



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

**TRANSCRIPT**

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DR. GUTMANN: Welcome everybody. It is my great pleasure to welcome members of the Commission and the Commission's staff to the University of Pennsylvania. This is the second meeting we've had here, and this is the first meeting, however, we had in the Smilow Center because when this Commission began several years ago the Smilow Center didn't exist.

And it not only exists, but it is fully occupied, and it is occupied with work that is obviously relevant to the subject of our Commission.

I am the president of the University of Pennsylvania, and I have the honor of also being the chair of the Presidential Commission for the Study of Bioethical Issues, and I would like to welcome everybody here including our wonderful presenters. I do so on behalf of myself and my distinguished vice chair of the Commission, Jim Wagner.

There is something, before we begin I want to note the presence of our designated Federal official bioethics Commission Executive Director, Lisa Lee. So would you stand up so everyone can see you? My recognizing Lisa makes this meeting official. So we are now official.

I want to begin with something that is sad, which is noting the recent passing of one of the great figures, founding figures of bioethics, Dr. Edmund Pellegrino. Ed Pellegrino died in June, and I would like to say a few words about him because he was such a seminal figure, both in bioethics and in the history of bioethics commissions. He served as chair of the President's Council on Bioethics during the second term of the previous US Presidential administration, so I thought it appropriate to pause as we begin this Fourteenth Meeting of our Bioethics Commission to pay our respects to Dr. Pellegrino.

Dr. Pellegrino began writing on the subject of medical ethics in the late 1950s well before the term bioethics was coined. In 1969 he helped to found the world's first formal bioethics society, the Society For Health and Human Values, which is the precursor to the current American Society For Bioethics and Humanity.

He served as a second president, and he was founding editor of the Journal of Medicine and Philosophy, and he served as the US representative in MONUSCO with development of the charter on bioethics. A medical scientist as well as a great humanist, Dr. Pellegrino served as chair of the Department of Medicine at the University of Kentucky.

He was the first dean of Stony Brook University Medical School, chancellor for health sciences at the University of Tennessee, president of the Yale New Haven Medical Center, president of the Catholic University of America, director of the Kennedy Institute of Ethics at Georgetown University and founded Georgetown Center for Clinical Bioethics, which was recently named in his honor. He received a mere 54 honorary doctorates. He received the Abraham Flexner Award of the Association of American Medical Colleges, the Benjamin Rush Award of the American Medical Association, the first Life Time Achievement Award of the American Society for Bioethics and Humanities, and the Henry Knowles Beecher award of the Hastings Center for Ethics and the Life Sciences.

He is a member of the Institute of Medicine and a master of the American College of Physicians. Above all, I have to say, and I think Dr. Pellegrino would agree, that above all, he as a scholar and a teacher. And he was a scholar and a teacher with extraordinary talents. His writings, which included 23 authored or edited books and 602 scholarly articles, were not only prolific but influential.

At the heart of his ideas were the notions that medical ethics could not be separated from the philosophy of medicine and that a phenomenological understanding of the fact of illness and the physician's response to the patient's predicament provided a basis for medical ethics. Medical ethics began with the experience of a patient and the patient-doctor relationship.

He was a tireless lecturer of immense enthusiasm, and he was a generous mentor to physicians, to grad students and to anyone coming to his office seeking advice and counsel. Many of us in this room owe him a great deal of personal gratitude. And I have to say that Dr. Sulmasy on our Bioethics Commission is somebody who found Dr. Pellegrino of particular inspiration and who I also have to say Dr. Sulmasy would really demonstrate what an amazing legacy somebody can have, of a legacy that will live on because of many of his students, not the least of which Dan Sulmasy.

I ask you now to join me in a moment of silence recognizing Dr. Pellegrino.

(Moment of silence.)

Thank you, Ed. We remember you, we honor you, we express our gratitude for all you did to begin this field of bioethics, and we hope that our deliberations as a Commission do justice to your memory.

So thank you to everyone for sharing that with us, and I would now like to ask the current members of the Bioethics Commission to briefly introduce themselves.

I will just introduce somebody who is on our Commission, a member who is calling in by phone today and so can hear all of our deliberations and speak up, and that is John Arras. John is a professor of philosophy at the University of Virginia and he directs the program in bioethics

there.

If we could start with Anita, would you begin and introduce yourself?

DR. ALLEN: Thank you. I am Anita Allen, and I am professor of law here at Penn, but recently became the vice provost for faculty.

DR. HAUSER: I am Steven Hauser. I am a neurologist and chair of the department at the University of California, San Francisco.

DR. FARAHANY: I am Nita Farahany. I am a professor of law and philosophy and genome sciences and policy at Duke University.

DR. GRADY: I am Christine Grady. I am the chief of the department of bioethics at the NIH clinical center.

DR. ATKINSON: I am Barbara Atkinson. I am the Emeritus executive vice chancellor and previous dean of medicine at University of Kansas Medical Center.

DR. SULMASY: Dan Sulmasy, the University of Chicago Divinity School and department of medicine and one of Ed Pellegrino's many students.

DR. GUTMANN: We have an ambitious agenda for this two-day meeting including potential recommendations for the ethical management of incidental findings across context, which we will do today. And tomorrow kicking off our deliberations regarding neuroscience and related ethical issues as part of President Obama's BRAIN initiative.

Before we turn to incidental findings, I want to let you know about some additional ongoing work of the Bioethics Commission. One of our primary goals in these deliberations and

in our reports is to generate and promote practices of pedagogy in the ethical conduct of research, innovation, health care delivery. And our staff, in consultation with Commission members, has used the Bioethics Commission reports to develop bioethical pedagogy and materials for both traditional and nontraditional educational settings.

Last year we published a study guide to what was entitled ethically impossible STD research in Guatemala from 1946 to 1948. And that is being used by higher education and other interested members of the public, and I am pleased to announce that additional materials will soon be available for download on our website, [bioethics.gov](http://bioethics.gov).

These materials are topic based educational modules and they integrate content across Bioethics Commission's many reports. And this format, this modular format allows us to update the materials as we complete educational projects, maximizes flexibility in how instructors can integrate the Bioethics Commission's educational materials into existing or stand alone curriculum.

Modules are being developed right now on informed consent and community engagement and they will be posted on [bioethics.gov](http://bioethics.gov) in the next several weeks. So, be on the lookout for them, and please do use them, and please do share any comments you have on them with us.

Now, I just want to take a moment before I turn it over to our vice chair to see if he wants to say any introductory comments to explain how we will take public comments.

At the registration table out front there are comment cards. You can write down any comments you have on one of those cards, hand it to any Commission staff member, they are all wearing name badges that say staff.

Can our staff members please stand up?

So, there they are. You can get a card from anyone and just pass cards to a staff member, they will pass it up to Jim or me. We welcome, welcome comments. Jim.

DR. WAGNER: Thank you Amy. In fact, that is the first thing I want to do is thank you and your colleagues at Penn for hosting this.

Welcome to all in the audience, welcome to the Commissioners and although Amy has already in the green room thanked you, and your staff. I would like for the record to thank you especially for the work in small groups in the context, several contexts of incidental findings.

Thank you Lisa to you and your staff also, not just for this meeting but for all the work in the meetings. I think, given our time, I think we better get on with things, and I will insert comments later on. Thank you.

DR. GUTMANN: We have always been on time so here we go.

## SESSION 1: Defining Incidental Findings and a Proposed Ethical Framework

DR. GUTMANN: We have two final presenters on incidental findings, both of whom contributed greatly to this subject.

We will hear first from Dr. Erik Parens, who is the senior research scholar at the Hastings Center. In this capacity he investigates how we use new technologies to shape ourselves and how emergent science shapes our self understanding. He has directed a wide range of research projects including ones in the disability community critique of prenatal genetic testing, the technologic enhancement of human capacities and on the meaning of results from neuroimaging technology such as fMRI.

He currently serves as an adjunct professor in the program of Science, Technology and Society at Vassar College, a visiting fellow at the Bioethics Center at Yale and a fellow at the Center for Neuroscience and Society at the University of Pennsylvania.

Previously, Dr. Parens served as a consultant to several government and non-government bodies including National Bioethics Advisory Commission and the American Association For the Advancement of Science.

Welcome Dr. Parens.

DR. PARENS: Thank you very much Dr. Gutmann. I am grateful to the Commission for the chance to participate in your conversation about incidental findings. For the extent to which I have worked out view on this matter I am grateful to Paul Applebaum and Wendy Chung who have generously shared with me their insights and their time. I am also grateful to the ELSI program whose support makes possible the sorts of collaboration that I've had the privilege of sharing with Dr. Appelbaum and Chung as well as members at Columbia and at my home. The Hastings Center.

So the Commission has asked me to kick off this conversation about the question how can the term incidental findings facilitate or impede consideration of the underlying ethical issue?

So it seems reasonable to begin with the question, what is the underlying ethical issue?

As I understand it, it is an incredibly broad issue. It goes something like this on my understanding: when research subjects or patients or consumers submit all or some part of their bodies for analysis, of all of the information that in principal could be sought and returned, which information should be sought and returned?

That underlying ethical issue regarding what information could and should be sought is old and is complicated, and it is made still more complicated by new technologies as all of you well know.

And nowhere are those new complications more obvious than the context of the genome sequencing technologies that I am going to focus on today. Alas, before I can speak directly to the Commission's question concerning how the term incidental can facilitate or impede discussion of the underlying issue, I need you to bear with me as I rehearse some basic facts regarding the process of creating useful genomic information.

So speaking very schematically, creating useful genomic information entails at least three steps. The first is to gather data, three billion based pair sequence. That raw data by itself is not meaningful to anybody.

The second step is to apply a filter to look for a gene sequence or sequences that are of interest. The investigator can create a filter to pick out as few or as many sequences, as much information; that is, that she wishes. She can filter for 57 genes or for one.

The difference effort between filtering for 57 and filtering for one is a matter of a few keystrokes.

Now, the third step is to validate and interpret that information. That is, the third step is to confirm that the finding is what one initially thought it was and determine what the finding means and what one initially thought it meant.

Please notice, today in practice it still does take more effort to validate and then interpret 57 findings than it takes to validate one, but as the filters and reference databases improve, and

they are incredibly rapidly, and as the amount of effort entailed by validation and interpretation thereby diminish, it really will require as little human effort to test for 57 genes as to test for one.

So the burgeoning technological capacity highlights some relatively specific ethical questions that increasingly press upon us and that we need to face squarely. Among them, is some information potentially so beneficial that looking for it and returning it should be mandatory? This is a question that is familiar to all of you from the recent ACMG recommendations.

When clinicians are looking for one clinically actionable finding should they while they are at it look for 56 others? And, of course, the ACMG recommendation was yes, they are to look for the 56 additional ones while they are at it.

A second question is some information too expensive to look for and/or return? A question that you've heard over and over in the context of research. Would we at the time entail by having to return results of genetics research essentially bring the research project to its knees?

Is some information potentially so harmful that looking for it should be prohibited? A question that will arise in the prenatal context and will be attended by very familiar concerns about eugenics, which I will say a bit more about in a moment.

Answers to those questions are going to entail considering many, many variables. I mentioned three only here.

The first one about which Professor Richardson will speak, I am sure, what is the professional role of the person engaged in the activity? What is the context in which he is engaged? Are we talking about research, clinical care, prenatal care, or direct-to-consumer

scanning, which I am going to take to include recreational scanning of companies like 23andMe. What is the nature of the trades? Are we looking for a disease that we treat it, one that can't be? Are we looking for a trade that isn't related to a disease at all? What is the strength of the results? How analytically valid is it, how much of a variance does the sequence actually have for it? Is it significantly meaningful or not meaningful?

So, finally, I can begin to identify a couple of ways in which the term incidental can facilitate consideration of the underlying ethical question that we started with, and that as we've just seen, entail so many variables and so many relatively specific ethical questions.

So, in medicine the term incidental is, of course, traditionally refer to a finding that was not sought but was stumbled upon. Insofar as the notion of incidental findings has a long history in familiar medical contexts, when we use the term incidental in the context of genetics, it may indeed help us to resist genetic exceptionalism. It may help us to resist the notion that there is something ethically special about these findings because they are genetic.

As you are all well aware the term incidental is, at least in some parts of the so called incidental findings literature, already being used in a sense that is much more expansive than that traditional sense. I already mentioned the ACMG recommendations which refer to those additional 56 sought out filters for findings as incidental.

Elsewhere, too, incidental is already being used in a more expansive sense. For example, it is my impression increasingly when we, and by we I include myself and my colleagues, when we talk about the return of research results we have a tendency to use the term research results and incidental results interchangeably.

So insofar as a more expansive sense of incidental is ever more commonly deployed in the

literature, we can think of incidental as a term of art.

We could just accept that it is not possible or that it is too costly in terms of academic energy to try to retain the more familiar or traditional sense.

So now, moving from a couple of ways in which the term incidental can facilitate consideration of the underlying issue that we began with, I want to identify a couple of ways in which the term incidental can impede consideration of that issue.

Given that in colloquial English incidental findings, one that is stumbled upon or is unintentionally discovered we might say that it is terminologically sloppy to use incidental to refer to findings that are intentionally discovered. As a general matter terminological sloppiness doesn't seem to produce productive conversation.

Referring to findings that are not incidental in the traditional sense as incidental is not only terminologically sloppy, but I fear invites ethical sloppiness; that is, terminological sloppiness here can, though of course does not have to, terminological sloppiness here can become complicit with our desire to turn away from the underlying ethical issue we started with.

Of all the information that in principle could be sought and returned, which information should be?

So imagine this, imagine that rather than talking about the research context or the context of clinical care invoked in the recent ACMG recommendations we are talking instead about the prenatal context.

An OBGYN recommends the analysis of fetal DNA because she wants to determine whether a rare single gene disorder is present. Should the lab that returns the analysis of fetal

DNA include information only about that disorder or should it include information about additional traits as well while they are at it?

If we are going to test for additional traits while we are at it which traits should those be? Referring to those additional fetal findings as incidental risks obfuscating what is going on here. We won't have stumbled upon those additional findings, we will have filtered for them. We will have intentionally sought them out because we want to do something with them, whether that something is to treat a disorder in utero or it is to help perspective parents prepare for the birth of a child with disability or it is to help perspective parents reach a decision about selective termination.

Using incidental in overly expansive sense could obfuscate what is really going on here, and could thereby undermine the sort of ethical analysis and democratic deliberation that everybody in this room is committed to. So I want to suggest that to face squarely both the underlying and the relatively specific ethical issues I have mentioned, it might be useful to continue to try to make some distinctions among types of findings.

I offer here a tentative four part distinction in the hope that it can cause all of you to come up with something better.

A primary finding is the target of the investigation. Target of the investigation is A, and somebody finds something directly relevant to A.

An incidental finding is, indeed, stumbled upon. The target of the investigation is A, but somebody stumbles across B.

A secondary finding is sought out or is filtered for. The primary target of the investigation

is A, but one tends to look for B through F too.

The final type, and I don't like this label much: general findings are in a sense untargeted. The investigation's purpose is to look for A through Z, think about recreational scanning, take the easiest example.

In some, as our technological capacity increases, as the human effort required to test for 57 genes or 507 genes is no greater than the effort to test for one, so increases our responsibility to choose which keystrokes to make and which not to.

The 57th gene that we find isn't incidental in any traditional sense of the term. We filtered for it, we sought it. To aid us in leading up to our responsibility to choose which genetic information to look for and which not to, it may help to be terminologically tidier than we have been of late.

The problem with terminological sloppiness is that it can contribute to ethical sloppiness. It can become complicit with the desire to turn away from the underlying issue that genome scanning technology raise especially in an especially different way. Of information that could be sought, which should be?

It is true that if we were to continue our current path using incidental in an increasingly expansive sense as a term of art we could conserve some academic energy.

My concern, though, is that that energy savings might come at great an ethical cost. It might come at the cost of open and clear deliberation about what we are and about what we should be doing.

Thank you.

DR. GUTMANN: Thank you very much, that was really very clear and very helpful, and we are going to, rather than take questions right now, I am going to ask our second presenter, Dr. Henry Richardson, to speak and I just offer a brief introduction.

Dr. Richardson is a professor and senior research scholar at the Kennedy Institute of Ethics at Georgetown University. He has worked principally on the nature of reasoning. Individual reasoning was the subject of his first book, *Practical Reasoning about Final Ends*; while collective reasoning was the subject of the second, *Democratic Autonomy: Public Reason about the Ends of Policy*.

The second of those books won the Herbert A. Simon best book award in public administration and the David Easton award in the foundations of political theory.

Dr. Richardson has held many prestigious fellowships, including a fellowship in ethics and the professions where I believe he and I first met. Fellowship from Woodrow Wilson International Center for Scholars, a humble fellowship, two fellowships from the National Endowment for the Humanities, and a Lawrence S. Rockefeller visiting faculty fellowship at the University Center For Human Values at Princeton University.

Henry has also served as a visiting scholar at the bioethics department of the National Institutes of Health. Gives me great pleasure to welcome you, Henry, thank you for being with us.

DR. RICHARDSON: Thank you Dr. Gutmann. It is a pleasure to be here and a pleasure to be able to talk with the Commission about incidental findings in these three very different settings of medical research, clinical medicine and direct to consumer medicine.

I have been told that the Commission has been exposed to my partial entrustment model of ancillary care obligations, and what I am going to try to do is to recap it in a way that directs it towards these three different contents where the different lessons come out than in medical research.

I will be focusing on the way in which the model zeros in on what I called transactional duties, and I will explain what I mean by that.

I will talk about the relationship between ancillary care obligations and obligations regarding the incidental findings. They are somewhat overlapping, but not equivalent, and then I will get to the three contexts.

So first a little more philosophical terminology, just how I am using some of these terms. I will be distinguishing between general moral duties and special ones.

The general moral duties are incumbent on all persons, no matter who they are or no matter how they have transacted with other people.

So obviously that leaves two types of special duties then. There are ones that are incumbent on people because of who they are, either they are members of a certain nation or they are somebody's father or somebody's child.

And then the ones I am going to focus on are the transactional duties. These are duties incumbent on somebody's moral duties especially because of how they have transacted with someone.

Examples of the general duties I will be talking about general duty of beneficence, I think a version or the general duty of beneficence is in need of specification and remains a duty that

we can specify.

Transactional duties, very important in this kind of context, are the broad category of voluntary undertakings where people voluntarily undertake. One has an obligation to the other, can be a promise, but importantly can also be entering into a fiduciary relationship, it is a transaction between people.

And I am going to be talking about what was the title of my ancillary care book, moral entanglements, which I think is a very interesting category and what I am trying to generalize to the direct to consumer context.

So let me explain what I mean by moral entanglements. It is a category that philosophers have neglected and should pay attention to.

There are moral obligations that arise independently of either party having intended it from a transaction that is perfectly innocent. So neither party has done anything wrong, they interact and without either of them having intended an obligation arises from one of the other.

Now, that sounds very strange, but I think when you think about ordinary life it is actually quite common. And the story I like to use to remind you of the familiarity of it is a story with the old woman with the groceries, you know, you are walking along the streets here in Philly and you see an old woman struggling with a heavy grocery bag.

You say can I help you? She says that would be great, I don't live far from here, but it is a couple of blocks. And as you are walking you notice she is having trouble hearing you and walking and she can't see very well. You get to her apartment building she says I live here on the first floor would you mind putting these on the kitchen counter for me? You say sure, I will

do that.

You go in and you see the kitchen counter and it is covered with dirty dishes with food scraps on it and slews of black mold growing up all over the place.

I don't know what exactly you should do in that situation. It's going to take some creativity and tack to act rightly, but I think you ought to do something to help with that problem, just call the appropriate civil services people, whoever it is.

You've helped her already, but the transaction is more than this, you've helped her pretty substantial, but you have been entangled in her life in a non-expected way. That is morally significant.

Now, ancillary care, so part of what I will be doing is I will be dropping ancillary care in direct to consumer, but just to remind you, when we were dealing with this ancillary care issue in the bioethics department at NIH the issue hadn't been touched, and we defined it negatively to begin with and defined it for the context of medical research.

It is the care that subjects need that isn't covered by any of the standard reasons why researchers would have an obligation to provide care to their participants. So, not covered by requirements of sound science, not covered by keeping the people safe and not covered by the promised care to get them into the study in the first place. So the ancillary care would be care that subjects need but is left over outside those rationales. This is negative definition.

Examples would include if malaria researchers encounter schistosomiasis, a different parasitic disease, or somebody doing a study of a new virtual colonoscopy machine or protocol discovers pancreatic cancer, and this is important, an historical case, historically important case

if you are doing an HIV vaccine trial and you discover people become HIV positive, what do you owe in regard to or they would have need for care subsequent to that for their HIV.

On at least traditional readings of the term, I think the first two of these are incidental findings to the research being conducted, but the later or the last, of course, is not. Because that HIV positive status is the thing you are looking for in an HIV vaccine trial is the key study end point. But the care that comes after the trial is over is not required by science, not required by the team, it is ancillary care.

I've argued that there are several kinds of grounds for ancillary care obligation. There are general grounds, grounds in the general duty to rescue being the most important. Sometimes just these considerations being relatively easy to save someone in dire care I will kick in saying you have to provide ancillary care.

What is sort of more interesting about the model that we developed was that we also argue that there is a special ancillary care obligation that researchers have to their participants in particular, which is something that intuitively researchers seem to think, and my argument has been that the special ancillary care obligation is grounded in a privacy based moral entanglement, and it has a scope that doesn't cover everything that you might find out about a participant but it covers what you find out by carrying out study procedures, which is the case in the three examples I have just given.

So, I wouldn't ordinarily jump into this, but since I have been told you were exposed to the model, I am just going to give on this slide that moral entanglement based argument for the special ancillary care obligation. I am going to give a schematic indication of my argument for the claim that there is an obligation arising from moral entanglement.

It starts from these three background moral considerations. People have privacy rights that are in play, there is the general specifiable duty of beneficence. These specifications are also capable specification. And then there is what might be thought of as a special case of the duty of beneficence, which is the duty to warn, a special case may be a duty directly, which is usually quite easy to warn people.

So there is a crucial transaction at the beginning, which is that when participants enter a research study they enter it by waiving privacy rights because they enter it by giving informed consent, which crucially has the effect of waiving privacy rights in the sense that they say yes, you can touch my body in these ways, you can take my bodily fluids, you can take my medical history.

And I argue that this solicitation and acceptance of waivers of privacy rights by the researchers transfers to them a special responsibility with regard to those privacy considerations, with regard to what the privacy rights protect.

First blush response to that would be well, they better be very careful about that information and tactfully silent about it perhaps, but in cases where there is an important ancillary care need the duty to warn will kick in to negate that road so you can't be technically silent about it. And so your second option for fulfilling your special duty with regard to them, your special responsibility with regard to the participant is to be tactfully engaged. You are going to be positively engaged in this matter and discover still, of course, being tactful as you always would.

So this is a special duty of positive engagement towards them, consequent on the transaction affected by the duty to warn, and that I argue, provides a hook on the basis of which

this specified agenda of duty of beneficence to generate the special ancillary duty and care.

So that is moral entanglement generating the special duty of ancillary care.

What I want to do in the time remaining is to broaden things out to get to your other context, the other two contexts.

So can just redefine ancillary care more broadly, obligations that arise for reasons incidental or ancillary to the aim or focus of the relationship, and can define a special ancillary care obligation more broadly to mean an ancillary care obligation arising from privacy based moral entanglement.

Here is a schematic, diagram of how I see the key differences among the three context from the perspective of my approach. Context of medical research differs from traditional clinical medicine in that medical research is aimed at generating generalized knowledge so this affects what obligations arise in the medical research and how it is different from clinical medicine in a crucial way.

I find that the new world of direct to consumer medicine very hard to understand, and

I am learning by the minute more about it as I am here, but it seems as best I can tell to have the same aim or focus generally to be promoting the health of the patient. I mean, money is involved in all these topics and that's not a differentiating factor., but the money may seem more prominent in the direct to consumer context not because it isn't there in traditional medicine but because in the direct to consumer context you don't have this regulated monopoly that you have in traditional medicine, and you don't have well understood fiduciary duty attachments like you do in clinical medicine.

As I've argued in the context of medical research ethics, the specialized ancillary care obligation adds a lot. In relation to traditional clinical medicine, I don't think the traditional ancillary care obligation adds much.

I think you can talk about it, I think there are some instances where it added something of the fiduciary obligation the physician didn't, but it is probably not that helpful. So the interesting context is the one that is direct to consumer medicine.

And there, I mean, I guess sometimes the physician is present. Sometimes a physician's fiduciary duty might be thought to kick in there, although it is not a standard context, but I guess often a physician is not present in the direct to consumer context and not where the physician would need to be to be helpful.

So let's suppose the traditional fiduciary duty of a physician doesn't apply in the direct to consumer context. Then what?

So things would look like this, you have a big oval indicating what the traditional physician's fiduciary duty would cover if it were there but it isn't, and if you just have the commercial agreement otherwise then a special ancillary care obligation would add to that, but, as I said, I am going to suggest the term ancillary be dropped out because the really interesting question is how could one get back something like the fiduciary obligation that's there in the traditional context of clinical medicine?

So drop out the ancillary care and just focus on the transaction. The transaction is the same in all these cases.

There is a waiver of privacy rights that says yes, you can touch my body, image it, you can take my gene sample, whatever it is. And so there is the same transfer of special responsibility for professionals, whatever type of professional they are, which means they have this, and then it is an entanglement if there is something unexpected. If it is not unexpected then it is just a straightforward fiduciary duty.

It is not going to be quite as broad as the physician's traditional fiduciary duty in clinical medicine because, I think, at least if it goes by a privacy based of moral entanglement, you are not going to get a duty to hunt whereas a traditional physician would have to, but otherwise it is much like a fiduciary duty.

DR. GUTMANN: Thank you. These are a great pair of presentations. I will begin with a question, and then open it up to other Commission members.

So I am going to start with Erik, where you ended, because I think it was particularly helpful the distinction you made between incidental and secondary findings. So just tell me if this is a friendly extension of what you are saying.

Incidental findings traditionally, the way they first came up and they still come up often, that somebody stumbles on, somebody who is looking at whether it is an x-ray done to look for one kind of malignancy, stumbles on something totally different that is troubling, and that will happen serendipitously, and that is a true incidental finding in a traditional sense. But once you take up the ethical question of what you should do with incidental findings of the traditional sort, you are just a thinking human being and understand the practice of research or medicine or DTC, have to ask the question, what should our general rule or general practice be since there are these incidental findings, should we actually expect and ask the people who find them to look for

them rather than just to stumble on them since some of them happened maybe more often than others, and it would be really helpful to the human condition of those whose incidental findings they are. If we didn't just say ethically speaking or medically speaking, oh, if you stumble on them this is what you should do, but you create a practice of actually looking for things that are not the primary purpose or intention of the study.

Is that basically what secondary findings are? Which would mean that they are intimately connected to the ethical problem with incidental findings, because if you are an ethical observer, you have to talk not just about the stumbling, but also about what practice we should have with regard to these findings that aren't the direct purpose of the research, the clinical practice, or the DTC.

What I am suggesting is that it isn't – that we have to when we ordinarily talk about incidental findings include the idea of secondary findings.

DR. PARENS: Yes.

DR. GUTMANN: That is a long, I think it is important that it is intimately connected.

DR. PARENS: Indeed. Intimately connected, and I think worth distinguishing in the context of a policy conversation.

DR. GUTMANN: But if we are going to make recommendations as a Commission I think that means any recommendations about incidental findings have to include recommendations about secondary findings because otherwise we wouldn't be talking about general practices, we would just be talking about stumbling.

Whereas, once you know people stumble on it you have to ethically and practically

speaking talk about general practice of what to do, and sometimes that general practice will be we don't want people just stumbling on these things, we want to ask them if you are looking for this, you should also look more broadly and here is what you should do once you do that.

DR. PARENS: Indeed. I think sometimes we might, in principal, say let's face the fact that there is a possibility of looking for something else and for these reasons we don't want to look for the prenatal context --

DR. GUTMANN: Absolutely. I am not saying -- I am not prejudging the answer, mind you. I am not saying there could be secondary findings, we ought to look for them.

I am saying you have to ask, should or shouldn't people look for them?

And the other thing is if you can't help but look for them, because sometimes looking at an x-ray, a trained eye can help, should or shouldn't you report them?

The only point that I am making is it would be not only -- it would be -- let me put it bluntly. It would be wrong and indeed foolish of anyone who is doing a study of incidental findings not to include the question of secondary findings.

DR. WAGNER: If I can follow up, and just, by the way, I agree with the two of you as well, but I have this concern about the expectation of what can come from a secondary study.

In the case of genetics or in the case of a blood study when I say yeah, I am really looking for this particular factor but let's go ahead and look for X other factors or 56 other genes in your particular case.

There is every expectation that I will receive back as a physician a definitive, what I would call something with high information content result when there is human interpretation involved

as there may be in reading an x-ray or radiographic study where it is being read by a soft tissue specialist for a specific purpose, but it turns out that there is evidence of osteoporosis in bone, bone cancer, I don't know, I am making that up, of course. But the fact is to say that every x-ray should be evaluated for a whole host of possible secondary issues, requires a different set of expertise to evaluate each x-ray. In other words, the data coming back aren't definitive. So I wonder about setting an expectation or a requirement around secondary studies that may actually be unreasonable. Do you see the point I am trying to make?

DR. PARENS: Secondary findings.

DR. WAGNER: Secondary findings, excuse me, secondary findings.

DR. PARENS: I thought maybe you would --

DR. GUTMANN: Do you want me to answer? I think that is the ethical question, which is should you expect if there is the -- let's take the clinical setting, you really have to use examples, some kind of example here.

So, in the clinical setting, if a doctor suspects that there is some malignancy and performs an x-ray for that purpose, I mean, I am using things very traditional just to show that this isn't some, you know, something, and finds an unexpected, something unexpected that is unproblematic, I mean, everybody.

Then the question that Jim is raising is when should you have, in my term, a practice that asks for looking at more general, something that you would find more and you intend to find more than your primary target?

And, Jim, there is no general answer to that question. I mean, I think you have to look at

specifically what good would come of looking for more.

And, of course, you have to ask can you, in your case, in the case you gave, you actually look for more. You are doing 57 rather than one.

DR. PARENS: There are many variables that play. One of the variables I didn't mention was the amount of effort that was actually entailed.

The reason why I went through the genome example different from the one you are imaging, Jim, we can't with a keystroke get as many looks through.

DR. WAGNER: Of course, it is quality data.

DR. PARENS: So that is an important variable, but it is hard to put an eye on it. And, of course, the problem with me is I am always thinking of the genome example and forgetting the other examples, but the variety is really important.

DR. WAGNER: And the need for interpretation is there. That is the primary point, it is not necessary -- there are certain kinds of tests that are definitive, and interpretation isn't required.

DR. GUTMANN: You will see that in our, you know, preliminary recommendations we break this down into different context dependent on what the expertise of the person doing the testing is to interpret more than what the test was designed to do, what the benefits are in reporting them, what the, you know, actual not only benefits but potential harms are for reporting it and a series of factors.

I have a list. I have Christine, but I have Nita first then Christine.

DR. FARAHANY: I would like to shift to the model, if you don't mind, to build out something that I have been grappling with both in reading your work and in the presentation today which was to focus on the issue of the duty to warn and to understand what gives rise to the duty to warn.

So you mentioned in the presentation today just that, you know, maybe it is a special duty that comes from beneficence and it is relatively easy to warn people, that is part of the rationale for the duty to warn. Although that isn't always true in every context to do so, but I am hoping that you can elaborate a bit more exactly from your perspective and the model, what gives rise to the duty to warn and what is included within it?

So what does that mean, if we build on Erik's model and look at secondary findings once you are aware, for example, of a regular incidence of secondary findings you might have a duty to warn before the study begins that your privacy might be compromised in that particular way because it is something we would come upon so often. But if you could just elaborate what is included. And I will tell you the context in which I am interested in this is in the legal context you have to have a particular type of relationship between the individuals that will give rise to the duty to warn, and only extend to certain people.

So if I am landowner, for example, and I become aware of a condition on my land then I would have to warn known invitees to the land but not necessarily trespassers.

So try to understand, that would help, I think, and then understanding it in other contexts because as you apply it to the DTC context I am not sure how I see the duty to warn would, if at all, arise.

DR. RICHARDSON: So pick up with the last point. There can be indicators on warning

people that come from minding your own business considerations, privacy considerations.

Relationship can put those out of the way, and there is a relationship that can do that in all these cases, whether it is with a physician or researcher or a direct to consumer purveyor. They are not precluded from warning, but not being their business.

I was thinking the source of the duty to warn as being a -- I didn't mean it was a special duty, but that it was a special case of general beneficence or even a special case of it being a special duty to rescue. So duty to rescue, to save people from the dire peril, one can do so easily.

So I was thinking the duty to warn, as I was using it, saving people from dire peril by giving them a warning, look, you have a problem here, which is usually very easy, although one of the interesting things about the research with bank samples, you can lose track of the donor, then it can be a little bit of a problem logistically to warn them.

DR. FARAHANY: On the duty to rescue because I thought that might be part of, you mentioned that a few times, but your duty to rescue generally given with respect to autonomy, we don't impose a duty to rescue on individuals and we might favor particularly when you've created the condition for a danger for a person or created a condition whereby a person needs to be rescued of a particular duty, and there are certain relationships and special relationships, parent-child, other types of relationships that create a duty to rescue, but I take your duty to warn to be a lot broader than that, on the idea that if it is easy to do so you should step in, and if you could just explain how you would balance that with the autonomy with respect to the individual in imposing additional duty.

DR. RICHARDSON: My understanding the respect for autonomy would limit our legal duty to rescue, but there is a moral duty to rescue, and it is much broader as in the child

drowning in a pond is the stock example, where there is no relationship, if you can get the child out of the pond, you ought to do so.

In this country the law is doing that for good autonomy reasons, and I wasn't speaking for the law.

DR. GUTMANN: So what Henry is speaking of is if you thought of as a Venn diagram, which would be the circles of legal duties and moral duties intersect and they don't completely overlap. Some moral duties are broader than legal duties and some legal duties aren't moral duties, they are just legal duties.

And I think almost every moral and legal theory has that while they may have different contents, they all agree that they don't -- so when you speak of duties you are speaking of moral duties and these open the question of whether there should be a legal duty.

DR. FARAHANY: I completely agree. These are not perfectly overlapping concepts so I wanted to understand where for you the duties to warn against, and I want to understand the basis for that duty because it seems like a lot of later action in your model comes from the duty to warn.

So giving kind of depth to what the scope of that duty is, I think it would be helpful in applying it to these different contexts.

DR. PARENS: Yeah, I can't really do more than say I see it as a duty to rescue. And that would qualify the understanding of duty to warn. So it bears on cases where dire peril of some kind comes into play, and it suggests that there is some limit to it, depending on how costly, significant it is to provide the warning.

DR. GUTMANN: The way you say it sounds you can't say more than that, but it is actually just logically inseparable to my -- if you have a duty -- if it is easy for you to catch somebody who is falling, and so you have a duty, a moral duty to catch them if you can easily, surely you should also have a moral duty to warn them if you see that they are about to fall.

So I think those two moral duties are just one and the same. It just happens that sometimes you see people who are falling and other times you see them about to fall, and in each case if you have a moral duty to one, you certainly have a moral duty -- if they are equally easy to do and the peril is equally great it seems to me it is just logically inseparable.

DR. RICHARDSON: Yeah, again --

DR. GUTMANN: I think it seems to you, I am trying to explain --

DR. RICHARDSON: Warning, the butting in considerations might come up intuitively more prominently in the verbal warning or in the warning than in the just catching somebody.

DR. GUTMANN: Well, it depends on what you have to do to do both of those. If you have to push other people aside to catch somebody, that is more complicated than you can just move over.

If you have to interrupt somebody who might be doing something, you know, might be doing something autonomy based like committing suicide where there would be a real argument, but if it is clear all you have to do is say stop because clearly they are not intending to fall.

All I am saying is I think you have a very strong moral basis for your general case, how it applies in particular cases will depend on the details of the case.

DR. RICHARDSON: I think it is bedrock, and I just want to be sensitive to the

autonomy related concern about butting into somebody else's affairs, but in these cases you have a privacy waiver to begin with so you are already under that relationship umbrella.

DR. GUTMANN: Christine. And then I have Dan, and then I am going to ask John who might have a question.

DR. GRADY: Thank you both for today, and for the work you have done before.

My question is about filtering. Erik, you mentioned it specifically with respect to genetic sequencing, but in the literature there are references to, you know, if we have to return incidental findings we will filter by anonymizing; in other words, pull further away from our entanglement.

So I wanted to ask whether or not the moral entanglement seems to be a little bit discretionary. You can decide to walk the woman to her house or not, once you do you take on certain obligations that you wouldn't have if you decided not to. But there is nothing that says you have to, right?

So in the front end could you filter, could you say I am the researcher, therefore, the extent of my moral entanglement is going to be circumscribed by how I filter the data I am collecting, and is that okay in the context? And I would love to hear from both of you about that.

DR. RICHARDSON: So in these cases everybody is walking the woman to the house in the sense that there is -- they are engaged in this relationship where this private information is being collected and gotten to the point of getting into the house so the analogy would be more should they, what if they make a practice of whenever they help somebody in with the groceries they make a practice of putting on a blindfold to tell me where to put them.

That will be, and what I argue about that is that if you are filtering just in order to evade

moral responsibility to help these people out, I can't say that is wrong, but it seems morally criticizable. It seems to me like going to the beach and you are a great swimmer, and you know there is this likelihood you are going to be interrupted by some kid out there who thinks he needs to be rescued so you are going to avoid that bothersome necessity of having to jump up to rescue kids out of the water by getting yourself blotto drunk so nobody would think of calling on you.

I think that is pretty sizeable to blindfold, to limit yourself just to not do the keystrokes or do the keystrokes to filter things out just to avoid.

The other reason it is costly for a matter of human interpretation of x-rays, that is a totally different matter.

DR. GRADY: Erik, do you want to tell me about filtering because you described the sequence of steps in genetic, you know, sequencing as involving filtering, you make a decision up front what to filter for, right?

DR. PARENS: Indeed. And I am prepared to believe that in different contexts, different people with different roles will have different obligations regarding filters.

Though as we all know, those boundaries between those roles and contexts is ever blurrier, but in principal I am prepared to say, yes, I can imagine that in one context one would use one filter and in a different context a different filter. We are using both filters in slightly different ways, but your point is a helpful one.

DR. GUTMANN: Dan.

DR. SULMASY: Henry, I very much appreciate your focusing on direct to consumer, and your role potentially in your model here in that area, and I was wondering if I could get you

to say a little bit more about it, particularly since I think lots of folks might begin by saying well, it is just a contract, right? I ask people to look for my calcium score in my coronary arteries and that is what they tell me back or, you know, I ask them to find whether I have X gene and that is what I paid them for and they tell me that.

But I am very sympathetic to your view, and some hints might be first you quickly threw up a slide that, you know, said what is the purpose of direct to consumer marketing of these sorts of tests, and you analogized it or put it exactly the same as that of a clinician, and might get some push back from the people who are doing the marketing of these tests that they're purpose is to promote health, but in some ways I think perhaps you are right, so I'd ask a little bit more explanation about that.

And then the other hint from me, and going back to your little old lady with the groceries analogy would be even if she paid you to do it and you came into the house and found it in the disarray that you described, do you still think it is intuitively impossible there would be a duty for the moral entanglement even under a contract situation. So maybe say a little more for us.

DR. RICHARDSON: Okay, that is great. It is a very intriguing concept this direct to consumer, and I know very little about it.

The reason I had on my diagram the purpose being the same as traditional clinical medicine, I was focusing on cases, it may not be fully represented of full body scans or people having their genomes decoded, not purely recreationally, but tell me what you find.

So that may not cover all the cases with direct to consumer body decoding, but it might -- but I spoke on direct to consumer medicine side of things, which promoting health. And I understand why you would say that, but maybe the reason that you want to think of it that way is

because there isn't this fiduciary obligation present as I understand it in that case, in which case that is what is affecting how you think of the promoting health in this general way.

So what I was sketching very briefly at the end was a way of recovering something like that fiduciary duty on the moral entanglement basis.

So the contract is the contract, and the interesting contract I am focusing on here is the one in which a privacy waiver is involved, that is an unusual. You could analogize it to borrowing somebody's car. You have the exclusive right to drive someone's car and they waive that right. So when you borrow somebody's car you got some special responsibility while you got it out there, you have to deal with the hassle, something. So it is a wild context out there, and it seems like one where people -- the difficult issue is whether people are asked to waive any ancillary care obligation, any care obligation, that might arise when they sign the contract, and that will take a policy intervention to prevent that from happening, I think.

DR. GUTMANN: I realize we should just say, this is not a household term, DTC is direct to consumer, just for everybody to know that. John, did you have a question.

DR. ARRAS: I do Amy. Can everyone hear me?

DR. GUTMANN: Yes, loud and clear.

DR. ARRAS: Great, okay. Well, I want to start out by saying how sorry I am that I can't be there in person to thank Erik and Henry for such really terrific presentations, but also for the background work of theirs on which we rely, which I find really eloquent indeed, and so thank you.

There are two questions in this area. First of all, there is a question of who has a duty to warn or to intervene and why? Secondly, there is the question of the strength of that duty. Does it have to be a life or death issue or to what extent can cost rear into the equation.

I want to ask you both to reflect on the relationship between these two questions; namely, between the issue of whether there is a duty and who has it, and the question of the strength of the duty or the requirement in a particular circumstance for that duty to be triggered.

So we are dealing here with three contexts; clinical, research and DTC. And I got to say at the beginning of our reflections on this I was hankering for some kind of unified field theory of obligation that would unify these three different areas, the clinical, the research and DTC, rather than basing our moral analysis on ad hoc categories, you know, searching for some sort of unifying approach.

And as a result I come to feel like the Vichtenstein slide floating around in that bottle. So there might possibly be a ground for a unified field theory through something like Henry's partial entrustment model, but as we've seen, both in the literature and your presentations today, that there are a lot of differences between these contexts. In the clinical sphere you might say that the duty is super justified or over determined. You not only have a moral entanglement of the sort that Henry is talking about, but you got very clearly articulated traditional physician fiduciary duties. In the research context you got some fiduciary duty and you have something like Henry's partial entrustment model at work. And then finally in the DTC area we seem to be simply left with something like the partial entrustment model.

So as we go from clinical through to research to DTC we find it kind of thinning out of the obligation. So I am wondering what the relevance of this thinning out is for policy

determinations with regard to incidental findings.

So; in other words, if the duty to assist or to warn is say weaker in the DTC context than in the clinical, does that weakness have a corresponding affect on the area of policy regarding how urgent the case seems to be for intervention?

So; in other words, in the case where the duty is strongest, like the clinical sphere, you might say that even relatively insignificant harm might come to the floor, might be something to worry about, whereas in the DTC context you need the level of stringency to be up there pretty high.

Does that sound like an accurate assessment of this moral situation? And, if so, what are the consequences for policy?

DR. GUTMANN: I am going to ask one of you to take a crack at that just because we have a number of other questions, we can come back to it, but it is a really good question.

DR. RICHARDSON: It is very good, and that is a very nice way of summarizing the relationships and differences among the three contexts, Dr. Arras. But I am not sure I would order them the same ways because one of the key differences between research and the other two as represented by the differences however exactly we parse them as between the purposes of the interactions, researchers aiming at generating generalized knowledge, and that is a very important task and a moral important task to engage in.

So that provides a reason that is peculiar to research for taking especially seriously the cost and the burdens on the enterprise if you do a lot of this stuff, whereas in the other context it is more the individual and the professionals, and the individuals may have become more central,

and the question just becomes can one reconstruct something like the fiduciary obligation in the traditional context and carry it over to the direct to the consumer?

DR. GUTMANN: Thanks. Anita.

DR. ALLEN: Most of my questions have been asked by Dan and Nita and John, but I have one remaining question for you guys, which is about this:

So we have been told that for some people direct to consumer testing is being done as an alternative to traditional healthcare distinctly, not purely recreational and motivated by desire to save money, because traditional healthcare may be more expensive, desire to have greater confidentiality because they don't want their information to appear in their official health records.

So if direct to consumer is becoming, to the extent it is becoming an alternative to traditional health care, does that in your mind think that we should think about obligations to return information more like the clinical setting where the obligation is very strong presumably or do we allow the idea of business and contracting caveat emptor, et cetera to cause us to think that well the obligation here is mainly only to return information involving dire peril throughout the same level of obligation we have in the context of clinical care.

DR. RICHARDSON: I will take a first crack at that. I actually think the ground for the physician's fiduciary duty is the one that I've indicated having to do with accepting the waiver of privacy and dealing with this person's private information, say okay I don't want to deal with it. Of course it is just so well understood that it has taken on kind of an intellectual autonomy on its own as we think that is the physician's obligation.

I was casting my remarks on the supposition that the traditional fiduciary duty of a

physician wasn't understood as covering this direct to consumer context.

And so suggesting in a way an argument for something like that fiduciary obligation in that context, but an alternative path that the Commission could take would be to say, at least for these cases where it is people's shot at a cheap entry into medicine, to say it should be incorporated into this regulated monopoly of medicine, and we need to extent our conception of physicians' duties somehow to cover this new context.

DR. ALLEN: Okay.

DR. GUTMANN: Erik, did you want to say something?

DR. PARENS: Just a general observation. I am stuck by the extent to which the conversation has been about the duty to warn regarding something unexpected, and that is enormously important.

As I was suggesting, increasingly we can expect and should expect findings. I am wondering to what extent this language of duty and autonomy can be complimented by the kind of language of learning health systems, collaboration that has begun to be articulated by people like my colleagues?

This is not much more than a free association, but I am myself a little puzzled by the extent to which we are talking about duty to warn regarding findings of fact. More and more the system develops, the more and more we are going to expect it and the more and more we are going to be talking about the complications.

DR. GUTMANN: I have a question from a member of our audience, which actually is an alternative that addresses this issue in an interesting way, and I will ask him to raise his hand.

University of Pennsylvania department of medical ethics and health policy professor, and here is what it says, “with respect to direct to consumer is there any principal to objection for us as a democratic polity imposing a legal duty to search and warn in some direct to consumer context just as a matter of good policy. As an analogy, consider the legal duty we impose on some professionals; teachers, psychiatrists, police, to report concern about child abuse or neglect just because of the good epistemic vantage point some of these individuals occupy.”

So to broaden this, and putting my philosophical hat on, this turns in some sense philosophy on its head instead of looking for the moral foundations, which people often disagree on.

This says why not begin with some examples and ask of what could and couldn't be reported and ask what would make good outcomes in these cases, and then you can ask, are you imposing too great a burden on the direct to consumer, but I take it this question is, begin with what would make as a practice good policy taking into account all of the ethical and practical considerations.

I see you have a furrowed brow Dr. Parens.

DR. PARENS: I am trying to get clear which DTC context we are talking about, people who are really trying to supplement or are using it instead of healthcare?

DR. GUTMANN: Right, here let me just extend this to, because I think Anita, so if this is the case, because it isn't always the case, that is why we need examples, and we will use them in our reports. We must, because otherwise I think it is very hard to know what is at stake.

But if it is the case that there is some direct to consumer testing that people use who can't

afford other ways of testing, and this would be a good thing for them to find out certain incidental findings because they otherwise would go unnoted and untreated, then what this suggestion is, if I understand how it is a suggestion, is couldn't a democratic polity as a matter of good policy say direct to consumer findings of this sort should be reported?

DR. PARENS: So we are going to require businesses, free enterprises to do some additional work. Now, I suppose one can imagine the world where that would happen, I would prefer to imagine a world in which people don't have to go to businesses to get their genetic information.

DR. GUTMANN: You would prefer that world, but if we don't have that you still have to ask the question, what businesses. I am not trying to prejudge this, as to that is what we should require, but I don't see why that is a bad question to ask.

We ask the question of corporations, do they have a legal or moral duty, let's begin with the moral, moral or legal duty to report when they find adulterated items in their stock.

That is a matter of policy. We don't have to require them to do it, but we do require them to do it because we think it is good policy. They could have in the larger fine print we have no responsibility, but as fact, as a democratic polity we generally impose obligations on corporations, moral if not legal, in this case legal as well as moral, to report some things that they find, and that we don't live in a pure caveat emptor society.

DR. RICHARDSON: That is a great question, and I just would counsel thinking in terms of lots of different analogies. So there are also accountants who are looking at your financial information, maybe they will see some sign of a gambling problem, do we want to require them.

There are all sorts of if you are going to redesign practices you can ask the plumbers when they are checking out your house, report anything they find. So it is just you are being so altruistic.

In terms of business, I mean, we are sitting in a wonderful academic hospital, a university hospital setting, but a lot of hospitals, businesses that understand that term, so I wouldn't draw too sharp a distinction myself between business and medicine.

DR. GUTMANN: I have two other questions, and then we will take a short break.

We have a member discussion so I feel we can cut into that a little bit because they are really good audience comments and questions.

Is it Betto Ortiz? Right there. From the NIH. I am not sure we are going to have time for all of these. "In the case of what is an incidental finding even of the secondary kind is the duty to warn without the responsibility of rescuing once information is given a little bit morally inappropriate? The duty to warn should exist if rescue would follow."

And that is another good question because it suggests shouldn't we take into account what will happen most likely if an incidental finding is reported to someone, whether they will be in some sense, have some opportunity to be rescued, am I understanding that correctly? Erik or Henry? Henry.

DR. RICHARDSON: I brought up the duty to warn, and the only reason I brought up the duty to warn is that the key crux in my argument had to do with if people have a special responsibility regarding the concerns underlying privacy rights wouldn't you think they had a duty to be quiet about things.

So it was overcome the duty to be quiet about things that brought in, reminded people of the duty to warn in this kind of case. The duty to warn as I have been saying, I am thinking of it as a special case of a duty to rescue, and the duty to rescue is there.

For a lot of ancillary care stuff in this country the duty to warn can do a lot of the work because you will discharge your ancillary care obligation by saying you have this problem that I didn't expect to find with your pancreas, you should talk to the pancreatic specialist down the hall.

But, of course, in developing countries things are totally different, you just warn somebody they have a problem that is making it a lot worse and you need to follow up with them.

DR. GUTMANN: This is another case, I agree with what you said, but it is another case where examples matter. Because an example of where this kicks in is there is the possibility with very little extra cost of finding out, for example, whether somebody is genetically disposed to early onset Alzheimer's to which nothing can be done medically speaking at this point.

Now, things can be done in your life and people vary. If we took a poll I think we would find that there is certainly division as to whether we in this room, individually, would want to know or not want to know under the current circumstances which you can't do anything medically about it.

So that is where this kicks in where the duty. Is there a duty to warn about something which is truly a life limiting medical condition for which there is no treatment?

DR. RICHARDSON: So maybe too limiting to view the duty to warn as a special case of a duty to rescue, but viewing it that way you are seeing it as a way of averting dire peril to

someone, and if nothing can be done to avert the peril.

DR. GUTMANN: Then on that it doesn't kick in. There is still the question about whether there is some other reason or not, but that is very good clarifying.

I have one final one, and Jim is going to read it because I am afraid my eyesight of small print is not as good as it was 10 years ago.

DR. WAGNER: You are obviously pushing the information density requirement for your students. Because this happens to be a student.

This happens to be a corollary to this question, we have been talking about the right to warn always about concern for a detrimental finding.

What he writes, what if part of the incidental findings were findings of purely positive interest with little burden to the subject to the consumer, is there moral or ethical uncertainty, and I think he also raises the question about who should make the decision about detrimental, is it the patient or is it the physician.

DR. GUTMANN: Can we just ask do you have an example, any example in mind, that you have the gene for living a particularly long life which we -- right?

AUDIENCE MEMBER: Sure, that you have found that a mother is in a research study because she has a child who has a genetic disorder so she wants to do her blood sequence. Up until that point she believes that she was going to be infertile, she now found out information that she now has the capability to still procreate. She did not enter into the contract, clinicians already have, they are already bound by a legal duty if there is a harm, they have recourse about that.

DR. GUTMANN: Thank you. By the way, this has been a terrific series of questions from the audience so keep it up. This is the final question before we take a break. Who would like to answer that? The furrowed brow of Dr. Parens has my attention.

DR. PARENS: It is difficult to imagine a duty to warn regarding information that is not lifesaving.

DR. GUTMANN: No, it is not a duty to warn, a duty to report, to inform.

DR. PARENS: Again, the process of informed consent, to make the offer to someone presumably it is very difficult to work the details out, but presumably we offer the opportunity to get access to information and not just hoist it on somebody.

DR. GUTMANN: So that is a great way to conclude because we have been focusing on the duty to warn or inform, but there is also the question in the practice, right, not the one off incident, the practice, what you, going into the practice, what the understanding is, you know, the professional contract, if you will, the moral contract. But the real understanding is of what will and will not be reported.

And to the extent that we can have practices and recommend practices that are good public policy, that makes it -- it reduces the traditional realm of incidental findings, and I think does what you are overall recommending to do, which is not to inflate incidental findings more than one has to.

Thank you, let's give a round of applause to Dr. Richardson and Dr. Parens. We will take a five minute break and we will reconvene 10 of or 10:50 we will reconvene.