Roundtable Discussion Regarding FDA and FTC Regulation of Advertising and Promotion of Genetic Technologies
Facilitator: Ms. Zellmer

DR. McCABE: Thank you very much. Please join us at the table, and Steve is going to join us. Steve actually covered the material from the FDA regarding advertising this morning, so that will give us even more time to discuss this afternoon.

So, Ms. Zellmer?

MS. ZELLMER: Mr. Daynard, thank you for your information. Again, I have a few questions myself, and then I'll turn it over to those of you who have questions.

You had mentioned at the beginning of your presentation that as of this point in time, there had been no actual actions taken on claims on genetic testing. How does something get on the radar screen of the FTC? I mean, does there have to be a complaint? Is this something that you actively monitor? I guess there are a couple of other parts to that question, then. Do you have people at the FTC who are physicians or who have the training that they would -- how do you know if there are deceptive claims, and is there the funding to pursue these?

MR. DAYNARD: Well, to answer your second question first, no. Sometimes I feel like I'm a physician because when I get heavily involved in something, I can at least talk sensibly with the scientists. But, no. We have economists at the Commission who look at studies to see whether they're methodologically sound, but otherwise we call the experts. We call you, we call the FDA, the NIH, and I have contacts with all of those folks. It's my coming to events like this that gets it on our radar screen.

So what's going to happen in the future? I really can't say. I expect that as this area evolves, there will be more and more marketing, and that's what will get it on the radar screen of my superiors at the FTC. Plus, I've been telling them about this for a while, so they'll be expecting it also.

MS. ZELLMER: Reed?

DR. TUCKSON: Well, first of all, it is just terrific that you're here.

MR. DAYNARD: It's my pleasure.

DR. TUCKSON: And I'm glad that it's on the radar screen. I think one of the questions is that it's sort of between FDA, Steve, as you sort of indicated I think in your comments earlier, that you all do not regulate or look at -- you don't have authority over laboratory ads or labels or direct-to-consumer advertising in this area. So it sounds like you're out of it completely. Does that mean, then, by inference, that the only folks who are in it is the FTC?

MR. DAYNARD: And states, I presume. Well, like other areas, I expect I'll be getting a lot of ads from my friends at the FDA saying what about this, what about this? That is, in part, what we rely on. We also rely on competitors and rely on watchdogs at the state level, consumer medical watchdogs.

DR. TUCKSON: The other thing would be that at our last meeting Dr. Collins, who presented not as a decision of a particular example being, in his mind -- I'm trying to be very careful -- he didn't present it as if it were over the line, but he presented a case of interest which I actually have a copy of with me, and I'll share it with you. I'll leave the manufacturer moot, but it was the one that had to do with do you think your child has a genetic predisposition to bad behavior or alcoholism, whatever? Just take this little swab and swab the inside of your mouth and put it here and send it to us, and we will study this and prescribe the right nutriceutical that is just perfect for you.

Obviously, I remember it and I've used it because it's driven me nuts as an example. The point I'm getting to with this is the notion of egregiousness of this, and I wonder does egregiousness, if there is such a word --

MR. DAYNARD: There is. We use it all the time.

(Laughter.)

DR. TUCKSON: Does it relate on an individual by individual basis, or can you look at an emerging class of problem, like direct-to-consumer advertising preying on genetics as an emerging issue and say that that becomes important enough to sort of get order in the world early on so that each individual case may not be -- this company may sell only $12.22 worth of product, but it starts to become an example that you want to set?

MR. DAYNARD: That can happen and has happened in the past, but typically we'd like to nip things in the bud if it's possible to nip things in the bud. You're absolutely correct. The FTC, generally what it does is it uses its law enforcement authority to set examples for the rest of the industry. So we get a quick consent without having to go to litigation. It's out there and we press release, and we have at the same time a joint statement with the FDA or NIH or somebody about here's what you should look out for. With a quick-fix genetic test, if it's too good to be true, it probably is kind of thing.

We have consumer ed people who are wonderful with sound bites. But at the same time, it's got to fit within our resources, because as I said, we're small. In the last few months, for example, since the beginning of the year, we've gone after dietary supplements that have safety concerns that amounted to a billion dollars in product sales, and this is one division. We've got a full plate. So I would have to convince somebody that we're going to nip this in the bud.

Now, if that had been a genetic test for some serious disease, it would have a better shot.

DR. TUCKSON: One last thing, and just as we think about the role for our committee, maybe that's one thing we can do as a follow-up.

The other thing as an afterthought is the idea of educating consumers about what to look for when they read ads. It would be terrific if you have any campaigns or activities that are going forward that are designed to educate the public in this regard, or if you're anticipating such, perhaps our committee, as we make recommendations to the Secretary, could suggest some things, especially given that we have a lot of patient advocates around the table, and others. Maybe we could do something there in terms of our energy.

MR. DAYNARD: That would be great. I mean, we've done things both ways. In the past typically we bring a number of cases, and then in a final push, so to speak, we'll issue a Facts for

Consumers kind of thing. But we've also done it the other way around. For example, in the LASIK area -- you all know what LASIK is -- I issued a joint statement with the American Academy of Ophthalmology called "Basic LASIK" about you have to go into this with your eyes wide open, not your eyes wide shut, the movie notwithstanding.

(Laughter.)

MR. DAYNARD: It was terrific. And then I brought two cases, because then I could say, well, you guys all knew what was coming down the pike here and you kept making these unsubstantiated claims, and you threw your glasses away when I told you directly that you can't make that claim. So here you are.

So that's a great idea, and again all I'd have to do is, one, get to know the science a little better so I can talk with you intelligently about it, which I will; and second, convince folks that this is something that's going to be very important to do. So we'll keep in touch on that one.

MS. ZELLMER: Francis Collins.

DR. COLLINS: Francis Collins from NIH. I want to follow up on Reed's question. I actually have the ad in front of me that he's referring to, and yes, it is pretty amazing, not only the fact that the test is completely without foundation but the nutriceuticals that they are marketing to you, and this is all direct-to-consumer marketing, also without foundation as far as I can determine.

I appreciate your being here and your willingness to consider looking into this area. I just wanted to comment that while it may still be the case that, compared to the billion dollar market that you're wrestling with of another sort, this is clearly an area of growth opportunity, and this may be a case where a little bit of prevention will save you and consumers a lot of trouble down the line if you could basically enter the fray in a fashion that puts a line in the sand to direct-to-consumer marketers for genetic tests and says basically if you cross over this, you're going to hear from us.

Right now, it's pretty clear that the marketers don't perceive that they're particularly at risk because one can simply, by googling under "direct to consumer genetic tests," appreciate that the number of offerors is going up month by month. There are two published articles in the peer-reviewed literature that have surveyed this, one of them in JAMA. So the information is out there about what exactly is going on in the field. They are certainly able to document not hundreds but certainly quite a number of websites that are doing direct-to-consumer marketing of tests which a trained geneticist would tell you really have no scientific foundation, and it is a growth arena.

So I appreciate your being here and your willingness to consider looking into this. I would argue that it may be your time well spent, as well as good protection for the consumers, to try to jump in on this before it gets a lot worse.

MR. DAYNARD: Well, you make very good points, and I'd be happy to see the ad. Is it a national ad?

DR. COLLINS: It's on the web.

MR. DAYNARD: That does it.

(Laughter.)

MS. ZELLMER: I have Debra Leonard, Chris Hook, Ed McCabe, and Hunt Willard.

Debra?

DR. LEONARD: Debra Leonard. So this is an instance where it's clear that there's no scientific basis, but eventually we're going to be able to understand the genetic basis for all sorts of what are now called personal characteristics, and so there would be truth in being able to do these things. It wouldn't be deceptive, and then I don't know whether the unfair part comes into this and whether it's ethical. But who in the government or which regulatory agency is going to decide what it's okay to test for and what it's not okay to test for? Because then you don't have the deception problem.

MR. DAYNARD: Well, it wouldn't be the FTC who decides. We don't regulate the quality of care. That's not our charge, as I said. So if the claim -- I mean, you could have a claim that has some truth to it which is also deceptive because it goes over the line by saying something else. Yes, we'll test you for predisposition to breast cancer, but then it says something else that goes way beyond its real efficacy. So it's always an ad hoc situation.

But no, the FTC doesn't -- there's no censorship, if you will, involved. We get involved in ethics, but it's a murky area. And lawyers, we don't like ethics. But the FTC is on the right side, so I'm not terribly concerned about that. But on the other hand, we do talk with ethicists. In fact, I remember I was on a panel at the AMA once on ethical medical advertising, not just deceptive or unfairness. So it depends on the claim, it depends on what the experts around the country think. In fact, if a test has some downsides, even if it truthfully can be done, and depending on what those downsides are, if those downsides are injurious, then maybe the claim does have a problem under the FTC Act.

DR. LEONARD: What would the FDA do with an IVD that was for a happy person gene or something?

DR. GUTMAN: Well, if it was offered by a laboratory, it would not be under our purview.

DR. LEONARD: No. I'm talking about a company that has an IVD, they're bringing it to the FDA and they can prove their claim.

DR. GUTMAN: Boy. Well, there's no predicate, so that's a PMA.

(Laughter.)

DR. GUTMAN: But the issue would be if you could establish safety and effectiveness. I actually don't know. I mean, being happy is really a good thing, so you have to establish the public health benefit --

DR. LEONARD: That was just an example. There are lots of personal characteristic kinds of things.

DR. GUTMAN: Everything with us is framed in terms of claims and in terms of risk/benefit analysis. The closest -- I have not gone even near where I think this might go, so I have no experience to draw from. The closest place where we carefully model risk/benefit analysis in this way is when we're looking at over-the-counter tests and we look at a test and we try to figure out

the risks and the benefits and try to make a profile. If we're not certain, we'll call a panel of experts in the field together to give us advice or do homework assignments. We have actually no experience to draw from, so the people who are lucky or unlucky enough to be on our panels are likely to help us chart that course when we get that first product.

MS. ZELLMER: Chris Hook?

MR. DAYNARD: There's one other thing I want to say in response to Dr. Collins. There's another thing I can do, and I do it in the health care area and other areas if we don't have the resources to actually sue them or go into federal district court or administrative court, and that is a voluntary advisory letter sort of thing. It harkens back to the days when the Commission used to have an insurance for voluntary compliance, which just meant you promise and I promise, and hopefully you'll do what you say you're going to do.

But it seems to have worked in the LASIK area. I get ads all the time from competitors about LASIK, local doctors saying throw your glasses away, or Wavefront is the best thing since sliced bread and you'll never have a problem. So I send them a letter that says we haven't determined if you've violated the FTC Act, but for health-related claims you need a competent lab with scientific evidence, and if you don't have it for this claim, give me a call because you may want to change your advertising, and it works. It works. They don't want to hire a prestigious thousand dollar an hour lawyer from Washington. So I get them to change their advertising voluntarily.

This also should not be recorded.

(Laughter.)

MR. DAYNARD: But that's another possibility if I can't get the resources to actually do a complete investigation and bring a case.

DR. HOOK: Chris Hook. I feel like I'm being redundant to Reed and to Dr. Collins, but I want to go ahead and share these just because I think it's important to emphasize again the prospective nature of intervening.

In addition to the one that you have recognized, I ran into another site. It was brought to my attention by a friend who was doing a visiting scholar program at Oxford this summer, and in a pharmacy there, right off of the little metal rotating rack was this 10-pound packet kit that said send this, give us the buccal swab, we'll send you a complete genetic analysis, we'll tell you all of your risks for cancer, what you can do to live longer, to have a happier life, and it was a company from the United States that was actually producing this product.

I ran into another site that may not have been promising the world in terms of we're going to make you younger and able to live longer and all this, but they again claimed that they would provide a complete genomic analysis, which they can't do. And even if they could provide a partial genetic analysis, the things that they were claiming they would tell you about would require significant appropriate genetic counseling in order to interpret appropriately. Yet they are sending this directly back to the patient. The patient believes that they understand how to use this information when clearly I'm sure they don't, and that to me is a major health problem.

MR. DAYNARD: There are two issues there, because we can't deal with the mind problem so much. The way we might normally deal with that is some failure to disclose an important point like that, that science has shown you need counseling when you get this kind of information. But

we wouldn't bring a case probably based on that alone. So the first point would be what we'd look at, that there is no test that does this. We could be interested in that kind of thing, sure.

MS. ZELLMER: I just have one comment to sort of expand on what you said, Chris. Certainly I think deceptive advertising is a problem, but I think to me an even greater problem that Chris brought up is having direct consumer access to this information without having a health care professional involved. I think that if someone is going to have genetic testing, I think that a large part of the problem is that a consumer can order on the Internet home genetic tests without having a physician involved, and it sounds like, at least at this point, none of the agencies would address that issue. I assume it would be the FDA, or perhaps CLIA would dictate who had access to the test results.

DR. GUTMAN: Yes. I actually think that the FDA could investigate that circumstance, and if that circumstance was a lab that was completely doing the practice, creating the reagents and providing the assay within its own location, then we probably would not touch it. But if they were using the ASR rule, if they were purchasing reagents, they can promote to consumers but they can't actually market the product without a prescription.

MR. DAYNARD: The FTC can't require that, but the FDA could.

MS. ZELLMER: Dr. McCabe?

DR. McCABE: A couple of comments, one to Matt and then the other to Steve. I want to follow up on this issue about trying to nip this in the bud when it comes to genetic testing, a follow-up on what several people have talked about. You were saying you would have to get up to speed. I would think that you could get help from professional organizations, from consumer groups, and from the industry groups as well, groups like BIO. Mainstream groups I think would want to get involved proactively because it's going to give everyone a bad name if these things proliferate. So I would encourage you to approach a variety of groups, and I'm sure people would be happy to help you out there.

MR. DAYNARD: One comment on that is that at least in some other areas, nipping things in the bud doesn't always work depending upon how many bad guys there are out there and how really bad they are, because the bad guys aren't going to care about crossing the line until they get caught. They're not going to stop until they get caught. I don't know, and I suppose you don't know yet, how many bad guys you're going to have out there. I presume and hope it would be far less than, for example, the magic diet pill that you see in your paper every day. But I don't know.

So that's something that my folks at the FTC would be considering. I expect, though, that if they're going to nip things in the bud, they might want two or three cases right off the bat with different kinds of folks in different kinds of testing, and that means a significant commitment of resources. I'm not saying we're not going to do that, but I haven't talked to anybody about it.

DR. McCABE: But what I was talking about was really issuing educational materials for the consumers.

MR. DAYNARD: Oh, great. Sure, sure.

DR. McCABE: So it's a way of educating consumers so that they will be more cautious and so that they'll know the questions to ask.

MR. DAYNARD: That's a great idea.

DR. McCABE: I'm sorry, I wasn't making myself clear. But I think it would be good. You could easily get these kind of individuals together, professionals, consumer groups, industry groups, to help you develop those materials.

MR. DAYNARD: Great idea.

DR. McCABE: And then for Steve, a follow-up on what Dr. Leonard said. If there are no health benefits, so it is just simply a characteristic, if there are no health benefits, does that fall under FDA?

DR. GUTMAN: That's actually a legal question. I'm not sure I'm in a great position to answer that. If there were no benefits? I guess if there were risks associated with it, health risks, there would be, and actually, the fundamental question would be if you could link it to the definition of an in vitro diagnostic device to diagnose a medical condition or a disease. I suppose if it didn't and you were evaluating something from a narrow legal standpoint, I suppose it's possible to imagine something that wouldn't be a device. But as soon as you move into risks or benefits, I think you start moving towards health conditions, if not actually disease states, and I think we would probably be interested in the product.

MS. ZELLMER: Hunt?

DR. WILLARD: Hunt Willard. Two questions, both for, once again, clarification of turf and purview here. I followed everything you said about the FTC and agreed with it totally.

MR. DAYNARD: Terrific.

DR. WILLARD: But I see the distinction between -- there's a disconnect between what you said and what I see on television and in magazines, and it's the following kind of an ad which, if not being a misrepresentation, is certainly a non or unclear representation, and I wonder why that isn't deceptive, and that is the advertisements that advertise by brand name for a product that no one outside of the medical community has any idea what this thing is.

MR. DAYNARD: Are you talking about a prescription drug?

DR. WILLARD: Right. So it is a certain color pill, presumably, and all I know is that if I take it, my chances of running down the beach looking happy with my golden retriever goes up.

(Laughter.)

DR. WILLARD: And then it says call your doctor and see if that's for you. Now, is there a way out? You can't get it without going to the doctor, and hence at best all you're doing is busying the doctor's phone lines. But it isn't clear why that's any different from genetic testing where, again, we might say see if genetic testing is for you. We think as this comes along -- it's almost like marking your turf in genetic testing. Maybe today there's only a few things we can test for, but people are smart enough to know there's a lot more things coming down the pike.

So if you can build up an ad campaign that has people automatically thinking of you and Company Q when it comes to genetic and genomic testing, and you will not only live longer but the chance of running down that beach with your golden retriever goes up, then that's the

company I'm going to think of once there are, in fact, five or six conditions that are worth testing for.

So what's the distinction there on these drugs that have no obvious --

MR. DAYNARD: I don't think we've talked yet about who has primary jurisdiction on consumer genetic testing advertisements. In the prescription drug area, it's clearly the FDA has primary jurisdiction over direct-to-consumer for all advertising for prescription drugs.

DR. WILLARD: But then my question, slightly off topic, is --

MR. DAYNARD: Genetic testing we actually haven't talked about yet. I'm not sure if that's a prescription drug or not. If it's a prescription device --

DR. GUTMAN: Well, there is guidance. I don't know if Larry is still here or if David can bail me out. There is guidance on what's allowed. I frankly have seen those ads and also wish that I had that beach or that my animals were as well behaved as those.

(Laughter.)

DR. GUTMAN: I presume -- I can't say this for sure but I presume that people in the Center for Drugs must also see those ads. They're rather visible. So they must fairly or unfairly fall within the -- I know they don't pose the use, but I do know they always tell you about the diarrhea and the vomiting and the weight loss or the weight gain. They do it, of course, in two seconds, but they do it. So I make the presumption, although I'd be happy to go back and talk to people to make sure that they've seen those commercials --

DR. WILLARD: It just seems like a disconnect.

DR. GUTMAN: I think that that must fall within the -- they're too visible for me to believe that we just missed them. So they must fall within the borders of what is permitted by FDA.

MR. DAYNARD: Just on the FTC side, though, I don't think it violates the FTC Act or advertising a brand name. If we do have jurisdiction, and I'm not sure we do --

DR. FEIGAL: In the trade, those are called reminder ads, and they're legal.

MR. DAYNARD: Yes, or image advertising.

DR. FEIGAL: Yes. They're legal.

DR. WILLARD: But there's no question, bringing it back to our topic today, that image advertising from that perspective could be something that for genetic and genomic testing we'll see far sooner than we'll see very many ads that say absolutely we can predict your cancer risk or your Alzheimer's risk or what-have-you.

DR. GUTMAN: And I hope I communicated -- if not, then I will re-communicate that the FDA in the area of oversight of diagnostic advertising, its hook is somewhat indirect, through labeling and through intended use rather than directly aimed at the advertising.

DR. WILLARD: My second question comes again to this question that I raised for an earlier presentation on to what extent is genetic testing different from other kinds of testing, and where are we going to say it is different and where are we going to keep reminding ourselves that there really is no difference other than the fact that it's newer. That comes to the home kit question. There are pregnancy home kits that all kinds of people use. It's a successful industry, and if it isn't actually written on the package, since I've not used one of these, but if it isn't written on the package, the message certainly must be that if this test tells you you're pregnant, you should go see your physician.

Is genetic testing, home kits of the kind that have begun to appear, could those be handled any different? Would that be different from pregnancy? You'll get tested, we'll say your risk is now five-fold up or ten-fold up for Disease Q, we suggest you see a physician. Would that be any different in that respect?

MS. ZELLMER: But Hunt, don't you think it depends on the type of genetic test and whether the consumer actually has the knowledge to be able to interpret the results? I mean, pregnancy tests or a lot of the tests that are on the market, most people are very familiar with what it is to be pregnant or not pregnant. But they may not know all the implications of a specific genetic illness, or they may not know the implications of a positive result on a genetic test that may need further interpretation.

So in my opinion, and obviously I'm not an expert in this at all, but I think there's got to be certain genetic tests where maybe there could be home test kits. Maybe there are genetic tests where it's just as simple as saying you've got X mutation and here's the answer to your question. But I'm going to guess that most of them are much more complicated than that and that it is going to require some interpretation that you would need the help of a health care professional.

DR. WILLARD: Well, I'm raising the question. I don't know if you're right. Whether you're pregnant or not, everyone knows how to interpret that dichotomy. But all the downstream follow-up of being pregnant is every bit as complicated as trying to interpret a ten-fold increased risk of cancer in the next 10 years. So I'm not sure I see the distinction in those two. I see them as sort of parallel tracks. At some point in each case, one goes to the medical professional, but I'm not sure otherwise I see the distinction.

MR. DAYNARD: From the FTC's perspective, it's possible that for a given test, if it's important for one medical health reason or another that the explanation of the results be supervised by a physician, one remedy if we brought a case would be to have that disclosure on the label or the product package or whatever.

DR. HOOK: Can I respond to Hunt? I'm thinking of what if you had someone like Janet Atkin, who was Kervorkian's first victim, who did a test for Alzheimer's before she was symptomatic and chose to commit suicide at that point because of the results she got? Or a patient who is tested for Huntington's chorea and also chose to take their life because of that result without seeking medical intervention? I know some people might do that with pregnancy, but generally the tendency is not to do that because they have other means. They have abortion, they have other things they might do. So I think there is a difference of some degree.

DR. LEONARD: And also, a pregnancy test is positive or negative, and you and I both know very well that there are very few genetic tests that when they're negative they're absolute. So it's not like you can say when it's positive go see your physician. It's like whatever result you get, go see your physician, or a genetic counselor may be more useful.

MS. ZELLMER: Brad?

MR. MARGUS: I'm going to dissent from everyone by saying that I think the web is here to stay, and on average I would argue that consumers are smarter by being able to look up stuff on the web than only relying on their physicians and genetic counselors and all that. All the genetic counselors who are going to speak tomorrow are going to kill me, but I don't think you can avoid the web. Don't forget that everyone in this room is a consumer, and to assume that no one can handle the information themselves -- there's cholesterol testing being done now at a cholesterol (inaudible) or something, and a lot more people want to be tested for it than if they have to go to a physician for it.

So I think it's going to come. The one thing that's most discouraging -- well, before I go to the discouraging thing, the one thing I want to mention is I remember seeing a site a few years ago, I think on the National Cancer Institute webpages, but it was kind of along your lines. It was all the pitfalls or red flags that should go off when you hear claims about medical things. I think it was the NCI, but I'm not sure. But it was things like if the people who are making all the claims are also the ones selling it to you, and it kind of added up, if it was in nutrition, there was a whole list of things that should make you more suspicious.

It was pretty simple. I mean, I could understand it. I think that those kinds of efforts to educate people that way would be really, really helpful, just how to be a little more street smart about health claims. That being said, I'm a little discouraged by the whole presentation, and I assume the answer is going to be that the FTC only has limited resources. But you mentioned that it really has to be a -- what was the quote you had? -- unfounded treatment claims for serious diseases, so it has to be a serious disease, it has to be national, I think it kind of has to be complained about somehow or someone has to bring it up.

You mentioned that it can't be just anecdotal evidence, but then in the same breath you mentioned those ads in the newspaper for fat that we all see, which are anecdotal evidence. I know that from the beginning of time there have been snake oil salesmen long before any genetics or any webs or anything else, so that's going to be out there, but it doesn't sound like we're really nailing a lot of the people who are out there. I mean, we're nailing the big ones and the ones where really, really dangerous things are happening right away, but there's an awful lot that we're not.

In fact, which agency regulates astrology? I mean, more people rely on astrology than will ever rely on genetics.

MR. DAYNARD: Not the FTC.

I'm sorry, but I'm not sure I understand your point, Brad. Is it that we're not suing everybody?

MR. MARGUS: Well, I don't think you can. Let me be clear. I'm not saying that the FTC is not doing its job. What I'm saying is that it seems like the whole world's out there making all kinds of claims. You have to pick your big ones that are really obvious or that are national in scope. You really have to pick the ones to make examples out of, but all of us can get on the Internet and find a million more claims.

MR. DAYNARD: Sure, but there's something else we do. I didn't think it would be so tough to toot my own horn. We do health claims surf days. I think the last one we did was a couple of years ago and we had 40 state AG offices and 30 foreign countries, and we got on the web for

eight hours and did a surf for websites that were saying bad things about, in this case, dietary supplements for serious diseases. I think in those eight hours we came up with something like 4,000 websites. You don't have to be wealthy, you don't have to pay a sales force, you don't have to have an MLN to do all this. You just put up a website and your sales could be small.

But what we did then was we sent them warning letters. We sent out or emailed 4,000 warning letters, and we've done this several times now, and we got about a 45 percent success rate in folks either dropping their bad claims or taking their site down altogether. It's something we might consider doing here.

We can't do it all, and that's why we get involved with you folks and with the AGs and with Mexico and Canada and the UK. You're not going to get an agency with a $150 million budget to do it all by itself. It's not possible.

MS. ZELLMER: Cynthia?

MS. BERRY: Cindy Berry. Thank you for your presentations, both. The problem of Internet spam I know cuts across all kinds of products, services, industries, you name it, obviously not particular to the health care industry. But I'm wondering if there are specific barriers to cooperating with the Internet service providers in some of these issues.

MR. DAYNARD: We cooperate with them sometimes, and sometimes we sue them.

(Laughter.)

MS. BERRY: Are there creative ways to work with them to prevent some of this? Because it's one thing where someone goes to a website and seeks out information. Finding the websites might be a little bit easier than finding the needle in the haystack, which is these spam email messages directed to individuals that they get at home, unsolicited.

MR. DAYNARD: Well, we get spam. We have a database of spam at the FTC. We're really doing miraculous things. We've got a database of spam that comes in that's anonymous, and we've got a whole list of the biggest spammers in the country, and sometimes it's a good thing. If the bad guy doesn't show his head, how are you going to shoot him down?

One case we just brought against this company called Cecil-something, a liquid dietary supplement. They said diabetics could stop their insulin. This was not true, but the reason we found out about it, in addition to the health surf we did, was that one of our Federal Trade Commissioners got spammed, and he goes "What the heck is this? Let's go after these bastards right away!"

(Laughter.)

MR. DAYNARD: So we are working with the providers, we're working with high-tech folks, we're working with the industry to do everything we can about spam. But when you have politicians spamming people, where are you going to go?

DR. TUCKSON: So what is his email address?

(Laughter.)

MR. DAYNARD: I ain't telling you.

(Laughter.)

MS. ZELLMER: Emily?

DR. WINN-DEEN: I guess one of my big concerns is in order to have the public believe in and reap the medical benefits that genetic testing we hope will offer in the future, not just for highly penetrant monogenic disease but for the common complex diseases where your genetic heritage is one component of your health management of your future, I have concern that if genetic testing is used for a lot of "junk science" and consumers lose confidence in its abilities and what it can really deliver because of junk science, then when the good science comes along they won't use it as they could and should to take better care of themselves.

We had an example in our previous briefing book of a company that was offering to take a cheek swab, send it in, and they would tell you which of several formulations of face cream was right for you. Now, there may indeed be something behind it, but they may just take this cheek swab, throw it in the trash and send everybody the same jar of face cream for $300 or whatever. I mean, it was very, very high-priced stuff. But it was purported to be customized for you. I can see in the area of let's call them beauty products, anti-aging, that whole thing, that there's enormous potential for some part of it to actually be based on real science but a lot of it to be based on just completely fraudulent kinds of claims.

So I guess I personally would like to see the FTC shine a little bit of light on not just the diet supplements, which are part of that, but some of the other health and beauty things that are going to maybe keep us from having the consumer confidence that we need in the medical applications.

MR. DAYNARD: Oh, we do, unless you're talking about genetic testing specifically. Bloussant is a breast augmentator pill that they sold 30 million dollars worth. We just had a big settlement with them. If you're talking about health care things in general, that's what we do, but we haven't done the genetic testing thing yet.

DR. WINN-DEEN: Okay. So we should forward you the ad on this one for the custom beauty creams?

MR. DAYNARD: Well, beauty creams -- you know, big deal. But if it's a beauty cream that's going to get rid of your extra fat or it's going to enhance your memory or it's going to get rid of all your wrinkles and make you look like a star or something. But the cosmetic thing, it's not going to fly too much with the Commission right now. We're into anti-cancer stuff, you know? How am I going to sell a beauty cream?

DR. WINN-DEEN: I guess I'm concerned that those kinds of things fall under the radar, and yet they can have more harm because they just erode confidence in what the technology can really do in a positive way.

MR. DAYNARD: Yes. Tell Congress to give us another $150 million.

I don't mean to be glib. I'm sorry.

DR. WINN-DEEN: Do I have to pay more taxes for that?

(Laughter.)

MR. DAYNARD: Yes. What's wrong with that?

(Laughter.)

MR. DAYNARD: I don't mean to be glib. It's just that we have to pick and choose, and it's impossible. I agree that if we can nip this in the bud, and if we can do it with a nice big fat serious disease case, that would be the way to go.

MS. ZELLMER: Does anybody else have anymore questions?

DR. SUNDWALL: My name is David Sundwall. This will be real quick. First of all, thank you very much. It was a very enlightening discussion. I represent the American Clinical Laboratory Association, but I also chair CLIAC, and I want you to know that in the last two meetings of our committee in Atlanta we have spent some time on direct access testing, been informed but perplexed about what is the role of the government in regulating this, if any. I think we've at the moment concluded that there's no role for CLIA per se, because in fact we've learned from the FDA that some of the most egregious claims are being promoted from CLIA-certified labs and CAP-accredited labs. So this is really kind of disconcerting.

So it's not the quality of the analyte per se, but serious questionable ethical concerns about what they're doing. So we are going to be inviting you to address our group because we have decided that the FTC probably has a role here that we haven't previously given enough time to. So thank you and I'm putting you on notice that we'd like you to address our committee.

Lastly, I'd just like to inform the --

MR. DAYNARD: Is that in Acapulco?

(Laughter.)

DR. SUNDWALL: Yes, right. Puerto Rico in January, right.

(Laughter.)

DR. SUNDWALL: No, unfortunately not. It's in beautiful downtown Atlanta, though. We've gotten away from the suburbs and moved into town, so that's progress.

MR. DAYNARD: I look forward to it. That's great. Thanks.

DR. SUNDWALL: Okay.

The last thing I think the committee, if you aren't aware of it, you might want to look at www.labtestsonline.org, a peer-reviewed, not-for-profit effort to put on the web absolutely honest, straightforward public information about lab testing, including genetic testing. I'm on the editorial board, along with Lisa Passaman, and I think some others who may be here, but it is professional organizations, consumers. We really try our level best to give as honest and clear and comprehensible information on testing as you can get, and it's won numbers of awards, and numbers of hits have gone up to 80,000 or 90,000 a month. So it's popular and been recognized for its validity.

In fact, with this committee and your expertise, we'd welcome your feedback on how we might make it better for information on genetic testing.

Thank you.

MS. ZELLMER: Any more questions?

Reed?

DR. TUCKSON: Just one comment that I thought was important between something that Brad said and something that Emily said which I thought sort of fit together. I think Brad's point is important, and I would think that all of us around the table on the committee would share that the concern in this area is not because we feel that consumers and the American people are not bright and that the inevitability for the movement for more consumer empowerment and more access to information is not only inevitable, as Brad has described, but also desirable.

I think that we, in our comments -- I want to make sure that we're at least clear on this. I want to make sure that the sense of the committee -- and I'm looking for dissent -- is that we absolutely respect the intelligence of the American people and their ability to need to be able to take control over their own health. But as Emily I think rightly points out as well, what happens is that if we don't get on top of this, if people are provided with misleading information, it makes it hard for them to do what they're trying to do. If information is deceptive in this growing area, the natural distrust in this area could also lead to unfortunate decisions being made and an unfortunate level of distrust out there.

So I think the points go together, but I think Brad does us a service by making sure that we are able to say in the record that nothing that we have described before is to in any way suggest that the American people aren't capable or shouldn't be able to make the decisions they need to make.

MR. DAYNARD: Can I comment? That's terrific. I'm wondering if NIH or the committee has a website that gives good information to consumers. When people get online to ftc.gov or consumeronline.gov, we have a list of health-oriented websites, like HealthFinder and others where they can get proven and solid information about health care to help themselves, and that's obviously, it seems to me, the thing to do here as soon as you can.

DR. COLLINS: So in response to that, NIH's website I think is at the present time the highest hit rate of any government site, and certainly in the sites that people go to for health information, it routinely ranks number 1 as well. Now, whether there is a place on the NIH website along the lines of this consumer beware theme, here are the kinds of claims that you ought to worry about if you see them out there in the big worldwide web, I'm not sure that I know the answer to that, but it's easy enough to go and do a quick search and look.

DR. McCABE: Well, thank you very much. Thank you, Kim, for facilitating that. Matt, thank you for coming. Steve, as always, it's a pleasure to have you participate in these discussions.

We'll take a 15-minute break. Please return sharply at 3:00.

(Recess.)