The Genetic Information Nondiscrimination Act

A new way for health care

Rep. Slaughter's Remarks to the Harvard Graduate School of Arts and Sciences Science Policy Group and the Biomedical Graduate Student Organization

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Thanks to all of you for coming today. I want to extend a special thanks to the Harvard Graduate School of Arts and Sciences Science Policy Group and the Biomedical Graduate Student Organization for inviting me here to speak to you.

It is always such a pleasure to speak with scientists and medical students about the congruence of science and public policy. It is absolutely critical for scientists and researchers to be engaged in the political process, because as we've seen over the past eight years, the policies coming out of Washington have a direct impact on your research or the way you practice medicine.

I am the only Member of Congress that has a masters in public health and I am a microbiologist by training and health care policy has been a special interest of mine since I first came to Congress 22 years ago. I have always strived to ensure that our nation's health policies are grounded in accurate science.

I'm here today to talk about the Genetic Information Nondiscrimination Act, or GINA for short. I worked on this landmark law for 13 years.

I also had the pleasure of working with your hometown Senator - Senator Kennedy - on this law over the past few years.

As most of you know, in 1991, Congress initiated the Human Genome Project as a collaborative effort with the Department of Health and Human Services and the Department of Energy with the purpose of decoding the human genetic sequence.

Three years later, the field of medicine was transformed by the discovery of the first genetic mutation linked to breast cancer.

Then in 2003, researchers completed the sequencing of the human genome. This momentous event threw open the doors of opportunity and researchers have been able to identify genetic markers for a number of chronic health conditions.

A thorough understanding of genetics offers great potential for early treatment and the prevention of numerous diseases.

As more genetic links to diseases have been identified, genetic tests have become commercially available, and genetic technology has become firmly embedded in the practice of medicine.

Everything from cancer to heart disease and diabetes are known to have a genetic component.

It is estimated that all humans are genetically predisposed to between five and fifty serious disorders. None of us have perfect genes.

It is important to note that just because a person tests positive for a genetic mutation, there should be no assumptions that the person will develop that disease. Genetic tests that reveal genetic mutations simply indicate risk. Despite testing positive for a genetic mutation, an individual may remain asymptomatic over their entire lifetime.

However, the ability to decode which diseases we are predisposed to, or at risk for, leaves each of us vulnerable to discrimination.

There were some in Congress who called GINA "a solution in search of a problem" and suggested that genetic discrimination is rare, if it happened at all.

Unfortunately, genetic discrimination was happening and it was well documented.

In 2004, Congress and the Secretary's Advisory Committee on Genetics, Health, and Society heard from several victims of such discrimination.

Prominent examples also include a 2000 case where the Burlington Northern Santa Fe Railroad performed genetic tests on employees without their knowledge or consent. The

workers involved had applied for workers compensation, and the tests were conducted to undermine their claims. One such worker had refused to submit a blood sample for genetic testing, and consequently was threatened with termination. Burlington Northern Santa Fe Railroad settled these cases in April 2001 for $2.2 million.

A few years earlier in 1998, Lawrence Berkeley National Laboratory was found to have been performing tests for syphilis, pregnancy, and sickle cell anemia on employees without their knowledge or consent for years. Throughout the 1970s, many African Americans were denied jobs, educational opportunities, and insurance based on their carrier status for sickle cell anemia, again, despite the fact that a carrier lacked the two copies of a mutation necessary to get sick.

We also heard from:

- A North Carolinian woman who when her genetic tests revealed a risk for a lung disorder was fired even though she had begun the treatments that would keep her healthy;

- A social worker whom, despite outstanding performance reviews, was fired because of her employer's fears about her family history of Huntington's disease;
- An adoption agency refusing to allow a woman at risk for Huntington's disease to adopt a child; and
- A woman who was tested and diagnosed with alpha-1 antitrypsin deficiency, which she could control with medication. Shortly following her diagnosis, she lost her job. Without employment, and having a pre-existing condition, she also lost her health, life and disability insurance

A 1996 study showed that a number of institutions, including health and life insurance

companies, health care providers, adoption agencies, the military, and schools were reported to have engaged in genetic discrimination against asymptomatic individuals.

A 2001 American Management Association survey of employer medical testing practices found that 1.3 percent of companies test new or current employees for sickle cell anemia, 0.4 percent test for Huntington's disease, and 20.1 percent ask about family medical history. When asked if the results were used in hiring, reassigning, retaining or dismissing employees, 1 percent of employers indicated that sickle cell, 0.8 percent indicated that Huntington's, and 5.5 percent indicated that family history results were used.

Given the prevalence of genetic discrimination, many individuals are deciding against having genetic tests or participating in genetic research.

Others are opting to take genetic tests under an assumed name or pay out-of-pocket in order to learn valuable information about their potential future health status, but not have it used against them.

In a 2006 Cogent Research poll, 66 percent of respondents said they had concerns about how their genetic information would be stored and who would have access. 65 percent said they were concerned about health insurance companies, and 54 percent were concerned with employers gaining unauthorized access.

Health care professionals also are hesitant to make genetic information available. In one survey of genetic counselors, 108 out of 159 indicated that they would not submit charges for a genetic test to their insurance companies primarily because of the fear of discrimination. 25 percent responded that they would use an alias to obtain a genetic test in order to reduce the risk of discrimination and maximize confidentiality. Moreover, 60 percent indicated that they would not share the information with a colleague, because of the need for privacy and fear of job discrimination.

Studies also have shown that even if early detection of a particular genetic mutation may help avert premature morbidity and morality, Americans are still deciding to forego genetic testing altogether due to fears of discrimination.

Hereditary nonpolyposis colorectal cancer (HNPCC) provides an instructive example. Six genes have been identified to determine if a person carries a mutation for HNPCC. HNPCC is the most common hereditary form of colon cancer and it is estimated that 380,000 Americans carry an HNPCC mutation. Those with the mutation have a 90 percent lifetime risk of developing one of the cancers associated with HNPCC. Between 1996 and 1999, people identified from families with the HNPCC mutations were asked to participate in a study that offered genetic testing for the mutation. While there were other considerations for not participating in the study, of those who declined genetic testing, 39 percent cited fears about losing health insurance as the reason.

The high fear factor led the authors of this study to conclude that without legal protections at the national level to address the public's fear of discrimination, a significant number of Americans will opt not to reap the benefits of advanced screening for cancer that would lead to healthier, longer lives.

We have laws to protect us from discrimination based on race, gender, and a host of other intrinsic characteristics. We desperately needed to enact similar law to protect against genetic discrimination not only to ensure that the tremendous potential of genetic testing and research could be realized but because it was the right thing to do.

GINA, now Public Law 110-233, will provide critical protections against genetic discrimination for all Americans.

Specifically, GINA will prevent health insurers from canceling, denying, refusing to renew, or changing the terms or premiums of coverage based on genetic information.

It also will prohibit employers from making hiring, firing, promotion, and other employment-related decisions based on genetic factors.

Because more than 61.8 percent of Americans get their insurance through their employers, without job security, there are no guarantees of insurance protections. If a person is protected from insurers but not their employer, they could be fired and lose their insurance coverage anyway. That is why it was critical for GINA to prohibit discrimination by both health insurers and employers.

Title I applies to employer-sponsored group health plans, health insurance issuers in the group and individual markets, Medigap insurance, and state and local non-federal governmental plans.

Title II extends prohibitions to employers, unions, employment agencies, and labor-management training programs.

As I mentioned, I first introduced genetic anti-discrimination legislation in 1995. Just last year, in 2008, GINA became law.

Looking at the tremendous need for GINA, it's difficult to imagine why it took 13 years to pass. To understand why, one must first understand the legislative process. I'll try to make this brief.

Once a bill is introduced in either the House or Senate, it is referred to a committee, which has jurisdiction over the bill. The legislation may be referred to one committee that has exclusive jurisdiction, or a number of committees that may share jurisdiction over issues.

Once referred, a committee will typically hold a hearing on the bill before it schedules a mark-up. A mark-up of a bill is scheduled at the discretion of the Committee Chairman, and Members of Congress serving on the Committee are allowed the opportunity to offer amendments.

After the mark up, the bill then goes before my committee - the Rules Committee - before it becomes available to be brought on the House or Senate floor for a vote. After floor passage, the bill is then referred to the other chamber. For example, a bill originating in the House is then referred to the Senate upon passage on the House floor. The bill will then go through a similar process in the Senate as it did in the House.

If the bill passes in both the House of Representatives and the Senate, but is not an identical version when it passes each chamber, it must then go to conference. Conferees from both the House and Senate reconcile any differences between the two versions of the bill. When conferees have come to an agreement on an identical version, both the House of Representatives and Senate have to vote once again on the conferenced version of the bill.

Only after an identical bill passes both chambers, it is it sent to the President. Upon receipt of the bill, the President may sign it into law or veto it. If a bill is vetoed, it must pass both chambers by a two-thirds majority in order for Congress to override the veto.

Sounds simple enough?

Most bills never make it out of Committee. That was the case for a long time with GINA. Although this bill had wide bipartisan support and over 200 cosponsors each Congress, under Republican leadership, the Committees of jurisdiction refused to hold hearings or mark ups.

So each Congress, I would reintroduce the bill, and at the end of the term, which is 2 years, the bill would die not having seen any legislative action.

Part of the problem was that despite the nearly 500 organizations which rallied in support of GINA over the course of 13 years, there was a smaller, but more powerful group opposed to the bill.

This group was known as the Genetic Information Nondiscrimination in Employment (GINE) Coalition. On the Coalition's steering committee were the powerful U.S. Chamber of Commerce, the Society for Human Resource Management, the National Association of Manufacturers (NAM), HR Policy Association, and the College and University Professional Association for Human Resources. They opposed the bill on several grounds and argued that new federal legislation was not needed.

Opponents mainly argued that GINA would create frivolous lawsuits for employers. However, GINA follows the format of other civil rights laws, like the Americans with Disabilities Act, by requiring the Equal Employment Opportunity Commission to review the merit of an individual's claim before they can proceed to a lawsuit.

These groups also argued that if an employer inadvertently got the information, they would be penalized. By the 109th Congress, we had protections in the bill that would not penalize an employer for inadvertently getting genetic information, as long as they did not then use that information to discriminate against the employee.

They managed to convince those controlling the agenda in the House of Representatives to ignore this bill. Yet, the bill passed in the Senate in both the 108th and 109th Congresses, unanimously.

Then the Democrats won the majority of House seats in the 110th Congress, which was ushered in on January 3rd, 2007.

On January 16th, 2007, I reintroduced GINA with my Republican colleague Congresswoman Judy Biggert of Illinois. Before passing the House, we again garnered over 200 bipartisan cosponsors of the bill.

It was in April 2007, and twelve years after I initially introduced a genetics antidiscrimination bill, that the House of Representatives took its first vote on the Genetic Information Nondiscrimination Act. And the vote was overwhelming - 420 to 3.

But then the bill was sent to the Senate where it was held up by a Senator, who is a doctor by training if you can believe it.For a while, I did not think GINA would ever become law.

It took us exactly a year and several negotiations to get agreement from the Senate and the Bush Administration. When the Senate did vote in April 2008, it passed GINA unanimously by a vote of 95-0.

And on May 21st, 2008, I watched as the President signed GINA into law. Thirteen years of hard work and dedication finally came to fruition.

Senator Ted Kennedy has deemed GINA, "the first civil rights legislation of the 21st century."

Although GINA was enacted last year, it takes time for an agency to implement a new law.

GINA states that Title I takes effect in May 2009 and Title II takes effect in November 2009.

This was done to allow the federal government to provide regulatory guidance as to how to implement the law. We have just completed this stage now.

The Departments of Treasury, Health and Human Services, and Labor and the Equal

Employment Opportunity Commission are in the process or have already completed regulations for GINA.

Meanwhile, genetic research is progressing at a rapid pace.

Researchers have identified genetic markers for a variety of chronic health conditions and increased the potential for early treatment and the prevention of numerous genetic-based diseases. There are already genetic tests for over 1,000 diseases, and hundreds more are under development.

The potential for genetic medicine is limitless. For example, it was about a year ago that the researchers at Moorefield Eye Hospital in London announced they had restored some eyesight to people who were disposed to a genetic disease that harmed their vision as children. To be able to restore eyesight is something none of us had ever dreamed of being able to do. But by injecting genetic material into the back of the eye behind the retina, they have received some sight. Researchers believe that once they are able to do this in younger children and are able to increase the dose that the success rate will be extremely high, and that, in itself, is such good news.

With workplace and health insurance protections in place, I believe we can dramatically change the way we do health care in this country. People will be more inclined to obtain genetic testing and may be able to prevent or at least seek out early treatment for a number of

diseases, thereby cutting down on long hospital stays and costly end of life treatments.

Some of you may have heard about my colleague, Congresswoman Debbie Wasserman Schultz. She represents Pembroke Pines, Florida and she's only 43 years old.

A few weeks ago, she bravely went public about her year-long battle with breast cancer. During that time, she would fly to Washington, DC for votes and then fly back to Florida for treatments.

In speaking about her ordeal, Congresswoman Wasserman Schultz has discussed the fact that as a woman of Ashkenazi Jewish descent, she was in a category of at-risk populations for the BRAC1 and BRAC2 gene mutation. Because of her family history, after she was diagnosed with breast cancer, she decided to get the genetic test and found out that she carried the BRCA2 genetic marker that suggests a greater susceptibility to breast and ovarian cancers. She also underwent a double mastectomy.

At no point during the year did we have any idea that she was ill.

She is now dedicated to educating young Ashkenazi Jewish women about the need for early and frequent breast cancer screenings and is encouraging them to get the genetic test for the BRAC1 and BRAC2 genes.

Whereas just a couple years ago, doctors cautioned women against overtly seeking a genetic test.

Now I can wholeheartedly support her efforts and am so proud that GINA will convey protections to at-risk groups, like Ashkenazi Jewish women, and hopefully they will be more inclined to seek out early testing for genetic predispositions without fear of job or health insurance discrimination.

When GINA is implemented this year, I believe many more Americans will participate in genetic testing and the demand for genetic tests will grow.

Because of this, it is critical that Congress ensure that genetic tests are regulated - specifically that they measure what they purport to measure and that they are valid.

This is something I intend to work on in the 111th Congress.

Now that GINA is law you can be sure that I am not done yet. I am working on a number of other health care initiatives and President Obama has vowed to make health care reform a priority for this year which is great new for our country.

I would like to speak about some other pressing health initiatives that I am spearheading. I have become increasingly concerned by the rise of antibiotic resistant diseases in the US. Two million Americans acquire bacterial infections during their hospital stay every year, and 70 percent of their infections will be resistant to the drugs commonly used to treat them. As a result, every day thirty-eight patients in our hospitals die of those infections. That's 18,000 more deaths per year than those who die of AIDS.

Moreover, the cost to our already strained health care system is astronomical. In fact, resistant bacterial infections increase health care costs by $4 to $5 billion each year.

While overuse of antibiotics among humans is certainly a major cause for increasing resistance, there is evidence that the widespread nontherapeutic use of antibiotics in animal

feed is another cause of heightened resistance. In fact, a recent *National Academy of Sciences* report states that, "a decrease in antimicrobial use in human medicine alone will have little effect on the current situation. Substantial efforts must be made to decrease inappropriate overuse in animals and agriculture as well."

Currently, seven classes of antibiotics certified by the Food and Drug Administration (FDA) as "highly" or "critically" important in human medicine are used in agriculture as animal feed additives. Among them are penicillin, tetracyclines, macrolides, lincosamides, streptogramins, aminoglycosides, and sulfonamides. These classes of antibiotics are among the most critically important in our arsenal of defense against potentially fatal human diseases.

Despite their importance in human medicine, these drugs are added to animal feed as growth promotants and for routine disease prevention. Approximately 70 percent of antibiotics and related drugs produced in the US are given to cattle, pigs, and chicken to promote growth and to compensate for crowded, unsanitary, stressful conditions.

Resistant bacteria can be transferred from animals to humans in several ways. Antibiotic resistant bacteria can be found in the meat and poultry that we purchase in the grocery store. In fact, A *New England Journal of Medicine* study conducted in Washington, DC found that 20 percent of the meat sampled was contaminated with Salmonella and 84 percent of those bacteria were resistant to antibiotics used in human medicine and animal agriculture.

Bacteria can also be transferred from animals to humans via workers in the livestock industry who handle animals, feed, and manure. Farmers may then transfer the bacteria on to their family. A third method is via the environment. Nearly 2 trillion pounds of manure generated in the US annually contaminate our groundwater, surface water, and soil. Because this manure contains resistant bacteria, the resistant bacteria can then be passed on to humans that come in contact with the water sources or soil.

This problem has been well documented. A 2002 analysis of more than 500 scientific articles and published in the journal *Clinical Infectious Diseases* found that "many lines of evidence link antimicrobial resistant human infections to foodborne pathogens of animal origin."

The Institute of Medicine's 2003 report on *Microbial Threats to Health* concluded "Clearly, a decrease in the inappropriate use of antimicrobials in human medicine alone is not enough. Substantial efforts must be made to decrease inappropriate overuse in animals and agriculture as well."

To address this problem I have a bill entitled the Preservation of Antibiotics for Medical Treatment Act (PAMTA). PAMTA would phase out the use of the seven classes of medically significant antibiotics that are currently approved for nontherapeutic use in animal agriculture. In addition, PAMTA provides that if an antibiotic that is now used only in animals also becomes potentially important in human medicine, the drug would be automatically restricted from nontherapeutic use in agricultural animals unless FDA determines that such use will not contribute to development of resistance affecting humans. Lastly, to assist public health officials in tracking implementation of the phase out of antibiotics in animal feed, PAMTA requires producers of agricultural antibiotics to report the quantity of drugs they sell, information

on the claimed purpose, and the dosage form of those drugs.

The fundamental solution to the problem of antibiotic resistance is to reduce unnecessary use. Then when antibiotics are required, use them prudently. As a mother, grandmother, and microbiologist, I cannot stress the urgency of this problem.

While the full impact of resistant bacteria has yet to be seen, there is little doubt that the existence of antibiotic resistant diseases is a public health emergency that calls for a high priority response. PAMTA answers this call by safeguarding the effectiveness of antibiotics and public health in the United States.

Another health issue that I care deeply about is the impact of synthetic chemicals in our environment on women's health.

Consider for a moment that a women's lifetime risk of breast cancer is 1 in 7 today, compared to 1 in 22 in the 1940s - over half of the casesareunexplained. And, over the last 30 years, the U.S. has seen a steep rise in the occurrence of childhood cancers, testicular cancer, juvenile diabetes, attention deficit disorder, learning disabilities, thyroid disorders, cognitive impairment, and autoimmune disorders. Autism cases alone rose 210 percent between 1987 and 1998.

About 100,000 chemicalsareregistered for use in the United States. However, 90 percent of these have never been fully tested for their impact on human health.Scientists have found that exposure to these synthetic chemicals disrupts hormone function and contributes to increased incidences of diseases. We already know the tragic impact that diethylstilbestrol, or DES, has had on the children of women who took this anti-miscarriage drug prescribed until 1971.

While the evidence is mounting that there is an association between these chemicals and hormone disruption, research remains limited, particularly on the impact on women and on how long-term, low-dose exposure to environmental pollutants impacts children at critical stages of development.

A few years ago, I participated in a study conducted by the Environmental Working Group to find out what toxic substances I, in particular, and Americans in general, have been exposed to throughout our lives. My stunning test results showed literally hundreds of chemicals pumping through my vital organs everyday. These chemicals include PCBs that were banned decades ago, as well as chemicals like Teflon that are currently under federal investigation.

The study also tested ten newborn babies and found that on average, each one had some 200 chemicals in their blood at the time of birth. The fact that we have children coming into this world already polluted and at the same time, do not know what the effects of that pollution will be on their mental and physical development, is both bad policy and immoral. We must test chemicals *before* they go onto the market, not *after* they get into our bloodstreams.

For several years, I have called on Congress to enact legislation that would allow NIH to expand its research on the impact of these chemical pollutants on the health of women and children.

I have a bill entitled the *Environmental Hormone Disruption Act* which authorizes the National Institute of Environmental Health Sciences (NIEHS) to conduct a comprehensive program to research and educate the public on the health effects of hormone-disrupting chemicals.

I truly believe that if we increase investments in research now, we could prevent and treat a broad range of diseases and disorders in future generations.

Before I conclude, I would be remiss if I did not talk about the biggest health care initiative that will probably come before Congress this year or next - health care reform.

Without question, our health care system is broken and in desperate need of reform.

Health care reform is not just a moral imperative, but also is an economic necessity.

More than 45 million Americans are priced out of the current health care system, but these folks still draw on services and expensive emergency room care. This adds an average of $1100 per year to family premiums.

In the past 8 years, health care premiums for family coverage have risen more than 7 times faster than wages.

And we have a crisis among health care professionals, with doctors and nurse shortages across the country and many physicians leaving the profession.

In the past few months, Congress has already done more to advance the goal of providing quality, affordable health care to all Americans than has been done in the past decade. Specifically, we've provided and protected coverage for 11 million children from working families and for 7 million Americans who have lost their jobs in this downturn under the State Children's Health Insurance Program or SCHIP. We've made the largest investment in history in preventative care; invested in electronic medical records that will save money, ensure privacy, and save lives; and launched a new effort to find a cure for cancer.

However, more work still needs to be done.

While previous attempts at health care reform have failed, this time is different. This time, the call for reform is coming from the bottom up, from all across the spectrum - from doctors, nurses, and patients; unions and businesses; hospitals, health care providers, and community groups and elected officials.

The Democratic-led Congress and President Obama have pledged to make comprehensive health care reform a reality. While the specific details are still being worked out, the key players have committed to eight specific principles for reform:

First, we must protect families' financial health. Health insurance premiums have doubled in the past eight years, rising almost four times faster than wages. For example, in New York State health insurance premiums increased by 80.7% from 200 to 2007! The average health care premium for a family was $12,812 in 2007.

We must make health care affordable. A quarter of every health care dollar goes to administrative and overhead costs. America spends over $700 billion per year on health services that yield no appreciable benefits. Reform must reduce administrative costs, unnecessary tests and services, waste and other inefficiencies that consume our hard earned money without added health benefits.

Without question, we must aim for universal coverage. There are 45 million Americans without health insurance, of which 81% are working families. Consequently, taxpayers and hospitals, like Niagara Falls Memorial Medical Center, ultimately end up footing the bill. Our local communities have reached the breaking point and cannot continue to eat the cost of covering the uninsured. Health care reform must aim to cover all Americans, whether it is through employer-based insurance plans or by offering a public health insurance option.

We must provide portability of coverage. Every 1% increase in the unemployment rate translates into 2.4 million people losing employer sponsored health insurance. People should not be locked in their jobs just to obtain health coverage and no American should be denied coverage because of pre-existing conditions.

It is imperative that we guarantee choice. 61% of Americans receive health care through their employer. Reform must give workers the option of keeping their employer-based plan and allow all Americans to choose their health plans and physicians.

And we must maintain long term fiscal sustainability: By 2018, it is estimated that America will spend $4.4 trillion on health care. Reform must include changes to reduce our long term health care costs and improve efficiency, including the use of technology.

Medical errors result in an estimated 100,000 deaths per year. We must ensure that reform includes **proven patient safety measures as well as incentives to improve the quality of health care** in this country.

Finally, we must invest in prevention and wellness. 133 million Americans have a chronic disease, and caring for these Americans accounts for 75% of all US health care spending. At the same time, we only spend 4 cents on every dollar on prevention efforts. We must invest in public health measures proven to reduce costly conditions and guarantee access to proven preventative treatments.

This last point, investing in prevention and wellness, brings me back to the Genetic Information Nondiscrimination Act. GINA will do more than stamp out a new form of discrimination, it will change the way we do health care in this country; it will expand and enhance scientific research; it will reduce health care costs; and it will help people make more informed decisions about their personal health.

This is both an uncertain and an exciting time for health care in this country. But I am hopeful that we will finally reform this broken system and improve the health of health care in this country.

Thank you again for inviting me here today.