FTC's Regulation of the Advertising and Promotion of Consumer Products and Its Application to Genetic Technologies

Matthew Daynard, J.D.
Senior Attorney, Advertising Practices Division
Bureau of Consumer Protection
Federal Trade Commission

DR. McCABE: Well, welcome back from lunch, everyone. Let's go ahead and get started again, please.

We're very pleased that Matthew Daynard could also join us today. Mr. Daynard is senior attorney in the advertising practice division of the FTC, and he will be explaining the Federal Trade Commission's role in regulating the advertising and promotion of consumer products, including genetic technologies.

Mr. Daynard?

MR. DAYNARD: Thank you, Dr. McCabe, and I want to thank you, Dr. McCabe, and the committee for giving us the opportunity to come here and talk about what we do and how it might apply to the marketing of genetic testing in the future.

That little blurb you see in the lower left-hand corner is supposed to say that these comments are my own and not necessarily those of the Commissioner, but don't believe it necessarily.

(Laughter.)

MR. DAYNARD: I hope that's not being recorded.

DR. McCABE: It's just being webcast.

MR. DAYNARD: Oh, is that all? Okay, no problem.

(Laughter.)

MR. DAYNARD: It will come back to me. After 32 years, they can't touch me.

(Laughter.)

MR. DAYNARD: I'll give you a quick overview of our jurisdiction, our advertising principles, our work in the privacy area which is also important here, and our work in health fraud, in particular with respect to home test kits, which are sort of analogous.

A big part of what we do is consumer and industry education. We have to get the most bang for the buck. We're a very small agency. I think our budget would run FDA for about 10 minutes, maybe 11 minutes, and we do get big bang for the buck. We do a lot of law enforcement, but at the same time we do industry and consumer education because the best offense is good prevention, a good defense. So I'll talk about that a bit.

Our jurisdiction is very broad, as you can see. We have a single statute. I love it. It says, "Unfair or deceptive acts or practices affecting commerce are prohibited." That's it. Boom. There isn't

anything else, no subsections, and we have a 70-year history of what that means. A nice little addition was added by Congress to make sure we don't step on the FDA's toes, Section 12, the second one there, "False advertisements for foods, drugs, devices and services are prohibited," and what that does for us, it just gives us an extra allegation in our federal district court litigation, I suppose. It's helpful.

The jurisdiction includes ad claims by anybody for anything, which would include marketers of genetic tests, including off-label uses. This is one area where the FDA and the FTC can often get together. As you were told this morning, off-label uses for ASRs can't be promoted. They can do it, but they can't be promoted. If what they say about it is not substantiated by competent and reliable scientific evidence or is false, we might want to get involved, so we'd work with the FDA.

Our main heart and soul is deception, and here's the definition of deception. You can read it. It's very simple. "If representation or omission is likely to mislead consumers and it's material" -- that is, consumers would find it important -- "it's deceptive." In the context of a genetic test, I suppose something like "We've developed a genetic test that will give you a 90 percent surety of whether you're going to contract a particular disease or not." If that's not true, that falls squarely within this definition of deception.

The other part of our unfair acts or practices is unfairness, and this is more particular in that it has to be a widespread injury, there have to be no other countervailing benefits, to use the FDA's cost/benefit analysis, and most of all I guess it's not reasonably avoidable by consumers themselves. I guess, for example, if a test had some inherent safety problem for a certain population of patients and consumers had no way of knowing that, we could charge that not only was the representation a deception but it was also unfairness.

I think as Steve alluded to this morning, we have a longstanding liaison agreement with the FDA, since 1954. They have primary responsibility for the labeling of devices, we have primary responsibility for the advertising. What does that mean? That means they go after manufacturers, we go after retailers, and we often get together and do coordinated actions. It does mean we can have dual jurisdiction for ads, for example, for unapproved home test kits.

Now, I have to make a caveat, of course, here, an admission and a concession that we haven't taken any formal action in this area as of yet, but everything I say is applicable to the marketing of genetic testing, so keep that in mind.

For us, true and substantiated health claims are an important part of the FTC mission, and we have a number of people working this area. I've been doing it for a couple of decades myself. We're concerned, among other things, that the injury to consumers can be serious should they use the wrong product or service or forego other treatment. But on the other hand, we don't regulate "the practice of medicine," which means if a doctor wants to encourage a patient to have a certain genetic test, we're not going to say, well, you might have said the wrong thing there. We leave that alone.

I guess there was one case, though. It had to do with infertility. It was a Dr. Jacobson in Virginia. It was an in vitro fertilization case, and he was telling women patients that they were pregnant when in fact they weren't, and that then the fetus had resorbed into the uterus or something like that. That was a doctor-patient relationship, which we'll usually stay away from, but that was just so far over the line that we got involved. We sued him in federal district court, and the AG in Virginia eventually put him in jail and took his license away. But generally we're

not going to get involved in what doctors say to their patients or what therapies they encourage.

These are basic advertising principles that we tell marketers. They're very simple, at least in theory. Tell the truth. Don't mislead consumers about efficacy or safety. Tell all the truth. Make sure you haven't omitted anything that consumers would find important and that would keep what you say from being deceptive. Make sure it's the truth, meaning you have to have substantiation at the time you make the claim -- before, not after.

Advertisers are responsible not only for express claims but also for implied claims. I suppose you can all infer what implied claims are. If the net impression of an advertisement, taking into account the text, the product name, the visual images, are that a test is going to give you a surety that you are or are not going to get cancer, even though it doesn't say that expressly, we can challenge that claim.

If there's qualifying information that's necessary to be disclosed to prevent deception, that's important. For example, as was discussed this morning, if there's some preliminary information that a genetic test works and works for some people some of the time, but it's only preliminary information and not definitive testing, then that ought to be disclosed and qualified, or the claim itself ought to be something less than this is going to apply to everybody. And those disclosures can't be in fine print at the bottom, and they can't be three clicks away on a webpage. They have to be clear and conspicuous and prominent.

Our substantiation standard is very important. As I said, you've got to have the substantiation before disseminating an ad, but the standard is flexible. We don't always require the gold standard of double-blind human tests. It depends on the claim, it depends on how that claim is presented, how it's qualified. The point of how we regulate is the substantiation standard has to ensure consumer access to information about even an emerging science or service, but at the same time it has to ensure that that information is accurate.

So we have a flexible standard, and it depends, again -- it's always an ad hoc situation -- it depends on what the claim is and what we think consumers are going to take away from that claim.

The standard, though, is rigorous. It's competent and reliable scientific evidence, and since we're not scientists, what do we do? Well, we call you folks. We call the FDA, the NIH, the experts around the country, the grandfather, if you will, of genetic testing if it came to that, and we'd ask them what do you think is adequate and competent and reliable scientific evidence for this particular claim? If they tell us double-blind, randomly controlled human studies, we say fine, then that's got to be the standard. Then we go back to the marketer and say, well, have you got these? If they say, well, no, but we've got 3,000 anecdotes, we'd say, well, anecdotes are just that, they're anecdotes and they don't suffice under the FTC Act.

Consumer tests. I don't know how big an issue this is going to be in genetic testing. Maybe it will be. It's big everywhere else. Just look at your weight loss ads in the paper every morning. The point here is that unsubstantiated claims can't be made indirectly through testimonials. A testimonial says, well, I had this genetic test 50 years ago and it told me I wasn't going to get this disease and, by gum, I didn't get that disease. The underlying claim is this test will tell people whether or not for sure they're going to get this disease. So the anecdote doesn't work. You can't hide behind the testimonial.

Third-party literature is also an interesting subject. We don't regulate content or accuracy of

books or articles or non-commercial literature. That's not our charge. But if in a doctor's office a study or a book is given out in furtherance of a commercial scheme, then we do have jurisdiction. If the primary purpose of using that literature is to propose a commercial transaction and not just to sell the book or the article or the brochure, then we have jurisdiction, and that's come up several times in the medical area.

We've also been involved very heavily since 1995 in the privacy area. You may have seen things about the FTC and privacy online -- "Do Not Call" for instance. That's another issue. But that's got to be of serious concern here also, it seems to me, and even though HIPAA may apply certainly to the caregiver, it may or may not apply directly to the laboratory. If there's an indirect relationship between the laboratory and the consumer, it's unclear to me at this point how it's going to apply.

So we might be interested or we might get involved with OCR at HHS also, and it could come into play. For example, if a laboratory says we're going to keep all this information confidential, when in fact they either don't have security adequate enough to make sure it's going to be confidential or they sell the list to somebody or sell your health information to somebody, the FTC could be concerned.

Whether it's a privacy case or a health fraud case, these are our case criteria. We have to pick and choose. We're a small agency, as I said. So what we look at are products and services that represent a significant safety concern. For example, we brought actions in the dietary supplement area for comfrey, which is toxic to the liver; for ephedra, which you all know about; for St. John's wort, which has interactions with other drugs, and it's an important issue for us, although it's not our charge. Our charge, again, is to protect the public from unfair and deceptive acts and practices, whereas the FDA's charge is to protect the public health, but we overlap when we can. It's important.

Also, unfounded treatment claims for serious diseases, as I've been talking about -- heart disease, multiple sclerosis, AIDS, diabetes, anything that you would consider a serious disease, we would consider a serious disease. Also, we don't get involved in local doctors, for example, or maybe even local laboratories marketing a test for a local or even a small region. We are charged to protect the public interest, and that means national to the extent possible. So we look for national advertising campaigns, infomercials, websites, direct mail that goes around the country, the freestanding inserts in big newspapers around the country. Put these three together and this is what we look at.

So in the genetic testing area, I suppose that if and when the Commission gets involved, it will be a large campaign, advertising campaign for false or unsubstantiated claims that involves a serious disease and that might have a separate safety component.

This is an old slide. I just left it in here because it shows that consumers are obviously concerned about genetic testing. I don't have to tell you folks about that.

These are privacy cases. I guess I'll do this pretty quickly. It just shows that the Commission is very serious about privacy. These were our first cases in the privacy area where we settled some charges where a website misrepresented the purposes for which it was collecting personally identifiable information from kids and from adults. With Liberty Financial, we challenged false representations on a site that claimed information collected from children and an online survey would be maintained anonymously when that wasn't true.

Here was a bogus pharmacy online. They paid a doctor $10 for each application they looked at, and they said they had a network of pharmacies around the country, and that wasn't true at all. It was this one doctor who was giving a cursory review to an application and getting ten bucks each time. But they represented online to consumers that the information the customers provided would be encrypted and used in SSLs, secure connections. None of that was true. They represented they would use personal information only for medical consultations and billing for prescriptions and consultations when that wasn't true.

Our order -- this was really our first big order -- prohibited all these representations and required the defendant to establish and maintain reasonable procedures to protect the confidentiality and security and integrity of personal information, and required a number of other things, including clear and conspicuous disclosure of the privacy policy covering these areas and information.

Eli Lilly got itself in trouble, to use another privacy case, where it unintentionally disclosed the health information, the fact that consumers had gone online to Prozac.com to all their mailing lists. So all the consumers on the mailing list got information about everybody else on the mailing list who had gone to this website, and it was unintentional. But nonetheless, we challenged them because they had represented that they had a secure, confidential website when, in fact, that wasn't true. There were holes and they made some mistakes. It was a quick settlement.

Microsoft, too, can have problems. Surprise, surprise. Consequences can also be of potential harm rather than actual or realized harm. Microsoft's Passport services actually had far less security than they represented, so the order requires them to implement a security system, prohibits misrepresentations and that sort of thing.

Guess? Online had false and misleading representations about the security of the personally identifiable information collected through their online store, and we alleged that they had misrepresented that the PII obtained and stored encrypted and unreadable format at all times, when in fact it was a pretty easy attack on the security system and anyone could get the PII.

I guess we're semi-sophisticated. We have a web online lab, an Internet lab, and we go after folks that do metatags and page-jacking and mouseovers and all the stuff where you come up with little claims that weren't there before, but still it was very easy to hack into this, a commonly known attack. So they weren't secure enough, not as secure as their representations led consumers to believe.

These are privacy resources the FTC has, and these are all in your handout, so if you have any interest in them you can go to them. I guess the most relevant area that we challenged were HIV home test kits. We had several cases like this. Here's one where the defendant falsely represented that their HIV home test kit accurately detected HIV when the test really didn't have a clue. So it was a slam dunk in this particular case in federal district court. The order bans the defendants for life from marketing any HIV home test kits. It may sound Draconian, but the FTC, as I said, has to get the most bang for the buck, and if we can convince a judge that a remedy is warranted in a particular case, we can get it. In this case it was pretty Draconian but warranted.

The defendants also had to pay back the money they received from the sale of their kits, and if they sell other medical devices, they're required to post a half a million dollar bond.

As I said, consumer education, industry education is equally paramount to law enforcement with

the FTC, so we have a number of items on our website that deal with advertising and what's required. When I get a call from a marketer, I give them the URL of this online "Rules of the Road and Dietary Supplements: A Marketing Guide for Industry and Facts for Consumers" on these other issues, because it generally answers most questions that folks have about what the law is and what you need to do, and we've gotten excellent feedback from industry about it being helpful and helping them comply with the FTC Act. It would apply equally to genetic tests. I'm not familiar with the industry members yet in this area, but I expect I will be.

That's me. That's my phone number. That's my email. Feel free to call me anytime about any of these issues. I wanted to make this brief to have more time for questions, so I hope that's cool with everybody.