

**FDA – FTC Collaboration**  
*Joseph L. Hackett, Ph.D. and Matthew Daynard, J.D.*

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DR. TUCKSON: I'm going to ask our speakers indulgence that if you get interrupted then—so play it easy and we'll be cool but I don't want to lose any more time. We have a lot to do.

Let me give you a sense of what we've got to accomplish here. By the way, Sarah, do I need to tap dance or are you guys having trouble over there?

MS. CARR: We're okay.

MS. TUCKSON: Okay. We want to do the direct to consumer marketing update. We need to do, quite happily—we have two very terrific guests on the genetic discrimination issues, which I really want to make sure we don't rush through because this is going to be good.

And then apparently there are some people who are deserving of certificates and honor, and I don't want to rush through that lest the rest of you think that when it's your turn—

(Laughter.)

--and you all decide to mutiny now. But also we need to spend a couple of minutes on restocking committees, which is sort of important. So we've got a real set of challenges so we're going to go ahead and move through and try not to have too much disruption whenever whatever is supposed to happen.

Direct to consumer marketing. In '04 we sent a letter to the Secretary urging FTC, FDA and other HHS agencies to collaborate on the regulation of advertisements for genetic tests marketed directly to consumers. We encouraged relevant HHS agencies to collect the necessary data and to conduct an analysis of the public health impact of direct to consumer marketing of genetic tests.

In very responsive response to these recommendations, two interagency workgroups were formed. One composed of staff from FTC, FDA, CDC and NIH, and they have been working on an assessment of the scientific accuracy of claims made by companies advertising genetic tests on the internet.

The second workgroup composed of staff from FDA, CDC, NIH and HRSA have been exploring mechanisms for collecting data on the public health impact of DTC market of genetic tests.

Matt Daynard, Joe Hackett and Scott Bowen will now give us updates on the work of these two important groups.

Let me turn it over to, I think, first—I guess, have you guys decided who is going first?

MR. DAYNARD: I will, yes.

DR. TUCKSON: Go ahead.

MR. DAYNARD: Sure, why not.

Thanks very much, Dr. Tuckson.

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Actually I think this will be brief but I think Secretary Leavitt really summed things up pretty well as to the status in his letter to you, Reed, earlier this month when he said that the FDA, the CDC and the FTC were developing a consumer alert that, among other points, encouraged consumers to talk to their health care practitioner about using at home DTC tests and about their interpretation. Also, encourage them or warn them, if you will, to question claims made by these companies because there may be scientific validity issues and there may be issues about whether they've had a full examination and in what context they're having these tests done.

And, in fact, things are pretty far along. The CDC has approved a draft, cleared a draft. The FDA and FTC are on in the process of clearance and we think we'll have something out in the not too distant future. So in a nutshell that is where the consumer alert is.

DR. LEONARD: How will it be sent out? I mean who and—I mean how do you get these public things out to everybody in the public?

MR. DAYNARD: Right. A good question. There are several ways. The FTC could release it as a consumer alert and have a variety of media alerts to go along with it so that it gets picked up. It's a press release. It's a consumer alert and then it gets released as if we sued somebody and had a consent agreement or if we went into court or something, we'd have a press release and then we'd alert the media and there are a variety of ways that our public affairs office gets it out to the media, and they usually do a pretty good job.

The FDA and the CDC are going to do a similar thing.

DF: I may have missed this in what you just said but part of that alert is then there a resource that the public can turn to go—because it's just—the presentation we just heard indicates the heterogeneity of what's out there and so there may be some groups where you'd say, okay, this is legitimate and others which are certainly not. So is there a resource that's going to be made available to the public?

MR. DAYNARD: Sure. Well, the first line of resources, if you will, are certainly the three agencies, the FDA, the CDC and the FTC, and we can direct them further if need be. And then the alert itself, of course one of the main themes is you must talk to your health care—your doctor or your health care practitioner or someone who knows about these tests and can direct you further.

DR. TUCKSON: Do you want to—I mean, I guess, I think part of your question is the specificity of the guidance that will be in the press release.

MR. DAYNARD: Well, the alert itself says do this, do A, B, C and D when you see these kind of claims.

DR. TUCKSON: Okay. So what we need to learn is what an alert is.

MR. DAYNARD: Ask these questions. Yes.

DR. TUCKSON: I think we need to respect the power of an alert.

MR. DAYNARD: Right.

DR. TUCKSON: It's a pretty big deal when FTC does that.

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MR. DAYNARD: We like to think so.

(Laughter.)

DR. TUCKSON: Humble though you are.

MR. DAYNARD: Yes.

DR. TUCKSON: All right.

DR. LEONARD: But is there a way that people—is there like a contact us or alert us if they're concerned?

MR. DAYNARD: Oh, sure. Yes.

DR. LEONARD: Is there a website or something?

MR. DAYNARD: There is a website and it will be—

DR. LEONARD: Some place to—

MR. DAYNARD: Yes. It will be on our—

DR. LEONARD: --that they go that they can provide you with names of companies that the public is concerned about?

MR. DAYNARD: Yes. There is a hotline number for FTC.

DR. LEONARD: Oh, okay.

MR. DAYNARD: Call if you need help.

DR. TUCKSON: When is it going to be available?

MR. DAYNARD: I'm sorry?

DR. TUCKSON: When will this be available?

MR. DAYNARD: Let me look in my crystal ball. Hold on.

DR. TUCKSON: When is this coming out?

MR. DAYNARD: I can't speak for the other agencies but I have to think it's going to be very soon. It depends on how things work with three agencies trying to agree on something. But I think it's going to be very shortly. Hopefully next month.

DR. TUCKSON: Okay. That's what—just a ball park.

MR. DAYNARD: But that's not cast in stone.

DR. TUCKSON: Got it. And we won't—we won't make you get in trouble—

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MR. DAYNARD: Thanks very much.

DR. TUCKSON: All right. The other thing is—

DR. LEONARD: But before the next meeting can we have a copy of it in your books? I won't be here.

DR. TUCKSON: Yes, we will, I'm sure, have that and we will also—

MR. DAYNARD: Oh, sure.

DR. TUCKSON: --have it on our website.

MR. DAYNARD: Right.

DR. TUCKSON: So, Sarah?

MS. CARR: (Not at microphone.)

DR. TUCKSON: Now you see there.

(Laughter.)

MR. DAYNARD: Yes.

DR. TUCKSON: That's what I like.

MR. DAYNARD: It's wired.

(Laughter.)

DR. TUCKSON: That's responsiveness. All right. Well, thank you.

By the way, one of the things that we will do—now, you don't mind if when we put it on our website sort of say that we called for this—we identified this as an issue and we called for it and look how terrific these agencies are?

MR. DAYNARD: I don't think we have jurisdiction over the committee's website.

(Laughter.)

So you can say what you want.

DR. TUCKSON: So the folks who are new to the committee, if you are sort of wondering whether or not we—

(Simultaneous discussion.)

MR. DAYNARD: Absolutely, of course.

DR. TUCKSON: Debra, you're not going to get your certificate.

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DR. LEONARD: (Not at microphone.)

(Laughter.)

MR. DAYNARD: We might even—who knows. Our office of public affairs might even attach the Secretary's response letter to you.

DR. TUCKSON: See that's what I'm looking for is credit.

MR. DAYNARD: Yes.

(Laughter.)

DR. TUCKSON: I want the committee to know that their work delivered something. By the way, just to conclude, although I'm joking because we do want credit—

(Simultaneous discussion.)

DR. TUCKSON: Well, we want credit. But I will say this in seriousness, this is an excellent and extraordinary example of government agencies working together and I'll tell you the speed with which this has occurred is by my way of thinking astounding. I would appreciate it on behalf of the committee if you would let your respective people know in the agencies that it was noticed and appreciated.

I think we probably, Sarah, need to send a letter to the Secretary sort of commending again these organizations for responsiveness. I mean this is a great thing and you deserve a round of applause.

Thank you all very much.

(Applause.)

MR. DAYNARD: Thank you.

DR. TUCKSON: With that, we're going to move then to—by the way, did I cut anybody else off that wanted to chat?

MR. DAYNARD: No.

DR. TUCKSON: Okay.

MR. DAYNARD: I just want to thank you, Dr. Tuckson. That's very much appreciated.

DR. TUCKSON: No, thank you.