National Committee on Vital and Health Statistics

Oral Public Testimony of

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Mr. Reynolds and Members of the Committee, thank you for this opportunity to testify at this hearing of the subcommittee on Privacy, Confidentiality and Security.

I am Sharon Terry, president and CEO of Genetic Alliance. In that capacity, I interact with approximately 1200 disease specific advocacy organizations. I come to this work because I am the founder of one of those disease organizations for pseudoxanthoma elasticum (PXE), a genetic disease that affects my two children. I am also a member of the Secretary's Health Information Technology Standards Committee, serving with your committee member, Dr. Suarez. I present my testimony informed by these experiences, the research of my colleagues, and partnerships with several nonprofits and companies engaged in the area of privacy, confidentiality and security.

I believe, as is true for all health information, that genetic information is contextual – the context determines a great deal of its value and sensitivity. I am convinced, from all of my work, that genetic information is both the same and different from other health information. First and foremost, it is intrinsically no different than other health information since, in the health context,

it is simply another data point or measure. However, in the family and community context, there are certainly privacy, security and confidentiality issues that require careful consideration. Genetic information is at once personal, familial and ethnically communal. The family, and sometimes the community, shares the tested individual's genetic information. In some cases, this means information is available to those entities or others that was not solicited, and may not have adequate interpretation, either for other family members or for the community at large. This is not typical of health information in general.

I'd like to speak to the questions you are considering in two separate contexts: in the practice of medicine and outside the practice of medicine.

<u>In the practice of medicine/healthcare delivery:</u>

Genetic information should be treated like any other health information in the course of treating an individual. It should be used and disclosed to the individual in the course of any treatment, much like non-genetic health information. In general, if the patient consults a healthcare provider for treatment regarding another issue, then s/he should be apprised of genetic information within reason, regardless of the intent of the healthcare visit.

This would be no different, for example, from consulting a medical professional for a sore knee, and learning in the course of the visit that you have high blood pressure. There are at least two caveats to this, however. The first is that in the explosion of genetic information that is upon us and will continue to increase as we acquire more knowledge, no health care provider should be expected to convey the totality of what is called the "*incidentialome*" – genetic information

learned in the course of testing that is not clinically relevant. The second is the individual's "right to not know." I cannot speak to the legal issues of this 'right', but in a social sense it makes sense. An individual tested for risk of one disease, let's say breast cancer, should not be told they have a risk for Huntington's disease.

As a person who has fought for decades in favor openness in our systems and transparencies in our relationships, these two principles may at first blush seem to contradict these values. In fact, I don't believe that they do. There is a big difference between "data" – meaning raw material and unorganized facts that need to be processed; and "information" – meaning the result that occurs when data are processed, organized, structured or presented in a given context so as to make them useful. In the field of genetics today, regretfully we commonly encounter far too much data and simply don't know enough yet to permit this to be transformed into information. The principles I described seek to address this fact, and to hold the communications about test results to the information portion – in the given context, the part that is useful.

Outside of healthcare delivery:

I believe the sequestration and access requirements related to the use and disclosure of genetic information for non-treatment-related purposes are different than for those in the healthcare delivery context. Direct access testing allows individuals to know their genetic risks, drug metabolism, and some ancestry information. In these cases, privacy should be the right of the individual and should be maintained through stringent privacy controls. At the same time, as this information becomes more relevant to the care context, then methods for releasing this information into the medical ecosystem supporting the individual should be provided such that

only the parts of the data that the individual wishes to release should be shared, and the rest of the information should remain confidential.

The coming merger of the two systems:

Genetic information, its aggregation, and its increasing correlation with phenotypes (both clinically manifested and cellular), will inevitably challenge the normal boundaries between health-related and what has been called 'recreational' genetic testing and information. We are already beginning to observe this trend today, and it will continue to accelerate.

The research to services continuum is a dynamic one, and there are no clear-cut boundaries to begin with. The public has the pleasure, or the peril, of seeing genetic information increase in relevance before their eyes – we aspire for this information to become ever more meaningful and relevant in a clinical context in the future. In order to harness this potential, I believe there is a need for dynamic sequestering and control systems to be applied so that the right information is in the hands of the right people at the proper time. This is critical. All health information should be afforded this privilege – to be used in the care context in a provider-patient partnership, to be stored in a EHR and a PHR, with appropriate controls to allow access for social sharing (as in families or communities), clinical trial participation, and other more basic research. Obviously such control systems should have a failsafe and allow override in the case of emergencies, much as this committee wrote about in its letter to the Secretary.

There are a number of entities working on systems whereby individuals can control their own information. There are certainly major public efforts with minimal granularity such as the PHRs

offered by Google and Microsoft, and dozens of other companies emerging in this space. I'd like to describe one that I have worked with extensively called Private Access (www.privateaccess.com). It allows individuals to input clinical information and directs them, through the use of an online guide, to establish 'private access' controls. The controls can be granular down to the data element if desired, and allow individuals to decide if their genetic, mental health, or any other information they deem sensitive, should be shared, and if so with whom. Moreover, the controls are dynamic – they anticipate that the users will wish to change their settings as their circumstances change and as different needs arise or levels of trust are established.

From simple scenarios such as releasing one's child's immunization record to summer camp, to making one's clinical information searchable by selected researchers, this online system provides a great service. Its initial implementations have been in the area of facilitating the search of otherwise confidential information by designated researchers for the purposes of expediting clinical trials recruitment. But the system architecture, the privacy ontology, the manner in which they assist consumers to cut through a mass of decisions to make highly granular settings without becoming overwhelmed, and other innovations provide an excellent roadmap for where I believe we should be encouraging others to head.

A final comment, while I believe genetic information is very similar to other information in many respects, and that "*genetic exceptionalism*" is to be avoided, it is important for this Committee to recognize that the general public does not believe that this is so. The public has heard spokespersons who express concerns that the government is running 'DNA warehouses' in

the form of stored residual newborn screening blood spots and conclude that the nation's newborns' privacy and freedoms are at stake. Many state newborn screening programs have been targeted in these campaigns, and Texas's lawsuit, which resulted in the destruction of over 5 million blood spots, represents an unfortunate reminder that if we are not careful to educate the public and put in place the proper systems to address concerns about trust and absence of transparency, then very bad decisions can occur.

Public distrust is real, and will continue to fester and grow unless we assure that the systems that are built around health information, including genetic information, allow for confidentiality and control that retains and builds the public's trust. These systems must also provide for standards-based information flow and avoid onerous, overly complex and/or irrelevant controls. The patients whom I know best through the work I do with the Genetic Alliance and PXE International are counting on this. In the end, as consumers, they require both privacy and easier access to the information they need to have better health outcomes.

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