

Impact of GINA: An On-Ramp to Genetic Testing and Health IT July 1, 2008

Presentations by

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Answers to participant questions:

1. *Regarding exceptions to disclosure in GINA, how is "health research" defined?*

Jeremy Gruber (JG): GINA does not go into detail. It simply talks about health research in compliance with applicable law. I suspect that the regulations might clear that up more. But there is not more detail than that.

2. *Does GINA cover the employment of parents of patients?*

JG: GINA covers all individuals in the employment context. If you as a parent are discriminated against, GINA is equally applicable to you as to your child or your child's child. There is no distinction; the discrimination provisions are applicable to anybody who is employed.

3. *Assuming that more people will want to participate in genetic testing now that genetic discrimination is less of a concern, do you suspect the passage of GINA will have an effect on the cost of genetic testing kits?*

Patrick Terry (PT): I think it will indirectly affect the cost and we can see it happening now with the number of new genetic testing services offering the same tests. Ultimately, as market forces become a factor and there is a highly competitive environment, prices do go down. This introduces a whole new challenge since there will be an environment of abundance rather than scarcity; when all these tests are available, distinguishing them on the basis of quality will present a new set of dilemmas. Prices will come down but understanding what information these new tests are delivering will be a new struggle.

4. *What have been the problems associated with gene patents and genetic testing?*

PT: This is a cyclical conversation; it depends on where you stand. The literature has attempted to quantify supposed damages or perverse effects of gene patenting. The IUM did a study on this issue and found that some of the claims that gene patenting was hurting patients or patient access were unfounded. As someone from industry who holds a gene patent, I am in favor of gene patents because ultimately I believe they will drive innovation. We will see more and more diagnostics entering the marketplace that are highly informative, highly complex tests that have intellectual property and patents around them. The debate so far has been around just two genetic tests and one circumstance relating to a particular gene patent that is perhaps overly broad with overly restrictive claims. The policy community has tried to deal with some of these dilemmas. But, ultimately, patent disputes get settled in the courts and no one has been able or willing to take these patents to the courts to settle what is appropriate and inappropriate in gene patenting. We get slightly distracted because the issue is not around gene patenting; it is about licensing and fair use. There is a significant amount of work there and Genetic Alliance has positions and activities around issues of licensure and fair use for research exemptions. This is a separate area of genetic testing that we have not addressed; there is a lot of meat there that needs to be chewed through. Genetic Alliance has also been involved with some proposed pieces of legislation that try to alter gene patenting and the patent regime.

5. *Many private companies such as Google have taken an interest in health IT. What role does that play in the debate for federal action for health IT? Do you believe it enhances or causes friction against the necessity for government action?*

Rob Tennant (RT): We have seen a lot of companies move into this personal health record space. Companies like Google and Microsoft are really providing repositories for health information. But there are questions about the type of standards required in order for that information to be as useful as possible to the clinician. If for example, a clinician is seeing ten patients per day who have PHRs and all the PHRs look different and describe medical conditions differently, they will not be very helpful. There is a huge role for the government to play in standardizing the nomenclature so that data can be easily transmitted from one point to another. The market will put a lot of pressure on the government to develop these standards. Unfortunately the government has not been moving forward with any great speed.

6. *Will this business model (Google's) be valuable in the implementation of a federal program?*

RT: We are starting to see the federal government moving into the general space of personal health records. They conducted a demonstration project recently with Medicare beneficiaries. We are seeing the two major trade associations for health insurance plans (America's Health Insurance Plans and the Blue Cross Blue Shield Association) working together to develop a claims based personal health record. We are starting to see a lot of coalescing around the idea of empowering consumers with more information. This is especially true when, for example, you are a caregiver to your elderly parents who are Medicare beneficiaries. Medicare itself is moving in that direction for a very important reason; they believe it will save money. The typical Medicare patient is seeing numerous physicians and has perhaps ten or twelve different medications. Better coordination of care will produce a higher savings for Medicare.

7. *With regard to GINA, is there any wording that allows wiggle room for the courts to say that a weak state law preempts the federal statute?*

JH: GINA does not preempt state law; it allows for a potential plaintiff to file a claim under state law if that law has superior protections. One of the problems we are going to see is in how the courts view state laws with relation to GINA. For the vast majority of these state laws there may be aspects that are superior to GINA but the laws are as a whole inferior to GINA. An example would be an individual who wanted to utilize a state law with a very limited definition of genetic information but unlimited damage recovery. GINA adopts the federal standard which caps damage recovery. Since substantive protections are significantly inferior, it is unclear as to how the courts would view that statute. There are only two state laws that are entirely superior to GINA in both substance and remedies, and those are Massachusetts' and South Dakota's. GINA is clear that it does not preempt superior state law, but it is unclear what superior state law is.

8. *Could you discuss GINA in terms of eligibility for life insurance?*

JH: GINA is comprised of two sections. Title I deals with health insurance and Title II deals with employment. GINA does not address life or disability insurance.

9. *What are policymakers doing to ensure that legislation addressing the regulatory framework of genetic testing is forward thinking rather than retroactive? How can we stay ahead of the curve?*

PT: That is the million-dollar question with public policy because it is usually looking at a situation of harm or corrective action. There has been a push to have public policy move forward on an information based regulatory framework. Genetic Alliance has been highly active in a variety of forums in which some of this debate has occurred. The Administration and Secretary Leavitt's office has commissioned a report from the Secretary's Advisory Committee and asked the President's Council on Science and Technology to produce a report coming out this summer. That is at an administrative level where Secretary Leavitt feels he can implement solutions without federal legislation or additional authorizations. There are a lot of people who believe Congress does need to get involved. Some of the most informed and active participants in Congress have been Senator Kennedy, Senator Obama, Senator Byrd from North Carolina, Senator Smith from Oregon, Representative Anna Eshoo from California, Patrick Kennedy from Rhode Island, and Louise Caps. There are a handful of legislators in both houses who are interested in having a really informed and responsive public policy that deals with this technology because it is evolving so rapidly. It is very difficult for Congress to produce legislation for hypothetical or future situations. We are more narrowly defined into a debate that has been taking place over a decade; it is really about how to oversee and regulate DNA-based genetic testing. That is the focus of a lot of public policy and probably the area that will receive the most attention and potential fixes in the next month to a year.

10. *Can you shed some light on the communication channels between the FDA and CMS?*

PT: There have been a lot of public contributions to open dockets (which are a public policy way of receiving community input). The Secretary Advisory Committee and PECAS have received a lot of public input about the lack of agency coordination around genetic testing and the controversy of either overlapping responsibilities or clear gaps in oversight between the agencies. Even though this debate was brought into crystal clear focus about two years ago there still has not been any meaningful change. The FDA has publicly stated that there are ongoing informal meetings between FDA and CMS but there really is not any formal, transparent engagement process between the agencies and the public or the agencies and policymakers. It is a disappointment that all these controversies are not forcing an overwhelming response from the agencies to deal with them. Genetic Alliance has advocated for a neutral forum or a more clear and robust dialogue. The Alliance had a summit on genetic testing last year and was really instrumental in creating an open dialogue but the government has not pursued that forum or that solution.

11. *Are there other countries that have had success in implementing health IT and which can be used as models as we move forward?*

RT: According to some figures, Britain has invested \$20 billion into creating an infrastructure between all their primary care physicians. That took an enormous investment and there are still a lot of issues with standardization there. However, it is a lot easier to do that in systems that have a standardized approach to payment. Single insurer systems lend themselves more to centralized planning. Here in the United States, you have 500,000 physicians and most of them are independent businesspeople. They have to make their own investments. The question has always been, can the United States make the decision to invest large amounts of money into the infrastructure of healthcare when it is essentially a privatized system? So yes, there have been successes in other countries. Can we emulate them? Probably not. Of course there is going to be a debate during the election campaign about how the healthcare system in America can be reformed. One of the debates will center on the idea of moving to a more centralized payment system much like Medicare or Veteran's Affairs. However, most of us do not believe that this will move forward with any great swiftness.

12. *With regard to intellectual property, what is the difference between a test, a gene, and the technology itself? Is the law too far behind and moving more slowly than the technology and discovery in genetics?*

PT: All three categories have the ability to produce novel inventions and thus are patentable. There are 'composition of matter' patents where an abstraction or a purified or altered form of a gene is being patented. There are also 'methods' patents around the application of a gene to a particular clinical circumstance or technology. So, a single gene disorder can have composition of matter patents, methods patents, and technology patents. This is called patent stacking where multiple patents from different perspectives exist for the same thing. The founding fathers designed the patent system to include a public pact that the inventor must completely disclose the information around the invention. Ultimately, this means that anyone can look at that invention and develop a workaround using the information. From a public policy perspective, this transparency will drive further innovation. It not only protects the inventor for a certain amount of time but also provides the community with information and prevents trade secrets. There is this ongoing balance between monopoly and public benefit.