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TRANSCRIPT

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DR. WAGNER: All right, we are now turning to the third and final, direct to consumer. Anita, thank you for chairing that sub group and we're interested to hear the report.

DR. ALLEN: Thank you. I am sorry that my two team mates, Raju Kucherlapati and John Arras, can't be with us this afternoon, so I am going to fly solo here in trying to present some of the things we talked about in our preliminary recommendations.

First of all, the direct to consumer context that I am going to be talking about is utterly fascinating, it is involving a phenomenon. Today, if I want to find out about my genetic profile I could go online and order a genetic test over the Internet. This product might have been advertised to me. I would voluntarily form a business relationship with a company, such as 23andMe, just to name one, I would consent to various terms of service. The company that I was dealing with would be for profit enterprise, it would not be a charity for the most part, and I might do this because of my health concerns or I might just do it for fun.

I might want to learn about my ancestry and so forth. So the question that comes up, if in the context of such testing, whether it is genetic testing or it is a full body scan that might be looking for heart disease, in these context, if something is uncovered that is not expected, that is surprising, that is quote-unquote incidental, what then are the ethical obligations of the direct to consumer company? So that is the kind of context that we are operating here with. So an initial set of questions that our group discussed was, first of all, how do we think about this whole idea of incidental findings in the direct to consumer context because in a sense, since these direct to consumer tests are rather open ended and they are conducted for the purpose of learning everything possible?

Very few findings would truly be incidental to the aim of the test. We use intentionality understanding of incidental findings we might want to define a way to the problem. There was no incidental finding here because the intent to uncover whatever we uncover, and that is what the consumer paid for. But it seemed to us, and especially to me, that since the direct to consumer tests do have broad aims and do lead to results that can be sensitive and unexpected to the consumer, that we do have an ethical problem here. Do you return sensitive and unexpected findings to consumers, and if so which ones? So we think that direct to consumer context does merit some of the same ethical scrutiny that the research and clinical setting calls for.

To grapple with this problem I think we need to move beyond definitional question of incidental findings, again focus on what are the obligations of a commercial vendor when they are offering health and medical testing that could result in some findings that may be in some way harmful to or unwelcome by or troubling to the consumer. That is where we are going to start. So, again, these may be simply general findings, to use the language of Erik Parens this morning, they could be truly incidental, but in any event they do raise the question how do we ethically respond to the information that comes from these direct to consumer tests.

Well, I think we then move beyond the question of definition and into the question of obligation. We do think that there is a very general obligation of consumer education around the direct to consumer industry. This testing, first of all, it can offer certain benefits and advantages to individuals over traditional routine clinical care in that it does involve or offer increased access to patients or subjects, excuse me, patients, customers. It can offer tests at reduced costs, a whole body scan for 400 bucks, and it can offer and sometimes greater confidentiality because sometimes the direct to consumer test can be done anonymously or use

pseudonym. So to get those kind of benefits, cost, easier access, anonymity, some people might prefer the direct to consumer over traditional medical care. But the benefits of the direct to consumer services really are contingent upon the quality of the test and the analyses and the informed and voluntary nature of the transaction. So consumers need to understand any issues around quality, any issues around voluntariness and informed consent that do relate to this field.

We believe, this is our major recommendation as far as consumer education goes that, I think, you know, we kind of unpack and discuss, where direct to consumer companies market health related testing to individuals outside the context of a patient-physician relationship, fairness, respect for persons, perhaps beneficence, to use Henry Richardson's language, require the company to reveal unexpected and sensitive information in an ethical manner regardless of whether it came to be in the hands of DTC professionals incidentally.

So we are calling for an obligation to return results that we describe in our initial thoughts as unexpected and sensitive, but I think that we could probably modify that a little bit because we talked today about certain kinds of unexpected and sensitive information; that is, that involves or relates to dire peril or serious medical conditions, probably add that kind of proviso recommendation.

In any event, we do think such information should be returned in an ethically appropriate manner even if it comes about somewhat intermittently, even if it wasn't the target of the direct to consumer relationship or contract. So as a proposal we are going to then suggest given that finding that companies should provide consumers with sufficient information about the services that they offer to enable them to make fully informed decisions regarding the purchasing of testing. This might mean certain kinds of policies and packaging, information on a website or on a box that the testing comes in, but information needs to be provided by the

company so that consumers can make an informed decision. And this information should include clear and specific language regarding the scope of the procedures, the kind of incidental, sensitive or unexpected finding that the company may discover and reveal.

We think government agencies and patient and health professionals should continue to educate the public about the direct to consumer testing. It is worth noting that the government already is providing some types of public education around direct to consumer testing. For example, the Federal Trade Commission has a whole web page on direct consumer genetic testing warning the public of some unfair trade practices, of some fraud and deception even that has gone on in this area, to alert consumers that they should be careful of the products they choose and the consequences of those choices.

In 2007 the General Accounting Office published a document called test purchase for genetic testing misleads customers, so that we are already, again, aware of and trying to get to the public about misleading consumer products in this genetic testing field. So the government is already aware of this direct to consumer market, especially it is a genetic testing, and there is some effort already to inform the public about some of the risks and benefits of such testing.

Which brings me to the next area that we looked at, which is the area of government regulations. So we have education going on, the question comes, should there be policies, rules, laws that bear on this field, and I think that there probably should be. In the meantime, at least state and federal government should be vigilant in monitoring and regulating the safety and reliability of health related products and services. And for me, and I think that this a too far astray from where the whole group was, for me, we need to think about these direct to consumer products and kind of put on our consumer protection hat when we think about them.

Government regulates and monitors all kinds of products; food products, automobiles, housing, eyeglasses, peanut butter, and it does seem to me it is a reason the government to be especially concerned here about the safety and reliability of these health related products. So using our consumer protection framework that also I think encompasses and is consistent with ethical principals like fairness and beneficence, we would like to suggest that a corollary of ethical principal is that we don't allow the idea of caveat emptor to prevent the government from engaging in responsible oversight, to place legitimate limits on the principal of buyer beware.

Traditionally the government has been reluctant to take on too much responsibility, but I think it is always taking on responsibility to insure the safety of certain products and services offered to consumers, and this is the kind of area we think where that responsibility ought to be in place. So at the moment we don't have a lot of oversight of direct to consumer generally, but we do think that there should be some oversight and regulation in this area. Of course, one difficulty is that we are not talking about one single product or in a sense one single industry.

Arguably everybody who makes automobiles is involved in the same industry, but if someone is offering genetic testing in the same industry as someone who is offering coronary artery scan or somebody offering prenatal fetus ultrasounds for recreation, these are very different kinds of products, but yet it does seem to have in common the idea that people are bypassing the medical system to seek out a commercial product for health reasons or for fun that will illuminate something about their bodies, and maybe it is that commonality, some basis for common set of recommendations or common approach to monitoring.

So we think that the government should evaluate the need for additional regulatory oversight of direct to consumer practices to insure the accuracy and validity of such testing. State governments we think should adopt regulations that insure that there is a consistent floor for protection, insuring the safety and reliability of direct to consumer services because such regulations I think might lead to the better handling when direct to consumer companies disclose or fail to disclose clinically significant actionable findings to consumers. This then brings us to our final set of findings, recommendations.

You have people who are voluntarily seeking out commercial products, you have ideally some public and government awareness of the problems these industry or industries might represent and taking action with respect to them. What then do we expect with direct to consumer industry themselves? And this question we discussed and came up with a finding that maybe the possible financial implications of identifying and returning incidental findings really does pose a problem. This may be too expensive to do it, but we think the financial problems, financial implications may present for profit direct to consumer companies for assuming what appropriately serves the interest of consumers. It is more expensive to check your peanut butter for insect parts or your automobile for defective brakes, but you got to do it anyway in the interest of consumer safety.

Businesses we think should behave in an ethical manner even if it does dig into their profits and guidelines of best practices as to how to handle incidental findings should be developed to assist companies in understanding the nature of their cost benefit assessments. So we propose that the direct to consumer companies create industry wide best practices concerning the handling of incidental, sensitive and unexpected findings and that these best practices include some kind of first and informed consent clause as it makes consumers as aware as possible of

those incidental as well as sensitive and unexpected findings would be discovered, and convey whether these findings will be communicated and the scope of these findings and to whom the findings will be communicated. And there is an interesting problem that we discussed here, it might be perceived by industry as not in the best interest of them to reveal the bad news. If you want to sell something to somebody you don't want to hear your product to be considered a bad news product.

So, there might be incentives to withhold information that might be of some clinical or personal interest to consumers. So we really, you have to think hard about how to deal with the conflict between some business motivations to give a lot to earn money and to hold back to earn money and the obligation to share with consumers. We also think that the best practice should involve enumeration of the circumstances under which incidental findings should be communicated and the methods for disclosing sensitive, incidental and unexpected findings. Do you tell folks over the Internet that they have cancer, can you tell folks through the mail? How do you get back bad news and what kinds of counseling or follow up do you offer them.

We'd love to see standards to secure and protect privacy of consumers as part of the best practices, and we'd also like delineation evidence based professional standards for counseling, medical referral or limited medical follow up to accompany disclosure. Just mentioned the idea of evidence based standards reminds me of the fact that in the medical clinical context, suggestion was made that professional organizations produce evidence based standards for proposed screening programs that take into account the cost and benefit associated with incidental findings. In this context we are not requiring that companies show that there is some reason to do the scan, some evidence to justify expensive scans or devise expensive scans or expensive tests and so forth, we simply say that is the product there, you want to buy it, fine.

As long as they stick to guidelines of fair trade on the legal side, and the ethical principals, beneficence, respect for persons, and fairness on the moral side. So lots of questions left to answer. One is whether the industry should be left to itself to develop its best practice, should we help it along, by what, and I think we might also want as a group to discuss some of these difficult questions around definition and the scope of the return, what kinds of results and what exactly. So I will stop there.

DR. WAGNER: Anita, thank you very much. I am sure your two colleagues are pleased with your presentation. I hope we weren't distracting you, we were chatting a little bit up here. It seems to me that the recommendation of government regulation is quite reasonable in that home diagnostics of other sorts already uncovered for safety and efficacy. It is this new dimension of how is it they could effectively claim to be testing for this broad range of findings, it will be interesting. Go ahead Dan, I have another question, but.

DR. SULMASY: I just want information related to that, who is from government regulating this sorts of genetic ones, is it the FDA, is it FTC, some of these things are done purely recreationally and it is ancestry, some are medical information, and I think Jim's suggestion was you treat more like a home pregnancy test, it probably would be regulated by the FDA.

DR. WAGNER: It is.

DR. SULMASY: So that is the current state of affairs. If there were some regulations who is doing the regulating?

DR. ALLEN: I am not sure I can answer your question. I know I can answer your question fully, but to the extent that these are like the home testing kits, the FDA is involved. I think the FDA has been looking a little bit into that. You can help me guys with the genetic

testing and requiring for the standard of genetic testing or not yet? No, not yet. So FDA would be plausible to be more involved. I mentioned the FTC only because the FTC has very, very broad jurisdiction over unfair trade practices, and a false or deceptive advertising scheme to get people to buy products. So, for example, I read about one company that was offering a test and then offered to sell you supplements, dietary supplements to take care of a problem that their test discovered that you had. So for that kind of fraudulent or semi-fraudulent scheme might be something that the fair trade concept would cover and the FTC jurisdiction.

So false advertising, over promising, not delivering, those kinds of problems could be the FTC. I am not sure why the General Accounting Office got involved in alerting the public about the dangers of certain kinds of website's offering genetic testing, but there too there is a little government in the process. So I am guessing that for some of these products, FDA, if you are talking about ultrasound, CAT scan, MRI, x-ray, genetic testing, blood testing, I think there is room for the FDA would be quite involved.

DR. ATKINSON: Doesn't CLIA approve of the good ones of these labs to do this?

DR. ALLEN: I think.

DR. ATKINSON: Which would be HHS.

DR. FARAHANY: FDA has held a number of hearings addressing DTC consumer testing, particularly with respect to genetic testing, to figure out whether or not they should regulate, to try to figure out their jurisdictions for regulating, but many of them would fall potentially under the medical devices or medical tests, that would be subject to FDA regulation and, yes, some of the good ones are CLIA right now for genome testing but not for other types of DTC testing that you can do.

DR. ALLEN: So I think that our recommendation should clearly state the extent to which it is already government interest, but we should emphasize it is not yet a coherent scheme of state and federal regulation around these tests, and yet I think we can consider such regulations and support.

DR. WAGNER: Anita, yours is the first of the three, the only of the three reports that actually talks very specifically about disclosing clinically significant and actionable findings. I am just interested in hearing from the group about the discussions you may have had in your individual groups about whether we mean that as a strict logical construct; that is, that we would recommend clinically significant and actionable findings be disclosed but not necessarily only clinically significant if they are not actionable. Does 23andMe tell someone if they got Huntington's?

DR. ALLEN: In the direct to consumer context in the first instance, what gets disclosure is going to be a matter of contract, what are you looking for, what did you agree to disclose. So in the case of, I hate to name specific, I have named specific services, but I don't want to make it sound like it is a talk about, a discussion of 23andMe, a particular company, but I think that some genetic testers would think that that is exactly the kind of thing that they are going to be looking for and will tell you. If you have a genetic predisposition that is relatively easy to identify if you are doing genomic analysis.

DR. WAGNER: But they don't add the second criteria that it needs to be actionable, right?

DR. ALLEN: No, no.

DR. WAGNER: So we may want to modify what your group proposed.

DR. ALLEN: Exactly.

DR. FARAHANY: Those aren't incidental, they are reporting. They are reporting, for example, ABAP 3 or 4 for Alzheimer's, they are reporting quite a few things, not as incidental findings, as the term of the contract they are going to tell you what they are going to return to you.

DR. ALLEN: Exactly. They are going to tell you about the breast cancer gene, the melanoma gene, the Huntington's gene, they are going to tell you that, that is what they think you want to know. But, see, our group considered this, that some of this information may be exactly what the consumer contracted to find out. Nonetheless, it is sensitive, and it may be surprising, I didn't think I had that. So there must be some ethical delivery of the information, the manner in which the information although asks for, may need to be delivered in a particularly ethically sensitive way.

DR. GUTMANN: I agree with that, but that really isn't about incidental findings. That is about what limits you want to put on an industry that serves as a surrogate deliverer of medical news that it traditionally has been delivered only by doctors and nurses and health professionals because that is the direct ask of the consumer, is for those findings. So that has nothing, it really is not about incidental findings, whereas your recommendations are about incidental findings, they are about what beyond those things that the consumer has directly contracted and asked for should industries be responsible for providing, and there there is a direct parallel with the research context, which it has to be something that has some benefit, potential benefit for the consumer either because you think they should know something or they should know it because it is actionable. But I really don't -- we have in previous, you know, reports talked a little bit about the responsibilities of health, you know, people who provide information relevant to the health of somebody, but if somebody contracts to get some information there is

nothing incidental about them getting it.

DR. ALLEN: I understand what you are saying, and we directly addressed that issue at the beginning of our conversation because we had nothing to do because there are no incidental findings in this context.

DR. WAGNER: What would be an example of an incidental finding in say a genetic screening?

DR. ALLEN: You pay someone to do an ultrasound of your fetus because you just want a cute picture of the unborn baby, and they discover that there is an abnormality, do they have an obligation to reveal the abnormality to you or just give you the cute picture of the fetus.

DR. GUTMANN: There are incidental findings in direct to consumer, in genetics, there are tons of incidental findings, 23andMe and other services don't report everything, and they have particular reasons for not reporting everything, they don't just serendipitously decide what to report and not to report. They report a subset for economic reasons, for reasons of what the consumer is likely to demand, and another reason which can vary with the context is those other two is what can they report that isn't going to get them into regulatory or other, you know, public opinion trouble. Industry is responsible, ones that survive over time with exceptions, but the ones that we come to admire most are those who are sensitive to what they think basic ethical principals are of action. So there are actually incidental findings in all of these, and they can put blinders on and tell their people just not to look, even though it would be no expense whatsoever to look for them because they don't want to have the burden of the incidental findings, but that is still a way of dealing with incidental findings. They do not report everything that they could easily find.

DR. ALLEN: We did talk a lot about the ethics of looking and discovering and avoiding discovery. We discussed those very, very difficult questions, and I think it is not so clear what kinds of specific recommendations we can make regarding some of those more subtle and nuance questions about the obligations to look, obligations, but it is clear to say that the economic motives of direct to consumer companies will play a big role in what they decide to tell us. And we may want them to tell more than they are inclined to tell and if so, we have to understand on what basis, and I do think that the dire medical problem or the actionable medical problem standards provides some beginning of a discussion about what we ought to disclose, required to disclose.

DR. FARAHANY: There is a context in direct to consumer genetic testing that has come up a number of times, which might be useful to talk about. So you can avoid incidental findings if you are a direct to consumer genetic company by just deciding not to look for most things, but the one area that you can't avoid is if I submit my information to a DTC genetic company and I want their ancestry option, the only way that I can get that is by also submitting who I believe to be my father's genetic information as well. So they can tell me my maternal line, but they cannot tell me my paternal line. So I get a sample from the person who I think is my father, and it turns out not to be my father. And now they have incidental information which is the person who you believe to be your father is not, in fact, your father. What do they do with that information. That is something that they actually can't really avoid so how do they deal with this incidental information of trying to actually address what is an incidental finding, what is a personal and private piece of information that you can't just not report about. That is the one thing that comes up most often.

DR. ALLEN: And they may not have in place genetic counselors and other people

to deliver that painful information in an appropriate way, and yet it seems to not acknowledge it at all would be doing some injustice to the patient.

DR. GUTMANN: Isn't there though, here, I would suggest there is a direct parallel with coming up with a plan and making sure the consumer in this case knows if they order finding out what their parental, you know, ancestry is and they provide the name of their father and their mother they may be told that their father is not -- who they think their father is, is not actually. And that is, you know.

DR. ALLEN: Yeah, to some extent if we can get people to do an informed consent process to warn them that this may be information coming their way does address the problem, but for me, I must say I think that even when people have given their informed consent they can still be extremely surprised and extremely upset and extremely bothered by the truth, and, therefore, we have some additional ethical questions about what to do.

DR. GUTMANN: Just to be clear, I am not denying that at all. I would just say to Anita, first that while the paternity thing is just a pure case, I think we haven't and we shouldn't define the realm of incidental findings artificially narrowly of stumbling upon because it is a way to tell your people you don't look at anything else, even if you can do so without any cost or any, you know, significant error because if you do you will be subject to ethical scrutiny about incidental findings meets the end run test.

DR. ALLEN: Yes.

DR. GUTMANN: In other words, it fails the end run. It says it is a way of just avoiding the question, the ethical question. I am not saying that they should do it, but we have to ask the ethical question, which arises, why should they or should they not ask their people not to look at other data if in that other data there may be some life, potentially lifesaving information.

And I am not saying it is wrong for them to say that, it just is a question that is a piece of the question of incidental findings.

DR. WAGNER: Dan.

DR. SULMASY: I was just going to comment that it does get us back to Erik's discussions this morning about the definitional questions, and I think you have raised that. And in some ways it is true that there is an ethics of broad based screening tests, whether they are done in the clinical setting or in the direct to consumer advertising. We really can't quite call these incidental findings when it is as Erik appropriately pointed out the purpose is to test for everything, but that doesn't mean there aren't some ethical problems with that approach that need to be looked at. The genome wide association, the whole genome sequencing, remember the questions about the ethics of that, you know, the whole body CT scan the same questions can be raised there. It is not, you know, in the research context it arises maybe in genome wide association studies where you are trying to look at everything in order to make a connection to a disease, and it is not as particular a problem as it is in these other two settings, but I think, you know, there are troubling questions about sort of testing for everything that we shouldn't. Maybe we need to comment on separately and shouldn't lose sight of if we are going to think about this broader topic of incidental findings because it is an issue. How much should we be pursuing this wide testing for everything, even in a clinical setting or in the direct to consumer. You might not be able to stop it in the market but you can at least warn people about it ahead of time.

DR. ALLEN: I agree with you, and I was reminded also that we had a discussion this morning about moral entanglements and entrustment and how we should understand the relationship between the direct to consumer providers and the public, and our group did discuss a lot, whether we should understand businesses as having some kind of special relationship with

their customers, such that that gives rise to an obligation to return incidental findings as a moral matter, and yet in the business ethics realm we don't generally talk about businesses having a fiduciary relationship or special relationship with consumers, it is a much more distant relationship than that. So we have no kind of business ethics tradition of seeing businesses as true fiduciaries with an entrustment relationship on the one hand, but on the other hand we do have this consumer protection model in the law where we think that companies whose products pose some risk of harm to public health and safety ought to be and appropriately can be regulated. I am not sure which way we ought to go, but we should have the knowledge of both perspectives in our discussion.

DR. WAGNER: Along those lines, did we really address your question of industry itself being in the best position to develop these practices?

DR. ALLEN: Yeah, it is tough because we discussed in this Commission, I guess in our last meeting, there are problems about defining the industry, how can we get people who do things as diverse as fetal ultrasound and genetic testing in the same room to talk about best practices and standards for the industry. It is not clearly an industry, there are a small number of players, and in some areas there is a decreasing number of players as opposed to an increasing number. I am told in the genetic testing there are actually fewer companies offering testing then there were three years ago.

DR. WAGNER: So, I am sorry, you leave that as an open question?

DR. ALLEN: It is an open question, I don't have an answer.

DR. GUTMANN: Could I ask a question? It actually relates to the next session we'll have on overarching recommendations. Do we know how big an issue or a problem this is in the direct to consumer? We heard from 23andMe, but I can answer the question is industry in

the best position to give you a full, impartial account of, you know, what the reaction of people is to their products, the answer to that is no, nobody is. I am not in the best position to give a full and disinterested account of the reaction of my students to me, a survey is much better than, you know, that, a survey which is anonymous and that I, you know, I can't take out on my, you know. So I suspect we don't really know that much, and it might be good to find out more here, but that is only a suspicion. We tried to find out some and, you know, I don't think we got much information about how big a set of problems this creates.

DR. ALLEN: Yeah, I agree. So to some extent we are addressing this question because of what we believe is on the horizon. I think we all believe that there will be in the future broader and larger array of consumer products that do involve the testing of body fluids and body parts and so forth. We also talked in my group about very, very forward looking concerns involving the use of Smartphones and other personal devices that will be monitoring our blood pressure and our heart rate and so forth. How are we going to think about the kinds of information that such products generate, and if they are generating information that may be in some sense surprising and unexpected and maybe incidental, what is going to be the obligation of the app developer to return results, information to consumers. I think that you are right in saying we need to try to get a better grip on this scope and the nature of the industry or industries at present, but also to keep our eyes on future developments, technological developments which will result in more consumer products of this type. And if we continue to have high cost medical care in the United States I think we are going to have a consumer demand for cheap diabetes testing, cheap coronary artery testing, cheap lung capacity testing, cheap stress testing. We are going to have a demand for outside the context of the medical care products, and it may then increase the importance of looking at these questions about incidental findings.

DR. WAGNER: Another question associated with this is what motivation would industry have to do this? In the late '70s, early '80s, mid to late '70s when the medical device regulations were adopted to parallel drug regulations in the FDA, quite magically couple of industry groups rose up and said, no, no, no, we will handle this ourselves. In other words, they clearly felt that they were under pressure that if they didn't propose standards, that they would be proposed for them. I am trying to remember some of the groups, but there were ANSI standards developed and STM standards developed around new medical devices, STM preexisting the law, and there is one other group that doesn't come to mind right now, that I can recall, but the motivation was clear that they felt as though if they would not take care of their own house the administration would. You know, back to our regulatory parsimony, I would sure like to find a way that through our recommendations of assessing what the industry does, what it is likely to look like, how it takes care of its own shop, that we can find ways to stimulate that kind of self regulation rather than go to government regulation if possible.

DR. FARAHANY: I think that is quite well said. I would say one of the challenges I think, Anita, that your group faced is that in the other two context they are pretty clear. There is a lot of thinking that has already gone into what the nature of the relationship and the duty is between patient and clinician and researcher and research subject, and it seems like we are asking a question that is, a secondary question to a bigger question that hasn't really been addressed fully yet, which is, what is the nature of the relationship and duties owed to direct to consumer companies and people who seek, you know, consumers who seek consults from those companies? And once we have that scope of the duty you are able to say, okay, what is it with respect to incidental findings in addition to that kind of broader duty, if at all, to individual consumers. So given that it seems like the third proposal, which focuses on developing industry

best practices, from my perspective needs the preliminary question of best practices around developing the norms of the relationship between consumers and direct to consumer testing companies more generally, and then identifying within that what and how they might deal with incidental findings.

So I think it is tougher in this arena than in other arenas where it isn't clear what the relationship is to begin with and if it purely, you know, if the answer to the first question is, it is a purely contractual relationship where you contract simply to receive the information that you seek and so the duties are general ones that you would provide in other consumer product cases where it is about insuring the quality of it, minimizing the harm of it and other types of things. That answers then what you would do with the incidental findings, which is no more than what we would do with the general findings. But I think it is harder in this area to say what the incidental finding is without defining the general scope of the relationship between consumers and DTC companies to begin with.

DR. GUTMANN: So let me, though, defend on the basis of everything we've said to this point. The vast majority, at least three out of the four parts of proposal three, because they all flow from those special obligation of industry. A consent process that makes consumers aware that incidental findings could be discovered, and convey whether those findings will be communicated, that doesn't require any special relationship, that flows from general ethical norms. And enumeration under what special circumstances incidental findings should be communicated, in methods that also flows from an informed, you know, making sure that the consumer isn't being deceived into thinking something is going to happen that won't happen. The third one is a list of standards to secure and protect the privacy of consumers and the confidentiality of data. That doesn't follow directly from the general. So that is why I said three

out of the four, but the fourth one, does a delineation of evidence based and professional standards for counseling medical referral or limited medical follow up to accompany disclosure. That is just a delineation of standards. You could think of that as if this is really something serious, that information you are getting, that anyone giving it should just give you some delineation of the standards for counseling, not that you give the counseling. So I think that those are pretty unexceptional, and especially if where the recommendation is that the DTC company should make these best practices publicly available, not that there should be a regulation imposed. It is really calling on them to be ethical companies, not saying that we are calling on a legal, you know, for legal regulation.

DR. ALLEN: Right. I think that the legal option needs to be kept in the back pocket in case there is a failure to respond appropriately, but I do agree that primarily we are asking, I think, at the moment, we have those companies take responsibility for these kinds of things.

DR. GUTMANN: Ethical responsibility. I would not be, although I am not in general against legal regulation of business in the case of pregnancy test or FDA control, I just don't think we have enough information now on what legal regulations would on balance do more good than harm to call for a set of legal regulations, and you are not calling for those.

DR. ALLEN: We do already have legal regulations that require --

DR. GUTMANN: That is on a different.

DR. WAGNER: On safety and efficacy.

DR. GUTMANN: On safety and efficiency, that is different than this.

DR. ALLEN: We do have legal regulations in say the financial sector that require that companies provide consumers with specific information about their rights and about their

options. And that is a kind of regulation which might someday be appropriate in this area. It is not terribly onerous, but business doesn't like it. We are not talking necessarily about saying you can't do it, but it may be that we have to ask people to do it in a certain way that is fair and appropriate. Amy, I just want to, I understand where Nita is coming from, I think that the devil may be in the details here. How we ultimately think firms ought to behave may depend a little bit on whether we are thinking of them as more or less like doctors or like autonomous commercial actors with arm's length relationships to a number of people, none of whom to whom they have any special responsibility. So what kind of information, in what context, in what manner may depend a little bit on how you are modeling these companies, what kind of things they are, how you analogize them.

DR. WAGNER: Dan.

DR. SULMASY: Again, going back to three and the questions I raised before about sort of broad based screening. To the extent you are using incidental as this unexpected and rare sense. I think there needs to be better education before people undertake these tests about the difficulty in interpreting a lot of the data that comes back, the small, the fact that there will be some things that include very small absolute risks, the possibilities for being upset by even what the data that they are actually looking for. Sometimes uncertain association between the findings and diseases, sometimes findings of health significance but that are not actionable, and there is probably a variety in terms of right now, of the standards that are used to inform people about those things. Is part of the reason why many clinicians would discourage people from getting whole body CT scans or whole genome sequencing, and I don't see that kind of thing built into the recommendation explicitly, and I would like to see it there because that is part of what we are calling incidental findings, but it is actually this sort of wide screening about

which raises its own problems.

DR. ALLEN: So we talked about, our group talked about whether we should expect fully informed consent prior to the testing, as we do in the medical context, or whether some other kind of consent would be adequate, and I was personally a little uncomfortable thinking that these direct to consumer companies should get fully informed consent of the type we require in the medical context.

DR. SULMASY: Regulate the test.

DR. ALLEN: So what is the nature of these consent process that we are going to hold the companies responsible for, is it going to be medical level informed consent or is it going to be just, you know, a casual warning or a casual list.

DR. SULMASY: It goes back to the question of what is the actual relationship.

DR. ALLEN: Yeah.

DR. WAGNER: Nita.

DR. FARAHANY: So to be clear, I don't find any recommendations at all problematic given that we haven't yet defined the scope. It is just I do think it matters a lot, for example, what counts as sufficient information because if it is sufficient information just to make a legal contract because you need to disclose material facts that is different than sufficient information, if we actually think this is more like a doctor patient-relationship than an informed consent kind of process. So I guess what I am suggesting is not that there is anything problematic about anything of these, except three, and I don't think three follows, but perhaps it makes sense for us to have an additional recommendation that says look, it is beyond the scope of this study because this is about incidental findings, this report, but to adequately consider the issue of incidental findings moving forward is an issue that likely expands. As DTC testing becomes

more prominent in its society it would be particularly important and useful to do ethical, you know, research on the nature of the relationship and how we come to define the relationship between DTC companies and the individual consumers. And then these may evolve as our understanding of that relationship, you know, comes to be defined and the prominence and role or insignificance of those companies becomes clear over time.

DR. WAGNER: Yes, Steve.

DR. HAUSER: Just a small thought. I agree with what you say completely, and perhaps we need to emphasize the current limitations of the value of the DTC testing for medically important issues in the first consumer education finding.

DR. GUTMANN: I think that is really important. I think because we haven't had a chance to talk about this directly, although I think a lot of what we have said to date indirectly supports what I am about to say. I think it is just wrong to think that a direct to consumer testing relationship is closely analogous to a doctor-patient relationship. I just think that is, I mean, there are analogies that are close and there are analogies that are wild, and that one is just wild. That doesn't mean there shouldn't be ethical responsibilities on industries that provide this. So I think the question is why are the appropriate ethical responsibilities given that this isn't a doctor-patient relationship. So I think we all agree on that, and I think most, if not all, of your recommendations are consistent with not thinking this is like a doctor-patient relationship, but more like, you know, client, you know, provider. What Steve said then flows very well from this; which is, that's totally consistent with thinking that agents that are more like doctors and clinicians and providers, government agencies that have fiduciary responsibilities specific, whether they are, you know, like the FDA, should educate people who are both patients and consumers alternately in different -- should educate them about what they get when they go to a

clinician compared to what they get when they go online to a DTC company. That is part of public civic education in a realm that is really important where there is a wide range of things you can get from DTC, some which can tickle all of our fancy about who we are that are, you know, more or less profound but don't have great health implications, and some which have profound either health or psychological implications. Psychological in the case of who our father may be, health in the case of a group of findings like for BRCA, for the BRCA gene that, you know, are pretty traumatic if you just get it in an envelope online for most women, and most women when educated and can afford it would much rather get that information from a clinician than get it online. I said most, people do vary, but we really need to have, back to Steve, an educational, civil educational process here.

DR. ALLEN: Part of that educational process I think needs to help consumers avoid confusion because the same consumer may get it in the mail on Monday, a letter from their old primary care doctor who is now with a boutique group who was inviting you to come in and get your annual health check up and have some cup of cappuccino, and the next letter get a letter from, you know, screening, Whole Body Screening, Inc., who wants you to come in and get checked for coronary artery disease and liver disease. So the consumer might not see any difference, even though the one may be coming from a practice, which would kind of fit into the general doctor-patient relationship framework, the other may be coming from a group that is completely commercial and is not offering you the same kind of fiduciary closeness, but from the consumer's point of view it may not be clear that they are really different because they are both advertising in a sense through the mail in their home. So part of the education needs to be help to understand the varieties of ways that we perceive healthcare today.

DR. GUTMANN: I just want to come back to something, just to address it

directly, that was raised at the very first session, very helpfully by Erik, and that is, because I don't like definitions to drive things as opposed to help us deal with the ethical issues, and I think Erik in calling, in noting that incidental findings are closely related but slightly different from what he called secondary findings. Findings that are not just stumbled on but are not the primary target, either of the provider -- it could go either way, it could be an either or, it doesn't have to be at both ends. Secondary could be it is not the primary target of the provider or it is not the primary target of the consumer. We are in this report dealing with incidental and with secondary findings, and it is very important that we deal with secondary findings because to just look at incidental is far too narrow, and I think that that is -- we are all nodding, I think that is really important at the very beginning to point out, to get beyond the definitional obstacle or hurdle that it has to be just incidental findings. Secondary findings raise a tremendous number, all of the issues where we are concerned about.

DR. SULMASY: With that are you though excluding what he called the broader general findings, which is problematically I think in many cases the explicit purpose of some testing, which is maybe being proposed clinically, and certainly a good deal of what is being done in direct to consumer advertising for testing?

DR. GUTMANN: I don't want to exclude the general, but most of what we are dealing with is the secondary and some, you know, the incidental. The reason it is mostly secondary is that once you have plans, once you follow our recommendations there will be fewer and fewer incidental findings. I agree with you that the general raises the question of -- some of the same questions not of what you have to find that you don't intend to find because you intend to find it all, but some of the same questions of what are your obligations for dealing, notification and follow up. The heart of what we are doing is probably, and the more and more progress we

make as a society on the plans and stuff, the more and more we are going to be dealing with secondary findings and general in the sense of omnibus.

DR. WAGNER: I am most comfortable with expanding to the full general piece, I understand the element of general in terms of how you notify and what sort of follow up is similar to what we would get in incidental and secondary, but really, general is, a recent case of the direct to consumer it is what we contracted for, tell me everything on this list, this whole general list, I think you said A to Z. Secondary as I recall is something like A to F.

DR. SULMASY: B to F.

DR. WAGNER: B to F right, because A is the target.

DR. GUTMANN: Except with one significant exception, which we talked about is very few of these DTCs give you everything. They select, and the reasons for their selection are raised similar ethical issues to the secondary and incidental findings.

DR. WAGNER: Absolutely. But don't misunderstand what I am suggesting. Just because there are examples of DTC where general is the specific purpose, in that case I don't know if that is where we want to add. There are many examples of DTC, however, where there are incidental and secondary findings. So just because there is a general. We got to wrap, right?

DR. GUTMANN: Yeah, take a break.

DR. WAGNER: Take a break and be back at 3:30. (Whereupon a short recess was taken.)