Public Comments

DR. McCABE: I have four speakers for public comment. We set aside time each day for this. It's very important to the committee, as has been expressed this morning, and we welcome and appreciate the views that are expressed in this public comment period.

I would ask all of the commentors to hold your comments to five minutes. If you can do it in less, it leaves more time for questioning.

The four I have in order, so you'll be aware of your order, are Joe McInerney from NCHPEG; Michael Murphy, president and CEO of Gentris Corporation; Kelly Ormond from the National Society of Genetic Counselors; and Gail Javitt, policy analyst, Genetics and Public Policy Center.

If there is anyone else who wishes to make public comment that is not on that list, please sign up at the desk outside.

We'll start off with Joe McInerney from NCHPEG.

MR. McINERNEY: Thank you very much. I'll be brief.

DR. McCABE: Joe, why don't you come up -- why don't each of the commentors come up to the table and take one of these mikes at the table, please.

MR. McINERNEY: Thank you very much. I'll be brief. I was listening to the discussion about genetics and genomics, and I certainly don't want to reopen that whole issue for the committee, but I think rather than simply relegating that distinction to the glossary, I would urge you to address that right up front in your document. I know from experience in working with a broad range of health professionals in the last few years that there's a great deal of confusion about what genetics is and what genomics is, and I think this committee should clarify that for people who are coming to this document without any background in genetics.

One of my concerns is that there is an assumption that genomics is somehow going to obviate genetics, or that from this point forward it's going to be only genomics and what we all know as sort of classical or traditional genetics, the study of inherited biological variation and its clinical application in terms of medical genetics, will somehow be left aside. So I would just like to make certain that that doesn't happen, that that perception or conception does not come through in this document and that the committee takes some time to define the terms up front in the context of the work that's going to follow.

Thanks.

DR. McCABE: Thank you, Joe. Why don't you stay there a minute, Joe. I would agree with you that genetics is the study of inherited traits, that genomics is the study of genomes, and I think that's how we intend to use the terms and will make that clearer in the document.

Okay. Any other questions or comments for Joe?

(No response.)

DR. McCABE: Thank you.

Next we have Michael Murphy, president and CEO of Gentris Corporation.

MR. MURPHY: Thank you. As a means of self-discipline to make sure I cover everything I want to in my five minutes, I'm going to read a pre-written statement.

Good morning. My name is Michael Murphy. I'm president and CEO of Gentris Corporation. I'm also serving on the Pharmacogenomics Advisory Group for the American Association for Clinical Chemistry. This is a group that we've put together from our government liaison to advise FDA and CMS.

Gentris is a clinical pharmacogenomics company. We perform testing for pharmaceutical companies during drug development, and we're also commercializing in vitro diagnostic products for physician-referred testing. It's a pleasure and honor to speak before the committee during the public comments session. I'm speaking in favor of the resolution direct-to-consumer marketing of genetic tests.

Pharmacogenomics is the study of an individual's genetic traits and the relationship it has to variable drug response. The field has made tremendous progress in the last 20 years. Specifically, we've been able to identify the dozen or so genes responsible for drug metabolism and clearance in humans. In addition, we understand the liver enzymes encoded by these genes are involved in the biotransformation of more than 80 percent of all commonly prescribed drugs. We also know that in general, 5 to 7 percent of all patients are so-called poor metabolizers. These patients are at risk for serious adverse drug reactions because they tend to accumulate drugs to toxic levels in their bloodstream.

Adverse drug reactions are now the fourth leading cause of death in the United States, with more than 100,000 lives lost each year. Most experts appreciate that many of the deaths might be prevented once pharmacogenomic testing is utilized prior to drug treatment.

We and others have developed clinical pharmacogenomic tests which can be used prospectively before drug treatment. In fact, most of our pharmaceutical sponsors do just that during clinical trials to make sure they develop safer and more effective drugs. Now we have developed clinical diagnostic products so we can do the same thing for all patients, not just those in clinical trials.

It's clear we're on the verge of early adoption of clinical pharmacogenomic testing into medical practice and health care. Direct-to-consumer marketing of genetic tests has the potential to slow or harm much of the progress we've made in clinical pharmacogenomics. So why shouldn't we let patients have access to these important tests directly, and why shouldn't we market to them?

Pharmacogenomic tests require a translation from a person's genotype to what is called the predicted phenotype. That is, we have to tell the physician if the patient fits the profile for one of four possible metabolizer types, including poor, intermediate, extensive, or ultra-rapid. Even if the laboratories supply this information to patients, there's still a need for a learned intermediary to help in further translating metabolism type to a drug-prescribing recommendation. It's critical to have a medical professional, such as a physician's assistant, nurse, or a doctor, use this information to guide drug treatment. It is conceivable that patients could use this genetic test result to change their own drug treatment regimen simply based on something they read on a website from groups that market direct to patients. Obviously, this has the potential to harm instead of help.

It's understandable that patients will seek genetic information that might be used for drug treatment. For example, in the May issue of Reader's Digest, a widely read lay publication, they featured an article entitled "Genetic Breakthroughs: Making Medicine Safe." In 2002, the FDA approved Stritera or atamoxitene for attention deficit hyperactivity disorder, ADHD, in children. The FDA took the unprecedented decision to label this drug with warnings about increased adverse events in poor metabolizers of a gene called 2D6. They also included in the label a statement "testing is available," recommending that physicians consider genotyping. So it's not hard to imagine that parents might seek out 2D6 testing for their child about to start this drug treatment.

As most of you know, some companies are marketing to consumers claiming to help patients by testing for genes related to nutrition, so-called nutrigenomics, and even genes related to lifestyle. Most of these tests have not been validated or substantiated in peer reviewed literature or case-control clinical trials. When clinical pharmacogenomic tests like the drug metabolism test we've described are packaged with these unsubstantiated tests, there is the danger that clinical utility might be overlooked or their credibility diminished in the eyes of medical practitioners.

Just recently, on May 11, 2004, the Wall Street Journal ran a short article in the personal health section about several of the companies that offer direct-to-consumer marketing of genetic tests. In the article, drug metabolism tests are lumped together with tests for nutrition and toxins, and the author describes the validity of all the tests as "the science behind

many such tests is shaky." Obviously, it's disappointing that on the one hand we've made such great progress towards testing patients for these critical pharmacogenomic traits, and at the same time have them possibly perceived by the general public as unreliable or unimportant.

Gentris and other companies have worked diligently to bring these new tests to market. These tests have the potential to decrease serious adverse events and allow for a more rational practice of medicine. Most in our industry believe that these tests, like other diagnostic tests, are best conducted in CLIA-certified laboratories. We urge the committee to recommend the necessary legal and regulatory changes needed to ensure that progress is not lost so that we can continue progress towards offering these potentially life-saving tests in the best medical setting possible.

Thank you.

DR. McCABE: Thank you very much.

If you have that typed up, if you could provide it to staff along with the copy that you had from the Reader's Digest, any of that material we would appreciate for our record.

Any questions or comments for Mr. Murphy?

Yes, Emily?

DR. WINN-DEEN: So I was wondering what your recommendation is for the CLIA-certified labs who are also marketing directly to consumers. I mean, just because you're a CLIA-certified lab doesn't basically keep you from unscrupulous marketing practices. It just means that you're performing the test correctly, not that the test has any real utility. So is your AACC committee working on some recommendations in that regard?

MR. MURPHY: No, that committee is actually just working on issues about reimbursement, CPT codes, et cetera. We understand that some CLIA labs might offer tests that have little or no medical relevance, and I'm sure they're validating those tests under CLIA guidelines, and I'm sure they're using physicians to order and report those results. I think what's important is that the marketing be honest and fair to the consumer and that they really know, the consumer buying this test through a physician. We know that consumers will ask physicians to do these tests. We get calls every day. We are a CLIA-registered lab, and we get calls every day from patients who want 2D6 testing. So we have to refer them back to their physician, following CLIA.

The benefit the patient will get for that test needs to be honestly and fairly described to the consumer, and it is not being done so. More importantly, obvious and well-established medical utility tests, like some of the ones that are coming out now for predicting adverse drug reactions, are being mixed with these others. So I think that's the real issue.

DR. McCABE: Other questions or comments?

(No response.)

DR. McCABE: If not, thank you very much.

Can we have Kelly Ormond come to the table, and then also Gail Javitt, if you could come to one of the other microphones at the table.

Kelly Ormond is from the National Society of Genetic Counselors.

You're the incoming president. Is that correct?

MS. ORMOND: Yes, that's correct. Thank you.

Good morning. I am Kelly Ormond, president-elect of the National Society of Genetic Counselors. As you're aware, NSGC represents over 2,000 member genetic counselors practicing in a variety of medical specialties and including academia, research and biotechnology companies. NSGC is the leading voice, authority, and advocate for the genetic counseling profession.

NSGC thanks SACGHS for taking our prior testimonies and support materials into account when developing the draft resolutions and reports. NSGC feels, with one exception that we will discuss today, that the vision report and included issue briefs accurately reflect our understanding of the issues. We encourage SACGHS to continue to address these issues as

proposed and discussed today.

We would like to address three areas: the draft resolution on direct-to-consumer advertising; the draft report on coverage and reimbursement of genetic services; and our concern regarding the draft resolution on genetic education and training of health care providers.

First, with regard to direct-to-consumer or DTC marketing, the NSGC code of ethics states that genetic counselors will strive to enable clients to make informed decisions by providing necessary facts regarding genetic testing. As discussed in the issue brief and SACGHS' draft resolution on direct-to-consumer marketing, many consumers view DTC marketing as providing them with additional information and options regarding their genetic health care, but we must be cautious about DTC efforts that provide misleading or inaccurate information.

NSGC supports an individual's right to full disclosure of all appropriate medical information regarding genetic testing, and that genetic counseling services by a board certified or board eligible genetics professional should be an essential component of any genetic testing program that is marketed directly to consumers.

Second, NSGC agrees with SACGHS' statements in the draft coverage and reimbursement report that genetic counselor billing is limited by the current lack of CPT codes for genetic counseling and by the lack of inclusion of genetic counselors as non-physician Medicare providers. While we recognize the challenges in doing so, NSGC encourages SACGHS and the Secretary's office to consider ways to address these two issues. We also ask that SACGHS promote the development of federal funding to support evidence-based studies of both genetic technologies and clinical genetic services.

As was discussed yesterday, this data can be used in discussions with purchasers of benefit packages such as employers to support the inclusion of genetic services and testing as a reimbursable option within health plans. NSGC has prioritized issues of billing and reimbursement as one of our three primary foci in our recent strategic plan, and are also working on addressing these issues.

Finally and most importantly, NSGC would like to address the draft resolution and issue briefs on genetic education and training of health care providers. First, we applaud SACGHS' efforts to actively consider the issues that impact the genetics workforce in health care and to recognize the educational efforts which are already occurring. Our greatest concern, which was not the focus of yesterday's roundtable discussion, is that this draft resolution does not address the need for additional training of genetic specialists. NSGC strongly believes that the provision of quality genetic medicine requires the involvement of health care providers of all specialties.

Members of NSGC and other professional genetics organizations have been instrumental in developing and implementing educational initiatives for other health care providers, and we expect that they will remain the driving force towards a broader genetics competence in medicine.

While NSGC does not wish to promote the concept that only genetics professionals can address these issues in health care, it is clear that any future delivery models for genetic services will require the input of individuals with specialty training in genetics and genomics. The NCHPEG competencies state that each health care professional should, at a minimum, be able to, number one, appreciate limitations of his or her genetics expertise; number two, understand the social and psychological implications of genetics services; and number three, know how and when to make a referral to a genetics professional.

These competencies make it clear that non-genetics health care professionals should not be expected to provide comprehensive clinical genetic care but rather to work in conjunction with genetic specialists. When one adds to this the fact that most health care providers are not comfortable with genetic information, particularly in the areas of ordering and interpreting genetic tests, and that fewer health care providers see the immediate clinical

relevance of genetic testing and related technologies, it becomes clear that if consumers of genetic services are to obtain high-quality health care, we must ensure that specialists are available to support the primary caregivers and referring specialists.

To echo the statements made yesterday by the American Board of Genetic Counseling, the recommendations to ensure that genetics education and training of all health care professionals is adequate will only be successful if there is an adequate genetics workforce to implement these recommendations. It is also clear that the current number of certified genetics providers needs to be expanded.

Additionally, if we are to address the issues in health disparities raised in Healthy People 2010, SACGHS must also consider the limited cultural and ethnic diversity in genetic professionals, and that most of these genetic specialists currently work at academic medical centers, often limited in their ability to provide outreach to underserved regions or populations. Furthermore, there continue to be multiple impediments to increasing the training pipeline for both medical geneticists and genetic counselors. An infusion of federal funding would increase the number of quality genetic training programs in a short time frame.

Genetics professionals, with their experience across various areas of medical specialization and ability to translate complicated genetic information into non-medical terms, are the ideal professionals to help bridge these training gaps. As NSGC testified at prior SACGHS meetings, to meet the increasing needs of genetic medicine, a two-pronged approach is necessary. First, we must increase the number and diversity of practicing genetic specialists trained in the United States. Second, as SACGHS has recommended in the draft resolution, we must increase the knowledge of health care professionals such that they can perform basic components of genetic medicine and develop knowledge of general genetic concepts and referral resources.

To reach the goals of an educated health care provider population, we must actively work to reduce the barriers to training genetic specialists at the same time that we are working to increase the genetics competence of non-specialists.

In conclusion, NSGC urges this committee to actively address the education and training needs for both specialists and non-specialist genetics training to ensure a competent genetics workforce in the future. NSGC is willing to work with SACGHS to develop an issue brief and draft resolution reflecting this approach.

Thank you, and I will provide a written copy of these comments to the committee for your reference.

DR. McCABE: Thank you very much.

Any questions for Ms. Ormond? Comments? Yes, Debra?

DR. LEONARD: So if there is a recommendation to increase the number of people trained as genetic counselors, are there training programs in existence that could expand to accommodate that extra training?

MS. ORMOND: I believe that this issue was covered when Robin Bennett came and presented to the committee several months ago. There are programs which are willing to consider expansion if there's funding to support that, as well as a number of programs which are in development and trying to establish the funding to get those programs underway, and I believe there are also similar issues facing medical geneticist training.

DR. McCABE: Muin, and then Agnes.

DR. KHOURY: I'd like to applaud the efforts of NSGC. Over time, you have been a good voice in this discussion.

MS. ORMOND: Thank you.

DR. KHOURY: In terms of this evolving nature of genetics and genomics in the 21st century, I'm wondering whether NSGC has discussed or considered the training needs of its own workforce in the sense that as we walk through this continuum from a genetic disease focus, where we are focusing on people with conditions and their families and trying to translate information that could be useful for their psychosocial support and decisionmaking to information

that is going to be used in the daily practice of medicine, there is that tension. On the one hand I do appreciate and think there is a big role for the practitioner geneticist community, but in the final analysis the number of conditions for which this kind of practice will be needed will probably be no more than 10 percent of human disease.

So how is NSGC going to or has begun to address this range of genomic information, from somatic cell to polymorphisms, and is there a role for something that we might call genomic counseling, and where does genomic counseling end and health education start, and the practice of medicine? So there is that tension between having more specialists versus integrating the genomics knowledge into the practice of daily medicine. Your thoughts on this will be appreciated.

MS. ORMOND: Sure, my pleasure. I think that genetic counselors have always been a very flexible group in finding ways to take the skills that we are trained in and applying them to the various clinical situations. I think that a perfect example of that is our integration into the cancer genetics setting over the past decade or so. Genetic counselors are certainly aware of this issue that you're raising and it considering it actively.

Within our most recent strategic plan we have raised the idea of addressing scope of practice and have set up committees that include medical geneticists as well as many of our members practicing in different clinical areas to look at how we may become integrated into these various areas of genomic medicine, also looking at genetic service delivery, as we do recognize that many of our more traditional approaches to genetic counseling may not be as applicable to the new mode of genomic medicine. So we are actively considering those issues and trying to incorporate health care professionals with different views into those committees.

DR. McCABE: Agnes?

MS. MASNY: My question was very similar to Muin's, and I was going to ask if the profession and the curriculum development for people who are coming into the field has begun to look at innovative ways to actually have different tracks, maybe as a genetic educator, maybe as a specialist who would be someone who would then train the trainers so there could be more people in the health profession in general who then could have access to this information.

Lastly, historically I know that the genetic counseling profession did have options for people with a public health background, nursing background, to be able to sit for the genetic counseling exam, and then there were specific requirements, of course, just to have the genetic counseling background. Would there be any opportunities to have a separate kind of track where we could make use of other health professionals that already exist to actually expand the amount of genetic counselors that are out there via different mechanisms of either certification, maybe not necessarily genetic counselor, but genetic counselor associate or something, but that would recognize other health professionals who then would have specific training in genetics and then could sit for the board.

MS. ORMOND: I think some of those questions would need to be redirected to the American Board of Genetic Counseling, who does take care of all of the professional certification. I know that they did change their certification processes. I believe 1999 was the last year that individuals who did not graduate from an accredited program could sit for the ABGC board exam. But certainly the training programs are cognizant of the changing needs, and we're always trying to readdress our curriculum to be training for five to 10 years down the road, incorporating many of these new specialty areas, and certainly educating our new students in areas like billing and reimbursement, health education, preventive services.

I am not aware of any programs that have specific tracks established, nor does the certification exam currently have tracks, but I know that these issues have been discussed and I'm sure will continue to be raised. Does that answer your question?

DR. McCABE: One last brief question and brief comment from Hunt, please.

DR. WILLARD: Your call for increased specialty training in genetics and genomics is clear. What isn't clear to me, though, is whether it's your recommendation that that

be done only in the specialty of medical genetics, capital M capital G, or whether you can get specialty training in genetics and genomics in all kinds of specialties.

MS. ORMOND: I think both need to happen. I think that there is historically a difference in the approach to management and assessment in medical genetics as compared to some of the other specialties, and I think we can all benefit from having a little bit of both.

DR. McCABE: Thank you very much.

MS. ORMOND: Thank you.

DR. McCABE: Our next presentation or commentor is Gail Javitt, policy analyst for the Genetics and Public Policy Center at Johns Hopkins University.

MS. JAVITT: I actually have some PowerPoint, so if I could approach the podium, that would be helpful.

DR. McCABE: While those are going up, I'd also point out that there is material in your table folder, the comments on the draft resolution on DTC marketing genetic tests.

MS. JAVITT: Good morning. My name is Gail Javitt, and I am a policy analyst with the Genetics and Public Policy Center at Johns Hopkins University. Thank you for the opportunity to present these comments this morning on behalf of the Center and its director, Dr. Kathy Hudson. We specifically would like to address the draft resolution concerning direct-to-consumer, or DTC, marketing of genetic tests.

The analysis of DTC marketing of genetic testing must clearly distinguish between advertising of genetic tests on the one hand and commercial availability of these tests on the other. Each of these activities is subject to distinct systems of regulatory oversight and is amenable to different possible policy solutions.

With respect to advertising, the draft resolution rightly identifies the FTC as potentially playing a key role in preventing companies from making misleading claims about genetic tests. But while FTC has a broad statutory mandate to protect consumers, this mandate is circumscribed by two factors. First, FTC may prohibit only advertising that is false or misleading. While establishing the falsity of some genetic test ads out there today would likely be neither difficult nor controversial, as to others, but ambiguity and disagreement can be expected.

Concerns about the impact of DTC ads on consumers that are unrelated to their truth or falsity would not likely provide a basis for FTC intervention. Indeed, the government is significantly constrained by the First Amendment in regulating truthful commercial speech.

Second, FTC must choose its enforcement actions carefully based on the nature and magnitude of the harm caused by the advertising in question. Evidence of this nature does not currently exist with respect to DTC genetic testing. We therefore recommend that the committee consider ways to foster data gathering concerning the harms and any benefits of DTC advertising to consumers. This data could then be provided to FTC and used as a basis for that agency's involvement.

With respect to commercial distribution, the draft resolution recommends that genetic tests should not be sold directly to consumers without the informed guidance of an appropriately trained health care professional. Some will view this position as unduly restricting patient choice. Others may feel such guidance should be required only for certainly types of tests, such as those that predict serious disease. Some may question whether health care professionals are adequately prepared to provide guidance and interpretation of these tests.

These are all important issues for the committee to consider, but these comments are intended to address whether as a practical matter there is a means of effectively implementing the committee's recommendation. Currently, no federal or state entity regulates when or under what circumstances genetic testing services may be commercially offered to consumers or health care providers. It is therefore unclear what entity would now have the

authority to implement the recommendation.

The draft resolution recommends that FDA enhance oversight of genetic tests while acknowledging that agency's limited oversight for most genetic testing. FDA regulates genetic test kits that are sold as free-standing products and not genetic testing services provided in-house by clinical laboratories. FDA has therefore had limited opportunity to review only a few DNA-based genetic tests, even though there are genetic tests for over 700 genetic diseases.

This is not the first committee to identify FDA as an appropriate body to provide more substantial oversight, and we do not disagree that FDA involvement could be both beneficial and consistent with that agency's broad public health mission. We question FDA's willingness, however, to step into this arena without a clear mandate to do so, particularly in the absence of more concrete evidence of consumer harm.

The draft resolution fails to mention another key player in genetic test oversight. The Center for Medicare and Medicaid Services administers the Clinical Laboratory Improvement Amendments, or CLIA. Laboratories that provide commercial genetic testing services are covered by the statute. Despite recommendations from advisory groups, CMS has not yet issued proficiency testing standards for most genetic tests. In enacting CLIA, the Congress recognized the crucial public health role played by clinical laboratories. More rigorous oversight of genetic testing laboratories under CLIA could enhance public health protection.

The federal government has not invested in any entity the ability to serve as a gatekeeper, meaning to decide when and whether genetic tests possess sufficient validity or utility to be used in the clinical setting. This is in contrast to the situation for many other clinical tools used by health care providers to diagnose and treat patients. Some would argue that increased government involvement is neither necessary nor desirable. Others believe that, given the increasing importance that genetic testing is assuming in health care, this gap in oversight could threaten public health.

This committee could play an important role in identifying the benefits and drawbacks of a more rigorous system of oversight.

The draft resolution rightly identifies several areas of potential concern related to DTC genetic testing. At the same time, much remains unknown about this enterprise. Is this a trend that will continue to grow? What is the impact of such testing today, and what can we predict about its future impact on consumers? Sound policy formulation in the months and years ahead on this issue will be greatly facilitated by sound empirical evidence. Thus, it is important that this committee identify the entities best equipped to gather such data and foster a mechanism for gathering these data and studying these issues.

In summary, we recommend that attention be given not only to the dubious claims made for some genetic tests but for preventing genetic tests of dubious value from getting on the market in the first place. To that end, we offer the following suggestions. First, the committee should foster data collection concerning consumer impact of DTC genetic testing, including whether and to what extent consumers are obtaining genetic testing through these means, whether such tests are causing harms or providing benefits, and the nature and magnitude of such harms or benefits.

Second, the committee should consider how CLIA could be harnessed to provide greater oversight of labs providing genetic testing services.

Third, the committee should identify the current barriers to greater FDA involvement and consider a means to overcome these barriers.

Finally, the committee should consider the merits and drawbacks of a federal oversight entity that would set standards that genetic tests must meet before they are made commercially available.

Thank you very much.

DR. McCABE: Thank you very much.

Any questions or comments? Yes, Chris?

DR. HOOK: Just a couple of observations and open questions that you raise. You mentioned the term the importance for consumer freedom or consumer access to information, yet in the vast majority of other medical tests that are available, consumers do not have direct access to those. The reason why genetic testing is being marketed in this way is that it can be done by a buccal swab rather than a blood draw or some other type of invasive means of gathering the information.

So conceptually we do restrict access to the majority of other types of medical information gathering processes without direct access by the consumer. So why are we now saying that we need to make an exception in the opposite direction with genetic information and allow them to have access to that when it's much more complex? That's a conceptual question I want to address to you.

My second one is that, again, I agree with you completely that we need to be collecting data, we need to be compiling a database of examples of potential abuse, trying to find how the public is interacting with this, and I think that's very important. But there still seems to be an inference, or at least that's how I'm taking your comments, that there needs to be blood on the pavement before we have a warrant to intervene, and I'm not sure I agree with that. I think if we can see that harms are going to be done, as for instance Mr. Murphy was pointing out earlier, that we have a significant amount of ambiguity on proven utility even of the cytochrome phenotype systems and various drugs, why do we have to wait to have people be harmed before we do our appropriate job of recognizing the potential for harm and intervening to prevent that?

MS. JAVITT: Let me start with your second question, because I wanted to just make sure that I didn't create a false impression. The distinction that I'm trying to draw is between information provided consumers and products or tests, actual concrete services. With respect to the services, I think that foreseeable harms could indeed be a basis for intervening before there is, as you said, concrete harms.

With respect to providing information to consumers in the commercial context, there are legal constraints that will come into play, and in crafting any oversight system, those need to be considered. The Supreme Court in the past several years has provided a much higher burden on the government to show that the information itself will cause harm, and part of what they've asked for is facts, facts on the ground. That is the distinction that I'm trying to draw.

Was there somebody else who wanted to respond, or was that another question? I thought I saw a hand.

DR. McCABE: Muin has a question or comment.

MS. JAVITT: Oh, okay.

DR. KHOURY: Actually, we didn't have much time to go into the public health response to the Myriad campaign this morning. We might have a chance to discuss it a bit later. But when you make some recommendations about role of different agencies and you put data collection as sort of hanging in there with no jurisdiction for that in any locality, it also begs the question of who is going to do this. The Myriad campaign taught us a few lessons.

The first thing was where the campaigns were running in the populations in Denver and Atlanta, Georgia, the health departments were beginning to get questions from the general public, from women who were concerned, and that led to the mounting of the public health assessment of what really happened. I think as direct-to-consumer in genetics, or in any other thing -- I mean, without the genetic exceptionalism, has the potential for both hurting and helping people -- somebody somewhere needs to keep their finger on the pulse. That's a function that should be well-defined and is truly a public health function that involves going out and collecting data in real communities involving epidemiologic tools and surveys, et cetera.

As this committee begins its discussion, I think we need to fine-tune that function a little bit more, because policy depends on data. If we don't have data, whether we want more regulation or less regulation or more oversight and different kinds of things, the data collection is so key to putting your finger on the pulse so that the right policy decisions can be

made. To me, that data collection is inherently and essentially a public health surveillance function.

DR. McCABE: I think that was more of a comment than a question. Do you have any response?

MS. JAVITT: I just didn't want to forget the first question that you had raised. My understanding in terms of providing testing to consumers directly is that it's a state by state decision about to whom labs may receive samples from and report back to, and that's a state decision rather than a federal one. So there isn't necessarily a distinction between genetic testing in that context and other laboratory tests.

DR. McCABE: Matt, I'll let the FTC have the final question here.

MR. DAYNARD: Well, it's really just a couple of points to clarify the Commission's legal authority for the group. I think all ads would be subject to our jurisdiction. If they're on the Internet, for example, they're certainly interstate, or even if they're local in a local paper. If the lab obtains any part of the test from out of state, it's affecting commerce. So that's not a difficult issue.

I agree with you 100 percent that proving whether it's false or lacks substantiation in the form of comparable reliable scientific evidence is another issue altogether, and it may be difficult in many of those cases to make that burden. But we have the jurisdiction.

The second point is the Commission in terms of deception only requires -- Commission law only requires that an ad be likely to mislead consumers in terms of their purchase or use decisions. We don't have to show blood on the floor necessarily. The unfairness jurisdiction might be a different story.

The third point is that there is simply no per se First Amendment protection for deceptive commercial speech. That doesn't mean we don't have to use reasonable means to the end of regulating it. But the Commission doesn't have the problem the FDA has had in a number of areas because it looks at ads before the fact. So it's a much higher First Amendment burden on the FDA, but we don't typically have that problem if we choose our targets wisely.

DR. McCABE: Any comment?

MS. JAVITT: No, thank you.

DR. McCABE: Thank you very much. We appreciate all the commentors for your input.

I'd also remind the committee that there are written comments that we received that are in your table folders.