2, there is something she can do. She can take Tamoxifen, an anti-estrogen, or have surgical removal of her breasts, to reduce the risk. The key to appropriate screening is the person screened has to be in a high risk group and there has to be something you would do clinically, based on the test results.

#### APPEALING RHETORIC—BAD RESULTS

Some individuals suggest that the safest way to assure that health insurers do not use genetic information to disadvantage members will be to prevent the insurers from having the information. This approach is both unnecessary and counter-productive and will impair insurers capacity to provide appropriate service to its members. Let me provide two straightforward examples.

For individuals known to have the gene for the familial form of colorectal cancer, their best interest, in terms of cancer prevention, survival and cost effective care, is to have frequent screenings via colonoscopy, perhaps at 6 month intervals rather than the much longer intervals recommended for the general population (Vasen, HFA; van Ballegooijen, M; Buskens, E; Kleibeuker, JK; Taal, BG; Griffioen, G; Nagengast, FM; Menko, FH; Meera, Kahn P: A Cost-Effectiveness Analysis of Colorectal Screening of Hereditary Nonpolyposis Colorectal Carcinoma Gene Carriers. *Cancer*, 1998; 82(9), 1632–1637).

If the insurance company knows that the individual is at high risk due to a genetic link, the individual will be able to obtain coverage for preventive screening at more frequent intervals than recommended for the general population. Additionally, if the insurance company is informed of the results of predictive gene testing, they can reach out to these individuals to ensure that they receive the necessary preventive screening. In addition to influencing the likelihood of developing a disease, genes may determine the response to a specific treatment. We have long known that individuals differ in their response to medication—both in having the desired therapeutic effect or having a serious adverse side effect. Now we can test for the presence of genes that govern some of these differences. For instance, in the case of a medication, Ziagen, which is effective in AIDS, certain individuals have adverse reactions that can be fatal. Eighty percent of those with the reactions have a specific gene that can be tested for, thus avoiding the adverse reaction in those patients.

Since health plans have sophisticated information systems and administrative data of the prescription medications individuals take, the health plan could provide a busy physician with a large practice a list of the individuals in the physician's practice, and insured by the health plan, who are known to have the genetic characteristic susceptible to certain medications. In such a case, the physician then could

take steps to assure that those individuals avoid the use of a specific medication which could place the patient at risk for a serious adverse reaction.

These examples—colorectal cancer screening and predicting response to medication (pharmacogenetics)—are but two of many possible instances in which it would be very important for the provision of high-quality, cost-effective health care for the results of genetic tests to be available to the insurers.

#### GUIDELINES

With these considerations in mind and with the appreciation of the fact that HIPAA already provides substantial protection relative to individual privacy, Aetna has recently offered the following guidelines which we hope will serve as a benchmark for the industry.

We feel that health plans should make available products to their self-insured plan sponsors and their fully insured customers that:

1. Cover genetic testing in individuals shown to be at risk where results may affect the course of treatment of the insured.
2. Cover genetic testing for a family member where the family member is not otherwise insured and results may affect the course of treatment of an at risk insured.
3. Cover consultation with qualified counselors and physicians and facilitate the appropriate interpretation of genetic testing results.
4. Support physician education in the appropriate interpretation and use of genetic tests, including guidance in selection of medication (pharmacogenetics).
5. Work with physicians to promote confidentiality and to use genetic information for the maximum benefits of the member.

And Health plans should not:

1. Establish rules for health coverage eligibility based on genetic testing.
2. Request or require genetic testing results as a condition to providing health insurance coverage.
3. Use genetic testing for risk selection or risk classification purposes in providing health coverage.
4. Disclose genetic testing results that may come into their possession without member authorization.

Health insurers aim to facilitate the cost effective utilization of the scientific method to enhance the health status of individuals. Individuals must be protected from discrimination, while having the advantage of appropriate use of genetic information to enhance their health status. Aetna has proposed guidelines to serve as a benchmark for the industry. We believe that genetic testing should be seen as an effective tool to enhance the health status of individuals and are working hard to accomplish that goal.

## GENETIC INFORMATION

### AETNA'S RECOMMENDED GUIDELINES FOR THE HEALTH INSURANCE INDUSTRY

#### WHEREAS...

Medical Science can detect the presence of a growing inventory of genes that influence either the development of a disease or the effectiveness and/or safety of a specific treatment.

Health plans can play an important role in promoting access to clinically useful genetic testing and the proper interpretation of test results.

There is substantial public concern regarding the potential for the inappropriate use of genetic information.

Legislation specifically regulating a health plan's use of genetic information, while present in most states, varies considerably from state to state.

There is a pressing need for the health insurance industry to establish guidelines for covering genetic testing and the interpretation of test results.

#### THEREFORE, HEALTH PLANS SHOULD MAKE AVAILABLE PRODUCTS TO THEIR SELF-INSURED PLAN SPONSORS AND THEIR FULLY INSURED CUSTOMERS THAT...

Cover genetic testing in individuals shown to be at risk where results may affect the course of treatment of the insured.

Cover genetic testing for a family member where the family member is not otherwise insured and results may affect the course of treatment of an at-risk insured.

Cover consultation with qualified counselors and physicians and facilitate the appropriate interpretation of genetic testing results.

Support physician education in the appropriate interpretation and use of genetic tests, including guidance in selection of medication (pharmacogenetics).

Work with physicians to promote confidentiality and to use genetic information for the maximum benefit of the member.

#### AND HEALTH PLANS SHOULD NOT...

Establish rules for health coverage eligibility based on genetic testing.

Request or require genetic testing results as a condition to providing health insurance coverage.

Use genetic testing for risk selection or risk classification purposes in providing health coverage.

Disclose genetic testing results that may come into their possession without member authorization.



Mr. CHABOT. Thank you, Doctor.  
Ms. Husted?

**STATEMENT OF JOANNE L. HUSTEAD, J.D., SENIOR COUNSEL,  
HEALTH PRIVACY PROJECT, AND ASSISTANT RESEARCH  
PROFESSOR, INSTITUTE FOR HEALTH CARE RESEARCH,  
GEORGETOWN UNIVERSITY**

Ms. HUSTEAD. Thank you. Thank you very much for the opportunity to testify here today. My name is Joanne Husted. I'm senior counsel with the Health Privacy Project at Georgetown and an assistant research professor at Georgetown's Institute for Health Care Research and Policy.

I want to thank you for holding this hearing today on such an important issue and especially for considering both collection and use of genetic information. The two are inextricably linked.

The best way to protect against discrimination or against inappropriate use of genetic information is to limit collection of the information in the first place.

It is essential that the law protect the privacy of people's medical information. Protecting privacy and promoting access to quality care go hand-in-hand. If we fail to protect privacy, many people will not seek the care they need, to the detriment of their own health.

It's difficult enough to decide whether to have a genetic test in a clinical or a research setting. In weighing the pros and cons, people should not have to worry about secondary ramifications, like not being able to get or afford health insurance or not being able to get a job.

I'm going to focus on two Federal laws today, HIPAA and the Americans with Disabilities Act, and why they do not adequately protect the privacy of genetic information.

Let's begin with HIPAA. HIPAA has two parts that are relevant to today's hearing, the part that led to the HIPAA privacy regulation and the part that contains the so-called nondiscrimination provisions.

First, the privacy regulation: The HIPAA privacy regulation does not explicitly refer to genetic information. The regulation uses the term "protected health information." That term is broadly defined, and it will encompass genetic information. But to be protected, that information must be created or received by a covered entity. The only entities that are covered under the privacy regulation are health plans, a subset of providers, and health care clearinghouses, not employers, not drug companies, not pharmacy benefit managers, not companies that make or sell genetic tests, not workers' comp insurers, not any other entity that creates or receives health information.

There are other significant limits to the HIPAA regulation. Let me give four examples. One, it does not generally prohibit covered entities like health plans from collecting genetic information or from requiring that people undergo genetic tests or provide genetic information. Two, it permits health plans to use genetic information for medical underwriting. Three, it allows providers, like pharmacies, and health plans to use health information without permission for what we believe are marketing or commercial purposes.

Four, the regulation does not provide meaningful enforcement rights when people's privacy is violated.

Now let's look at the HIPAA nondiscrimination provisions. Unlike the privacy regulation, the nondiscrimination provisions explicitly refer to genetic information. They prohibit the use of genetic information in some enrollment and premium-setting determinations. But there are significant gaps. Let me highlight five. One, health plans and insurers can still request and require and collect genetic information. Two, insurers can refuse to cover an entire group of more than 50 people because of the genetic information of one person. Three, insurers can charge an entire group more because of the genetic information of one person. Four, insurers in the individual market can refuse coverage on the basis of one person's genetic information unless that person falls within a very narrow subset of individual policy-seekers who are protected under HIPAA. Five, insurers in the individual market can use genetic information to set premiums.

Finally, let me look at the ADA. The Americans with Disabilities Act permits employers to collect much more medical and genetic information than they need to assess whether a person can actually perform the essential job functions. Indeed, the ADA allows employers to go on a fishing expedition once the employer extends a conditional job offer. By that, I mean an offer that is conditioned upon passing a medical examination.

Keep in mind that an employer does not need to operate a genetic testing program or require that people take genetic tests in order to collect genetic information at this post-offer phase. All they need to do is require that a person sign a blanket medical release that authorizes the disclosure of their medical records to the employer. Getting the job can be conditioned upon signing that release.

Employers can then use any medical or genetic information they come across during this fishing expedition to take away the conditional job offer, as long as the person isn't a person with a disability or regarded as having a disability. Because of court decisions interpreting the ADA, it is becoming increasingly difficult for people with actual, serious medical conditions, like cancer and epilepsy and mental illness, to come within the law's protections. In this environment, people with genetic predispositions are not likely to fare well. The ADA's protections are, in short, uncertain at best.

Given these shortcomings in Federal law, there is much that Congress can do. Filling the gaps that I just mentioned would be a good place to start. Doing so would give people greater confidence that their genetic information will be used to help them and not to hurt them.

Thank you.

[The prepared statement of Ms. Husted follows:]

PREPARED STATEMENT OF JOANNE L. HUSTEAD

Chairman Chabot, Congressman Nadler, and Members of the Committee, thank you for the opportunity to testify here today on behalf of the Health Privacy Project. I am Joanne L. Husted, Senior Counsel for the Health Privacy Project and Assistant Research Professor at Georgetown University's Institute for Health Care Research and Policy. The Health Privacy Project is part of the Institute for Health Care Research and Policy.

## I. OVERVIEW OF THE HEALTH PRIVACY PROJECT

The Health Privacy Project's mission is to press for strong, workable privacy protections in the health care arena, with the goal of promoting increased access to care and improved quality of care. The Project conducts research and analysis on a wide range of health privacy issues. Recent Project publications include: *Genetics and Privacy*, American Journal of Law & Medicine, 28 (2002) 285–307;<sup>1</sup> *Genetics and Privacy: A Patchwork of Protections*, published by the California HealthCare Foundation (2002); *Implementing the New Federal Health Privacy Rule in California* (set of three guides for various types of health care providers, health insurers, and health care service plans), published by the California HealthCare Foundation (2002); *Exposed Online: Why the New Federal Health Privacy Regulation Doesn't Offer Much Protection to Internet Users*, published by the Pew Internet & American Life Project (2001); *Privacy and Confidentiality in Health Research* (2001), commissioned by the National Bioethics Advisory Commission; *Best Principles for Health Privacy* (1999), which reflects the common ground achieved by a working group of diverse health care stakeholders; *The State of Health Privacy* (1999), the only comprehensive compilation of state health privacy statutes (an updated version of these state-by-state summaries can be found on our Web site ([www.healthprivacy.org](http://www.healthprivacy.org))); *Report on the Privacy Policies and Practices of Health Web Sites* (2000), which found that the privacy policies and practices of 19 out of 21 sites were inadequate and misleading; and "Virtually Exposed: Privacy and E-Health," published in *Health Affairs*, Vol. 19 (#6) 140–148 (2000).

The Project also staffs the Consumer Coalition for Health Privacy, comprised of over 100 major disability rights, disease, labor, and consumer advocates as well as health care provider groups. The Coalition's Steering Committee includes AARP, American Nurses Association, Bazelon Center for Mental Health Law, National Association of People with AIDS, Genetic Alliance, National Multiple Sclerosis Society, and National Partnership for Women & Families.

## II. SUMMARY OF TESTIMONY

The purpose of this testimony is to examine the extent to which certain existing federal laws protect the privacy of genetic information in the insurance and employment sectors. The protections in the insurance sector stem from two aspects of the 1996 Health Insurance Portability and Accountability Act (HIPAA)—the HIPAA privacy regulation and the HIPAA "nondiscrimination" provisions. To assess privacy protections in the employment sphere, it is necessary to begin with an assessment of the privacy protections (and gaps) in the Americans with Disabilities Act (ADA). This hearing correctly focuses on both *collection* and *use* of genetic information, because collection and use are inextricably linked. The best way to protect individuals from inappropriate uses of their genetic information is to prevent collection of their genetic information in the first place.

**HEALTH PLANS AND INSURERS.** The HIPAA privacy regulation protects genetic information to the same extent that it protects other types of health information. There are significant limits to what the HIPAA privacy regulation can and does accomplish. For example, the HIPAA privacy regulation does not generally prohibit the entities subject to the privacy regulation from collecting genetic information from individuals or from requiring people to provide genetic information or undergo genetic tests. Nor do the HIPAA nondiscrimination provisions. The privacy regulation permits health plans and insurers to use protected health information, including genetic information, for a broad range of health care purposes, including medical underwriting. The HIPAA nondiscrimination provisions prohibit some underwriting uses of medical and genetic information, but many gaps remain, especially in the individual insurance market. HIPAA does not directly regulate employers; instead, it reaches group health plans that are sponsored by employers.

**EMPLOYERS.** There is no federal law that explicitly regulates the collection, use, or disclosure of genetic information by employers. In fact, employers can, consistent with federal law, obtain vast amounts of medical and genetic information about employees (and, in some cases, their dependents). Because of the ADA's wide applicability, it is the most important federal law to consider when evaluating medical and genetic privacy in the workplace. It establishes a regime where access to medical information and use of medical information hinge on when the information is requested and the context in which it is used. Unfortunately, the ADA permits em-

<sup>1</sup> Significant portions of the text in this testimony are taken from this law review article published in the American Journal of Law & Medicine. The Health Privacy Project wishes to thank the American Society of Law, Medicine & Ethics and Boston University School of Law for permission to include portions of this (c) 2002 article in this testimony.

ployers to collect more medical and genetic information than is necessary to assess whether an individual can perform essential job functions. Moreover, due to narrow and limiting court decisions, it is increasingly likely that the ADA will fail to protect individuals from adverse employment actions on the basis of such genetic information.

Given these shortcomings in existing federal law, the enactment of additional legislation targeting the collection and use of genetic information by insurers and employers would provide additional and significant privacy protections.<sup>2</sup>

### III. THE NEED TO PROTECT THE PRIVACY OF MEDICAL AND GENETIC INFORMATION

Medical information constitutes the most sensitive and personal information. Genetic information, which is a subset of medical information, is particularly sensitive because it reveals unique and immutable attributes, because those attributes are not just personal, but shared by family members as well, and because this information has the potential, in some circumstances, to give us (and others) a frightening (or reassuring) glimpse into the future. Faced with potential discrimination, loss of benefits, and stigma if their health information, including their genetic information, falls into the wrong hands, people are withdrawing from full participation in their own health care.

According to a national survey released by the California HealthCare Foundation in 1999, 15 percent of adults say they have done something out of the ordinary to keep medical information confidential. These privacy-protective behaviors include paying out-of-pocket despite having insurance coverage, doctor hopping to avoid a consolidated medical record, not seeking care to avoid disclosure to an employer, and giving incomplete or inaccurate information in a medical history.<sup>3</sup> A 1997 survey documenting people's fears about genetic discrimination showed that 63 percent of people would not take genetic tests if health insurers or employers could obtain the results, while 85 percent believed that employers should be prohibited from obtaining information about people's genetic conditions, risks, and predispositions.<sup>4</sup> A recent study involving genetic counselors documents that fear of discrimination is a significant factor affecting willingness to undergo testing and to seek reimbursement from health insurers.<sup>5</sup>

### IV. FRAMEWORK FOR ASSESSING THE ADEQUACY OF MEDICAL PRIVACY LAWS

There are four basic components to protecting the privacy of medical or genetic information:

- *Access* (Who should have access to a person's genetic information, under what circumstances, and for what purposes?)
- *Use* (How should those who obtain such information be allowed to use it? What uses should be prohibited?)
- *Disclosure* (To whom should those who create/obtain/receive genetic information be permitted to disclose it, and for what purposes?)
- *Storage/security* (What safeguards and safety precautions must be in place to make sure that medical or genetic information is not obtained, used, or disclosed inappropriately?)

Because this hearing concerns the collection and use of genetic information by insurers and employers, this testimony will focus on the first two: access and use.

The access component involves whether and when one person or entity can request or require that an individual divulge genetic information or undergo genetic testing. Policy makers may very well conclude that the divulging of genetic information in some circumstances is appropriate (*e.g.*, voluntary treatment-related disclosures) yet totally inappropriate in others (*e.g.*, requiring genetic tests as a precondition to applying for health insurance).

The use component encompasses how people or entities should be allowed to use a person's genetic information. The concept of use implies not only permissible uses but impermissible ones as well. Thus, as part of an effort to protect the privacy of

<sup>2</sup>One bill pending in the House of Representatives would do just that: the Genetic Non-discrimination in Health Insurance and Employment Act (H.R. 602).

<sup>3</sup>This survey is available at the California HealthCare Foundation's Web page: [www.chcf.org](http://www.chcf.org).

<sup>4</sup>This and other surveys are summarized in a joint report, *Genetic Information and the Workplace*, issued on January 20, 1998 by the U.S. Departments of Labor, Health and Human Services, and Justice, and the U.S. Equal Employment Opportunity Commission.

<sup>5</sup>Hall, Mark A. and Stephen S. Rich, *Genetic Privacy Laws and Patients' Fear of Discrimination by Health Insurers: The View from Genetic Counselors*, 28 *Journal of Law, Medicine & Ethics* 245-57 (2000).

genetic information, health care professionals may be permitted to use genetic information for treatment purposes, while health insurers may be prohibited from using such information for medical underwriting (i.e., deciding whom to insure and at what price).

Laws that achieve the latter (prohibiting certain uses of genetic information) are often referred to or categorized as genetic “nondiscrimination” laws rather than as privacy laws. Yet, viewed through the lens of the four components listed above, protecting privacy is, in part, about allowing certain uses while *prohibiting* other uses, including discriminatory uses of genetic information.

The best way to prevent discrimination of all kinds is to use a two-pronged approach. First, where possible, cut off access to information about the characteristic at issue, whether national origin, religion, disability, or genetic predisposition. This exemplifies a strict “privacy” approach. Second, prohibit the use of any information obtained despite shutting down the flow of information. Rather than treating privacy laws or policies as separate from nondiscrimination laws or policies, or as addressing different harms or promoting different values, it makes sense to consider both together under the expansive privacy rubric laid out above.

#### V. THE HIPAA PRIVACY REGULATION

The medical privacy regulation was issued by the U.S. Department of Health and Human Services (HHS) in December 2000 in response to a mandate from Congress dating back to the 1996 HIPAA law. It is a milestone in federal law. It is the first—and only—federal law to protect the privacy of medical information in the hands of private health care providers and health plans. HHS published final modifications to the regulation on August 14, 2002. Most entities that must comply with it have until April 2003 to do so.

The privacy regulation had significant shortcomings when it was first released in final form in December 2000. One of the most notable shortcomings is the limited range of entities that must act to protect patient privacy.<sup>6</sup> It does not directly regulate all people or entities that have access to protected health information, such as employers (except possibly in their potential role as health care providers), pharmaceutical companies, workers’ compensation insurers, and many researchers. Another significant shortcoming is the lack of a federal private right of action for people whose privacy rights are violated. These shortcomings reflect the limited authority given by Congress to HHS in HIPAA.

Due to final modifications released in August 2002, the HIPAA privacy regulation has been furthered weakened. The Health Privacy Project is particularly concerned by HHS’ decision to eliminate the provider consent requirement and to open up people’s medical files for marketing activities without prior authorization. While HHS claims to have strengthened the marketing provisions by requiring prior authorization for marketing, the Department has done quite the opposite: HHS has defined the term “marketing” in a way that effectively legalizes some of the most egregious marketing tactics of the chain drug stores and their partners, the pharmaceutical industry.

##### A. The HIPAA Privacy Regulation and Genetic Information

The HIPAA privacy regulation will protect the privacy of genetic information, with one important caveat: it will only protect genetic information to the extent that it protects other health information. Because there are limits to what the HIPAA privacy regulation can and does accomplish, the enactment of additional legislation targeting genetic information could provide additional and significant privacy protections.

Although the HIPAA privacy regulation singles out only one type of health information for special treatment—psychotherapy notes—genetic information will be protected by this regulation as long as it meets the definition of “protected health information.” This term—protected health information—is defined broadly and includes information about the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present,

<sup>6</sup>The following entities are required to comply with this new federal law:

- health care providers (doctors, hospitals, clinics, pharmacies, laboratories, etc.) that transmit claims-type information electronically in standard formats;
- health plans (broadly defined to include private insurers, employer-sponsored health plans, and HMOs, as well as a number of health programs sponsored by the federal and state governments); and
- health care clearinghouses (which act as claims processing intermediaries between health care providers and health plans).

or future payment for the provision of health care to an individual. HHS, in the preamble accompanying the final regulation, confirmed that “the definition of protected health information includes genetic information that otherwise meets the statutory definition.” See 65 Fed. Reg. 82621 (Dec. 28, 2000).

Under this definition, information about genetic tests, services, or counseling will clearly be protected, as will information about an individual’s family history—an important component of genetic information. Although the definition of protected health information does not explicitly refer to family history, HHS clarified in the introductory preamble to the regulation that medical information about a family member contained within an individual’s medical record is information about the individual. See 65 Fed. Reg. 82493 (Dec. 28, 2000).

Health care providers that provide general medical services and that create or receive genetic information, as well as specialists that provide genetics services, perform genetic tests, or interpret genetic test results, will have to comply with the HIPAA privacy regulation if they otherwise meet the definition of a covered provider. The essential prerequisite for providers to be “covered” is that they transmit claims-type information electronically using HHS-prescribed standard formats.<sup>7</sup> This may mean that genetic information compiled, or genetic testing performed, in a research context will not be protected by the HIPAA regulation. Protection of genetic information in the research context will depend on whether the researcher is functioning as a health care “provider” and, if so, whether the researcher (or the institute that employs him or her) bills insurance companies electronically for health care services.<sup>8</sup>

Falling within the scope of the HIPAA privacy regulation means that genetic information will be protected to the same extent as other health information. Within the confines of the HIPAA privacy regulation, genetic information is not treated differently than other types of protected health information. Thus, providers and health plans can, without consent or authorization, use and disclose protected health information, including genetic information, for treatment, payment, and health care operations purposes (the latter is especially rather broadly defined). As with other health information protected by this regulation, some uses and disclosures will require the opportunity to opt out in advance, some will require specific individual authorization, and other uses and disclosures can proceed without authorization or the opportunity to opt out. One of the more controversial aspects of this regulation is that it will permit health care providers and plans to use (and disclose to a business associate) protected health information to send commercially motivated communications, including communications paid for by a third party, recommending that the patient use the third party’s products or services. We consider such communications to constitute marketing, but the regulation defines them as *not* marketing.

It is important to note that the HIPAA regulation will *not* prevent covered health plans from requesting that individual plan members provide genetic information to the plan or from requiring applicants for insurance to provide genetic information or undergo genetic tests as part of the insurance underwriting process. The regulation will, however, impact health plan or insurer requests that a covered health care provider disclose a patient’s genetic information. How the privacy will impact those requests depends upon the context, specifically the purpose of the request. For example, an insurer seeking genetic information about an insurance applicant from a covered health care provider would need to provide the health care provider with an authorization signed by the applicant. Also, the regulation’s “minimum necessary” standard should prevent a health plan from insisting that a covered health care provider disclose to it the results of a genetic test involving a plan member when the results of that test are not necessary for the health plan to reimburse the provider for conducting the test.

#### *B. The HIPAA Privacy Regulation and Employer-sponsored Group Health Plans*

As noted above, employers are not covered entities under the HIPAA privacy regulation. The regulation does, however, attempt to limit disclosures of protected health information, including genetic information, by group health plans and insurers to employers that sponsor group health plans. This is important because of the

<sup>7</sup> A recent federal law (Pub. L. No. 107–105) eliminates, for the 6-month period between April 14, 2003 and October 16, 2003, any requirement that the electronic transmission conform to HHS-prescribed standard formats. This law does not delay the compliance time frame for the privacy regulation.

<sup>8</sup> Research involving genetic information will also be impacted by the regulation to the extent that researchers attempt to obtain protected health information from an entity that must comply with the regulation. Before covered entities can disclose patient identifiable information to researchers, certain requirements must be met.

legitimate concern that many have about their employer having access to private medical information. The HIPAA regulation goes as far as it can to protect workers and their dependents from inappropriate disclosures to employers/plan sponsors and from inappropriate uses by employers/plan sponsors, but it does *not* shut down the flow of information. Only Congress can close this pipeline.

The HIPAA regulation permits group health plans and insurers to share protected health information with the employer/plan sponsor only when certain requirements are met. In essence, the employer must first amend the documents that govern the establishment of the health plan to include assurances that the employer will use the information only to administer the group health plan and will not use the information to make employment decisions. The employer/plan sponsor must also erect firewalls to separate the group health plan functions of the employer/plan sponsor from the rest of the employer/plan sponsor. Under the regulation, only employees involved in health plan administration would have access to protected health information. Employees wearing multiple “hats” could legitimately use other employees’ protected health information to *administer the group health plan*, but they could not use this information for any other purpose.

The HIPAA regulation may impact one other way that employers obtain protected health information about their employees. An employer that actually provides health care services to its employees, such as through an on-site medical clinic, may, with respect to the provision of such care, be a health care provider that is required to comply with the HIPAA regulation. As with all other health care providers, the provider would have to engage in standard electronic HIPAA transactions in order to be a “covered” provider under the privacy regulation.<sup>9</sup> In general, providers will meet this electronic transmission prerequisite by engaging in electronic transactions with insurers, such as submitting claims for services to insurers. Since it is hard to imagine an employer’s on-site clinic engaging in such transactions, the health information created or received in these programs will generally not be protected by the privacy regulation.

#### VI. HIPAA NONDISCRIMINATION PROVISIONS

Unlike the HIPAA privacy regulation, other provisions in HIPAA *explicitly* address genetic information. These provisions are referred to as the HIPAA “non-discrimination” provisions, and they are in a different title of the HIPAA statute than the provisions that led to issuance of the privacy regulation. These non-discrimination provisions prevent health plans and insurers, in the group market, from refusing to enroll an individual due to that individual’s (or a dependent’s) genetic information. These provisions also prohibit charging one individual (or family) in a group more than others in the group on the basis of the individual’s (or a dependent’s) genetic information. These provisions also prohibit insurers in the individual insurance market from refusing to enroll, for any health-related reason, a subset of individuals who are leaving the group market and meet other prerequisites.

Although the HIPAA nondiscrimination provisions provide important federal protections, significant gaps remain. Even with the nondiscrimination provisions, health plans and insurers can collect genetic information, and there are a number of ways that insurers can use genetic information in the underwriting process. For example:

- Groups health plans and insurers may request, require, purchase or otherwise collect genetic information about an applicant’s genetic information in the group and individual markets.
- Insurers in the mid- and large-size group market may refuse to cover an entire group because of the genetic information of one individual in the group. (Under HIPAA, employers with between 2 and 50 employees are considered to be the “small group market.”)
- Insurers in the group market may charge an entire group (of any size) more than another group because of the genetic information of one individual in the group.
- Insurers in the individual market may deny coverage because of an applicant’s genetic information unless the individual falls within the narrow category of individual market applicants that HIPAA protects (generally those leaving the group market who meet other prerequisites).
- Insurers in the individual market may treat a genetic predisposition as a pre-existing medical condition (and refuse to provide coverage for expenses relat-

<sup>9</sup>See footnote 7 regarding the temporary elimination of the standard format prerequisite.

ing to it) unless the individual falls within the narrow category of individual market applicants that HIPAA protects.

- Insurers in the individual market can set premiums based on an applicant's genetic information.

To more fully protect privacy, each of these gaps should be filled.

#### VII. EMPLOYER COLLECTION AND USE OF GENETIC INFORMATION<sup>10</sup>

Not surprisingly, people are extremely concerned about employer access to health information, including genetic information. When it comes to the collection and use of medical information, employers occupy a unique position because they play multiple roles. As employers, they decide whom to hire and fire. As sponsors of health plans for employees and dependents, they pay for health care services. In this "payor" role, employers have access to claims information.<sup>11</sup> Indeed, according to a recent survey, a startling 36 percent of large employers have the ability to link medical care data to individual employees.<sup>12</sup>

People are especially alarmed at the prospect of employers using medical claims information for non-medical employment-related decisions such as deciding which employees to promote or to lay off during a reorganization. Just over 40 percent of people surveyed are concerned about their job opportunities being affected adversely if their employer sees their medical claims information.<sup>13</sup> This alarm is justified, given that people have so much to lose—their job, their livelihood, their reputation, their self-esteem, and the very health insurance that gave their employer this window into their private life.

The recent case of Terri Seargent illustrates what can happen to an employee when her employer, which provides her health insurance, learns that she has a genetically based condition. Ms. Seargent was fired from her job, despite favorable performance appraisals, after she began receiving preventative drug therapy for Alpha-1 antitrypsin deficiency and submitted claims for that therapy to her employer's health plan.

Medical claims information is just the tip of the proverbial iceberg. There are many different ways that employers obtain health information about employees (and sometimes dependents) other than through the claims submitted to the group health plan. Other avenues for collection of medical information include:

- Post-offer, pre-placement medical exams;<sup>14</sup>
- Periodic medical exams to assess fitness for duty;
- On-site medical clinics;
- Employee assistance programs;
- Occupational safety and health examinations;
- Workers' compensation claims;
- Paid or unpaid sick leave;
- Family or medical leave; and
- Accommodations for disability.

All of the ways in which employers may obtain health information could result in employers obtaining *genetic* information. For decades, some employers have performed genetic testing on their employees or obtained genetic test results, and some

<sup>10</sup>This section of the testimony deals with genetic information in the hands of private employers. Federal government workers have additional protections as a result of an executive order issued by President Clinton in February 2000 (Exec. Order No. 13,145).

<sup>11</sup>As noted above, the HIPAA privacy regulation regulates employer access to medical information from the group health plan but does not stop the flow of information.

<sup>12</sup>See Kaiser/HRET Survey of Employer-Sponsored Health Benefits: 2001, as reported in Kaiser/HRET, *California Employer Health Benefits Survey, 2001* (Feb. 2002), chart #30.

<sup>13</sup>Harris-Equifax, *Health Care Information Privacy: A Survey of the Public and Leaders* (Louis Harris and Associates 1993), at 83. This survey did not probe attitudes about employer access to genetic information via health plan claims.

<sup>14</sup>Many employers, indeed most large employers, require that newly hired employees take medical examinations. According to a 2001 survey by the American Management Association, 65 percent of major U.S. firms require medical examinations of new hires. A summary of this AMA survey is available at: <http://www.amanet.org/research/summ.htm> (accessed 9/9/02). Medical examinations required by employers can be quite far reaching, especially at the post-offer, pre-placement stage, and the AMA survey confirms that employers use the results when they make decisions about hiring, placement, retention, and dismissal.

have used that information for employment purposes, but such practices have never been widespread.<sup>15</sup>

Unfortunately, there is no solid source of empirical evidence to document how often or for what purpose employers currently obtain genetic information about job applicants or employees or require them to undergo genetic testing. What little evidence there is—the 2001 survey of the American Management Association—it is far from authoritative. Nonetheless, this survey reveals that some major U.S. firms acknowledge conducting genetic testing of employees. According to this survey, one percent of major U.S. firms test new hires or employees for sickle cell anemia, .4 percent conduct genetic testing for Huntington’s Disease, and 14 percent conduct medical examinations to detect susceptibility to workplace hazards (which the surveyors acknowledge might involve genetic testing). The three percent of major U.S. firms that perform testing for breast and colon cancer appear to be conducting genetic testing to assess predisposition to breast and colon cancer, rather than testing for presence of actual disease.

Most striking, this survey shows that 20 percent of major U.S. firms collect information about family medical history, a rich and important source of genetic information. After all, employers may be just as likely to decline to hire someone whose mother and sisters died of breast cancer in their 40s as they are to decline to hire someone who has actually undergone testing for the known genetic mutations that may indicate an elevated risk of developing breast or ovarian cancer.

One employer’s genetic testing policy recently made front page news and resulted in lawsuits brought by the U.S. Equal Employment Opportunity Commission (EEOC) and a union representing affected workers. The lawsuits challenged the testing as a violation of the ADA. The Burlington Northern and Santa Fe Railway required employees who developed carpal tunnel syndrome to undergo genetic testing—testing that the employer asserted would show whether the employee was predisposed to carpal tunnel syndrome. This testing was done without the employees’ knowledge. As part of an effort to eliminate or minimize the employer’s responsibility for workers’ compensation claims, the employer presumably intended to argue that the injuries of such “predisposed” employees were not sufficiently “work-related.” Respected leaders in the scientific community soundly denounced the genetic testing done by Burlington Northern as “junk science.” As a result of the publicity and lawsuits, the company stopped the testing and entered into a series of settlement agreements. Thus, the complex legal issues raised by this type of testing were not thoroughly hashed out in the courts.

#### A. *The Americans with Disabilities Act (ADA)*

The ADA was enacted in 1990 to protect people from discrimination on the basis of disability, and, because of its wide applicability, it is the most important federal law to consider when evaluating medical and genetic privacy in the workplace. It establishes a regime where access to medical information and use of medical information hinge on when the information is requested and the context in which it is used.<sup>16</sup>

##### 1. *Collection of Medical Information and Conditional Job Offers*

Under the ADA, employers are prohibited from requesting medical information about job applicants prior to an offer of employment. At this point, an employer is limited to collecting job-related information. But the rules change after an employer extends a “conditional” job offer, where such offer is contingent upon “passing” a medical examination. At this stage, employers are permitted to require a comprehensive medical examination and ask any medical questions. The employer also has the option of requiring the prospective employee to sign a blanket release authorizing his or her health care providers to provide the employer with a complete set of medical records. It is important to emphasize that employers do not need to conduct genetic testing programs in order to collect genetic information about prospective employees. All employers need to do at the conditional offer stage is require the signing of a blanket release authorizing others to disclose the individual’s medical records to the employer.

Medical examinations or inquiries at this “conditional offer” stage do *not* have to be related to the person’s ability to perform the job. This clearly results in employ-

<sup>15</sup> For a history of workplace genetic testing, see Congress of the United States Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace* (1990). See also L. Camille Hbert, “Genetic Testing,” *Employee Privacy Law* (West Group 2001).

<sup>16</sup> 42 U.S. C. § 12112(d). For a recent, comprehensive discussion and critique of the ADA’s approach to medical examinations and inquiries, see Sharona Hoffman, *Preplacement Examinations and Job-Relatedness: How to Enhance Privacy and Diminish Discrimination in the Workplace*, 49 *Kansas Law Review* 517 (2001).

ers collecting much more medical information than they need to assess the individual's ability to perform the job.

The only aspect of the ADA that may operate to limit the frequency of open-ended post-offer medical exams or inquiries is the requirement that all entering employees be subjected to such examinations; the employer cannot pick and choose, arbitrarily or based upon some particular suspicion, which specific prospective employees shall be required to undergo the examination or answer medical questions.<sup>17</sup>

While, theoretically, the employer is permitted to use this medical information to retract the job offer *only* if the medical examination shows that the person is unable to perform the essential job functions, the ADA only protects *certain* people from job discrimination: people with a current or former disability (or a record of such a disability) and those "regarded as" having a disability. The U.S. Supreme Court has consistently narrowed the scope of the ADA's protections by limiting who fits within these disability-related categories, thus making it hard to stop an employer from using medical information to retract a conditional job offer. If the person does not fit within these narrowly defined categories, the ADA does not protect him or her. To fit within the "regarded as" prong, it is not enough to show that the employer retracted the conditional job offer because the employer perceived the person as having a disability. Instead, the person must show that a range of employers would have perceived the individual as having a disability, a difficult burden of proof indeed.

What does this mean for a healthy individual with a genetic predisposition to developing some sort of medical condition in the future? Although the EEOC takes the position that the ADA prohibits employers from discriminating against people on the basis of their predictive genetic information,<sup>18</sup> it has become increasingly clear that this interpretation may rest on shaky footing. This interpretation of the ADA relies on the "regarded as" language in the ADA, which is supposed to protect people who are not presently or formerly disabled but are regarded as having a disability. A person who is not disabled, but who is genetically predisposed to have a medical condition in the future might, theoretically, be protected from discrimination under this prong of the ADA. Unfortunately, as a practical matter, people with predictive genetic information will not likely fare too well in ADA challenges because of the trend of court decisions in recent years eroding the ADA's protections, especially the protections for people seeking protection under the "regarded as" prong.<sup>19</sup>

## 2. ADA and the "Threat-to- Self" Issue

There is another aspect of the ADA that is relevant to whether employers can legally refuse to hire (or fire) people who have a genetic predisposition to developing some medical condition in the future. This aspect of the ADA would be relevant in circumstances where a person might develop a condition associated with a genetic mutation in response to some occupational exposure. In such a case, the employer might argue that working in the job poses a threat to the individual's own health.

Under the ADA, an individual seeking the law's protections must be qualified to perform the essential functions of the job. In June of this year, in *Chevron v. Echazabal*, the U.S. Supreme Court upheld EEOC regulations stating that a person who poses a danger to himself or herself in the workplace is not deemed qualified.

<sup>17</sup> While intended to prevent discrimination against people with disabilities, this aspect of the ADA also protects privacy if it operates to limit the frequency of such medical examinations and inquiries. On the other hand, privacy would be compromised if this aspect of the ADA actually led to more people being required to undergo medical examinations or answer medical inquiries.

Another ADA-related access issue concerns access to medical information within the employer entity. Uncertainty about how the ADA limits internal access to medical information (within the employer entity) has led to many *requests* by management and supervisory personnel that occupational medical personnel release an employee's entire medical record or disclose an employee's underlying diagnosis when much less information would suffice to answer the question at hand: Is the employee fit for duty, or what kind of workplace accommodation is needed to enable the person to do the job? Under a proper interpretation of the ADA, such overly broad requests should be denied. Unfortunately, uncertainty regarding the ADA's rules often results in such requests being accommodated. The best way to handle access within the employer entity would be to require that medical personnel act as the custodian of all medical information and that they be authorized to provide only the specific information needed to respond to a legitimate—and narrow—inquiry from management or supervisory personnel.

<sup>18</sup> For a thorough discussion of the ADA and genetic discrimination, see Paul Steven Miller, *Is There a Pink Slip in My Genes? Genetic Discrimination in the Workplace*, 3 J. Health Care Law & Policy 225–265 (2000).

<sup>19</sup> For a comprehensive discussion of how the ADA's coverage has been significantly restricted, see Chai R. Feldblum, *Definition of Disability Under Federal Anti-Discrimination Law: What Happened? Why? And What Can We Do About It?*, 21 Berkeley Journal of Labor and Employment Law 91 (2000).

The result is to give employers even more of an incentive to probe into the medical histories and medical status of new hires and employees. Employers have the green light, and in the wake of *Chevron* may perceive a heightened duty, to assess whether the individual might have some medical condition (or even a predisposition to getting a condition) that might be aggravated on the job. However, before making a hiring decision on the basis of such a perceived threat to the individual's health, the governing regulations require the employer to assess the immediacy of the threat and the nature and significance of the threat.

#### VIII. CONCLUSION

In 1996, Congress began to protect the privacy of genetic information by including "nondiscrimination" provisions in HIPAA and by setting in motion the process that led to issuance of the HIPAA privacy regulation. But HIPAA and the ADA—even together—do not constitute a comprehensive approach to protecting the privacy of genetic information. Even in the insurance and employment sectors—the sectors impacted by these laws—much remains to be done. Bills pending in this Congress would build upon HIPAA, including the HIPAA privacy regulation, and upon the ADA to provide additional significant privacy protections for genetic information in the health insurance arena and in the employment sector.

Mr. CHABOT. Thank you very much.  
And our final witness will be Dr. Peel.

#### **STATEMENT OF DEBORAH PEEL, M.D., PRESIDENT, MENTAL HEALTHCARE FOUNDATION**

Dr. PEEL. Thank you, Chairman Chabot and Members of the Committee. I am so honored to be here. I am so thrilled to have this opportunity to talk to you about this absolutely critical need to protect genetic information. And the urgency could not be greater because, starting October 15th, the Federal Government, through the new amendments to HIPAA, is going to give regulatory permission to health plans, for purposes of health care operations, to have access to your cradle-to-grave medical records.

This is retroactive permission to access everyone's medical records, yours, your family's. Every citizen in this country is about to have the complete loss of control over all of their most sensitive information. And the information about our genes, our genomes, is absolutely the most personal medical information that exists. It's the information from which we were created.

I'm honored to be here because I'm not a researcher and I'm not a legal scholar, and I'm a regular doctor. And that's all I've been doing, is seeing real people for the last 25 years. And I'm a psychiatrist and psychoanalyst.

And I have to tell you that every person that I see in my practice, these issues of privacy are not theoretical. They are real issues. People would not tell me anything sensitive; they would not disclose any information if they thought that it was going to be on the Internet or if it was going to go to their employer.

And that's the reason that so many people that come for treatment to see me pay out of pocket. There are people that even pay cash because they know that with Gramm-Leach-Bliley, your banks can share financial information, such as—you know, you see "Dr. Peel" on your check. They can share that with all of their affiliates and nonaffiliates and the whole universe. That's that cartoon that I distributed.

So the urgency of this issue could not be greater. And I believe these are constitutional issues. In my testimony, in my written testimony, I think I outline for you why I believe, why we believe, that

the rights to privacy really are constitutional issues protected by the First, Fourth, and Fifth amendments.

Let me just say one other thing about what happens in our practice. As a physician, I know exactly how frequent discrimination is based on people's medical mental conditions and even genetic conditions. In fact, we give our patients Miranda warnings: "If you use a third-party payer, anything you say, any test we get, can and will be used against you in the future." I mean, that's what the practice of medicine is today. If you have an expensive, chronic, or stigmatized condition, you better watch out.

And I think the way to really personalize this is think about what can happen right now. A mother with two sons under the age of 5 is going to get a divorce. She's served with divorce papers. Her father is schizophrenic. Okay, should her risk of getting breast cancer in the future or schizophrenia in the future determine whether she gets custody of her children? Should it?

Okay, the couple separates. Should genetic testing of the children be used to determine their risks of future health conditions and determine how much child support the father has to pay? Should it?

Okay, they get a divorce. Now the single mother with two children has to try to get a house. Should the mortgage company be able to use the results of genetic testing to determine whether or not to give her a loan to buy a house.

And finally, shortly after the divorce, her husband is killed in a car accident. Should the genetic testing results that would predict his life expectancy be used to help the insurers determine what kind of death benefits go to his family?

Okay, that's not "Future Shock." That's not a "Brave New World." That is possible right now. That's possible right now.

And I think it goes against everything that we think is important in America, which is, we're not all equal, you know, and particularly not genetically, and we have no control over our genes. But what we need is equal opportunity, equal access to opportunity, to education, and to jobs.

And, you know, I have to tell you, in my practice, people are protecting their medical information, they're protecting themselves because they suffer real harms. The harms are very extensive: job loss, bankruptcy, shame and humiliation in the community.

And the problem is that the HIPAA and the amendments to HIPAA do not, in any way, prevent genetic information from being accessed with the new Federal regulatory permission.

And I hope your Committee will look carefully at this Federal regulatory permission, because this is an unprecedented taking of individual rights by the Federal Government, by fiat.

Congress has not even reviewed the HIPAA amendments. And I would urge you to consider reviewing and denying these major rule changes, these major rule changes, the two primary effects of which are to take away everyone's right to consent to the releases of their information and to replace it with a new Federal right called regulatory permission, which the Federal Government is going to give to health plans to access retroactively all of your past health records.

And there's only one further thing that I want to say, that I've learned in my practice. If you want to keep your genetic informa-

tion private, you can bet the only way to do that is to have testing under an alliance.

Thank you very much.

[The prepared statement of Dr. Peel follows:]

PREPARED STATEMENT OF DEBORAH C. PEEL

Chairman Chabot, Representative Conyers, and Members of the Subcommittee:

The mother of two sons under the age of five was served with divorce papers. Her father is schizophrenic. Should the risk of her having breast cancer or a mental disorder in the future keep her from having custody of her children? The couple separates. Should genetic testing of the children be used to assess their potential health problems and alter the amount of financial support their mother receives? The couple divorces. Should the mortgage company be allowed to access the results of her genetic testing to assess her life expectancy before deciding to offer a loan? Shortly after the divorce, her ex-husband was killed in a car wreck by a drunk driver. Should her husband's genetic testing results be used to determine his life expectancy before the accident, to help insurers determine the death benefits for his sons?

This scenario is not science fiction, and it is not future shock. It can happen now in America, in 2002. It may not shock you or me, but the inability of Americans to protect their medical and genetic privacy is very real. Americans are in total denial about the federal government's elimination of their rights to genetic and medical privacy.

The use, sale, and sharing of highly sensitive identifiable genetic and medical information for non-medical purposes is widespread, because our federal, Constitutional, and common law rights have been increasingly ignored. The genetic and medical records of our entire country, which are stored in massive databanks, are being accessed to make business, credit, insurance, educational, and employment decisions, without our knowledge or consent.

Chairman Chabot and members of the committee, thank you for inviting me to speak. I very much appreciate the opportunity to address the urgent need to protect genetic privacy. The urgency comes from the elimination of the federal right to consent to the release of medical records when the amendments to the HIPAA Privacy Rule become effective on October 15, 2002. 67 Fed.Reg. 53,182 (August 14, 2002).

In the history of the right to privacy, October 15th will come to symbolize infamy just as December 7th came to symbolize the most infamous attack in American history prior to Sept 11th.

In only five weeks, the Constitutional right to the privacy of the most personal information that exists about each of us, our genetic information, will be completely stripped away. No man or woman will own or control his or her genetic and medical records, when the amendments to the Privacy Rule go into effect.

INTRODUCTION

I am a physician. My name is Deborah C. Peel. MD. I have been a practicing in Texas for over 25 years. I specialize in psychiatry and psychoanalysis. Privacy is the foundation of my work. No one would ever talk to me about their deepest problems or disclose personal information if they thought their fearful thoughts, their disturbing fantasies, their most personal memories, or their feelings of shame, guilt, and humiliation would ever be revealed. In fact, for decades, the ethical standard of practice for record keeping in psychoanalysis has been NOT to record notes of psychoanalytic sessions. The very existence of records damages trust and impairs the patient's ability to disclose the most sensitive material.

Treatment cannot be effective if privacy is not guaranteed, because patients do not feel safe to fully disclose what is on their minds. The US Supreme Court recognized that even the threat of disclosure of the records of psychotherapy would deprive Americans of effective mental health treatment, because people would either not seek help or not trust the therapist enough to confide in him or her. (US Supreme Court, *Jaffee v. Redmond*, 1996) Reasoning that it was in the public's best interest to have access to effective psychotherapy, the Supreme Court rejected "balancing" the need of federal courts to know what was communicated during the course of treatment with the privacy rights of patients in psychotherapy. The Court upheld the right to the privacy of patient-therapist communications.

I am here to speak on behalf of myself, as well as the American Psychoanalytic Association and the Mental HealthCARE Foundation. The organizations I represent share very strong interests in protecting the right to medical privacy. We want to thank you and commend you for your interest in genetic privacy, a unique component of medical privacy.

But, I'm not here only to represent professionals and advocates. The main reason I came is to speak for the rights of each and every individual American, who stand to lose one of the most vital and important Constitutional rights: the right to privacy, through the public exposure for profit, of their genetic and medical records. Frankly ladies and gentlemen, if the general public understood what has actually been taking place they would be outraged. A June 2000 Time/CNN Poll showed that 75% of those surveyed did not want any information about their genetic code revealed to their insurance company. But insurance companies are the primary depositories of the identifiable genetic information of Americans.

#### THE END OF GENETIC PRIVACY

Every man, woman, and child in this country will be deprived of control of his or her genetic and medical records on October 15th. Let me walk you through what the loss of the right to privacy will mean for every American.

Beginning today, TV, radio, newspapers, and magazines in Atlanta and Denver will be saturated with ads by Myriad Genetics, Inc. encouraging women to get genetic testing for breast and ovarian cancer, at a cost of \$300–\$2,800.

After October 15th, the genetic test results of every woman who undergoes screening for those cancers will become not only the commercial proprietary information of Myriad Genetics, Inc., but become the commercial property of her health plan or insurer, her employer, and also be accessible to over 600,000 other businesses and entities, as well as financial institutions, whether or not she pays for the tests herself, and whether or not she had the tests before October 15th. Access to all genetic and medical records will be retroactive. If she refuses consent for the release of her test results, the government's new "regulatory permission" will override her refusal.

Protecting genetic privacy is a matter of great urgency: every citizen's right to consent to the release of his or her genetic information will be eliminated by the changes in the HIPAA Privacy Rule. By fiat, the federal government has usurped unprecedented new powers which destroy our most precious individual right, the right to be left alone, the right to privacy.

Will we allow control of the most sensitive information that exists about us to be taken from us: knowledge of the genes that make up our genome, the genetic code from which we were created? Will most of us even realize the loss until we are fired, or turned down for insurance, or denied promotions?

#### BRAVE NEW WORLD: GENETIC TESTING WITHOUT PRIVACY

Let's look at the example of Myriad in more detail. A woman who wants to learn her risk of getting cancer by obtaining genetic testing will have her test results owned and shared by a for-profit research corporation and her for-profit insurance company or health plan. Does Myriad Genetics Inc. share genetic testing information with its business partners, currently including Dupont, Bayer, E Hitachi, Novartis, Oracle, Pharmacia, Roche, Abbott, Schering AG, Schering Plough, and Syngenta?

Myriad has an interesting business plan. First they sell genetic tests to individuals. Do they profit further by sharing these same genetic tests results with other corporations with whom they have entered into "strategic alliances"? Myriad's financial reports for Fiscal 2002 showed "the revenue growth profit margins on predictive medicine revenues were 60%." [From Myriad Genetics (ticker: MGYN, exchange: NASDAQ) News release—22–Aug–2002] Identifiable genetic information is a very valuable corporate asset.

In fact, untold numbers of individuals' identifiable genetic testing results are in the hands of many other private, for-profit genetic testing businesses. Companies selling paternity tests are the most common. Myriad is just one example showing the kind of aggressive direct-to-consumer marketing we can expect to see far more of, which will result in the accumulation of vast amounts of sensitive individual genetic information in the hands of for-profit corporations.

The sale, use, sharing, or re-disclosure of individual genetic test results should not be permitted unless consent is obtained. Individuals should be able to choose to have genetic testing without fear of subsequent disclosure to any third parties.

For-profit health care corporations have a disturbing history of warehousing identifiable medical records in databanks and appropriating the data for corporate use, as if it were commercial proprietary information, i.e., transforming individuals' personal medical records into corporate assets. HMOs and PBMs (pharmacy benefits management companies) are well-known examples of this industry-wide practice by for-profit healthcare corporations. This practice amounts to the illegal search and seizure of the most sensitive identifiable information that exists about each of us: our genetic and medical data.

Starting October 15, 2002, the individual right to consent to the release of genetic and medical information will be eliminated and re-disclosure of all sensitive individual medical information will become the norm as health plans invoke the new federal “regulatory permission” to gain access to everyone’s entire medical and genetic records, past and future, for any purposes related to “health care operations.” There will be no notice of any access and no audit trails.

The only way anyone can obtain genetic privacy going forward will be to have all genetic testing under an alias. If you didn’t have the foresight to obtain genetic testing in the past under an alias, you will not be able to keep the results private, because the HIPAA Privacy Rule amendments provide retroactive access to the results.

#### GENETIC PRIVACY AND THE CONSTITUTIONAL RIGHT TO PRIVACY

The right to genetic privacy, an aspect of medical privacy, is a key Constitutional issue, so there is no more appropriate place in Congress to consider the implications of depriving Americans of that right. Information about specific genes is the most sensitive medical information that now exists about our bodies. Soon our entire genomes will be mapped and stored (warehoused) in databanks.

Genetic information deserves a very high level of privacy protection because it reveals vitally sensitive information that is easily misinterpreted and imperfectly understood, not only about the individual who has genetic testing, but also about current blood relatives of that individual, and about future generations. Genetic test results from a single person can be used to discriminate not only against that individual, but also against literally hundreds of his or her living relatives, including parents, cousins, children, grandchildren, and all offspring.

When implemented, the amendments to the Privacy Rule will eliminate the right of each American to control the release of his or her medical and genetic records. The rights of individual citizens will be replaced by new governmental “regulatory permission” for the release of medical and genetic records, even if patients object to the release, pay privately for medical care, or if the records were created in the past with the expectation they would be kept private forever. Genetic information was NOT specifically excluded from the vast reach of the new governmental “regulatory permission” for disclosures.

Should the government be able to unilaterally deprive citizens of their most valued basic right, the right to be left alone, the right to privacy, without obtaining Congressional approval? Should the government be able to establish the precedent of depriving citizens of their fundamental rights guaranteed under the Constitution by giving blanket “regulatory permission” on their behalf? Should the government be able to deprive citizens of fundamental rights via amendments to HIPAA without a Congressional review?

In the words of Justice Brandeis, “They [the makers of the Constitution] conferred as against the Government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized man.” (*Olmstead v. U.S.* 1928)

The breadth and scope of the intrusions into individual medical privacy permitted in the Administration’s amendments to HIPAA are unprecedented in the history of our nation. Our courts have always affirmed very strong protections for the rights of individuals to the privacy of their personal medical information. Nothing could intrude more on individual’s rights to privacy than the loss of the ability to consent to the release of medical information. By federal fiat, the 2000-year-old principles and ethics underlying the practice of medicine have been eliminated: the right to privacy and the admonition to physicians to do no harm. When sensitive genetic and medical records can be used to harm patients, not to help them, because doctors and patients cannot stop access to the records, then the doctor-patient relationship will be destroyed, i.e., the foundation of our health care system will be destroyed.

In *Sterling v. Borough of Minersville*, 232 F. 3d 190 (3d Cir. 2000). A young man was accosted by a police officer who knew him and threatened to tell his grandfather that he was gay, if he would not tell his grandfather himself. The young man killed himself rather than be forced to make such a disclosure. His estate sued the police department. The Third Circuit Court found that the “right not to have intimate facts concerning one’s life disclosed without one’s consent—is a venerable one whose constitutional significance we have recognized . . . *Sterling*, 232 F.3d at 194, citing *Bartnicki v. Vopper*, 200 F.3d 109, 122 (3d Cir. 1999), aff’d, 532 U.S. 514 (2001).

In *Ferguson v. City of Charleston*, 532 U.S. 67, 78, 121 S. Ct. 1281 (2001), the Supreme Court noted that “[t]he reasonable expectation of privacy enjoyed by the typical patient undergoing diagnostic tests in a hospital is that the results of those tests will not be shared with nonmedical personnel without her consent.” As the

Court further noted, “[i]n none of our prior cases was there any intrusion upon that kind of expectation.” And in a footnote, the Court stated, “In fact, we have previously recognized that an intrusion on that expectation may have adverse consequences because it may deter patients from receiving needed medical care.” *Citing Whalen v. Roe*, 429 U.S. 589, 599–600, 97 S. Ct. 869 (1977). And this case involved a very circumscribed effort to obtain the results of someone’s drug tests and urine samples.

On October 15th health plans will gain open access not only to the results of a few diagnostic drug and urine tests performed in hospitals and to patient communications about sexual orientation with their physicians, but to the all the genetic and medical records of every citizen of this nation. Access to all past and future medical records, in every place where patients receive (or received) medical care, will be permitted by over 600,000 covered entities, business associates of those entities, and all their employees. The effect of eliminating the right to consent is breathtaking in its scope and comprehensive in its inclusiveness.

*Never, in the history of our country has there been an invasion of medical privacy that is as pervasive as that permitted under the amendments to the Privacy Rule, which should more properly be called the Disclosure Rule.*

#### WHY THE “OPTION” TO USE CONSENT ELIMINATES CONSENT

Physicians and others will still have the “option” to continue to use the consent process after October 15th. In practice however, “options” will soon cease to be used, because refusing to consent to release genetic and medical information will no longer stop any data from being released. Even if patients refuse to consent to a release, the new federal “regulatory permission” will always override the patient’s refusal. Physicians and patients will quickly realize that the consent process has been rendered little more than a meaningless sham.

“Although HHS insists that the doctors will still have the “option” to allow you to give or withhold consent, the option will be at the discretion of your doctor, not you. And your doctor will be put in a very difficult position. Will it be in his or her best interest to serve you, the patient, or the insurance company that is cutting the checks? Let’s say your doctor does refuse a regulatory request from your insurer for your records—there is nothing stopping the insurer from claiming that it cannot properly conduct its health care operations without your records and dropping your doctor from its network of providers for failing to comply with federal regulations.” (From “Bye-bye doctor-patient confidentiality? Your medical records may soon be up for grabs,” April 24, 2002, by Vicki Lankarge, Senior Editor at insure.com)

#### EFFECTS OF THE LACK OF MEDICAL AND GENETIC PRIVACY

Most patients I see in my office pay out-of-pocket for treatment in order to insure privacy. Some even pay cash, fearing bank disclosures. Many request sample medications for the same reasons. People with mental illnesses, addictive disorders, and those who were abused as children know full well that disclosure of these disorders or problems can ruin their lives, cause job loss and financial ruin, as well as causing them and their families to suffer intense shame and humiliation.

Managed care, heavily assisted and subsidized by government agencies, has accumulated the medical records of every insured and/or hospitalized patient in the entire nation. A stated promise of managed care was to identify and promote the most effective medical treatments. Instead, the primary use of the vast governmental and private databases of identifiable medical, genetic, and prescription records has been to enhance corporate profits by denying, delaying, and substituting inferior care for all costly and chronic medical illnesses (especially mental illnesses), and for the direct marketing of medications.

To have a mental illness (which has complex genetic, inherited determinants) and possibly have another genetically determined illness is a double whammy. My patients already fear that their children will be predisposed to getting the mental illnesses from which they suffer and worry that they will be discriminated against for having parents with mental illness. Additionally, others fear getting Alzheimer’s disease, breast cancer, or other cancers, because relatives have been affected. But they refuse testing to allay or confirm their fears and potentially enable early detection and treatment, because they fear the harm from unknown disclosures, since there are no audit trails of disclosures. The fear of having a predisposition to cancer or to a degenerative neurological disease will pervade their lives indefinitely and become a source of chronic stress as well as a focus in psychotherapy (from “Protecting Privacy in the Behavioral Genetics Era,” a manuscript by Harold J. Bursztajn, M.D. Co-Director and Richard Sobel Ed. D, Senior Fellow, Harvard Medical School Pro-

gram in Psychiatry and the Law, currently being reviewed for medical journal publication).

Genetic records have become valuable commodities. The economic value of identifiable medical records is so staggering that it has subverted the fundamental ethic of putting the patient and the patient's needs first. My patients want to know their genetic predispositions without fear of discrimination. If they were in the Mayo Clinic system, it appears to me that their needs would be secondary. The Mayo Clinic reportedly intends to implement a three-stage plan to warehouse the personal genetic information of its 5 million patients for medical research purposes. Ultimately, Mayo hopes the world's research community will pay for access to the data (Mayo Clinic Must Guarantee Patient Consent for Genetic Database, by Twila Brase, President of the Citizens' Council on Health Care, July 2002). The Mayo effort appears similar to what has already occurred in Iceland. Iceland has sold its entire nation's medical and genetic database to a US corporation, deCODE Genetics, Inc., which in turn plans to sell the Icelanders genetic data for profit internationally.

Today, tragically patients and their governments are being forced to choose between providing health care or providing privacy. But effective medical treatment cannot occur without ensuring privacy.

Without federal protection we are fast approaching the day when the government and giant private corporations will possess the genomes of every person in America. Will they decide who receives higher education based on genetic predispositions? Will they decide who receives the best medical care based on genetics? Will they decide who is allowed to bear children? The horrific potential for eugenics and the total control of every person in the nation is at hand.

#### CONSEQUENCES OF THE AMENDMENTS TO THE PRIVACY RULE

The amendments to the federal Health Information Privacy Rule published in final form on August 14, 2002 contain serious constitutional defects.

The most serious legal issues appear to be raised by the portion of the amendments that repeal a federal right on the part of all citizens to not have identifiable health information used or disclosed without their consent. This right, as a regulatory matter, was incorporated as part of the "floor" of federal health information privacy protections set forth in the original version of the Privacy Rule that went into effect on April 14, 2001. (66 Fed. Reg. 12,434)

That right will be repealed when the amendments to the Privacy Rule become effective on October 15, 2002. 67 Fed. Reg. 53,182 (The "compliance date" by which "covered entities" must implement changes mandated by the Rule is April 14, 2003, but the date on which the rights of the public are vested or are repealed is the "effective date" of the Rule and its amendments. The effective date of the amendments also is significant for the "chilling effect" it will have on communications between patients and their physicians.)

The two most significant changes contained in the amendments are

- (a) They repeal the federal right of individuals to not have their identifiable health information used or disclosed without their consent; and
- (b) They provide "regulatory permission" by the federal government for covered entities to use or disclose identifiable health information for the purposes of treatment, payment, or health care operations. 67 Fed. Reg. at 53,211

These amendments have the following practical effects on the right to privacy of identifiable health information under federal law:

1. Personal health information can be used and disclosed without the individual's knowledge or consent.
2. Personal health information can be used and disclosed even over the individual's objection.
3. The amendments apply retroactively and permit the use and disclosure of personal health information currently in medical records even if that information was disclosed to a physician or provider with the expectation that it would not be further used or disclosed without consent.
4. The blanket "regulatory permission" granted by the federal government creates a presumption that all medical information is available for use and disclosure unless the individual can assert some state law or standard of medical ethics to rebut the presumption.
5. Individuals are powerless under the amendments to prevent the use or disclosure of communications with health care professionals in the past, present or future.

The amendments to the Privacy Rule provide government permission for over 600,000 entities and literally millions of their employees and “business associates” nationwide to use and disclose the personal health information of “virtually every American.” 66 Fed. Reg. at 12,739. The only limitation is that the information be used or disclosed for “treatment, payment, or health care operations.” “Health care operations,” however, is defined so broadly as to provide little if any discernable restriction, in that it includes such activities as “business planning and development,” “business management and general administrative activities,” and “the sale, transfer, merger, or consolidation, of all or part of a covered entity and the due diligence.” 164.501

#### CONSUMER RIGHTS IN THE ORIGINAL HIPAA PRIVACY RULE

Any doubt about whether consumers have a reasonable expectation that their medical information will not be disclosed without their consent was removed by the findings in the rule making record of the original Privacy Rule, which states:

“Privacy is a fundamental right.” 65 Fed. Reg. at 82,464

“[F]ew experiences are as fundamental to liberty and autonomy as maintaining control over when, how, to whom, and where you disclose personal material.” *Id.*

“The need for security of ‘persons’ is consistent with obtaining patient consent before performing invasive medical procedures—Informed consent laws place limits on the ability of other persons to intrude physically on a person’s body. Similar concerns apply to intrusions on information about the person.” *Id.*

“Comments from individuals revealed a common belief that, today, people must be asked permission for each and every release of their health information—Our review of professional codes of ethics revealed partial, but loose, support for the individuals’ expectations of privacy.” 65 Fed. Reg. at 82,472.

“. . . many comments that we received from individuals, health care professionals, and organizations that represent them indicated that both patients and practitioners believe that patient consent is an important part of the current health care system and should be retained.” 65 Fed. Reg. at 82,473.

“Many health care practitioners and their representatives argued that seeking a patient’s consent to disclose confidential information is an ethical requirement that strengthens the physician-patient relationship.” *Id.*

“The comments and fact-finding indicate that our approach [requiring consent for use and disclosure of personal health information] will not significantly change the administrative aspect of consent as it exists today.” 65 Fed. Reg. at 82,474.

In the light of these findings in the rule making record, it cannot be disputed that citizens have a “reasonable expectation” that their personal health information will not be used or disclosed without their consent.

#### CONSTITUTIONAL DEFECTS IN THE PRIVACY RULE

The amendments to the federal Health Information Privacy Rule published in final form on August 14, 2002 violate the 1st, 4th, and 5th Amendments to the Constitution.

##### A. Violation of 5th Amendment

It is now well-recognized that all citizens have a “clearly established” right to privacy under the Fifth Amendment of the U.S. Constitution. The right to privacy of medical tests falls squarely within the contours of the recognized right [under the 5th Amendment] of one to be free from disclosure of personal matters. It is now established that the United States Constitution provides some protection of individual’s privacy. Although the full measure of the constitutional protection of the right to privacy has not yet been delineated, we know that it extends to two types of privacy interests: One is the individual’s interest in avoiding disclosure of personal matters, and another is the interest in independence in making certain kinds of important decisions. In *Olmstead v. United States*, 277 U.S. 438, 478, 48 S.Ct. 564 (1928), Justice Brandeis wrote of “the right to be let alone—the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion of the government upon the privacy of an individual—must be deemed a [constitutional] violation.” (Brandeis, J., dissenting).

By granting “regulatory permission” for any covered entity to use or disclose personal health information for any citizen, the amendments eliminate the right to privacy in personal information guaranteed by the Constitution.

The degree of protection afforded by the 5th Amendment varies with the type of information, but the constitutional protections are greater for personal matters and particularly high for medical information. Private medical information is well within the ambit of materials entitled to privacy protection under the 5th Amendment. The disclosure of the results of medical tests falls squarely under the contours of the recognized right of one to be free from the disclosure of personal matters under the 5th amendment. It has been recognized in various contexts that medical records and information stand on a different plane than other relevant material.

The compelled involuntary disclosure of medical information without consent warrants particularly close scrutiny under the 5th Amendment. The right not to have intimate facts concerning one’s life disclosed without one’s consent is a venerable one.

#### *B. Violation of the 4th Amendment*

It would also appear that the authorization granted by the government to covered entities to obtain virtually any health information about citizens would be a violation of the 4th Amendment protections against “unreasonable searches and seizures.” Drug tests on urine samples by a public hospital were “indisputably searches within the meaning of the Fourth Amendment” in *City of Charleston* (2001).

Under the amendments, covered entities would be entitled to obtain all types of genetic and health information without the consent of the individuals, and even against their will, under the authority of “regulatory permission” furnished by the federal government.

#### *C. Violation of 1st Amendment*

The amendments’ authorized use and disclosure of nearly any personal medical information that may arise in the course of communications between a patient and a physician would seem to violate the 1st Amendment right to private conversations and to have a chilling effect on future communications between physicians and patients. The rule making record contains findings indicating that this will be the inevitable result of the amendments. Those findings state that patients who are worried about their medical privacy “often take steps to protect their privacy,” including refusing to participate fully in the diagnosis and treatment of their medical conditions, and “changing physicians or avoiding care altogether.” 65 Fed. Reg. at 82,468.

As the Supreme Court recently noted, the 1st Amendment protects the “freedom to not speak publicly, one which serves the same ultimate end as freedom of speech in its affirmative aspect.”

Further, the fear of public disclosure of private conversations “might well have a chilling effect on private speech.” Such a “chilling effect,” according to the rule making record does, in fact, occur and has an adverse effect on access to necessary health care. “In short, the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers.” 65 Fed. Reg. at 82,467. There is also little doubt that a constitutional violation can occur with simply a threat. The threat to breach some confidential aspect of one’s life then is tantamount to a violation of the privacy right, because the security of one’s privacy has been compromised by the threat of the disclosure.

#### THE GRAMM-LEACH-BLILEY FINANCIAL SERVICES ACT OF 1999: IMPACT ON GENETIC AND MEDICAL PRIVACY

This act permits financial institutions to share sensitive individual financial and medical data with affiliates and non-affiliates. Unfortunately, insurers and health plans are often affiliated with financial institutions, so individually identifiable health information can be shared and used to determine credit rates and evaluate mortgage and loan applications, not just to determine insurability or eligibility for benefits. The potential abuses of medical and genetic information by financial institutions and their affiliates and non-affiliates are virtually unlimited. Picture credit rates based on blood pressures, car loans based on HIV viral loads, or mortgages denied if your parent is diagnosed with Alzheimer’s disease or if you test positive for the breast cancer gene.

Knowing that medical and genetic data will affect credit and financial transactions can only further destroy the nation’s already compromised health care system. More and more people will totally avoid medical care, or lie about or omit important physical or mental symptoms or details, and endanger their own lives and the lives of those in their communities.

## CONCLUSION

The Preamble to the Constitution states that one of the purposes of the Constitution is to “secure the blessings of liberty for ourselves and for posterity.” That is exactly what we fail to do if we allow the federal government to eliminate the right to consent to the release of medical and genetic information. Our children will lose their privacy and their liberty. James Madison’s vision was that the Constitution should protect each citizen from the government, because he understood that the real danger to private citizens would always come from entrenched government power.

Ironically, the privacy of the medical records of animals in zoos is being guarded more carefully than the privacy of human genetic and medical records. After the death of Ryma, a beloved giraffe in the National Zoo, Washington Post staff reporter D’Vera Cohn requested his medical records, necropsy, and pathology reports. “The Smithsonian Institution’s National Zoo has taken the position that viewing animal medical records would violate the animal’s right to privacy and be an intrusion into the zookeeper-animal relationship.” (National Zoo Cites Animal Privacy Concerns in Its Refusal to Release Animal’s Medical Records, by James V. Grimaldi, in the Washington Post, HEARSAY, The Lawyer’s Column, May 6, 2002, page E12). Animals are being granted their privacy rights by zookeepers just as the federal government is usurping basic human rights to privacy guaranteed under the 1st, 4th, and 5th amendments to the Constitution.

This new doctrine of federal “regulatory permission” establishes a dangerous precedent. It provides a mechanism for the extraordinary centralization of power and information in the federal government and creates a mechanism to deprive citizens of basic civil liberties. The government is substituting its power in the place of the right of individuals to choose who has access to the most personal information that exists about them, their genetic and medical records. The precedent of eliminating individual’s basic rights by fiat and substituting governmental power is anathema to democracy and liberty.

Across history and across cultures, people have been willing to die for the liberty of future generations. Will we squander our precious liberty? Will we squander our privacy and that of our children and future generations? Will we fail to fulfill the promise of our Constitution?

If we allow the federal government to give “regulatory permission” to take away our basic right to privacy, what will prevent the government from taking away other basic freedoms?

## REMEDIES

I believe the American public would benefit from the following actions:

- 1) Congress has 60 days review the major changes in the Privacy Rule proposed on August 14th. Congress should vote down the amendments. Every US Representative and US Senator should have to vote on the rule changes, so that citizens will know whether or not their elected officials are defending the right of individuals to protect sensitive genetic and medical records by keeping the right to consent.  
The right to medical privacy is important to even the holders of the highest office in the land. If we had known Ronald Reagan had a high risk of developing Alzheimer’s disease, would he have been elected president?
- 2) Restore the basic right of individuals to consent to the release of their medical and genetic information.

I believe every American, including those yet to be born, will thank you for your courage and leadership in this effort to keep the corporate health care industry and the federal government from appropriating everyone’s vital genetic and medical information. In the final analysis, the systemic breach and disclosure of genetic and medical privacy puts every American who now suffers, or will suffer from illness, at great risk of harm and discrimination.

Thank you so much for the honor of addressing you on genetic privacy, a critical issue for medicine and health care, and a basic Constitutional right.

**ADDENDUM: FEDERAL HEALTH PRIVACY RULE AMENDMENTS:  
IMPACT ON QUALITY HEALTH CARE,  
A Briefing for Members of Congress and Their Staffs  
August 19, 2002**

**FEDERAL HEALTH PRIVACY RULE AMENDMENTS:  
IMPACT ON QUALITY HEALTH CARE**

**A Briefing for Members of Congress and Their Staffs  
August 19, 2002**

*"...few experiences are as fundamental to liberty  
and autonomy as maintaining control over when  
how, to whom, and where you disclose personal material"*

*"The right to privacy, it seems, is what makes us civilized."  
Preamble to the pre-amendment Privacy Rule,  
65 Fed. Reg. 82,464-65*

**1. What has happened with respect to the rights and standards for health information privacy?**

**Answer**

On August 14, 2002, the Department of Health and Human Services issued final amendments to the current federal Privacy Rule. (67 Fed. Reg. 53182) Those amendments made radical changes in key rights and responsibilities of consumers and entities covered by the Privacy Rule that went into effect on April 14, 2001. Major changes were made in the areas of consent, marketing, minimum necessary disclosures, notice, and accounting for disclosures as well as others.

The two most significant changes were

- A. The repeal of the right of consumers to not have their identifiable health information disclosed without their consent; and
- B. "Regulatory permission" provided by the federal government for most uses and disclosures of identifiable health information.

[*"The consent provisions of 164.506 are replaced with a new provision at 164.506(a) that provides regulatory permission for covered entities to use or disclose protected health information for treatment, payment, and health care operations."*] (67 Fed. Reg. at 53,211)

**2. What is the significance of the changes in the Privacy Rule?**

**Answer**

The repeal of the right of consent eliminates the most essential and fundamental element of the “federal floor of privacy protections” for the right of medical privacy contained in the current Privacy Rule. (65 Fed. Reg. at 82,471) Without the right to give or withhold consent for the use or disclosure of protected health information, consumers will lose their power under law to protect their right to medical privacy.

Furthermore, the blanket “regulatory permission” provided by these amendments for the use and disclosure of identifiable health information sets a dangerous precedent for the proposition that the federal government may waive “fundamental rights” on behalf of citizens of the country, regardless of their wishes and even against their will. (See 65 Fed. Reg. at 82,464 where HHS recognizes that “privacy is a fundamental right.” )

Finally, the loss of medical privacy results in the loss of access to quality health care. As the preamble to the current Privacy Rule found,

“Privacy is necessary to secure effective, high quality health care. While privacy is one of the key values on which our society is built, It is more than an end in itself. It is also necessary for the effective delivery of health care, both to individuals and to populations.” (65 Fed. Reg. at 82,467)

**3. When will the amendments to the Privacy Rule become effective?****Answer**

The effective date of the amendments to the Privacy Rule is October 15, 2002. (67 Fed. Reg. at 53, 182) The “compliance date”, the date by which “covered entities” must be in compliance with the Privacy Rule, is April 14, 2003, approximately 6 months later. (67 Fed. Reg. at 53,183)

**4. Since the compliance date for the Privacy Rule is April 14, 2003, are the rights under the pre-amendment Privacy Rule in effect?****Answer**

Yes, the rights under the pre-amendment Privacy Rule, including the right of consent , vested in all Americans on the effective date established by the Bush Administration which is April 14, 2001. (65 Fed. Reg. 12,433)

In announcing the April 14, 2001 effective date of the pre-amendment rule,

Secretary Thompson stated that

“President Bush wants strong patient protections put in place now. Therefore, we will immediately begin the process of implementing the patient privacy rule that will give patients greater access to their own medical records and more control over how their personal information is used.”

Secretary Thompson also stated:

“The President considers this a tremendous victory for American consumers...”

On October 15, 2002, the effective date of the amendments, the right of consent which vested on April 14, 2001, will be repealed.

**5. Under the amended Privacy Rule, who will have access to what health information without the patients' consent?**

**Answer**

The Privacy Rule applies to “covered entities” and their “business associates”. As the attached summary of the terms shows, covered entities are health plans (such as HMO's and Medicare Part A and B), health care clearinghouses (entities that process health information), and health care providers (any person or entity who furnishes, bills, or is paid for health care). Business associates are a broad range of entities and individuals that provide services to or for covered entities. 160.103

HHS has estimated that the Privacy Rule affects “over 600,000 entities and virtually every American”. 66 Fed. Reg. at 12,739.

The health information that can be covered by the Privacy Rule is any virtually any identifiable health information relating to the “past, present, or future physical or mental condition of an individual”. 164.501

The amendments to the Privacy Rule would permit these covered entities and business associates to use and disclosure identifiable health information for three broad purposes-treatment, payment and health care operations. 67 Fed. Reg. at 53,211. Many of these purposes, particularly health care operations activities, are related to the business operations of covered entities rather than the need to provide health care to an individual. They include, for example, “business planning and development”, and business management and general administrative services”. The definitions of treatment, payment and health care operations are so broad that they encompass most of the uses and disclosures of health information. See attached list of activities.

Under the amendments, hundreds of thousands of entities and individuals nationwide will be able to use and disclose identifiable health information without the patient's consent or permission so long as they contend that they need it for a purpose related to treatment, payment and health care operations. It is unlikely that any identifiable health information would be immune from use and disclosure without the patient's consent under this standard.

**6. What about the HHS' contention that consent under the pre-amendment rule was "mandatory" and that HHS is merely making it "optional"?**

**Answer**

Consent is only "mandatory" under the pre-amendment Privacy Rule in that it must be obtained for the use or disclosure of the patient's identifiable health information. The patient has the "option" to give or withhold consent depending on whether he or she wants identifiable health information used or disclosed.

Under the amended Privacy Rule, the patient has no option. The patient's identifiable health information is disclosed regardless of the of the patient's wishes. The "option" to obtain consent is only "optional on the part of all covered entities". 67 Fed. Reg. at 53,211. If the covered entity does not wish to provide an opportunity for consent, the patient will no longer have a right under law to insist that the opportunity for consent be provided.

**7. What about HHS' contention that patients' medical privacy can be protected by the "right to request restrictions"? (67 Fed. Reg. at 53,211)**

**Answer**

The Privacy Rule is quite clear that covered entities are "not required to agree to a restriction" with respect to the use and disclosure of identifiable health information. 164.522(a)(1)(ii) Covered entities may have a consent process "if they wish to do so". (67 Fed. Reg. at 53,211) Accordingly, the right to request restrictions is tantamount to a "right to beg" a covered entity to enter into a consent agreement. The patient has no right to obtain such an agreement.

**8. What about rights of consent under state statutory and common law and ethical and other practice standards of medical professions?**

**Answer**

The preamble to the pre-amendment Privacy Rule pointed out that approximately half of the states have statutory medical privacy laws that require consent for disclosure of varying types of identifiable health information and that common law in many other states recognizes that the right to privacy implies a right of consent. (65 Fed. Reg. at 82,473) Further, consent is commonly required for

the use and disclosure of health information by the ethical and practice standards of professional medical associations. (65 Fed. Reg. at 82,472)

The preamble to the amendments does not contest this finding but merely states that the amendments do “not interfere with such laws and ethical standards”. (67 Fed. Reg. at 53,212) Accordingly, the final amendments tacitly acknowledge that they are out of step with state law and professional medical ethical standards. The failure to retain the right of consent as part of the floor of federal privacy protections will breed confusion and loss of trust by patients who must determine what their rights are under 50 state laws as their identifiable health information is increasingly transmitted around the country with the punch of a button.

**9. Does the “minimum necessary” standard provide adequate protection for the right of medical privacy?**

**Answer**

The “minimum necessary” standard is unlikely to provide the type of reliable privacy protection that will preserve the public’s confidence in the health delivery system. The basic concept of this standard is to limit the identifiable health information that is requested or disclosed to that which is necessary for the purpose of the use or disclosure. 164.502(b)

First, the standard only requires covered entities to use “reasonable efforts” to limit the amount of identifiable health information that is used or disclosed for a given purpose. 164.502(b)(1). Second, the range of health information subject to the “minimum necessary” standard varies with the size and sophistication of the covered entity seeking the information. As the preamble to the amendments states, “the Department’s intent [is] that the minimum necessary standard is reasonable and flexible to accommodate the unique circumstances of the covered entity.” (emphasis supplied) (67 Fed.Reg. at 53,196) Third, the minimum necessary limitation does not apply to (1) uses or disclosures required by law, (2) disclosures initiated by the individual, (3) uses or disclosures required for compliance with the Privacy Rule, and (4) disclosures to HHS for the purposes of enforcing the Privacy Rule. (67 Fed. Reg. at 53,195) Fourth, the amendments add an exemption from the minimum necessary standard for any uses or disclosures made pursuant to an authorization provided by the patient. Fifth, covered entities can request, use and disclose the patient’s entire medical record, thereby abrogating the minimum necessary standard, “provided that the covered entity has documented the specific justification for the request or disclosure...” 67 Fed. Reg. at 53,197.

The preamble states that the covered entity who holds the information always retains the discretion to make its own minimum necessary determination and that this standard is intended to be “consistent with, and not override, professional

judgment and standards". 67 Fed. Reg. at 53,197. However, covered entities are permitted to assume that any information requested by another covered entity is the minimum necessary for that covered entity's intended purpose. (67 Fed. Reg. at 53,197) Further, it is unclear whether ethical standards, which generally do not have the force of law, would prevail over the blanket "regulatory permission" granted in these amendments for the use and disclosure of virtually all health information.

In any event, the minimum necessary standard provides little, if any, effective protection for medical information privacy.

**10. What about the Administration's contention that the elimination of the patients' right of consent is offset by the requirement for a strengthened privacy notice? (67 Fed. Reg. at 53,211)**

**Answer**

According to the preamble to the amendments, the privacy notice is only intended to provide patients with "the opportunity to engage in important discussions regarding the use and disclosure of their health information". (67 Fed. Reg. at 53,200) The notice process does not provide patients with any right or power to control the use or disclosure of their identifiable health information.

Further, the amendments make clear that covered entities with direct treatment relationships with patients are only required to make "a good faith effort" to ensure that the patients receive the notice. (67 Fed. Reg. at 53,239) Covered entities without a direct treatment relationship are not required to make even this effort. (67 Fed. Reg. at 53,239)

**11. What about the Administration's claim that the consent requirement in the current Privacy Rule could have prevented access to needed health care? (67 Fed. Reg. at 53,210)**

**Answer**

The principal reason cited for eliminating the right of consent in all situations for all consumers and all covered entities was that having to obtain consent for the use and disclosure of health information could have prevented providers from making necessary arrangements prior to their first encounter with the patient. (67 Fed. Reg. at 53,209) HHS acknowledged that commenters had suggested solutions which would ensure that the patients' wishes would be carried out and access to health care would be preserved. However, HHS repealed the right of consent because it wanted a "global fix to the consent problems". (67 Fed. Reg. at 53,210)

In any event, HHS indicates that it is not repealing the requirement for consent

for treatment, so providers will still have to obtain consent for this purpose, but covered entities will not have to obtain consent for the use and disclosure of identifiable health information.

Thus, HHS has repealed the only effective protection which consumers had for the "fundamental right" of their medical privacy in an effort to address the concerns of certain covered entities in limited circumstances. In taking this action, HHS has ignored nearly all of the findings set for in the preamble to current Privacy Rule which show that most citizens expect and want medical privacy and the right of consent and that these protections are essential for access to quality health care. (See attached list of findings.)

- I. What information is covered by the Privacy Rule?-individually identifiable health information which is any information oral or recorded in any medium that
- A. is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university or healthcare clearinghouse and
  - B. relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to the individual.
  - C. identifies the individual
  - D. there is a reasonable basis to believe that the information can be used to identify the individual 160.103
- II. Who will have access to it? "Covered entities" which are
- A. a health plan (including a group health plan, a health insurance issuer, an HMO, and Part A and B of Medicare)
  - B. a health care clearinghouse
  - C. health care providers
  - D. "business associates" of all of the above including those outside the covered entity's work force who perform any of the following functions
    1. claims processing or administration
    2. data analysis
    3. utilization review
    4. quality assurance
    5. billing
    6. benefit management
    7. practice management or repricing
    8. legal services
    9. accounting
    10. actuarial services
    11. consulting services
    12. data aggregation
    13. management
    14. administrative services
    15. accreditation
    16. financial services
    17. anyone else performing a service on behalf of a covered entity which involves the use or disclosure of identifiable health information
- III. For what purposes can the information be obtained without consent or authorization?
- A. Treatment-provision, coordination or management of health care and related services, consultation between providers relating to a patient or

the referral of a patient from one provider to another. 164.501

- B. Payment -activities by a health plan to obtain premiums or determine coverage, by a provider to obtain reimbursement
- C. Health care operations
  - 1. conducting quality assessment and improvement activities;
  - 2. population-based activities related to improving health or reducing health care costs, protocol development, case management and care coordination;
  - 3. contacting health care providers and patients about treatment alternatives;
  - 4. reviewing the competence and qualifications of health care professionals;
  - 5. evaluating practitioner and provider performance;
  - 6. evaluating health plan performance;
  - 7. conducting training programs;
  - 8. accreditation, certification, licensing or credentialing activities
  - 9. underwriting
  - 10. premium rating
  - 11. other activities relating to the creation, renewal, or replacement or a contract of health insurance or health benefits
  - 12. ceding, securing or placing a contract for reinsurance of risk relating to claims for health care;
  - 13. conducting, or arranging for medical review, legal services, and auditing functions;
  - 14. business planning and development;
  - 15. business management and general administrative activities;
  - 16. the sale, transfer, merger, or consolidation or all or part of a covered entity and the due diligence;
  - 17. creating de-identified data or a limited data set and ;
  - 18. fundraising.
- D. 12 other specified uses such as law enforcement, public health and oversight 164.501 and 164.512

**HEALTH INFORMATION PRIVACY RULE  
Congressional Briefing  
August 19, 2002**

**I. History**

- A. **August 21, 1996**- Health Insurance Portability and Accountability Act enacted, section 264 requires Congress, by August 21, 1999, or the Secretary of HHS, by February 21, 2000, to establish the rights that individuals "should have" with respect to individually identifiable health information.
- B. **September 11, 1997**- Secretary of HHS submits recommendations to Congress with respect to privacy rights and standards.
- C. **November 3, 1999**- HHS issues proposed Privacy Rule to implement section 264 of HIPAA. (64 Fed. Reg. 59,918)
- D. **December 15, 1999**- HHS extends comment period by more than 30 days. (64 Fed. Reg. 69981)
- E. **December 28, 2000**- HHS issues final Privacy Rule implementing section 264 of HIPAA, with an effective date of February 26, 2001. (65 Fed. Reg. 82,462)
- F. **February 26, 2001**- HHS, under Bush Administration, delays the effective date to April 14, 2001 in order to provide Congress an opportunity to review the Rule under the Congressional Review Act. (66 Fed. Reg. 12,434)
- G. **February 28, 2001**- HHS reopens comment period of Privacy Rule for another 30 days. (66 Fed. Reg. 12,738)
- H. **April 12, 2001**- HHS announces that the Privacy Rule will be put into effect on April 14, 2001 stating that "The President considers this a tremendous victory for American consumers..." (Statement by HHS Secretary Tommy G. Thompson (April 12, 2001); 65 Fed. Reg. 12,433)
- I. **March 27, 2002**- HHS proposes major changes in Privacy Rule and provides 30-day comment period. (67 Fed. Reg. 14,776)
- J. **August 14, 2002**- HHS publishes final amendments to Privacy Rule reversing policy announced on April 12, 2001. (67 Fed. Reg. 53,182)

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PRE-AMENDMENT PRIVACY RULE FINDINGS

1. "Privacy is a fundamental right. As such, it must be viewed differently any ordinary economic good." 65 Fed. Reg. at 82,464.
2. "A right to privacy in personal information has historically found expression in American law. All fifty states today recognize in tort law a common law or statutory right to privacy." *Id.*
3. "In the Declaration of Independence, we asserted the 'unalienable right' to 'life, liberty and the pursuit of happiness.' Many of the most basic protections in the Constitution of the United States are imbued with an attempt to protect individual privacy while balancing it against the larger social purposes of the nation." *Id.* (citing the Fourth Amendment's 'right of the people to be secure in their persons' as an example).
4. "The need for security of 'persons' is consistent with obtaining patient consent before performing invasive medical procedures. . . . Informed consent laws place limits on the ability of other persons to intrude physically on a person's body. Similar concerns apply to intrusions on information about the person." *Id.*
5. ". . . [F]ew experiences are as fundamental to liberty and autonomy as maintaining control over when, how, to whom, and where you disclose personal material." *Id.*
6. "Privacy covers many things...It protects our right to be secure in our own homes and possessions, assured that the government cannot come barging in." 65 Fed. Reg. at 82,465.
7. "Privacy is necessary to secure effective, high quality health care. While privacy is one of the key values on which our society is built, it is more than an end in itself. It is also necessary for the effective delivery of health care, both to individuals and to populations." 65 Fed. Reg. at 82,467.
8. "Patients who are worried about the possible misuse of their information often take steps to protect their privacy" including "providing inaccurate information to a health care provider, changing physicians, or avoiding health care altogether." 65 Fed. Reg. at 82,468.
9. "Health care professionals who lose the trust of their patients cannot deliver high-quality care." *Id.*
10. "The issue that drew the most comments overall [when the current Privacy Rule was proposed] is the question of when individuals' permission should be obtained prior to the use or disclosure of their health information." 65 Fed. Reg. at 82,472.

11. "Comments from individuals revealed a common belief that, today, people must be asked permission for each and every release of their health information...Our review of professional codes of ethics revealed partial, but loose, support for individuals' expectations of privacy." Id.

12. "While our concern about the coerced nature of these consents remains, many comments that we received from individuals, health care professionals, and organizations that represent them indicated that both patients and practitioners believe that patient consent is an important part of the current health care system and should be retained." 65 Fed. Reg. at 82,473.

13. "Many health care practitioners and their representatives argued that seeking a patient's consent to disclose confidential information is an ethical requirement that strengthens the physician-patient relationship." Id.

"The comments and fact-finding indicate that our approach [recognizing the individual's right to consent] will not significantly change the administrative aspect of consent as it exists today." 65 Fed. Reg. at 82,474.

Mr. CHABOT. Thank you very much, Dr. Peel.

At this time, rather than go directly to the questioning of the panel, I'm going to defer to Mr. Nadler for purpose of making an opening statement for 5 minutes, the Ranking Member of the Committee.

Mr. NADLER. Thank you, Mr. Chairman. I apologize for being late. I went straight to the floor for the Whip meeting. And this will not take 5 minutes; it will be brief.

I want to thank the Chairman for scheduling this hearing on what I believe is a very important issue that will become only more pressing as technology advances. While the cracking of genetic code holds the promise of significant advances in our understanding of disease, improved treatment, longer life, and improved quality of life, that information, if misused, can deprive individuals to access of medical care, or employment, or make public the most personal information imaginable. That invasion of privacy and the abuse of that information must never be permitted.

I might add that it has always seemed to me, on this issue, that failure to really deal with this will destroy the insurance industry, because the insurance industry is based on spreading the risk. But if we know, as we develop our knowledge of genome, 5 to 10 years from now, we will know everybody's risk of every genetically implicated disease. Therefore, you will be able to get insurance for everything except what you might need it for, and people won't buy insurance, because why should they buy insurance for what they will then know they don't need it for. And the insurance company won't insure them for what the insurance company knows they will have to pay.

The only way you can have insurance is basically because you do underwriting and balancing your risk because you don't know everybody's individual risks. Now, we're not at that point yet. But if we don't enact some sort of legislation, we're going to be at that point in 5 or 10 years.

And so I would hope that the insurance industry will take another look at this because, literally, people are going to become uninsurable, and they're not going to want to buy insurance for what they don't need. So I think there's a real interest, or there ought to be; if the insurance is thinking about this, think in a little broader term, and you really need privacy legislation in this field.

I'm pleased to welcome our witnesses today. I've listened to their testimony and will have some questions.

I'm especially delighted that my New York colleague, Representative Louise Slaughter, has been the leading voice in Congress on genetic discrimination issues. For over 6 years, she has sponsored legislation that would ban genetic discrimination in health insurance and employment, and she's gone to enormous lengths to educate the public and our colleagues on this important issue.

Her bill, H.R. 602, the Genetic Nondiscrimination in Health Insurance and Employment Act, which, I must brag, was partly drafted by my chief of staff when she was the director of legislation at Hadassah. Anyway, that bill has the support of 266 co-sponsors, including over 50 Republican co-sponsors. I think a number of Members of this Subcommittee from both sides of the aisle are co-sponsors of the bill.

I commend the Chairman for holding this hearing, and I hope that he will join me in urging the leadership of the House to bring up this critical legislation in this session.

I look forward to the balance of the hearing. And I thank you, Mr. Chairman. I yield back the balance of my time.

Mr. CHABOT. Thank you very much, Mr. Nadler.

I'll recognize myself for 5 minutes to ask questions. Before I ask the first question, let me just comment that present here this morning, we also have Member Connie Morella from right next door in Maryland, who has also been one of the leaders on this issue in the Congress, as well as Ms. Slaughter, and, hopefully, Ms. Slaughter will be here shortly.

And we have recognized by unanimous consent both Ms. Slaughter and Ms. Morella to ask questions when the other Members of the Committee are finished asking questions.

My first question I'd like to address to Dr. Peel, and then any of the other Members who would like to comment can do so.

I consider myself a strong advocate for individual privacy rights, and I am concerned about how personal genetic information might be used now and especially in the future. Could you comment on whether you would support a complete ban of the use of genetic information by employers? Or, do you think that there should be some situations where it would be acceptable for employers to have access to employees' genetic information? And what situations, if any, would warrant the use of personal genetic information by employers, if you think there should be some? And then I'd ask the other Members who would like to comment as well.

Dr. PEEL. Sure. Thank you, Mr. Chairman.

This gets back to some of the comments that you made, Mr. Nadler. The problem really is that when very personal information, genetic information or medical information, is not used by people who are actually treating patients. That's the problem, is when this information ends up being used by others, others having access to information that can harm people.

And so I think the solution is to restore consent, to restore meaningful consent, so that every person in this country can control that access and make sure, make the decision, that it goes to people that are actually going to help them and not harm them. And I'm talking about not only employers but insurers, researchers. As you know, there's a tremendous amount of for-profit research today. You know, is that truly benefiting patients or is it benefiting the researcher or the drug company or whatever?

There's a lot of questions about who should have information.

So the only protection—the only one who should really decide is the person who the information is generated about, and particularly this incredibly sensitive information.

So I would say it should be the individual's right to control the access.

Mr. CHABOT. Thank you. Any other panel members who would like to comment?

Ms. HUSTEAD. That's an excellent question, and I would like to comment on it.

I think that genetic information is rarely ever relevant in the workplace setting. And there are only a couple of instances where I think it does have some relevance.

In my view, the key workplace issue is, is the person able to perform the essential job functions? If a person has a medical condition that has a genetic basis, what's relevant in the job setting is what the limitations are on their ability to perform that job, what accommodations might be needed.

But the employer does not need to know the diagnosis of the condition, whether it has a genetic basis or not. But particularly where it has a genetic basis, they don't need to know that you have Huntington's. They need to know that you need this particular accommodation in order to perform the job.

Where a person merely has a genetic predisposition to develop a medical condition in the future, then I think its relevance in the workplace setting is even more tenuous. And the only context in which I think employers should be involved to some extent in genetics and their employees are the following: If—if, and this is not the case now—but if at some point in the future there is a clear genetic link between occupational exposure to a particular toxic agent and subsequently developing a medical condition that's associated with that genetic mutation, then I think—and if the Occupational Health and Safety Administration requires that people be monitored in the workplace for this genetic mutation, then I think there should be some sort of program established which empowers employees to learn about that and to evaluate their own personal risk and to have testing done away from the workplace, but under circumstances where the employer never learns who had the test, who tested positive. And then leave it up to the employee to make the decision about whether, given where they are and what their risks are, whether they want to continue in that job setting.

Mr. CHABOT. Thank you. Dr. Rowe or Mr. Miller, if you'd like to—

Mr. MILLER. Yes, Mr. Chairman. Your question was about a complete ban of genetic information and genetic testing. Now, we should know that, you know, you're essentially regulating information, and information flows in all kinds of places, even when you try to prohibit it and ban it. It flows under, around, through, and in between the barriers you put out there. Some in cases, you're trying to kind of trap something which is going to migrate in any case.

In addition, as I indicated before, a complete prohibition on any genetic information also inhibits positive uses of that information. What about the folks who have good genetic risks who would like to voluntarily disclose that? Are you saying they are not able to do that?

On the other hand, if we try to sort this out between, "Well, this is negative information which might harm me. This is positive information which might be good for me," you get into all kinds of complications of how to do that consistently, predictably, and coherently.

A lot of genetic information is woven into other types of health information, and you can't simply sort it out. The same thing that might be predictive through genetic information could also be par-

tially predictive through what you pick up from someone's family history, water cooler conversation at the workplace.

When you say there ought to be a law, what you're really saying is there ought to be a lot of lawsuits that will continue to complicate this down the road.

And finally, I think in the words of Richard Epstein, when you kind of have this partial permission and partial prohibition regime, you allow kind of the person to have this one-way option where they get to kind of operate under a regime of "can't ask, may tell, may lie," depending upon how the information works to their benefit.

Mr. CHABOT. Okay. My time has expired, but, Dr. Rowe, if you'd like to briefly comment.

Dr. ROWE. I don't have a specific comment with respect to your question about the absolute ban in the workplace, but I'd to respond as one of the physicians here on the panel and make a medical point. I think it's very important for the Members to realize that genetic information comes in many forms, and it is not all predictive of a disease.

For instance, your blood type is the result of genetic test. And there might be instances in which it's important for someone to have a record of your blood type, if you need an emergency transfusion. There are all kinds of genetic tests. They're not all predictive markers for the development of a dread disease.

So we just need to be a little careful about the language, as we're talking about genetic testing versus, you know, predicting disease. That's all. Just a medical point.

Mr. CHABOT. My time has expired. The gentleman from New York, Mr. Nadler, is recognized for 5 minutes.

Mr. NADLER. Yes, thank you, Mr. Chairman.

Let me ask Ms. Husted first, you weren't implying a moment ago, in answer to the question, that it would be proper for a company to discriminate based on genetic predisposition to certain toxins in employment, as opposed to protecting all their employees from those toxins in the workplace, were you?

Ms. HUSTEAD. No, no. Obviously, the employer has an obligation to maintain a safe workplace. They have that obligation under OSHA, and that always applies.

What I was suggesting is that there are some people who, despite protections that are adequate in the workplace, cannot be protected against certain conditions. They are hypersensitive. And in some cases, it may be because of a genetic mutation that they are hypersensitive. So even—I am positing an employer that is following all of the OSHA standards, doing everything that they can do to make that workplace safe, and yet there is nothing more that they can do.

And in that case, in that fairly unusual case, I would imagine, I could see a genetic testing program established, but where the employer has no access to individually identifiable genetic information. The employees, if they choose, could be tested away from the worksite, they could be counseled away from the worksite.

Mr. NADLER. Okay.

Ms. HUSTEAD. And it would be their decision, whether to stay in the job.

Mr. NADLER. Okay, thank you. You also noted, in your testimony, gaps in current law; that is, not protected by private sector initiatives, including Aetna's. Could you mention some of them?

Ms. HUSTEAD. I'm sorry, I didn't understand the question.

Mr. NADLER. I said, you noted that there are gaps that are not protected by some of the private sector initiatives, such as Aetna's.

Ms. HUSTEAD. Right.

Mr. NADLER. Could you mention some of those gaps?

Ms. HUSTEAD. Well, although I applaud what Aetna is doing—I think everything they said makes a lot of sense to me. Although, on the “shall not” side, most of what Dr. Rowe mentioned is already required by Federal law.

Aetna sells in the group market. They do not provide insurance in the individual insurance market, and that is where the real concern is, or, I should say, a heightened concern, because there is medical underwriting, insurers do ask for information about whether people have had genetic tests, and they do use that information in making decisions about what they're going to charge someone.

Mr. NADLER. So the gaps you're referring to are mostly in the individual, not in the group market, is what you're saying?

Ms. HUSTEAD. Correct. And I would also note that in the list of “shall nots,” I don't believe that their list includes not asking people what tests they have done. They do say that insurers should not require genetic tests as a condition of getting insurance, but I don't believe those principles include whether they can collect information or inquire about genetic information about which the person is aware.

Mr. NADLER. Thank you.

Dr. Rowe, a press statement from Aetna, from last June, seems to imply that Aetna would support Federal legislation in this area. But there wasn't anything, at least in your written testimony, about that. Does Aetna support—do you think that it would be a good idea to have Federal legislation in this area?

Dr. ROWE. Mr. Nadler, let me—I would say that what we have nationally currently, as we have in many instances with respect to insurance, is a hodgepodge of various State regulations, and they vary from State to State, and some States have none. And I believe there should be a standard. Whether that standard is established by the industry, which we have tried to do, or established by law federally, I would support either. So I would support that, yes; I believe there should be a standard.

I'd like to respond to Joanne's comment, if I could, for a second, Mr. Nadler, with respect to our “shall nots.” And I'd like to—while we're delighted to have her support and encouragement, she did overlook that we have a number of “thou shalls” that we think are new additions here.

But we do say specifically that health plans shall not request or require genetic testing, not just require.

Mr. NADLER. Thank you. I have two more questions for you, if I can get them in.

Dr. ROWE. Yes, please.

Mr. NADLER. What's been the reaction of other insurers to Aetna's guidelines?

Dr. ROWE. I think that we've been very pleased with the reaction. The American Association of Health Plans has asked me to come and meet with the policy committee of their board and present our position, so that they could consider whether they would recommend it as an industry standard. So that is underway, so we've been pleased with that.

Mr. NADLER. Thank you, Mr. Chairman. I ask unanimous consent for one more question.

Thank you.

This is a combined question. Mr. Miller stated that having a given mutated gene is just bad luck, and we shouldn't do anything about it; the individual should suffer the consequences. Combining that with what I urged before—first of all, do you agree with that? And would you comment on the statement I made before? Do you think it's real or fanciful that, if we don't do something here, eventually, with knowledge of the genome, it's going to make people unable to get insurance for what they need and, therefore, make insurance companies unable to supply insurance for what people don't need, because they will know they don't need it?

Dr. ROWE. I believe that your—I hate to disagree with another Manhattanite, but I think you're really an optimist, Mr. Nadler.

Mr. NADLER. An optimist with respect to scientific progress, you mean?

Dr. ROWE. Yes. I think most of the data that we have currently indicates that only about one-third of the morbidity and mortality that people experience as they grow older is related to inheritance, and two-thirds are related to lifestyle decisions or to other factors that have not been identified. And even in diseases which have some clear, heritable pattern to them, like diabetes, we have been unable to identify a single gene. There are many, many genes that seem to play partial, complimentary roles.

So I think that we're not likely to get to where you think we're likely to get as quickly as you think we might get there. But if we get there, then we could make the rules. I would certainly agree with that.

But I just think it's overly optimistic, based on my understanding of the information. As far as whether we should be interventionists, I'm a physician; I believe the role of medicine is to use the scientific method to improve the well-being of individuals and populations. And I believe that we should be very interventionist. And I believe in gene therapy. I mean, if people have a gene, and they're not yet sick, I would be in favor of giving them gene therapy, if that will prevent a disease, certainly.

Mr. CHABOT. The gentleman's time has expired.

Mr. NADLER. Thank you.

Mr. CHABOT. The gentleman from Alabama, Mr. Bachus, is recognized for 5 minutes.

Mr. BACHUS. Thank you. Mr. Chairman, with deference to Mr. Forbes, I would ask unanimous consent or ask the Chairman to ask unanimous consent to let the gentlelady from Maryland go before me, in the order, out of deference to her contribution to this debate.

Mr. CHABOT. I have no problem with that, if there's no objection from other Members of this Committee.

Mr. SCOTT. Mr. Chairman, by unanimous consent, you said that she could go after all the Members.

Mr. CHABOT. That's what I said.

Mr. SCOTT. If he could just defer his time to her, and she could defer her time to him, you would get to the same place.

Mr. BACHUS. That sounds good.

Mr. CHABOT. I'll consider that an objection.

Does the gentleman want to yield?

Mr. BACHUS. I defer my time to Ms. Morella.

Mr. CHABOT. All right. The gentleman has yielded his time.

Ms. MORELLA. Thank you very much. Actually, I was willing to wait my turn, because I'm just so pleased that you offered me the courtesy of being able to hear those people testifying on this very important issue, particularly since I'm not a Member of this Committee or this Subcommittee.

And I thank you very much for offering your time, and I will certainly give you my time. And others on the Committee have been here waiting, on both sides of the aisle.

My interest in this, obviously, stems from the fact that I have in my district the National Institutes of Health, which has been involved with the Human Genome Project. And I have the honor of representing what we call "Human Genome Alley." And as someone who chaired the Technology Subcommittee of the Science Committee for 6 years, we had a number of hearings on this. And I have heard so often from many of the companies about the problems they have with getting people into clinical trials, particularly because they don't have the safeguards of the Genetic Non-discrimination in Health and Employment statute.

I do want to mention, too, Mr. Nadler talked about the H.R. 602, and I am the Republican prime sponsor on that, and think it is the right way to go. And I'm very interested in hearing Dr. Peel kind of imply that she was in favor of it.

And I think, Dr. Husted, you probably similarly feel that that is legislation that would help to remedy some of the problems that you have indicated?

Ms. HUSTEAD. Yes. The Health Privacy Project doesn't endorse specific legislation. But from our analysis of the bill, it would clearly address, and address well, many of the concerns that I've talked about today, yes.

Ms. MORELLA. Dr. Rowe, I did have a chance to read your testimony, and I very much appreciate your being here, with Aetna.

And as you know, as of April 2002, 41 States had enacted laws prohibiting insurers from using genetic information to discriminate against individuals, and State law does vary significantly, with some States explicating prohibiting the use of information ranging from family medical history to DNA testing, and others ban discrimination based on chromosomal test results alone.

And these statutes generally fall into one of two categories. The first group prohibits insurers from using genetic information about an individual, except for research or investigative purposes. The second group specifically names permitted uses of genetic information.

Does your company have to keep track of the different laws in the various States in which you operate? And if so, as genetic test-

ing becomes more commonplace, don't you think that this will become not only confusing but burdensome?

Dr. ROWE. Yes. [Laughter.]

Ms. MORELLA. Giving me more time. Thank you. That's very good.

And, Doctor, you've heard Dr. Peel's testimony and her assessment of the impact of the final modified privacy rule. I'm wondering what your assessment of the impact of this rule is.

Dr. ROWE. I'm less concerned about some of these hypothetical or potential outcomes than Dr. Peel. I would just describe myself, in the interest of time, as feeling less concerned about the practical aspect of this, that some of the concerns I think are somewhat overblown. That's my view.

Ms. MORELLA. Speaking of the practical aspect, if Congress does not pass comprehensive genetic nondiscrimination legislation, do you think that insurers might well use or do use genetic information to set premium rates?

Dr. ROWE. With respect to group insurance—I think a distinction has been made between group and individual, and I will speak about group insurance. We have no evidence that that's the case. And as Mr. Miller said, there really isn't a lot of incentive for insurers to do that.

So I'm not concerned that—the data, and it may have been before you arrived, Ms. Morella, but I pointed to some literature from some scientists that indicated that the presence or the absence of State regulations seemed to have no influence on the incidence of any episodes of this kind of use of the information. So there are no data to indicate that this is as big a problem as people are concerned.

I think that, in this case—and I understand it. I'm a doctor; I've treated patients; patients are very concerned about this. But the lawmakers are way ahead of the lawbreakers in this case. We do not have evidence that this has been a prevalent or even rare problem.

Mr. CHABOT. The gentleman's time has expired. Can I have unanimous consent to give an additional 15 seconds, if the gentleman, Mr. Miller, would like to respond?

Mr. MILLER. I'll just follow up quickly, because, actually, I had a conversation with Mark Hall yesterday, who is one of the scholars on that. And it's still the case that there's no evidence of this type of underwriting in the group market.

Now, what Congress does is it passes laws that ratifies what the private sector is doing, and feels good about it. It says, "Look what we accomplished." In fact, you pass laws that kind of were not—the practice was not being done in any case, but it makes you feel good to do it.

Mr. CHABOT. The gentleman's time has expired.

The gentleman from Virginia, Mr. Scott, is recognized for 5 minutes.

Mr. SCOTT. Thank you, Mr. Chairman.

I want to follow up on that, Dr. Rowe. Underwriting kind of works both ways, because you have adverse selection. Is Aetna concerned about people getting the test and then using the test to decide whether they'll sign up for insurance or not?

Dr. ROWE. That's not an important consideration for us, at this point. It's not been a major concern. I don't think we have any evidence that it is a highly prevalent—it is obviously, perhaps, in some people's minds, an unethical behavior, but we don't think it's highly prevalent. We sell group insurance to large groups, distribute the risk, et cetera.

Mr. SCOTT. Well, for individuals, do you know if there's any concern in the insurance industry, those that sell to individuals, that people may consider themselves at higher risk and, through adverse selection—

Dr. ROWE. Sure. I believe there is, that people might be tempted to buy individual insurance policies if they know that they're at risk and don't disclose that. Certainly, that's a concern.

Mr. SCOTT. That's a concern to the insurance industry?

Dr. ROWE. I believe so, yes.

Mr. SCOTT. Okay.

Dr. Peel, if someone has an indication that they're at high risk for, say, cancer, for example, what happens under present law? And how are things going to be different your patients on October 15th?

Dr. PEEL. And you're saying there's evidence that they have risk for—

Mr. SCOTT. If they have a marker, if they've got genetic information that they just assume people not know, what is the present law? And how will things change October 15th?

Dr. PEEL. My understanding is that, until October 15th, we still retain, each American still retains the right to consent to the release of their medical information under the HIPAA privacy rules. October 15th, that right to consent is eliminated and replaced by Federal regulatory permission for health plan access to all information that exists, you know, about your health status—cancer, genes, mental health—that exists anywhere in the past, and they can have access at that point, through Federal regulatory permission.

Mr. SCOTT. And that is by regulation, not by statute.

Dr. PEEL. Okay, I'm not a lawyer; I don't know about regulation and statute. My understanding is that it will have the effect of law, unless Congress reviews these major rule changes or these amendments and says, "No, we do not endorse the Federal Government accumulating such vast amounts of information about every person." It's really accumulating information for both the Government and private industry. I think Congress, obviously, should not endorse these changes.

Mr. SCOTT. Does anybody disagree with that assessment?

Mr. MILLER. Sure. The regulatory permission is permissive. I mean, there's been a lot of kind of exaggerated analysis of this. I just had a conversation with privacy attorney Jim Pyles in the audience on this, and we disagree on this.

You're not prevented from still restricting this information at the point of encounter with the provider in which you engage. State laws can be more restrictive than the Federal law. It sets a floor, not a ceiling. You can attach contractual restrictions to how your information is being used.

We may have a problem with the retroactive reach-back, where, for a short period of time, people may have believed there was a

right to consent—it wasn't fully rolled out in practice—and now it's being taken back. We have some problems with kind of making too much public access through the Government to this information. But I think there are self-corrective means through the private sector in which we could kind of control that information.

It should just be harder to do, and you'd actually have to pay attention to how your health information is being used when you engage with the medical community.

Ms. HUSTEAD. In order to figure out sort of how things will be different, it's actually come April of 2003, because that's when entities have to apply with the HIPAA privacy regulation. You have to look at sort of how the HIPAA privacy regulation is going to intersect with State Law. And that's going to vary by State to State.

There's no question that—

Mr. SCOTT. Federal regulations do not preempt State laws?

Ms. HUSTEAD. The HIPAA regulation preempts contrary State laws that are less protective of privacy. It does not preempt State laws that either protect privacy better or provide a greater right of access to one's health information. And that's an important standard, because we think it's important for States to be able to go further than the HIPAA privacy regulation.

But what is rather dramatic about the recent change to the HIPAA privacy regulation in the area of consent is that, until the middle of August, providers were required to get prior consent before using health information for treatment, payment, and health care operations purposes. And as a result of the changes that were announced in August, that consent requirement has been eliminated.

And what that means is that, unless State law puts some greater restriction on the freedom to use and disclose health information, the HIPAA standard has a fairly broad range of uses and disclosures that are permitted without consent.

Mr. SCOTT. Like what?

Ms. HUSTEAD. Well, the health care operations category alone goes on and on: purposes relating to business development, to training of health care professionals, accreditation purposes. And, again, the HIPAA reg would allow use or disclosure of information that is fully identifiable for all of those purposes.

Mr. CHABOT. The gentleman's time has expired.

The gentleman from Virginia, Mr. Forbes, is recognized for 5 minutes.

Mr. FORBES. Mr. Chairman, I'd like to defer my time to Ms. Morella, please.

Ms. MORELLA. Thank you very much.

I'm going to pick up and give you a chance, Dr. Husted, to respond to that question about the genetic information being used to set premium rates. I think you wanted to respond to it before.

Ms. HUSTEAD. Sure. Thank you very much.

What I wanted to comment on was the discussion that we were having about the work that's been done by Professor Hall. I don't dispute that there are—that discrimination on the basis of genetic information is not a rampant problem. It does not happen 100 times a day. It is not like the civil rights abuses in our history. It is not of the same magnitude yet.

But their work, Hall and Rich's work, does show that the concern about misuse of genetic information by insurers and employers impacts people's willingness to undergo genetic tests and to submit that information to their insurance company for reimbursement.

There are at least three reasons why one might encourage the enactment of the Federal legislation. One is the problem is rampant, and the abuses are happening every day. Another is that it happens, and it shouldn't happen. And another is that the concern that information will be misused by certain actors inhibits people in making clinical decisions about their own health care.

And I think that, at the very least, the last two reasons apply in this circumstance.

Ms. MORELLA. That's an excellent response. And picking up on that with Dr. Peel, since you're an expert on mental health privacy issues, I just wondered about what you think the impact of passing comprehensive genetic nondiscrimination legislation would be on those who might undergo genetic testing that would reveal a predisposition to something like the possibility of a mental illness like schizophrenia.

Dr. PEEL. I think it's absolutely critical. In my practice, I have several people who are very worried about getting Alzheimer's disease because they have a parent with Alzheimer's disease, and they will not get the testing, even though this would be very important information for themselves and taking care of themselves, because they understand, having already been discriminated against for having a mental illness, you know, what that would mean for employment and insurance in the future, and for all of their other close family relatives, close blood relatives.

And so I don't think that the impact of protecting privacy or not protecting privacy is theoretical. That's what I'm really here to tell you.

You know, the problem with the discrimination based on using genetic and medical information is, because we don't have audit trails of who gets the information, people can't prove they've been discriminated or harmed by it.

My patients have all had effects in their lives based on people knowing about their having a mental illness or taking a medication that's typically used to treat mental illness. They've all experienced this. That's why they're so fanatic about protecting their privacy.

And, Mr. Nadler, I think it's not just the insurance system that's going to be destroyed if genetic and health privacy is not protected. It's the health care system, the health care system, because people just—they will not seek care. They will avoid care, they will avoid the testing, if they think it's going to be used against them. It's not just the insurance system, the health care system. Doctor-patient relationships are over if what somebody says to me is going to be used to harm them.

It's exactly the same case with genetic testing, you know, except what I see as discrimination directed at one individual, the person I see, with genetic testing, you can then discriminate against hundreds, not just the one that was tested. So the risks are extreme.

Ms. MORELLA. So the chilling effect actually paralyzes or freezes—

Dr. PEEL. The chilling effect is real, I'm here to tell you. It's a big factor. And think about the impact on the person, the course of their therapy, worrying if they're going to lose their mind.

And if we think about it, this is truly going to be an election issue. Suppose we had known that Ronald Reagan had a risk of Alzheimer's, a genetic risk of Alzheimer's disease, would he have been elected President? I mean, I think these health issues, the privacy of health information, is going to become—and genetic information—is going to really become critical for the leaders of our country. And that's partly why I think the President is always releasing these things about how great his jogging and running status is and his low body fat. He's trying to say, "I'm okay."

With the genetic testing, people are not going to get it unless they're certain it's safe.

Mr. CHABOT. The gentleman's time has expired.

The gentlelady's time now comes into being, so the gentlelady is now recognized for 5 minutes, which she can defer to the gentleman down here or she can take it herself.

Ms. MORELLA. I will only take like 30 seconds to give Dr. Rowe an opportunity to respond.

Dr. ROWE. Sure. I'd just say, I disagree. I do not believe the American health care system will be destroyed if Federal legislation is not passed with respect to genetic testing.

And in my experience as a physician and president of a medical school and head of Mt. Sinai Medical Center in New York City, which is a large institution, patients generally act in their own best interest with respect to their health care. If patients have genetic testing and they have a gene for a disease, and a treatment is available which will prevent them from developing that disease, such as a breast cancer or colorectal cancer, I believe that patients will avail themselves of that treatment rather than be concerned that going to get the treatment exposes them to disadvantage because of the use of the genetic information.

That's just another opinion. I believe people will use these tests to get treatment, if treatment is effective for these risky conditions.

Ms. MORELLA. Thank you.

You've assembled a great panel here, Mr. Chairman. And I thank you all for the courtesies, Mr. Forbes, Mr. Bachus. I yield my time to Mr. Bachus.

Mr. BACHUS. Thank you. Dr. Rowe, you kind of have two hats on. You're an M.D., and you're also CEO and president of Aetna.

Dr. ROWE. Right.

Mr. BACHUS. You have offered that Aetna has proposed certain guidelines, and you do use the words that you won't "request" it or "require" it.

Dr. ROWE. Right.

Mr. BACHUS. I think what maybe the public is more interested in—I know I would be—is not whether it's requested or required, but whether it's obtained or used.

Dr. ROWE. Right.

Mr. BACHUS. Isn't that the key?

Dr. ROWE. Yes. I think that I'm not an expert on the specifics of the words that are being debated in the various bills, but I understand there is a lot of discussion about what the word "collect"

means. And what it means—what do you have to do to have collected something, and whether it's active or passive or whatever. So I don't want to comment on that. I'm not a lawyer, and I don't draft legislation.

But the use of the information is, I think—the reason I came out with these standards, and our company did, is because people are really concerned about this, and I think they feel that this kind of discrimination is very common. And it isn't, and we should promise that we will not do it.

But on the other hand, Mr. Bachus, I do believe that we should have the capacity to have the information so we can use it to the benefit of the patient, like the examples I gave. And not letting us use it in any way really blunts a positive effect that health plans can offer and add value to the health care of the individual. That's really our point, that discrimination should be separate from any use.

Mr. BACHUS. Okay. And I would agree with you, that if you're using it for a positive purpose, to help people, then it's a good use. Now, sharing it is another thing. You know, sharing it with someone else goes beyond—

Dr. ROWE. I agree with that.

Mr. BACHUS. Let me ask you this: I just drew up something here. Would you agree to this as a guideline, that: "No decision by a group health plan or health insurance insurer to offer, expand, limit, deny, or terminate health coverage, or to set or increase premium charges, deductibles, or exclusions, shall be influenced by genetic information"?

Dr. ROWE. They told me that this wouldn't happen to me. [Laughter.]

Dr. ROWE. But given that it is happening to me, and given that I reserve the right to study this proposal and get some advice, it sounds good to me.

Mr. BACHUS. Okay. Let me go further and say that: "Nor shall"—

Dr. ROWE. If there's something else I should be reserving, Ms. Morella, please tell me here.

Mr. BACHUS. Really, I just drew this up while—

Dr. ROWE. No, no. I think that's consistent with what I've said.

Mr. BACHUS. "Nor shall said information be requested, compiled, maintained, or reviewed in connection with these decisions," the above decisions, "or other underwriting decisions."

Dr. ROWE. I'd have to think, Mr. Bachus, about the implications of that. You know, we're talking about the group insurance, right, market?

Mr. BACHUS. Yes.

Dr. ROWE. That's what you're talking, right? Read that again to me, that second part.

Mr. BACHUS. "Nor shall said information be requested, compiled, maintained, or reviewed in connection with these decisions or other underwriting decisions."

Dr. ROWE. I think the problem would be—I'd reserve judgment on that, because my concern is that somebody is going—if we're sent some information because we pay for some tests, so we get some information in our database, we're not using it, but it was

sent to us and it's in our database, then somebody is going to come and say we compiled that information.

Mr. BACHUS. Well, but you would have compiled it, but you wouldn't have compiled it in connection with——

Dr. ROWE. That's right.

Mr. BACHUS [continuing]. The above decisions, nor——

Dr. ROWE. I'd want to make sure that was the case.

Mr. BACHUS [continuing]. In connection with other underwriting decisions.

Dr. ROWE. Right.

Mr. BACHUS. And, you know, further, and this has kind of become popular, with all the CEOs kind of reporting once a year, certifying they follow——

Dr. ROWE. Yes, yes. We're on the record as having done that.

Mr. BACHUS. "And every health plan and insurer shall certify compliance with said prohibition to every insured group and to"—— and I don't know the appropriate secretary enforcing the provisions; you could say—"U.S. Department of Justice on an annual basis," or whoever.

Dr. ROWE. Right. Well, those kinds of mandates——

Mr. BACHUS. Or the Public Health Service.

Dr. ROWE. Yes, I think that the question is, if there's a law—if we're talking about having legislation, then we don't want to break the law. I guess what you're saying is that, in addition, you'd like to have the CEO certify, just as the SEC has recently certified, that to the best of his or her knowledge, that this is—that they're in compliance. And I certainly feel, personally, I would be willing, personally, to make that certification. I don't want to speak for the industry.

Mr. BACHUS. Sure.

Mr. CHABOT. The gentleman's time has expired.

Mr. BACHUS. I thank——

Dr. ROWE. Am I responding to your question?

Mr. BACHUS. Oh, absolutely.

Mr. CHABOT. The gentleman's time has expired.

The purpose of this hearing was to explore the privacy concerns raised by the collection of the genetic information by employers and insurers. And I think this panel has really done an excellent job of exploring the issues, and we had a lot of give and take between the Committee and the panel.

I want to thank you all for your time here this morning.

And I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and to include extraneous material.

Mr. BACHUS. I've got one other question that I'd like submitted in writing to the panel.

Mr. CHABOT. Without objection, that will be done.

So thank you very much for coming. We have a vote on the floor, and without further ado, this Committee is adjourned.

[Whereupon, at 11:51 a.m., the Committee was adjourned.]



## A P P E N D I X

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### MATERIAL SUBMITTED FOR THE HEARING RECORD

IN FOLLOWUP TO THE LETTER FROM REP. STEVE CHABOT, DATED SEPTEMBER 18, 2002,  
FOLLOWING IS THE RESPONSE TO REP. BACHUS' QUESTION

Bachus Question:

**I understand that genetic mutations can be either inherited or acquired, and can be classified as either multi-factorial or single-gene disorders. While multi-factorial disorders only make a carrier susceptible to developing a disease, single-gene conditions virtually guarantee that a person will develop the genetic disorder. What effect would the knowledge that an individual has a single-gene condition have on an employer or insurance carrier? What are the privacy concerns raised by this knowledge?**

Dr. Rowe's Response:

Existing law effectively prohibits employers and their group health insurers from refusing to provide coverage to an individual employee or family member based on health status, and this protection extends to latent health risks such as the presence of a multi-factorial or single-gene disorder. So long as that individual is an employee and is otherwise eligible for coverage (e.g. works the requisite number of hours, enrolls at the appropriate time), they are eligible to join their employer's health plan or the plan of their choice, if their employer offers more than one. HIPAA has narrowly-crafted pre-existing condition provisions that do permit benefit waiting periods in the case of a new employee without prior coverage, but these waiting periods are time limited and short ended or eliminated by all prior creditable coverage. For the vast majority of employees these waiting periods do not apply.

In some instances group health carriers may collect health information about group members solely for purposes of pricing the group. Both the collection of this information and its use in determining rates is governed by robust state insurance regulation, and any subsequent disclosure or use is strictly limited by HIPAA and state privacy laws. The information obtained in this process is limited to known illnesses and injuries. Group carriers cannot compel testing (genetic or otherwise) and would rarely if ever obtain genetic information about asymptomatic individuals. This sort of rating is limited almost exclusively to the smaller employer market, i.e. 50 or fewer employees. For large employer groups, the health status of any one individual is likely to be insignificant and would most likely not impact the group's cost. Medium sized employers are often rated on the basis of historical claim experience. Larger employers typically bear their own risk (self-funded). In either of these circumstances the genetic risk factors in the absence of a manifest illness would be irrelevant to the insurance carrier's pricing decisions.

With respect to our group life business, we generally do not underwrite on an individual basis (except for late entrants or those seeking large amounts of insurance). In those cases where underwriting is done, HIPAA prevents us from using protected health information we collect as a health insurer, such as genetic information, with respect to our other lines of business.

PREPARED STATEMENT OF THE HONORABLE LOUISE M. SLAUGHTER, A  
 REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

I appreciate the opportunity to submit testimony on an issue with which I have become extremely involved over the past several years: the privacy of genetic information, and the potential for its misuse. I would like to commend Chairman Chabot and Ranking Member Nadler for holding a hearing on these matters, which are becoming more pressing every year.

Almost seven years ago, I introduced legislation banning health insurance discrimination on the basis of genetic information. At the time, genetic discrimination seemed like a futuristic concept—the stuff of science fiction, not a timely public policy issue. A scant five years later, however, scientists announced they had all but completed a full map of the human genome. Today, dozens of genetic tests are commercially available, and there have even been some successes in gene therapy in humans. Clearly, the future has arrived.

Unfortunately, Congress has made little progress in the policy arena, even as science rocketed ahead. In 1996, we passed modest legislation limiting health insurers' ability to discriminate based on pre-existing conditions, including genetic information. But we have gone no further in banning such discrimination in health insurance, and there has been no action at all to address the use of genetic information in the workplace.

This inactivity represents an abdication of Congress' responsibility to examine public policy issues and craft appropriate legislation. Genetic discrimination is a very real fear for many Americans, and a reality for a handful. While the practice is not yet widespread, Congress should not have to wait for scores or hundreds of people to suffer before taking appropriate action.

Genetic discrimination is simply wrong. Allow me to explain why I believe discrimination based on predictive genetic information should be illegal.

1. *Genetic science is not yet fully understood.* Immediately following the discovery of the first breast cancer gene, scientists estimated that having this gene conferred an 85% risk of developing breast cancer. Within two years, however, the risk had been downgraded to only 50 percent. Over time, we will further refine our understanding of these and other genes, as well as the interplay among genes and the impact of the environment. Using genetic information to discriminate at this point in time is so inaccurate as to be almost useless—especially in the context of determining who should get a job, or who should be eligible for affordable insurance.

2. *Having a predictive gene does not necessarily mean you will ever get sick.* And even if you do, the disorder might not develop for 10, 20, or 30 years. No one should be passed over for a promotion at work or lose their insurance coverage simply because they might get sick someday.

3. *We all have genetic flaws.* Scientists estimate that each person has between 5 and 50 significant genetic mutations, making us all ultimately unemployable and uninsurable. By allowing genetic discrimination to persist, we effectively penalize the people who happen to have the genes that were discovered first.

All Americans are at risk for genetic discrimination because we all have genetic flaws. It is only a matter of time before we identify them. Given these facts, it is appropriate for Congress to protect our constituents against this hazard that is faced by everyone, and which will only grow in the future.

Witnesses at this hearing will raise some concerns that should be addressed because they reflect common misconceptions. While I respect these individuals' right to oppose genetic nondiscrimination legislation, I believe their arguments collapse on examination.

\*\* *Health insurers should be allowed access to genetic information in order to manage patients' care.*

The past decade of controversy over managed care has made one thing clear: Americans want their health to be monitored by doctors, not insurance companies. We can give physicians and health care providers access to genetic information while keeping it private from underwriters or insurance company bureaucrats.

\*\* *There is no evidence that health insurers use genetic information to discriminate today or will do so in the future.*

Some insurers will not engage in such discrimination. For example, I applaud Aetna's decision to disavow the practice and to cover genetic tests and counseling. But other insurers have already discriminated against consumers on the basis of their genes, and we must therefore assume that more such cases will occur in the future. Aetna and other forward-thinking insurers would benefit from a federal law that establishes a level playing field and prevents less scrupulous insurers from using genetic information to select customers or set rates.

In addition, this argument ignores the fact that the fear of genetic discrimination is playing a major role in many patients' health care decisions. I have spoken to dozens of doctors and genetic counselors who say that an individual's decision whether to take a genetic test may hinge on their confidence in the privacy of the information. For example, one constituent wrote to me saying that he wanted very much to take a genetic test for Alzheimer's disease—which had killed both of his parents—but that he would not do so as long as genetic discrimination was legal. Patients should be free to make medical decisions based on sound health care and their own personal preferences, not on their fear that the information will be used to undermine their best interests.

*\*\* By hiding genetic information from an employer, a worker may misrepresent him or herself to the employer's detriment.*

Employers should have access to health and other information that is directly relevant to an individual's ability to perform the essential duties of a position. There is no reason for an employer to learn other information that has no bearing on a person's qualifications for a given job. Employers are currently prohibited from prying into certain parts of a worker's life; for example, an employer may not ask a female prospective employer whether she intends to get pregnant in the near future. Similarly, there is no reason for an employer to know whether a person might develop cancer a decade hence.

*\*\* Banning genetic discrimination in health insurance will allow high-risk individuals to obtain insurance at bargain rates.*

This argument has two distinct flaws. First, it assumes an Us vs. Them situation, where there are a limited number of individuals at high risk of genetic disease on one side and the general population on the other. But we are all at high genetic risk for some condition or disorder. There is no Us and Them; there is only Us.

Second, the argument undercuts the very concept of insurance and risk pooling. In a properly-designed risk pool, there are people who will be expensive to cover and others who will remain relatively healthy. The healthy subsidize the ill. This is the most fundamental purpose of insurance.

*\*\* Being at high risk for a genetic disorder is just "bad luck" and does not deserve a legislative remedy.*

Numerous government programs seek to mitigate all kinds of "bad luck"—the misfortune of being born into a low income family, or losing one's job, or being the victim of a natural disaster. The entitlement programs that represent about one-third of the federal budget could all be characterized as helping those suffering "bad luck." To argue that genetic information is one type of misfortune that does not merit assistance is not only callous, but illogical.

I am proud to sponsor legislation that would ban genetic discrimination while preserving privacy and the flowing of medical information among health care providers. H.R. 602, the Genetic Information Nondiscrimination in Health Insurance Act, has the support of 266 cosponsors and over 300 organizations. I am pleased to have as an original cosponsor my colleague, Rep. Connie Morella, whose district encompasses both the National Institutes of Health and numerous biotechnology companies engaged in genetic research.

H.R. 602 would ban genetic discrimination while avoiding the pitfalls described by some of the witnesses. The bill has broad support both inside and outside Congress, having been reviewed and perfected over the past six years. We have a solution to the problem at hand; it only remains for the House to act upon it.

Once again, Mr. Chairman, I thank you for holding this hearing and allowing me the opportunity to testify. I am hopeful that the Subcommittee's next action will be to urge the majority leadership to schedule H.R. 602 for consideration by the full House of Representatives.



## **Nondiscrimination in Employment Based on Genetic and Other Health Information**

**(Approved by the IEEE-USA  
Board of Directors, 20 August 2002)**

IEEE-USA supports restricting the use of non-job-related genetic and other health information in employment decision-making, to discourage potential employment discrimination.

IEEE-USA recognizes that the American public needs to be able to embrace the increasing health benefits provided by genetic information without fear of consequent discrimination. Protection against such discrimination is essential for the adoption of new genetic technologies, the advancement of genetics research, and the realization of personalized medicine that improves outcomes and decreases suffering.

Electrical and electronics engineers are at the forefront of health systems engineering and health informatics. As such, they offer unique insight into the complex technical and legal paths that may allow sensitive health information to migrate beyond an individual's intent. Like all health consumers, engineers also stand to benefit from the accelerated arrival of personalized medicine. And like all employees, they have an interest in eliminating all forms of unfair discrimination in the workplace.

Presently, employers are able to obtain unrestricted access to an individual's health information by requiring that an applicant sign a general medical release following a conditional offer of employment. If the conditional offer is withdrawn, the individual usually has no legal right to an explanation of the reason for withdrawal.

Such an environment affords little protection against employment discrimination based on any sort of sensitive health information, particularly relating to one's genes. The current situation discourages the public from seeking out the benefits of genetic testing and impedes the widespread adoption of genetics technologies and the advancement of genetics research.

In response, IEEE-USA supports:

1. Restricting employers (including employment agencies acting on behalf of employers) from requiring, requesting, collecting, purchasing, or otherwise obtaining health information about an individual or the individual's family member(s), unless the requested information is:
  - a. directly related to the requirements of an individual's current or applied-for job position, or
  - b. necessary to support workplace health and safety monitoring, or
  - c. necessary for other health research activities for which, the employer will only receive aggregate data (not revealing the identity of individual employees).

Further, we recommend that employers must obtain voluntary written consent from employees or applicants who are requested to undergo medical tests and measurements. Prior to obtaining such written consent, the employer must provide:

- i. purpose of the test or measurement;
  - ii. details of the analyses to be performed;
  - iii. applicable privacy policies and possible ramifications of the test results;
  - iv. details regarding the storage/destruction of test samples;
  - v. process for accessing test results and correcting errors in records; and
  - vi. proof of the testing program's compliance with applicable government regulations.
2. Restricting employers from making employment-related decisions based on health information, except in cases where that information is necessary to support workplace health and safety or to demonstrate an individual's ability to perform a specific job (e.g., meet minimum prerequisites for weight, height, and eyesight).
3. Adding safeguards against discrimination in employment decision-making where an individual's health information may be a contributing factor. In particular, employers should be required to inform an applicant in writing of the reasons for retracting a conditional offer of employment.
4. Minimizing the economic incentives that encourage employers to obtain non-job-related health information for use in their employment decision-making (e.g., restricting or eliminating the use of such information in the determination of group health insurance rates).

*This statement was developed by the IEEE-USA's Medical Technology Policy Committee and represents the considered judgment of a group of U.S. IEEE members with expertise in the subject field. IEEE-USA is an organizational unit of The Institute of Electrical and Electronics Engineers, Inc., created in 1973 to promote the careers and public policy interests of the more than 235,000 electrical, electronics, computer and software engineers who are U.S. members of the IEEE.*

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