

Testimony of Jane Massey Licata, Ph.D., J.D.

Next we'll hear from Jane Massey Licata.

DR. LICATA: Again, thank you very much for inviting me here to testify today. I've come at this issue over the past decade from a number of different perspectives. I'm a biotechnology patent and FDA lawyer, and I also teach at Rutgers School of Law in Camden, both patent and FDA law. I was trained as a scientist with a background in biology and biochemistry, and I hold a doctorate that I received in 1978. So that was back when we didn't know that much about genes. But over the past two decades I've been blessed to learn a lot about molecular biology and genetics from some of the greatest scientific minds in our country and the world.

My interest in genetic privacy is both academic and practical. I've served on and advised institutional review boards on genetic and biotechnology research issues. I've evaluated genetic technology for venture capital firms and pharmaceutical companies. I filed over 2,000 patent applications concerning biotechnology inventions, most involving the use of genetic information to develop new diagnostics and therapeutics. I've negotiated hundreds of research agreements concerning genetic research. So I've worked in both the non-profit and the private sector.

I come at this from a practical sense in that one message I've taken from all of my constituents is that there is a need for some certainty in the marketplace and in the academic research community as to how we're going to deal with both the ethics and the dissemination of this information. Now, I've been very fortunate, I guess, in that I've been asked twice to testify before congressional committees on the legislation. I started working on this issue as an academic in the early '90s, and the first time I testified before a congressional committee was in September of 2001, and at that time there was quite a bit of hope that the legislation was going to be passed.

I recently testified again before a congressional committee in July of 2004 in an effort to try to encourage the House to follow suit on the compromise bill that had been passed by the Senate. There's been a lot of progress in definition in the issues that are pending and are being considered by Congress. There are three specific issues, after listening to the testimony today, that I would like to address because in each of the cases where I testified before Congress as an objective basically friend of Congress with a technical and legal background, a gentleman from the Chamber of Commerce was sitting on my left, and I think there are three issues that have been raised that I think are important to address.

The first is there seems to be a misperception in some parts, not on the part of Congress in general or the council to the Congress, because these people are incredibly knowledgeable and have, in fact, analyzed really where we stand with respect to all of our federal laws and genetic nondiscrimination. But basically, there is really very little federal protection for genetic information. We've heard discussion today about HIPAA, the Health Insurance Portability and Accountability Act, that was passed in 1996. HIPAA does some very good and important things.

It does prohibit group plans from using any health status-related factor, including genetic information, as a basis for denying or limiting eligibility for coverage, or for charging an individual more for coverage. So in the group health setting, not all group health insurance plans, as was so articulately explained by one of the other panelists, but in some group situations, it is helpful.

It does limit exclusions from group plans for preexisting conditions for 12 months, and prohibited exclusions for people who had been covered previously for a condition for 12 months or more,

and specifically states that genetic information, in the absence of a current diagnosis, does not constitute a preexisting condition. So a good first step.

But HIPAA does not prevent insurers from collecting genetic information or limit the disclosure of genetic information about individuals to insurers. It does not prevent insurers from requiring applicants to undergo genetic testing, and it doesn't cover a lot of Americans because it doesn't apply to the individual market or many group plans that are exempt.

Another federal law that we've heard mentioned is the Americans with Disabilities Act, the ADA. Now, the ADA does protect individuals with symptomatic genetic disabilities. It does allow an employer to obtain extensive medical information about a person that is under a conditional offer of employment, including obtaining and storing genetic samples, requiring genetic screening as a condition of employment, to purchase genetic information about applicants from a genetic information databank, and once employed, the employer can request medical information that is job-related and consistent with business necessity. So there's a positive and a negative here in what's allowed under the ADA.

But the ADA does not explicitly address genetic information or deal with unaffected carriers of a disease who may never get the disease themselves, individuals with late-onset genetic disorders who may be identified through genetic testing as being at risk of developing a disease, or others identified through family history as being at high risk for developing the disease. Those people just aren't covered. It does not protect workers from requirements or requests to provide genetic information to their employers.

Another federal law that's been mentioned is Title VII of the Civil Rights Act. Now, this is the stuff that law professors love. It does provide a basis for an argument that genetic discrimination based on racially or ethnically linked genetic diseases constitutes unlawful race or ethnicity discrimination, but it's an argument, and there's not a lot of cases where there's going to be that link, where it's going to be possible to establish that that link has a direct relationship to race or ethnicity. So although it's the stuff that we like to talk about in law school, on a practical level I don't think it's something that the American people can rely on to protect them.

Now, another issue that I've heard mentioned from the business community is a concern that if we do pass this legislation and we do have federal law and create a new right of action, that this is going to create all of this new litigation and this is going to be a huge problem for employers and health insurance companies, a huge cost to the community. I respectfully disagree with that for a couple of different reasons.

One is there's been an evolution. When I first started working with this legislation, there was in fact a private right of action in there for the individual who felt that they had experienced genetic discrimination. But even then, all that they were going to get was some reasonable attorneys fees, including costs of expert witnesses, in cases in which a plan sponsor, health insurer or any third party acting on behalf of the plan or insurer violated the law, and the civil penalties would not exceed \$50,000 for a first violation or \$100,000 for any subsequent violation. So it was always a fairly limited right of action, and to be fair I think it's been pointed out by the panelists that it's something that's not likely to happen. Folks aren't really so concerned about bringing a private right of action. It's a huge emotional and financial investment.

What they're concerned about is keeping the health insurance and keeping their job, and this is what the Senate compromise did. It listened to the concerns of business and basically it established enforcement for violations of the provisions, but in a way the business can deal with,

because what they said is this is what it's going to cost you for not complying, this is what it's going to cost you if you don't respect this right and you don't figure out a way to build it into the way that you do business, like lots of other things that you do on a day to day basis.

Basically, the penalties are \$100 per day for each day the group health plan is in violation, payable to the participant or the beneficiary, with a minimum fine of \$2,500 or a maximum of \$15,000, and even if you go the whole way and there's found to be a willful violation, you're talking about a cap of a half a million dollars. That's what you pay your lawyers to figure this out. I mean, let's be practical. The businesses that I deal with, they want to know what am I supposed to do to comply. This is what the health systems ask. Everybody figured out how to deal with HIPAA, and they found out how to do it in a cost-effective, respectful way because they were told you have to do it.

If we apply it across the board to all insurance plans, I really can't see, when you work out the economics, particularly when the penalties are encouraging compliance but not outrageous, there's not this huge specter of risk and cost that was originally suggested. It's simply not true. It's not in the compromise bill, and I think it's a respectful way to try to balance the concerns.

One thing that the compromise bill does that's absolutely awesome for the individual is that it allows them to keep their health insurance while this is getting worked out, and that's the big issue that people were concerned about. They don't want to lose their health insurance. So while this process is going on, they're not sitting in a gap wondering what's going to happen to me, what's going to happen to my family. What's been built into the compromise legislation is an assurance to the individual that they will be able to have their insurance protected while this issue is being evaluated, and I think that that's also very good for all parties. It's a fairly minimal cost to the business community, and it's a huge benefit to the worker.

Now, another issue that I've heard as an objection to this legislation is we don't need it because the states all pass these laws anyway, so let's just leave it to the states. Now, I have great respect for home rule. I'm from the State of New Jersey, and we're really big on that there. So far, 41 states have enacted legislation related to genetic discrimination in health insurance, and 31 states have adopted laws regarding genetic discrimination in the workplace. So the states have actually been very active and creative, but it's a patchwork, a patchwork of laws.

For example, in the State of Florida, it doesn't concern health insurance at all. The law that was passed in 1978 prohibits any person, firm, corporation, unincorporated association, state agency, unit of local government, or any public or private entity from denying or refusing employment to any person or to discharge any person from employment based on sickle cell.

That is the law in Florida. Here, Florida was one of the earliest ones to act, but that's the only coverage there is in the State of Florida for genetic discrimination under state law.

Now, in New Jersey, we actually enacted in 1981 and then brought in the law in 1996, and we actually have one of the toughest genetic privacy statutes in the nation. Under my state basically says, it covers situations of health insurance, life insurance, and employment. So it covers all of the issues, which is not the case, it's a very rare thing to have all of those covered. Basically, the problem is that these issues, as we've talked about, cross state boundaries and affect all of our citizens.

So if you're lucky enough to live in New Jersey and you have a problem in New Jersey, you're going to have a law that's going to say that genetic information is personal information that

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should not be collected, retained, or disclosed without the individual's authorization. The act prohibits discrimination by employers against employees carrying genetic markers of diseases or behavioral traits. It's unlawful for an employer to refuse to hire or employ or to discharge or require to retire an employee because of the employee's genetic information or a typical hereditary cellular or blood trait, or because the employee refused to submit to a genetic test or make available the results of a genetic test to an employer.

It also prohibits the use of genetic information in the fixing of rates or withholding of life insurance. It bans the use of genetic information to establish the amount of insurance premiums, policy fees or rates charged for health insurance contracts, whether it's an individual or group plan. The penalties for violation of the provisions in the act include fines and prison terms. Actual damages, including economic, bodily or emotional harm proximately caused may also be recovered.

MS. MASNY: You have one minute more.

DR. LICATA: Under New Jersey, you have a very strong law. Now, no case has ever been brought under this law, but people doing business in New Jersey understand what the rules are, and what they have done is they have managed the risk and they have built into their way of doing business, their way of making insurance decisions, their way of making workplace decisions consistent with the law because they know what the rules are.

So what I'm suggesting is that we need predictability. People need to understand where they stand. If we have at least a threshold level in this country, I think it would be extremely helpful to all of our citizens.

MS. MASNY: Thank you very much.