



**Presidential Commission**  
*for the Study of Bioethical Issues*

## **TRANSCRIPT**

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DR. GUTMANN: We are ready to do our wrap up session for this afternoon. Appropriately the wrap up session is about some overarching recommendations that span the three contexts.

They are important because incidental findings don't just occur in the clinical, research, and DTC context, and they are not just generated by large scale genetic sequencing, imaging, and testing of biological specimens.

We take to heart where we do not think there is genetic exceptionalism, these are issues that span not only the three contexts but other contexts as well.

So the principals and duties we discuss here have broad ethical applications. And an example that I want to put before you as we engage in this overarching discussion is from the blood and biologics field in the context of blood donation.

As everyone knows, when you donate blood, that blood is screened for some infectious diseases such as HIV. If, for example, it is discovered that the donor is HIV positive the donor is notified because of the critical health implications of that information, but most importantly to protect the safety of the nation's blood supply. The donor does not have an opportunity to opt out of learning this information.

There are other findings, however, such as the sickle cell trait, that do not raise the same concerns regarding the safety of the nation's blood supply as they do not have a detrimental effect on most recipients, but they can be incidentally discovered or they can be as we could now say, a secondary finding, right? And have important reproductive and/or social implications for the donor.

Some of these implications could be positive, others potentially less so. So practitioners that are discovering the sickle cell, how you are on sickle cell can go either way,

right? So the practitioners in these other context, for example, in the context of public health are faced with similar decisions about whether various findings should be returned.

And I want us to keep in mind the type of real life situations that healthcare professionals face every day. Because as the nation's Bioethics Commission, we want to make sure that our ethical deliberations are as applicable and practical as possible so that they can be used in as many of the healthcare contexts and by as many healthcare professionals as might find them helpful.

So keeping practical applications in mind, I would like to begin this overarching discussion with noting the reoccurring theme of a need for additional and empirical research in this important field.

While we've heard presentations regarding some very interesting work that is being currently undertaken, to date, relatively little data have been published focused on the management of incidental findings generally and almost none in the clinical or DTC context.

We thank those who presented us with data in these contexts from their particular small or not so small operations, but almost none of these data have been published in peer review journals in a way that we could take as impartial data.

Certainly any recommendations regarding the best practices for management of incidental findings in any context should be supported by empirical data including empirical data about recipient preferences.

Therefore, we should consider recommending further funding for scholarship and research into the type of incidental findings that arise from various modalities, the frequency of incidental findings and the potential benefits and harms of identifying, disclosing, and treating incidental findings.

That is, and I will read you a potential recommendation, which basically encapsulates what would apply to all of the settings.

Federal agencies such as the National Institutes of Health and other interested private and public entities should continue to fund research concerning the discovery and disclosure of incidental and secondary findings.

This research should include continuing efforts to identify the types of incidental and secondary findings that arise from various modalities, the frequency of these findings and the potential benefits and harms of identifying, disclosing and treating incidental and secondary findings.

Research should also ascertain the preferences of practitioners and potential recipients concerning the discovery and disclosure of these findings.

So that is one overarching recommendation. I will run through all of them and then open it up for discussion.

Another closely related topic is that insofar as our Commission encourages professional and institutional guidelines be developed in the clinical, research and direct to consumer context these too should be based on both empirical evidence and the applicable ethical principles.

Professional guidelines should incorporate the best available ethical thinking as well as evidence regarding the ways in which practitioners should anticipate, interpret, and respond to these findings.

Here is the potential language for such a recommendation. Professional institutional guidelines that set forth best practices for managing incidental and secondary findings should be based on ethical principles and empirical evidence. These guidelines should

incorporate the best available evidence regarding the ways in which practitioners should anticipate, interpret, and respond to these findings. To the extent possible, vigorous evidentiary standards should be developed and shared across contexts. So that is second overarching.

Third area that is worthy of our consideration, and all of these, I am not asking for, we can pass around wordsmithing, but if there are some substantive -- if there is substantive agreement or some significant, you know, modifications or discussion that you want to have here.

Third area is for practitioners to establish a plan or procedure for managing these findings before the situation presents itself.

That is compatible -- that is not only compatible, it is necessary for really meaningful autonomous decisions and professional responsibility.

It is the way of bringing professional responsibility together with individual autonomy is to have a plan and discuss a plan ahead of time.

So here is a potential language, practitioners including clinicians, researchers and direct-to-consumer companies should have protocols in place regarding the possible discovery, management and return of incidental and secondary findings generated by their work.

Practitioners should educate patients, participants and consumers of tests and procedures with a high likelihood of generating incidental or secondary findings about this possibility and inform them of how the finding will be handled before tests or procedures are conducted, and also inform them of the reasoning behind these procedural choices. So that is another overarching.

Last but not least, and consonant with the principal of Democratic deliberation I wanted to bring up the importance of educating stakeholders regarding incidental and secondary

findings.

And this we have talked about frequently today across these contexts and includes educating practitioners about their obligations with regard to these findings as well as educating the public so they can make more informed decisions about whether to undergo procedures and tests that might produce such findings.

And here is a potential language for your consideration. I like the parsimony of this. Educational materials should be prepared to inform all stakeholders including practitioners and potential recipients about the ethical, practical and legal concerns raised by incidental and secondary findings. Those are the overarching.

I want to just make one overarching comment about these overarching recommendations.

I think they are important to have because they tie together the context, the three context, and include some other context that are not naturally seen under clinical research and DTC such as public health, but standing alone may be far too general.

They just really point out that there is not a unified field theory here. By the way, science doesn't have a unified field theory so we should not expect to. But there are some common themes, which in the specific context we can be more specific in our recommendations.

So we are notably general here because the DTC context requires more particular, different recommendations than research than clinical.

I do think, and I am asking the Commission members if you agree or disagree, I do think it is helpful to have these overarching recommendations to call out the unifying themes here, and with that overarching comment about the overarching comments I will open it up for members' reaction and discussion. Nita.

DR. FARAHANY: First thank you for these, I think they are quite helpful and provide a nice framing of the issues overall. I have one friendly addition and one question.

So the institutional guidelines I think is incredibly helpful, and the few contexts we have seen that happen has been constructive in our deliberations and the communities more generally.

Based on what we heard and implicit in what you said, it would be useful for institutional guidelines to also take into account the economic impact of incidental findings, and to consider the implications of doing so.

So that is just a friendly amendment, which I think it would be helpful to specify that.

DR. GUTMANN: So accepted.

DR. FARAHANY: The last one, which is educating stakeholders, the way you said it doesn't specify to whom we are directing that particular recommendation, and I think if we look at what the staff has been helping in developing wonderful educational materials alongside our reports I would imagine this might be a place in which such materials could be used but providing I think some direction as to whom we think that is directed toward and who we are inviting to do so would be helpful.

So if you had thoughts about that, to whom we are directing that, I think we would be more likely to see actionable results.

DR. GUTMANN: Yeah, I think we could be more specific, at least in the preface to the recommendation. I mean, all stakeholders is meant to be that there are many different stakeholders here, but we could be more specific in leading up to this about the different stakeholders who exist; that is, the stakeholders, everybody is a stakeholder in this, I mean, so we

should basically say prepare to inform everyone about, because really everybody is a stakeholder here, but we ought to say in the preface to this, the different roles that individuals have as stakeholders.

DR. WAGNER: Nita, did you imagine also the question about who would be charged with doing the education?

DR. GUTMANN: Okay.

DR. FARAHANY: I agree that for each of the different stakeholders it would be useful to have educational materials, but who would be charged with development of educational materials would be useful.

DR. GUTMANN: Good. I think this is a case where we might take some responsibility as a Bioethics Commission on behalf of ourselves and future Bioethics Commissions to say include -- Bioethics Commissions should take on some of this responsibility in preparing or guiding, giving some guidance for the preparation of educational materials.

I am not saying we are the primary, Bioethics Commission are the primary educators here, but we ought to be -- I would like the idea of being specific but not exhaustive about who might be particularly competent and institutionally well situated to be an educator in this realm.

I open it up to Commission members to give some ideas about what institutions we should call out here in our discussion, not necessarily in this succinct recommendation, but in the discussion, the short discussion leading up to it. Dan.

DR. SULMASY: Another hopefully friendly amendment to the first recommendation, to make sure that there is enough room in there for comparative effectiveness of broad versus focused testing, and I think that would imply across the settings actually.

It seems like it was only sort of -- I am not sure if the language here is broad enough to capture that, and I think we want to make sure that it is also part.

DR. GUTMANN: I take that as another friendly amendment, yes. Addition actually.

DR. SULMASY: And then with respect to your later question, are you thinking about groups like the Association of American Medical Colleges or people like that who would be, one, helpful; that is, one sort of, at least from a clinical perspective, we call for education of a clinician, and the AAMC might be a place to start.

DR. GUTMANN: Exactly. And I think if we could ask for any public input on who might be -- institutions that the public looks to towards this and ask the Commission members to give some input after this meeting on the specific organizations and institutions who are productively engaged in education and should take this in particular on because it is a very important area for patients, consumers and research subjects, and it turns out for public health it also comes up. Anita.

DR. ALLEN: So I mentioned the Federal Trade Commission earlier. I am a huge fan of Federal Trade Commission because they have done such a great job with educating the public around issues of privacy, identity theft and other issues that relate to the new economy and to the information age, and they have, for example, special web page for children about protecting their privacy.

It seems like the FTC would be a real good organ of government to more deeply involved in these issues, especially as they relate to direct to consumer because again we want to try to make sure that to the extent that people are advertising products of this sort to the general public that they are doing so in a clear, fair and lawful manner.

So I would strongly recommend the FTC. They are already engaged, but I like to see them more engaged.

DR. GUTMANN: So could I ask Christine or anybody else who knows, whether we should call out the FDA because it seems to me that what the FDA doesn't regulate, because it can't and shouldn't regulate everything. It can actually provide an, you know, educate people about what, you know, why they regulate some things and not others and what consumers can do to inform themselves about the effects of non regulated projects.

DR. ALLEN: I just want, you said FDA, I was talking about FTC.

DR. GUTMANN: No, no, I accepted your FTC.

DR. ALLEN: FDA has its realm and FTC has its.

DR. GUTMANN: They have totally different realms. I was accepting yours, but I was then thinking of this other realm. The things that agencies don't regulate but are continually called upon to regulate.

The FDA is continually called on to regulate things that it doesn't have either the power or the, you know, the ethical responsibility, you know, to regulate.

I would think that, and I do think it does this to some extent, in the case of, I wonder if they would want and would be good at taking on some of this educational.

DR. GRADY: I don't know.

DR. GUTMANN: I really ask it as a question.

DR. GRADY: Education is not a traditional role of the FDA, although you would think they would, at least, feel compelled to explain what they are doing.

MS. GUTMANN: Let me just say that education, sitting here in an educational institution I think it is important to explain that when we make a call for education here, we are

not just talking about traditional educational institutions.

I know you weren't suggesting that, but one way that governmental institutions educate, one very central way is giving reasons for the things they do and do not do.

In that regard even though courts, the judicial system is often seen as a less accountable institution because many judges are not elected.

It is very accountable in another way that it gives reasons for its decisions, and that is very directly educational and indirectly it provides educational materials. So that is why I thought of asking government agencies that are not primarily educational to give some reasons that the public could know why they do or do not.

DR. GRADY: Okay. I think that is a great idea.

It may also be, I don't know, I am thinking about education for clinicians and researchers; there are other organizations that have that as their main mission.

DR. WAGNER: CMS.

DR. GRADY: Even private organizations too, that do mainly education of researchers.

DR. GUTMANN: Good. Barbara.

DR. ATKINSON: The ACGME, the accreditation for the graduate medical residents.

DR. GUTMANN: Good. Okay. Are there any other reactions because we will adjourn as soon as, you know, we will wrap it up, but I don't want to, if anybody has anything, if anybody in the audience has any questions or comments now is the time.

Okay. We have overarching, the draft of overarching recommendations, and we are done for today, and I really -- it has been incredibly productive, I really thank the speakers, I

thank the audience.

As you could tell, you generated some really good questions and revisions in our thinking.

As always, I invite anyone to submit comments on our website, [bioethics.gov](http://bioethics.gov), and I want to thank my terrific vice chair, Jim Wagner, and the Commission members.

So thank you very, very much for carrying us forward.

DR. WAGNER: Right back at you.

DR. GUTMANN: Thanks. We are adjourned for the day. We begin tomorrow at 9 o'clock.

Thank you all very much.

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(Meeting adjourned at 4:01 p.m.)