

Public Comments

DR. TEUTSCH: One of the important things that this Committee does is to serve as a public forum for deliberations on all of the issues surrounding the human health and societal issues in the area of genetic technologies. So we always appreciate it when we get comments from the public and welcome all the perspectives they have to share with us.

I have a list of two individuals who are scheduled. If there are others, please let me know.

We would like to first hear from Sue Friedman, if you are here, who is the executive director of FORCE, Facing Our Risk of Cancer Empowered. Dr. Friedman, we look forward to your comments. Thanks for being here.

DR. FRIEDMAN: Thank you for having me. I want to thank the Secretary's Advisory Committee for inviting me to present today. I am founder and director of the national nonprofit organization FORCE, which stands for Facing Our Risk of Cancer Empowered. We deal specifically with hereditary breast and ovarian cancer and families that have been affected by the disease.

I came here from Florida to your weather, so I'm very motivated to speak before this panel. This is freezing cold for me.

Part of our mission is about advocating for the health and well-being of our community of people and families affected by these hereditary cancers. The goal of my testimony is really to alert the Committee about a growing issue that we are seeing and really trying to document, but it is a problem.

Once a test is out there and once it has been offered, the consumer has assumed that it has clinical utility and that it has been validated. I saw that you are looking at those issues. I think it is really important.

One of the problems with the tests that are already out there at CLIA-approved laboratories is that there really is very little oversight. We know there is a lack of knowledge and information in the healthcare community and on the part of consumers, and that gap is being filled in by the companies that are developing the tests. Certainly, I think, they have a place at the table, but I don't think they should be the exclusive source of information to not just consumers but the healthcare community.

What we are seeing is not just a direct-to-consumer marketing of genetic tests but also a direct-to-doctor marketing of genetic tests that really wouldn't have been allowed had they been pharmaceutical companies and had to go through the FDA oversight process.

We are seeing this, literally, daily. I often staff our help line and we get calls every day. It is wasted dollars. The wrong tests are being ordered. The wrong individuals within a family are being tested and people are being given wrong information about what the results mean. A lot of this is based on the fact that the company that develops these tests is providing doctors and consumers with all the information that they are getting. There is no one else filling in the gap.

Obviously, this doesn't happen when people are referred to genetics experts. There are standard-of-care guidelines for hereditary breast and ovarian cancer. I sit on the NCCN panel that developed standard-of-care guidelines for genetic testing. It does say that there needs to be a

three-generation pedigree, there should be access to genetic experts, and there are some clear guidelines. These are not being followed.

We are hearing a lot of cases, and I provided some examples. I sent a letter that outlined one woman's experience. She was allowed to fill out her own genetic test. She ordered the wrong test, and this was at her OB/gynecologist's office. Based on her test results, she proceeded with a lumpectomy, believing that her breast cancer was not hereditary, only to find out after her lumpectomy that the wrong test had been ordered. That would not have happened, in my opinion, had she sought out expertise from a genetics expert.

Her letter is very telling because we hear this a lot. People love their OB/gynecologists, so they don't want to indict them. They almost feel bad that their OB/gynecologist didn't know how to guide them through this. In many cases, we can look back and find out that that OB/gynecologist just had a recent visit from the company that is making the genetic test that they are selling and that the information that they are getting is not complete information about the test, what it means, and how to properly do a risk assessment on someone to determine if they are the appropriate person for genetic testing and if this is the appropriate genetic test.

We are seeing cases where people are being told their tests were normal when they have a mutation. We have seen cases where people have been told while they were driving that they carry a BRCA mutation. We had one 23-year-old who was told by a nurse that her risk for breast cancer was 85 percent. She was 23 and her risk was not 85 percent at that moment. So, inappropriate information is given at inappropriate times.

We have reports of people being ordered full-sequencing testing when a \$300 or \$350 test would have been more appropriate. Insurance companies are footing the bills on this, or the consumer is footing the bill, or taxpayers are footing the bill. This is happening a lot.

With respect to where the information is coming from and where consumers are getting the information, I have followed sales representatives at conference calls and listened as they have promoted testing to doctors and nurses and said that they do not need to refer people to genetics experts. I have heard that on more than one occasion. At a professional society meeting I saw a nurse raise a continuing education guideline booklet that was produced by a genetic test lab and say this is all you need to start doing genetic testing in your office. That booklet only spoke about the test that that lab produced.

Unfortunately, we know that the healthcare community in some ways is only getting information from one area.

For our community to improve things, as you are determining where to go from here, I think it is really important that there be at least one government agency that has oversight and jurisdiction over genetic tests even from CLIA-approved labs and has oversight as to how they are marketed to consumers and to physicians. Currently, at least to my understanding, there really isn't oversight and these companies can say pretty much whatever they want. They can be the single source of information for physicians and consumers.

Consumers need to know and be given access to trained experts in genetics. I know there is an argument that there aren't enough genetics experts. Part of it, though, is it is really hard to argue that a 23-year-old woman without cancer had such an emergency for having genetic testing that she had to have it in her doctor's office as opposed to being referred to one of the many good

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genetic clinics in the City of Chicago. We are seeing this in big cities, where there isn't a long wait and where there is no immediacy. So I don't know that that argument always holds water.

I think consumers don't know that they are being denied standard of care or even that there are experts in genetics. I think that is part of it. I think people have a right to know that, especially if they are getting below-standard of care genetic services.

Laboratories need to be held accountable for their marketing materials for consumers and for physicians. I don't think it is enough to just scrutinize what laboratories are saying to the consumer. We also need to be looking at what they are saying to physicians and what they are telling physicians that they can and cannot do.

I certainly am not qualified to say who can and cannot do genetic counseling, but I don't think that the laboratory should be doing it, either. I think they are setting the bar very low.

We need an agency to track adverse events. Currently, because there is no FDA labeling for some of these tests because they are coming from CLIA-approved labs, there really is no off-label use of the test and there really is no way to say what is and is not an adverse effect and to be able to track it.

I do believe that it should not be up to the test developers to govern themselves or determine the appropriate amount of information, nor to designate the minimal competency for conveying this information.

Thank you for your time and attention.

DR. TEUTSCH: Thank you. Thank you for putting a face to those issues. We did write a report on oversight, but I don't think we addressed this issue very completely. So this is important.

Why don't we take a couple of comments. Jim.

DR. EVANS: I just wanted to add my thanks to you for coming. I had not met Sue before but I have been very familiar, as somebody who takes care of patients, with genetic predisposition to breast and ovarian cancer. I have been very familiar with your website. Your organization is of huge use to patients.

It is very useful to get your impressions that these types of things are occurring. It has been my anecdotal experience, but that is just anecdotal experience. I would just ask, if you can try to keep track in a systematic way of these things, that will be very helpful.

I would also just echo your plea that there be sources of information for patients. I think it is something we should keep in mind. We should have sources of information for patients that are apart from the commercially driven sources by some of these testing laboratories. We all have conflicts of interest, but patients need access to differently conflicted types of information.
Thanks.

DR. FRIEDMAN: If I can just make one comment on that. It is my understanding that the New York State Department of Health, when Myriad did their direct-to-consumer marketing campaign in New York, developed posters that went in the primary care and OB/gynecologists' offices that did tell people about what standard of care was with regard to genetics.

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The other thing that I would say is, FORCE is happy to be a source of information. Really, it is an honor that you speak highly of our organization. Funding is a big issue for us on an ongoing basis. I know you were talking about funding before. It is very hard for us to meet the gaps and meet those needs. We do need assistance with that. So, thank you.

DR. TEUTSCH: Great. Thank you very much. That is very helpful.

The second speaker is Amy Miller. Dr. Miller is the public policy director for the Personalized Medicine Coalition. Welcome. We look forward to what you have to say.

DR. A. MILLER: Thank you. My name is Amy Miller. I am the public policy director of the Personalized Medicine Coalition, an organization that represents all the stakeholder groups within the framework of personalized medicine. I have spoken to this group before on a number of occasions about your work. Today I am speaking about consumer genomics and our work in that arena.

It is unavoidable to recognize that consumer genomics has received more attention than any other one product or sector or aspect of personalized medicine. Part of the PMC's charge is to educate consumers and doctors on personalized medicine.

To that end and based on some federal conversations that have taken place over 2008, PMC has taken three different tacts to address consumer genomics. One is, we organized the leading consumer genomics companies to come together around standards of operation in their field. The companies that have joined PMC in this effort in particular are 23andME, DECODE, and Navigenics.

The aspects of standards of practice they have agreed on are scientific, and they are going to be presenting that work at a CDC conference on consumer genomics later in this month.

They have agreed on a number of scientific standards. Where they haven't agreed, they have agreed to be transparent. They have put together a brief document on that work and will be sending that out in advance of the CDC conference.

During the CDC conference, their scientific teams will be available to answer questions from the field.

The second is a consumer guide. Part of the PMC's work is educational. We have worked on a consumer guide on Warfarin dosing, for example. We think that to inform the consumer guide we need to hear from consumers. So we are going to have a roundtable where we are going to have consumers and healthcare providers that work with these particular consumer groups and talk about what the standards are in this field and what consumers want from these products.

As has been mentioned, they are available. They are being used and they are being purchased. So we need to know what consumers find useful and risky about these tests. We are looking to develop a very balanced document that addresses some of the scientific issues and some of the concerns about these products and then what they can be used for.

Those are the three efforts that PMC is doing in consumer genomics. I would be happy to keep this group informed of that work and in any way assist the SACGHS in their work in this area. Thank you.

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DR. TEUTSCH: Thank you, Amy. We appreciate the work that you are doing to try and get us to a good set of standards.

Any comments or questions for Amy?

[No response.]

DR. TEUTSCH: Good. Thank you very much.

Are there any others who desire to make public comments?

[No response.]