

10-16-2013

Panel 2: Ethical, Privacy and Budgetary Considerations of Personalized Medicine

Ben Berkman

Stacey M. Brandenburg

Melanie Teplinsky

Wayne Rosenkrans

Lindsay Wiley

American University Washington College of Law

Follow this and additional works at: <http://digitalcommons.wcl.american.edu/hlp>

 Part of the [Health Law Commons](#)

Recommended Citation

Berkman, Ben, Stacey M. Brandenburg, Melanie Teplinsky, Wayne Rosenkrans, and Lindsay Wiley. "Panel 2: Ethical, Privacy and Budgetary Considerations of Personalized Medicine." *Health Law & Policy Brief* 5, no. 2 (2011): 15-25.

This Article is brought to you for free and open access by Digital Commons @ American University Washington College of Law. It has been accepted for inclusion in *Health Law and Policy Brief* by an authorized administrator of Digital Commons @ American University Washington College of Law. For more information, please contact fbrown@wcl.american.edu.

PANEL II: ETHICAL, PRIVACY AND BUDGETARY CONSIDERATIONS OF PERSONALIZED MEDICINE

OPENING REMARKS FROM LINDSAY WILEY*

MODERATOR (Lindsay Wiley): After that fantastic introduction to personalized medicine, to the possibilities it raises, and to the potential hurdles to fulfilling that promise, we're going to turn now to a more in-depth discussion of ethical, privacy, and budgetary issues raised by personalized medicine. I'll do a quick introduction of each of our panelists and then give them the floor.

First, we will be hearing from Ben Berkman, who is the deputy director of the Bioethics Core at the National Human Genome Research Institute and is also a faculty member in the National Institutes of Health (NIH) Department of Bioethics. He's also an adjunct professor at Georgetown Law and the University of Maryland School of Law, where he teaches courses on bioethics and science policy. Ben and I worked together at the O'Neill Institute for National and Global Health Law, where he was deputy director. His previous experience also includes work with the Ethics Department of the American Medical Association, ABC News

* Lindsay F. Wiley, JD, MPH, *Assistant Professor of Law and Faculty Director, Health Law and Justice Program, American University Washington College of Law*. Lindsay Wiley is an assistant professor of law at American University Washington College of Law. Professor Wiley teaches torts, health law, and public health law. Her current research focuses on access to health care and healthy conditions in the United States and globally, including law and policy issues at the intersection of public health, food systems, and environmental change. Prior to joining the faculty at WCL, Professor Wiley was the Global Health Law program director at the O'Neill Institute for National and Global Health Law at Georgetown University Law Center. She also previously worked at the Center for Law and the Public's Health at the Johns Hopkins Bloomberg School of Public Health; the American Society for Law, Medicine and Ethics; and Gordon, Feinblatt, Rothman LLC in Baltimore, MD. She received her AB and JD from Harvard University, where she served on the Harvard Law Review, and received her MPH from Johns Hopkins University. Recent publications include, Lindsay F. Wiley, *Moving Global Health Law Upstream: A Critical Appraisal of Global Health Law as a Tool for Health Adaptation to Climate Change*, 22 *Geo. Intl. Env'tl. L. Rev.* 439 (2010) and Lindsay F. Wiley & Lawrence O. Gostin, *International Response to Climate Change: An Agenda for Global Health*, 302 *J. Am. Med. Assn.* 1218 (2009).

Medical Unit, and the Economic and Social Research Institute. He's worked on projects with the World Health Organization, the Centers for Disease Control and Prevention, and an Institute of Medicine Committee relating to pandemic influenza preparedness.

After Ben, we'll be hearing from Stacey M. Brandenburg, who is an adjunct professor of law here at the Washington College of Law (WCL). She focuses on emerging privacy and information technology issues, including online behavioral advertising, social networking, and identity theft. Previously, she served in the Federal Trade Commission's (FTC) Division of Privacy and Identity Protection, where she addressed information privacy issues from a policy and enforcement perspective. Prior to joining the FTC, Professor Brandenburg practiced at Steptoe and Johnson, LLP, where she advised technology and telecommunications clients on e-commerce, privacy, and data security issues.

Next, we'll hear from Melanie Teplinsky, who is also an adjunct professor of law here at WCL. Her area of expertise is cyber law, and she practiced, as well, at Steptoe and Johnson, LLP, where she counseled leading financial services, telecommunications, and other multi-national clients on a wide array of issues, including cyber security, data protection, and electronic surveillance. She also previously worked on information technology and privacy policy issues in the Executive Office of the President at OMB, and the Office of Science and Technology Policy.

Finally, we'll hear from Wayne Rosenkrans, who is the non-lawyer on the panel. He holds a PhD in cell and molecular biology from Boston University. He's chairman of the board of directors of the Personalized Medicine Coalition, a distinguished fellow at the Center for Biological Innovation at the Massachusetts Institute of Technology (MIT), and a member of the Ethics and Systems Medicine Program at Georgetown University. He's also vice president for Strategic Consulting at Fuld and Company, and chief scientific advisor at Expertech. Previously, he was director of external relations for Personalized Health Care and Evidence-Based Medicine at AstraZeneca. Prior to that, he was involved in

research and development and strategy policy at both AstraZeneca and Smith-Kline Beecham. He is a former president of the Society of Competitive Intelligence Professionals and has received the Society's Fellows Award and Lifetime Achievement Award in Intelligence. He's active on several advisory boards, including the Institute of Medicine, IBM Life Science, and HP Life Sciences. We'll save a bit of time at the end for questions.

REMARKS FROM BEN BERKMAN**

So, I suppose I'm a lawyer. I'm trained as a lawyer, but I sometimes don't identify as a lawyer. So what I want to do today is take a step back. This is going to be a little bit different than the first panel; I want to change our frame. Personalized medicine is built on research, genetic and genomic research, and what I want to talk about is some of the ethical issues that are being raised by next generation genomic sequencing technology. I work at the National Institute of Health (NIH) with lots of investigators doing this kind of personalized medicine research, building the blocks on which the genomic-influenced clinical practice will be based.

This next generation sequencing has some very, very complicated ethical questions that it raises. There are, obviously, implications beyond research into clinical care, including prenatal, whole genome sequencing. But my focus is going to be on research ethics. We're not quite ready for clinical applications, so these are the ethical problems that we're being faced with right now.

First, I want to describe the magnitude of incidental results. We'll be talking about incidental genomic research results, and you'll figure out what that means in a second, but I want to describe what they are and the magnitude of the problem. I want to present some of the research ethics literature to show you how this is really a very controversial topic and that there's no ethical consensus yet. Then I want to give you my gloss on it and show you some of the questions and controversies that I think we need to look at as the debate moves forward.

Let's start with a definition. There are a number of definitions, but what we're talking about, an incidental result, is a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research, but is beyond the aims of the study. So

** Benjamin Berkman, JD, MPH, *Deputy Director, Bioethics Core, National Human Genome Research Institute*. Benjamin Berkman is the deputy director of the Bioethics Core at the National Human Genome Research Institute and is also a faculty member in the NIH Department of Bioethics. He was formerly the deputy director of the O'Neill Institute for National and Global Health Law at the Georgetown University Law Center, and continues his work there as an adjunct professor. Prior to his work at the Georgetown University Law Center, Mr. Berkman worked for the American Medical Association Ethics Department, ABC News Medical Unit, and the Economic and Social Research Institute. He has also worked with the World Health Organization, the Centers for Disease Control and Prevention, and has served on an Institute of Medicine committee relating to pandemic influenza preparedness. Mr. Berkman has also coauthored a number of works in the public health field, and serves as a guest lecturer and conference presenter across the United States. Mr. Berkman holds a BA magna cum laude from Harvard University, a JD cum laude from the University of Michigan Law School, and a MPH from the University of Michigan School of Public Health.

imagine you come in and you enroll in a cancer study. They're sequencing your genetic material and they discover that you have a gene that predisposes you to Alzheimer's or to schizophrenia, or that you're a carrier for a certain rare but serious genetic condition. These are all things that have nothing to do with the reason you came to the research.

So, let me give you a little background, some technology. We're on the cusp of seeing the widespread adoption of whole genome sequencing; in the first panel, people maybe made a couple of references to this, but we're moving from a paradigm where we're doing targeted genetic testing to one where we can sequence the entire genome. The cost of, the efficiency of, and the speed of sequencing has taken a huge leap forward.

The cost is dropping, and because you all know about Moore's law [Gordon E. Moore], one of the founders of Intel postulated that every eighteen months the speed of computing for any given costs will double. The rate of improvement in genomic sequencing technology has moved even faster. This improvement in sequencing technology has resulted in a substantial increase in the amount of data that can be generated about someone's genome.

Let me give you three definitions. There's targeted genetic testing, where you're just sequencing a little bit of gene that you're interested in or a region that you're interested in. There's exomic and genomic sequencing. An exon is a protein coding region; the exome is all of the protein coding regions in the genome. So that's basically your genes, and the exome is the entire set of genes, the entire set of protein coding regions in a given person's genome. And that accounts for, depending who you ask, 1 percent to 3 percent of the whole genome. The genome is the entire body of an individual's genetic material. Just to give you a sense, it costs about \$2,000 to do a whole exome sequence and about \$7,000 to do a whole genome sequence.

A few years ago, it was science fiction to talk about the \$1,000 genome. It's almost a reality now. Whereas it took ten years and a billion dollars to do the first whole genome sequence, now it takes a few days and a few thousand dollars. What does this mean for the ethics of genetic research? The general argument is that the whole exome or whole genome sequencing does not raise novel ethical concerns, but significantly magnifies and makes more concrete many of the risks that have been relatively theoretical to this point. Incidental findings are one of those huge problems. I work with institutional review boards (IRB), and I work with investigators. They're all scratching their heads: "What do we do? We're going to generate so much information, some of which is going to be really important, really clinically important. What do we do with it? Do we return it? Do we not return it? How do we convey this information to subjects?"

There are some IRBs who say, "You know what? We're not touching it. You can't return any incidental findings," and there are other IRBs who say, "You know what? You have an ethical obligation, and we're not going to approve your study unless you come up with a plan for returning incidental findings." I just want to give you a sense. These are some numbers. The numbers themselves aren't

that important, but I have a colleague who just did a whole genome sequence, so I want to give you a sense, tangibly, of what this means.

He was looking at a very, very rare disease. He's not interested in things like cancer or heart disease or schizophrenia; he's just interested in finding the gene associated with this rare disease. And he did a whole genome sequence on a pair of monozygotic twins. The bottom number is the big one, 430 variance. He found 430 variants that he thought could be clinically important. That's a big number. When he went through and checked it really carefully, and this took him days, he got down to about eight likely pathogenic variants and thirty potentially important pathogenic variants. He's looking for these things because he's trained to do this, but this is not part of his research. His research is specifically to look for the gene associated with a specific rare disease, but he's found all of these other things, and the question is what to do with them.

As we're thinking through this problem, we have a paper coming out soon that really challenges the three assumptions that genetic research has relied on. The first assumption is that genetic research will produce very few clinically significant incidental findings, but that's wrong. It's no longer a question of whether clinically relevant results will be found, but how many. The second assumption is that there's this distinction between incidental findings and findings that are explicitly related to the disease under investigation. But that's wrong too because when you're sequencing someone's whole exome or whole genome, your methodology is to look at everything. That's why you've sequenced everything. So, there's really not this clear distinction between incidental and non-incidental findings.

Third, there's this notion of "don't look, don't tell." It's been the norm in the research ethics community that researchers don't have an obligation to act as clinicians and affirmatively search for incidental findings. There's some controversy about that, but generally the view is that you don't have to proactively go look for things. You're not their doctor. You're a researcher. But with whole genome sequencing the act of looking for all possible results becomes much, much easier, and so the question is, "What obligation does a researcher have to look for and return these incidental genetic research findings?" In the research ethics community, there are really two poles, and there's a continuum of positions.

Let me describe the poles first. Some people have argued that there's a very strong obligation—I'm not talking about a consideration; I'm not talking about an option to return incidental findings. Investigators can do whatever they want. If they say, "I feel personally that I need to return findings." That's fine. But this is a question about whether there is, beyond that, a proactive obligation for all investigators who find these unexpected things to return them. And so, some of my colleagues actually have argued that based on the principle of respect for persons, there is a very strong obligation to return research results when a subject asks for them and, even in some cases, where it's so important you have to go ask them to ask you for the research results. Others have argued, based on beneficence, reciprocity, justice, and investigator integrity and professional responsibility, that there's this very strong obligation to return genetic research results.

On the other side of the continuum is this notion that there's no obligation, and in fact, it's probably a bad idea to return incidental research findings. This argument boils down to the notion that the purpose of research isn't to benefit individuals, it's to generate generalizable knowledge, and that there are very real risks associated with conflating research in clinical care. And this has very practical implications for resource limitations. Remember the investigator I told you about only had basically one set of subjects. They were twins with identical genetic codes. It took him two or three days to analyze all that data, looking for those incidental findings. If you have an n of a 100 or an n of a 1,000, can you really expect researchers to spend that much energy looking for things other than the question that they want to answer?

Those are the poles, and I'm setting up a false dichotomy here. In the middle there are quite a few of the more reasonable frameworks. These are some of the papers in working groups that have tried to come up with the way to deal with this incidental findings problem, but they don't agree. There's no consensus.

I ask the question, "Why is this so difficult?" It's not fair to say that there's no consensus; there's some consensus. Most of these proposals have focused on the kind of information that we would want to return. There's a threshold where information deserves to be returned. We can quibble about where that threshold is, but generally, there's agreement that you need it to be analytically valid. You need it to be clinically relevant, you need it to be actionable, you need to be able to do something about it, and it needs to be desired by the subject.

But that's not quite fair, because clinical relevance has proven to be a nebulous term that's hard to define. There are at least four different ways that you can define it, all of which draw the line at a different place. Even this kind of fundamental idea that people shouldn't be given information that they don't want is actually being challenged, and we have an investigator at NIH who puts it in his consent form that there's a certain class of extremely important genetic information, that even if someone checks the box to say "I don't want any incidental findings," he's going to return them anyway. And then there are some very interesting legal issues about analytic validity and whether the Clinical Laboratory Improvement Amendments (CLIA) regulatory regime is appropriate, given the volume of data that we're generating with whole genome sequencing. Most of the people have focused on this notion of the importance of the information, the validity, and the clinical relevance.

There's an emerging idea that I'm exploring, that the obligation to return incidental findings could also be a function of the research context, the study characteristics, and the population's characteristics. And so there, you'd think about things like the nature of the study. Is it a clinical trial? Is it a natural history study? Is it a bench science, a basic science protocol? You think about study resources. For example, does the study have genetic counselors on staff? You think about the investigator expertise. Is it an MD researcher, or is it a PhD researcher? People that have PhDs, not MDs, aren't necessarily qualified to look for and interpret clinically relevant information. The specific aims of the study—is it a broad study? Is it a narrow study? What is the feasibility of re-contact? A

lot of the studies are one-time blood draws where you don't even keep their name or contact information.

Those are study characteristics. You could also think about it in terms of subject characteristics. Do the subjects have an alternate way of accessing the information? Are they dependent on this study for their genetic testing? We had one case where it was an investigator sequencing the BRCA, Breast Cancer Region, looking for a novel variance, but it was foreseeable that he was going to find a known variance in some of the subjects. The question was whether he had an obligation to return that information. The salient fact here is that this was a population that wouldn't have had access to genetic testing and genetic counseling outside of this study.

The degree of vulnerability—and vulnerability is a problematic word—and the depth of the relationship. If I'm a clinical investigator and I have monthly visits with you, that's a different consideration than if I just take your blood once and don't even know your name. Add up all of these study and population characteristics and put them on the Y-axis. The X-axis is this type of information of clinical significance that I described before.

Generally, people agree that the more important the information is, and the more salient research context factors you have, the more obligation there is to return findings. I think we have an agreement that for really important things—where there's a really strong nexus between the subject and the investigator—we should probably say that there's an obligation to return those incidental findings. I think we can also say that for unimportant information—facts that won't impact your clinical care, but might be interesting to you—and in cases where there's not much of this research context nexus, that maybe there's no obligation to return findings there.

But the problem is defining the marginal cases. I'm going to show you two lines defining where the threshold is between that. Because there are some kinds of studies where it's going to be really hard, where there's some moderate relationship, where maybe it's a slightly vulnerable population, where you're going to be discovering some important information. And so, how you draw this line becomes very problematic, and that's part of what my work is about. We're seeing a range of cases, and IRBs are really struggling with this notion of whether there's an obligation to return incidental findings and how to weigh these situational factors.

I've gotten in some pretty—"heated," let's call them—discussions, with some of my colleagues about how hard investigators should look for incidental findings. Some of them utilize a "stumble strategies," thinking, "Well, I've sequenced a whole genome. I'm only looking for the specific information that I'm interested in. If I stumble on something, I'll return it. If I don't, no big deal." But is that an acceptable strategy? Or do they have to have a proactive, systematic approach to interrogating a whole genome, looking for potentially clinically relevant incidental findings? And then, is it appropriate to hold different kinds of investigators to different ethical standards because medical geneticists could come up with a very rigorous way of looking at a genome, but a PhD biologist might not be able to do that? Do research teams have to hire a medical geneticist or genetic counselor? There's an open question

about the temporal limits on an investigator's obligation to look for incidental findings, so what we know now is different from what we will know in five years or in ten years. Do I have to keep going back and looking at this data, trying to find new incidental genetic findings? And how much work should this resource excuse be allowed to do?

At NIH, we're struggling with this. Actually, the whole genomic research community is struggling with this—the NIH Ethical, Legal, and Social Implications (ELSI) Research Program just put out two large grant proposals. It's their big focus, and this next year we'll be funding research into answering this question about incidental findings. So, I'm happy to talk about any of the details in more depth during the questions and answers. Thank you very much.

REMARKS FROM STACEY M. BRANDENBURG***

Good morning. I've been asked to speak on the privacy implications of personalized medicine, and this topic is very vast, and there are any number of avenues we could take. Before I go into that, I just want to say listening to all of this has been fascinating. I appreciate Justin Shore and the Health Law and Justice Initiative for inviting us to participate, because it's an aspect of these issues that we don't always get to delve into. Among the issues that we could look at are electronic health records, the genetic issues, some of which my colleague will address next. I want to focus on personal health records.

When you think of a medical health record, probably most of us envision the manila folders that our doctor brings to each visit and reviews containing our charts and records. That's not exactly what I'm talking about here. What I'm talking about are personal health records. So they are records that you maintain through a resource for yourself. Now, you can grant access to those records to any number of parties, and we'll go into how this would work. But the key here, and what distinguishes these records from those that you typically would find in a doctor's office, is that you have control over this database of information.

Let's talk through how personal health records work. Many of you may have heard of this; some of you may already be enrolled in one of them. Personal health records are typically maintained online, and companies such as Google operate them—Google calls theirs Google Health. What you do to participate is to go into Google Health; you sign up, you create a user name, you create a password,

*** Stacey M. Brandenburg, JD, *Adjunct Professor of Law, American University Washington College of Law*. Stacey M. Brandenburg is an adjunct faculty member at American University Washington College of Law, where she focuses on emerging privacy and information technology issues, including online behavioral advertising, social networking, and identity theft. Previously, she served at the Federal Trade Commission's Division of Privacy and Identity Protection, where she addressed information privacy issues from a policy and enforcement perspective. Prior to joining the FTC, Ms. Brandenburg practiced at Steptoe & Johnson LLP, where she advised technology and telecommunications clients on e-commerce, privacy, and data security issues. Ms. Brandenburg received her law degree from the New York University School of Law, where she was a Truman Scholar. She received her BA in political science from the University of North Carolina at Chapel Hill.

and then you decide how you want to participate. You can give access to your physicians to deposit records into your personal health record, or PHR. You could grant a specialist the right to view your primary care physician's records, which could simplify the process of making a copy, say, of a test that's administered by a specialist and then sending it to your primary care physician. The idea here is to help facilitate your management of your records. In addition to having your doctor's records in a common place, there are other possible uses; you could give access rights to your personal trainer at the Washington Sports Club. She could then upload your training program and track your progress, tell you you're going to run three miles next week at an eight-minute mile pace instead of the ten-and-a-half-minute mile pace you've been working at this week.

You could also take advantage of some of the online applications, and there are many of these out there. There's one, which I just read about, called "Withings," which apparently is a scale that allows you—in real time—to weigh yourself in the privacy of your own home and then upload that information into your personal health record to allow you to manage your weight, your diet, your exercise, whatever it is that you want to do that pertains to your health. Another example of a possible application is to enable a pharmacist to send you, either by e-mail or through a text message, reminders to take a daily medication or to refill a prescription. So you have all this information in one place, and that seems like a great benefit.

One other benefit is that a PHR allows you to access this information, since it's online, from any location. For example, if you have a medical problem away from home, you can log on and obtain whatever information you need to know. Let me give you a slightly silly example, but it's something that actually happened to me. Imagine that you're traveling and you step on a rusted nail. It punctures your shoe, goes into your foot. You find yourself in the emergency room, and the doctor asks, "When was your last tetanus shot?" You have no idea. I had no idea. Well, using a PHR, I could hop on my Smart Phone, my Blackberry, or any available computer and log in and pull up my doctor's records, and answer the question right then and there, any time of day or night.

So far, this sounds like a great resource. So what's the problem? I'm here to talk about privacy implications with personal health care, so there clearly has to be some issue. Well, there are several. Most of them arise out of the unintended, undesired, and sometimes even unknowing disclosure of health related information to third parties. Basically, by placing information on a PHR, you're sharing that information with more entities than those you specifically grant access. So now I'm sure you're asking, "How is that possible if the whole point is that I can control my medical information and I have access to it?" Well, many of the PHRs are advertising supported vendor services such as Google. I don't mean to pick on Google, but it's a brand that you would know, so I think it is a useful example.

What this means—to be an advertising supported vendor service—is that the business model often depends on sharing user patient information with advertisers. This information may be shared in de-identified form, which means that your name and specific identifiers may be separated from whatever information is shared, but there's a catch. Let me explain to you how this might work.

A pharmaceutical company, which would be the advertiser in this case, would come to your PHR, to Google Health, and say, "I would like to serve an ad, call it, 'ad A,' for an acne medication, and I would like it to be delivered to those individuals who are single, between the ages of fifteen and thirty-five, and who suffer from acne." Well, Google Health has all that information on you, and in an anonymous way, it will serve ads. Even Google Health may not specifically know who receives the ad. It will probably collect that information in some sort of aggregate form. It may not say that Stacey Brandenburg fits this demographic, but it will serve the ads, nonetheless. The pharmaceutical company, at this point, has still received no information about you.

Until you click on the ad. As soon as you click on the ad, you are now in that pharmaceutical company's website, or in their database, and they know that they served "ad A" to this particular demographic. And so therefore, they know that you, who are now on their site, have these conditions or have an interest in this product. If you combine that with the fact that most users have cookies on their computers and these cookies may be read by other entities, the pharmaceutical company could probably pair you with this particular health condition. Or, they may be able to learn other information about you, which they could use to then target more ads. That's the next step. Once that pharmaceutical company has this information, there are no restrictions as to how they can use it. They could keep it for as long as they like. They can share it; they can de-aggregate it; they can do whatever they want with it because disclosure to either the PHR or the pharmaceutical company in this case, is not in any way protected. They're not covered entities, so there are no privacy protections for you, as the patient, once your information is there.

Now, there's been some discussion about whether PHRs that are operated in part by a covered entity—maybe the hospital is running its own PHR or a health care plan is running its own sponsored PHR—are covered. In these cases, a PHR could be considered part of a covered entity under the Health Insurance Portability and Accountability Act (HIPAA), but most of these are not. Congress tried to capture the PHRs with some language that it added in the American Recovery and Re-Investment Act in 2009, which said that if a PHR has a certain kind of relationship or a contract with a covered entity, say, with a clinic, it could be brought in under the definition of a covered entity under HIPAA. So Google Health has a relationship, I believe, with the Mayo Clinic, and that arguably would qualify. Yet Google Health states very clearly and very explicitly on its website that it is not HIPAA covered; your information is not protected under HIPAA. This issue is yet to be worked out, but for the time being you can assume that whatever information you've provided is outside the purview of any privacy protections.

This raises a potential concern about sharing health-related information with a third party. By providing your information, even inadvertently, to the pharmaceutical company or to the PHR, you've arguably waived, certainly for the purpose of litigation, a doctor-patient privilege protection. And for those of you who are attorneys, or planning to be attorneys, that's something important

to keep in mind. There's even been some speculation that if you were to view your PHR while, say, on an employer's computer—most employers are explicit when they give you the right to have a computer that they are monitoring your e-mail and monitoring your Internet use. That's a right that they have, and they often do that. If you pull up your PHR and you view that information on your employer's computer, not only have you likely waived the privilege, but you may have inadvertently shared some information with your employer that you didn't intend to share.

The key here is not that PHRs are evil—there are some tremendous benefits to them—but to note that they also pose very real risks, and it's important for users to understand those risks and understand how they choose to utilize them in order to protect themselves. Thank you.

REMARKS FROM MELANIE TEPLINSKY****

Good afternoon. I'm thrilled to be here, and I'm going to be talking about some privacy issues in personalized medicine. This is really a critical time in the field of personalized medicine. The promise of both genomic research and individualized approaches to health care is phenomenal, but our ability to realize that promise is limited. And it's limited, I think, in part, by fear. Americans are very wary of having genetic testing done for fear that their genetic information will be used against them. In a 2000 survey of about 1,200 Americans, 93 percent of respondents, or nine out of ten people, said employers and health insurers should not have access to their genetic test results. More than 68 percent of patients in another survey said that they would not bill their insurance companies for genetic tests, recognizing that these tests are very expensive. They wouldn't bill their insurance companies for genetic tests and clinical oncology for fear of discrimination, and more than a quarter of survey respondents said they would take tests only if they could use an alias.

Patients need to feel confident that their genetic information is not going to be used against them, or the great potential of personalized medicine may never be realized. That's how genetic information privacy was born. Initially, genetic privacy in the United States

**** Melanie (Schneck) Teplinsky, JD, *Adjunct Professor of Law, American University Washington College of Law*. Ms. Teplinsky is an adjunct professor at the American University Washington College of Law. Her area of expertise is cyberlaw, and she has written and spoken extensively in the field. Ms. Teplinsky practiced cyberlaw at Steptoe & Johnson LLP, where she counseled leading financial services, telecommunications, and other multinational clients on a wide array of issues including cybersecurity, data protection, and electronic surveillance. Prior to joining Steptoe & Johnson, Ms. Teplinsky addressed information technology policy issues in the Executive Office of the President. She divided her time at EOP between the Office of Management and Budget's Office of Information and Regulatory Affairs, Information Technology Branch and the Office of Science and Technology Policy. At OMB, Ms. Teplinsky reviewed proposed federal information technology legislation and also developed a comprehensive handbook of federal electronic surveillance law. While at OSTP, Ms. Teplinsky worked on digital intellectual property initiatives, authentication, encryption, PKI and privacy issues. Ms. Teplinsky began her career in 1991 as an analyst at the National Security Agency and continued her technical work at the Institute for Defense Analyses' Center for Communications Research. Ms. Teplinsky is a graduate of Princeton University and received her JD from Harvard University.

largely was governed by a patchwork quilt of federal and state laws. At the federal level, HIPAA, which we've already referenced, the Americans with Disabilities Act, and the Civil Rights Act of 1964 each offered some limited federal protections against genetic discrimination. In addition, about thirty states have genetic privacy laws, and those laws varied widely. One of the problems was that they were inconsistent and sometimes had inadequate definitions of genetic information, and the state laws just failed to provide some meaningful remedies for genetic discrimination. So in the nineties, genetic experts were convinced that reforms were needed. They urged the government to pass legislation, and they urged that it be passed as soon as possible. They wanted to provide all Americans with protection against genetic discrimination and health care and employment.

The first federal legislation was then introduced in 1995. As soon as possible turned out to be thirteen years later. Congress passed the Genetic Information Non-Discrimination Act, GINA. President Bush signed the law in 2008, and GINA plugged some of the most obvious holes in the patchwork quilt of federal and state statutory protections against the misuse of genetic information. GINA effectively set a floor; it set a minimum level of protection against genetic discrimination. The federal floor superseded weaker state laws, but it left state legislators free to enact stronger protections where necessary. Senator Kennedy—the late Senator Kennedy—who co-sponsored GINA in the Senate, referred to it as the first major civil rights law of the twenty-first century because it protects individuals from discrimination on the basis of their genetic information in both the employment and the health care context.

Although GINA is described as an anti-discrimination law, it's also appropriately viewed as a privacy law because it helps to ensure that a patient's genetic information is going to be used only for the purposes that the patient desires. Controlling use of one's information is considered by many to be the touchstone of information privacy. All right, one additional point about the substance of GINA, that GINA actually amended HIPAA. HIPAA itself is probably the most significant federal medical privacy statute in the United States. As you know, it includes substantive privacy protections for protected health information, which is a defined term under the Act. GINA effectively amended HIPAA so that genetic information is now deemed to be protected health information under HIPAA. Therefore, the information is afforded the same privacy protections as other protected health information.

There's general agreement that GINA is landmark legislation and that it removed serious obstacles to personalized medicine, but it isn't a cure-all. First, it protects against employment and health care discrimination. It doesn't protect patients from discrimination outside of those contexts: in obtaining life insurance, disability insurance, or long-term care insurance. Second, it only protects predictive genetic information; it doesn't protect information from a genetic test that's related to a condition a patient already has. If genetic testing were performed on a tumor to form treatment decisions, that wouldn't be protected by GINA. And finally, GINA classifies information as protected health information under HIPAA, so genetic information can be shared without patient

consent, to the extent permissible under HIPAA. This means it can be shared without patient consent in connection with treatment, with payment, and with oversight of the health care system, as an example. So, critics are arguing that GINA effectively legalized the sharing of genetic information among many health care entities without patient permission. Note that to the extent that this criticism is valid, it's really a criticism of the underlying HIPAA regulations and not a criticism of GINA. That said, there are lots of potential weaknesses with GINA, but it does mark an important step in the journey toward genetic privacy.

It really specifically protects two different aspects of privacy. First, it amends HIPAA to apply to genetic information, and in doing so it substantially restricts disclosure of genetic information in the first place. Second, it prohibits the misuse of genetic information once the information has been disclosed.

We kind of have a sense now of the existing legal framework for genetic privacy, and what I'd like to do is take a few minutes to address what I see as the threshold legal question in the creation of a framework for the protection of genetic information privacy, and that question is, is genetic information property? Lots of theorists advocate treating genetic information as property. The leading group of bioethicists who drafted the Genetic Privacy Act have taken the position that certain identifiable genetic information should be treated as property. Numerous states have taken this position in their statutes, many of which were based on the Genetic Privacy Act. New Jersey, for example, has one of the broadest state protections of genetic privacy, and they expressly declare an individual's genetic information is the property of the individual. So, should we use a property rights framework to protect our interest in genetic information? Well, we already conceptualize genetic information as property in some contexts. Federal law allows researchers to patent genes and gene fragments, and some researchers have embraced a propertization of genetic information as a way to reap monetary rewards from their work.

An often heard argument in favor of propertizing genetic information is that genetic privacy protections might be stronger if people thought of genetic information as a property right. Historically, what does property protect? It protects things that are important to us, things like our home and our land. We use the language of property to talk about these things, and property has a very long, well-established tradition. Propertizing genetic information would enable people to take ownership of it and to protect it. In addition, there's a market in personal information already. So propertization of genetic information simply allows individuals to participate in this market because it allows individuals to bargain and to sell their personal information. That's already being done; we're just not participating at the individual level. Treating genetic information as property also gives us control over information. It allows us to make choices about when to relinquish our information and on what terms. And this is true because property rules require a negotiation before a taking. So, for example, I'm wearing a ring. I can sell it to you for fifteen dollars, or I can refuse to sell it to you on the grounds that it has sentimental value to me. No one can take my ring from me without first negotiating with me. Property rules permit me

to waive a right or protect it as I see fit, and they also respect the different values that a person places on something, whether they're sentimental or otherwise.

That said, propertizing genetic information obviously is not without drawbacks. Critics of the model argue that it doesn't capture many of the most important interests that we have in genetic information. Specifically, under a property rights model, genetic information is viewed as a commodity; it is disaggregated from the individual to whom it relates. Under a privacy model, genetic information is something in which we have a dignity interest. It relates to our personhood. Property also connotes control within the marketplace, and it essentially protects economic interests in genetic information. In contrast, privacy connotes a different kind of control: control over access to ourselves. It can protect us against improper use of genetic information in ways that property can't. Another difficulty with propertizing genetic information is the difficulty assigning a proper value to genetic information. Potential future uses of genetic information may be unknown when the information is being bought or sold. It precludes individuals from making an appropriate valuation.

Also, to the extent that a property model invites us to sell our genetic information, one real concern is that we will sell our genetic information and the price will be disconcertingly cheap, as it has been in other contexts for personal information. How many of us have traded away significant amounts of personal information in return for a grocery store discount card or for a free Gmail account? All of us, right? Another concern with propertization is that patients might decide not to sell their genetic information to doctors or to researchers or to sell it for a prohibitively high price. If genetic information were propertized, a patient could enjoin medical researchers from using patient data in certain ways, even if the uses of that data were socially beneficial.

For these reasons, medical researchers and biotechnology companies are often concerned about the availability of genetic information for research. They have a vested interest in making sure the patients can't exercise property rights over their own information. Indeed, biotechnology companies have lobbied heavily against statutes like the New Jersey Genetic Privacy Act because they declare people to have a property right in genetic information. And what's interesting to note here, of course, is that medical researchers and others in the medical community are not necessarily objecting to the treatment of genetic information as property. They're just concerned about the property right being assigned to patients.

So one final point: when we propertize genetic information, there's an issue. Property generally is sold without restrictions on alienability. This means that the buyer of the property is generally free to do with it as he wishes. So you buy my car. I can no longer control what you do with my car. This worked really well when we were talking about cars, but it's unclear how this concept of alienability applies when it comes to genetic information. Just because I decide I'm willing to give my genetic information to my doctor doesn't mean that I want my doctor to be free to use my genetic information as he wishes. And one of the weaknesses

of propertizing genetic information is that it doesn't address this problem of keeping data subject to a variety of different constraints.

Okay, so the point of this whole discussion: we have to take care not to undermine our privacy in our very attempts to protect it. Genetic privacy laws in New Jersey and other states are propertizing genetic information, but it's unclear that the approach is optimal, and as we work to develop our legal framework we have to address these issues and not lose sight of some of the underlying values at stake.

Final issue: regardless of whether we propertize genetic information or not, there may be limits on genetic privacy. In this regard, I want to mention just briefly, a very important case that's likely to have substantial impact on the future contours of genetic information privacy. The case is called *Sorrell v. IMS*, and the Supreme Court granted certiorari just about a month ago, on January 7th. *Sorrell* was the third in a series of challenges to privacy legislation in New England, and it involves the constitutionality of a privacy law that was passed in Vermont. Apparently, when you go to fill a prescription in Vermont, the pharmacy is required by law to keep track of the drug that was prescribed, the doctor who prescribed it, and some information about the patient, most notably, their gender and their age. The pharmacies then routinely sell this information to data mining companies. An example of such a company is IMS. They're a data mining company that collects and sells data on about three-quarters of the prescriptions that are filled in over one hundred countries. As you can imagine, that's an enormous amount of data.

The data mining companies process the information; then they produce very detailed reports. These reports detail individual doctors' practices: for example, what a doctor prescribes, when they prescribe it, and to whom. The data mining companies sell their reports to pharmaceutical companies so that the latter can more efficiently target their prescription drug marketing. Vermont passed a law restricting the use and the sale of prescriber identifying data for pharmaceutical marketing. IMS, one of the largest of these data mining companies, challenged the law, and it's very interesting to see on what grounds. They challenged the law on First Amendment grounds. At issue in *Sorrell* is the extent to which the First Amendment restricts Vermont's ability to regulate the sale and use of data identifying health care providers' prescribing patterns. The Second Circuit in this case said Vermont violated the First Amendment by placing these restrictions. The First Circuit, which looked at the laws in Maine and New Hampshire, came out on the opposite side. They said, "No First Amendment violation." These restrictions were restrictions on conduct and not on speech, and they were permissible restrictions on conduct. There's now a circuit split, and that's how the Supreme Court got the case.

So keep your eyes on this case. *Sorrell* could have enormous consequences for personalized medicine. To what extent is the First Amendment going to act as a limit on privacy? How will the Supreme Court weight patient privacy interest in these matters involving the transfer of sensitive prescribing information? These questions are for the moment unanswered, but one thing is very clear. Patients must feel confident that their genetic information

won't be used against them or the great potential of personalized medicine will never be realized. Thank you.

REMARKS FROM WAYNE ROSENKRANS

Hello! I'm the token scientist on Panel Two. My good friend and colleague Julie DeLoia was the token scientist on Panel One. I don't know who the token scientist is on Panel Three. But because I'm the token scientist, and I'm in a room full of attorneys and budding attorneys, I feel I can tweak you a little bit.

So I want to ask a question. Does anybody in the room know what the Selden Patent is? You who have laptops open, if you get really bored during my talk, you can Google the Selden Patent. The Selden Patent may have something to do with all the patent issues around patenting of gene sequences, in my opinion, that is. And since I'm not part of the federal government, I don't have to give a disclaimer on that. So, let's talk about money, okay? The topic I was asked to address was budgetary considerations of personalized medicine, and my first thought on that was, "Oh my god, I'm a scientist. I can't talk about money." But then I realized I came from industry so I have to talk about money. So budgetary issues, and a lot of the data I'm going to be talking about is coming from several studies that have been done, really, in the last several years—one from Deloitte and one from MIT—looking at return on investment.

I'm going to focus on three broad areas: one is the costs to health care of personalized medicine approaches, one is the cost of product development in the personalized medicine space, and I'm going to make a few comments on reimbursement. You've already heard quite a bit about reimbursement, and then I'm going to just ask some "what if" questions at the very end. And to frame the "what if" questions so you can start thinking about this a little bit, Julie did a wonderful job of going through the science and the technology behind genomic medicine. But, I didn't really hear anybody get up and give a definition of personalized medicine, so I'm going to give you one. This is actually the definition that's been somewhat accepted by the President's Council and by the Secretary's Advisory Council for a definition of personalized health care. Notice I did not say, "personalized medicine"; I said, "personalized *health care*,"

***** Wayne Rosenkrans, PhD, *Chairman, Personalized Medicine Coalition and Distinguished Fellow, MIT Center for Biomedical Innovation*
Wayne Rosenkrans is chairman of the board of directors of the Personalized Medicine Coalition, a distinguished fellow at the Center for Biomedical Innovation at MIT, and a member of the Ethics and Systems Medicine Program at Georgetown University. Dr. Rosenkrans is also vice president for Strategic Consulting at Fuld & Company, focusing on strategic simulations in health care and chief scientific advisor at Expertech, focusing on Air Force Medical Systems. Previously, Dr. Rosenkrans was the director of external relations for Personalized Health care and Evidence-based Medicine (EBM) as part of External Medical Relations at AstraZeneca. Prior to that he was involved in long-range strategy development and R&D policy at both AstraZeneca and SmithKline Beecham. He is a former president of the Society of Competitive Intelligence Professionals and has received the Society's Fellows Award and Lifetime Achievement Award in Intelligence. Dr. Rosenkrans is active on strategy and advisory boards of several organizations including the IOM, IBM Life Sciences, and Hewlett-Packard Life Sciences. He holds a BS in biology from MIT, a PhD in cell and molecular biology from Boston University, and received post-doctoral training in cancer and radiation biology at the University of Rochester.

and that definition runs something like this. Personalized health care is the medically meaningful segmentation of patient populations by whatever technology is appropriate: it might be genomic; it might be imaging; it could be informatic; it could be something we haven't even thought of yet, in order to increase the benefit of therapy.

Notice it's not specific to genetic or genomic medicine; it broadens it out considerably into a somewhat broader concept of personalization of care. So, let's talk about costs to health care of personalized medicine or personalized health care approaches. And I have to reframe that question a little bit. Does personalized medicine have a quantifiable return on investment for the various segments of health care? I'm going to cite a couple of examples, and one's already been mentioned several times. It's in the area of adverse event avoidance, warfarin testing, and this was talked about a couple of times. Let me give you some data. Genetic testing to guide warfarin dosing could avoid 85,000 serious bleeding events and 17,000 strokes annually in the United States. The cost for severe bleeding event is approximately \$13,500. The cost for stroke is \$39,500. You can do the math. Estimate a potential annual health care cost savings from individual dosing of warfarin, based on genetic testing, between \$1.1 billion and \$2 billion, with a range from \$100 million to \$2 billion. What a deal! Pretty good savings on the health care system from a simple genomically based multivariant array test, approved by the Food and Drug Administration (FDA). Evidence of clinical utility was acquired for that approval. Yet as you heard earlier today, it is not widely adopted. And there are various reasons for that. Yes, it is only partially reimbursed by some of the public payers. It is used by the active military—Army, Navy, and Air Force. So since I'm talking about money, let's ask the question. Whose cash cow is being gored by warfarin testing? Where is the testing that is done over a period of seventeen days if you are receiving warfarin to find out if you are hypercoagulated or hypocoagulated? Anybody know? The hospital. The hospital owns the Coumadin clinic. On average, a patient being put on Coumadin/warfarin will spend seventeen days in and out of a Coumadin clinic while they set the dose because, let's face it, Coumadin is nasty stuff, and you've got to be real careful with it.

So how much incentive does a hospital have to implement a genomic test that is going to cut that, say, from seventeen days to a couple of days? You start to see part of the issue here. It is not all about science and ethics; sometimes money gets in the way, too. Let's talk about treatment costs. I'm going to talk about a drug called Gleevec. Most of you have probably seen stories about Gleevec. It was touted a number of years ago and was on the cover of *Time* as the wonder drug for treatment of chronic myeloid leukemia. Not everybody responds to Gleevec, and there is a diagnostic test to predict who will respond which is used in conjunction with a prescription for Gleevec. The treatment cost of chronic myeloid leukemia progression includes chronic phase in-patient costs of \$998 a day; accelerated based in-patient costs of \$1,400 a day; and if you're in rough shape and in blast crisis, \$1,433 per day. For those patients that respond to Gleevec (which, by the way, is not a cheap drug; not quite as expensive as Avastin, but pretty pricey) and we can identify those patients that will respond to Gleevec therapy, that's a pretty good deal, too, isn't it? Avoidance of those

downstream costs, by treatment with Gleevec? And we can identify the responder in populations so there's no futile therapy with an expensive drug?

Now, let's talk about the cost of care, specifically viral genotyping for interferon treatment of Hepatitis C. And by the way, the studies that I'm about to talk to you about were not done by the pharma companies, and they were not done by academia—they were not done by NIH or FDA. They were done by a payer, Aetna, who was interested in finding out whether there were potential ROI from a personalized medicine approach to therapy. And, of course, Aetna, being a major payer, has access to massive amounts of patient information and patient data. They can say to their member physicians, "Here is the guideline for therapy we want you to follow, and we will collect data on the results." The guideline they put forward was mandated viral genome testing for Hepatitis C virus to determine the dose of interferon that would be used to treat the Hep C infection. If you don't get the dose of the interferon right: it is not a pleasant thing, but tailoring the dose to the specific genotype of the Hep C virus could eliminate a lot of the issues around interferon therapy, some of which have to do with compliance—patients tend not to take things that make them feel lousy.

They actually stopped the trial after about six months because what they were finding was astounding. By instituting viral genotyping into the physician guideline for dosing of interferon, they saw changes in the efficacy of the therapy, including changes in compliance, and moreover, they were able to show the savings in treatment costs to their leadership. So, is there evidence of return on investment from personalized medicine-based therapy? The answer is yes. Is it enough? No! We are still in the early days of trying to quantify the actual benefit of therapy for using personalized medicine therapies.

So does personalized medicine have a quantifiable return on investment? Yes, but it's probably going to be horses for courses. Some sectors of health care will derive more benefit than others. There was a study that was done last year by Deloitte which looked at the sectoral differences in return on investment and saw some really defined differences in that return, but through them all, the group that benefited the most, in terms of return on investment from personalized medicine were patients. Payers were sort of plus-minus. It depended a bit on the type of therapy and the area being looked at. The pharmaceutical companies were a bit iffy, again, depending on the area. Providers were routinely positive on the return on investment, but patients were way above all the rest of the sectors. That should drive something.

Let's move on to cost of product development. The costs of developing a new drug currently, depending upon who you read, is something north of \$2 billion. That's an awful lot of money. Now that does include lost opportunity costs, one in ten drugs make it, but I don't care how big you are, whether you're a Pfizer or a Glaxo-Smith Kline, whoever, no company can sustain that level of investment for long. If you simply tack on the cost of developing an associated diagnostic plus—and we haven't really talked about evidence-based medicine here—have to do a comparative effectiveness trial as well, those figures go rapidly north of \$3 billion per drug. The return on

investment is something on the order of four times the development cost. You can't run a business that way. So a lot of people look at the pharmaceutical industry and say, "Why aren't they getting on board with this?" The fact of the matter is, they're behind the eight ball, big time right now. And you're starting to see some of the effects.

There is increasing recognition in the industry that if we keep going the way we are currently developing and commercializing products, whether it's a pharmaceutical product or a drug device (and you heard it, all the issues are about regulation and reimbursement for devices as well as pharmaceutical products) that return on investment is going to drop steadily, and it will kill innovation in new product development in this country. We have to rethink the way products are developed. We have to start looking at associated diagnostic development at day one of the development process, not the end, which is where it is done now. We have to start building in plans for doing comparative effectiveness research, guided by a diagnostic comparison in an effective way to start to bring that development cost down. There's been some figures done, at MIT that we may need to completely rethink the entire development process. That means rethinking the regulatory process as well. And you've heard all the problems around laboratory development tests. Those are going to pale in comparison to the rework that we need to do on the development process.

Reimbursement, again, we heard about that at the beginning of the first panel. In terms of real world immediate things that have to get done, we have to fix reimbursement for medical devices and associated molecular diagnostics. Pharmaceutical products are reimbursed on the basis of their value to medicine. This drug, and you have produced data for that (that's a lot of the \$2 billion cost of development) benefits patients and medicine this way. Therefore, we will approve coverage and reimbursement at this level. That doesn't happen for diagnostic tests, no matter how sophisticated the test is. Right now, if you go to the trouble to develop a diagnostic product, and you put it either through the FDA processes or through the CLIA process, you will likely be cross-walked to something that vaguely looks and smells like this test for your reimbursement rate. And guess what? It's nowhere near the reimbursement value of the pharmaceutical product, even for a linked product. And not only that, if you are a good boy—you take your tests, and you go back and you have a six-step test and you make it a two-step test, you pull some steps out and make it easier—you've just cut your reimbursement by two-thirds because you now have a two-step test rather than a six-step test. What's the incentive? What's the ROI for a diagnostic company to play that game for much longer?

And part of this is indeed the relationship between pharma and the diagnostic companies, in terms of companion diagnostics. Part of it is still the conundrum or the murkiness at FDA, which hopefully, is about to get resolved. All these things are in play, but at the bottom line, it comes back to who's going to make the investment and what is the return on that investment? From a company, from society, from its governance. Now, I'm going to ask some of the "what if" type questions. There's always been some interesting dialogue going on among the intelligentsia in personalized health care around evolution of the "p." The "p" in "personalized medicine,"

or the "p" in "personalized health care." Today, that "p" is defined as "prescriptive care." You go in to the doctor; you present with symptoms. He may or may not choose to do a test; he reacts to that test; he puts you on something or gives you some sort of therapeutic modality to take care of you. You may or may not comply. In most cases, you don't (there's a lot of statistics around that) and part of that is because you really don't know what is going to work for you.

So the doctor engages in essentially trial and error medicine until they find something that works for you. In the meantime, it's costing an awful lot of money. It may or may not have been futile, in terms of your therapy, if not toxic to your actual well-being. Well, what we want to do is move the "p" from being "prescriptive" to "precision." We'll use a diagnostic test, an informatic test, whatever, to increase the precision of our diagnosis so that we may treat you more effectively. We will increase the benefit of therapy. Well, then, where after that? The most usual interpretation is we're going from "precision medicine" to "preventive medicine." We will figure out what's going to be wrong with you before it actually happens to you, and we make sure it doesn't happen, either to be watched, changed, or some palliative therapy ahead of time. The problem is nobody will reimburse for that right now; no single payer will reimburse for preventive therapy right now. A lot of the genomic research being done—and it's good research, and it should be done, and it needs to continue—centers around how to predict disease, yet the system is not prepared for that.

The next "p" that people talk about is "participatory medicine," "personalized records." How do we move to true patient-centric care? Right now we have provider-centric care. Even in the widely touted medical home concepts that are being thrown around, they are still provider-centric care. How do we move to true patient-centric care, where the patient is completely and optimally positioned in their own care decisions, using genomic information to help make their joint treatment decision with their caretaker? That's a ways away, and we don't even know how to think about that one in terms of ROI.

And there's a last "p" that's just starting to be discussed. It's called "performance medicine." I'm not going to say a whole lot about this one because it is very new, and I'm not sure I want to go there. When the "p" actually equals "preventive medicine," will we reap the benefits of improved personal health? When the "p" equals participatory medicine, will we reap the benefits of improved community health? Can we even measure that right now? Not very well. Thank you very much.

QUESTION AND ANSWERS

QUESTION: You said a lot about a lot of states and federal things moving to propertizing genome or genetic information material. Have you seen any states moving towards a privacy version of that? And is that changing?

STACEY BRANDENBURG: Yes. It is, actually, and it's something that is still in flux across the country, in terms of information and privacy more generally. We haven't yet figured out what the right model is or if there's one model that's one size fits all, or whether

it needs to be based on the context and genetic information. It does seem to be that property is the dominant model.

QUESTION: Are doctor records comprehensible to you, and do you have access to them? Does their availability have a chilling effect on what your doctors write?

STACEY BRANDENBURG: Good questions. Your records, including your doctor's notes, you have a right to obtain them. Whether you can decipher their handwriting, their notes, it's a short form that's left to you and your doctor to work out. As for the chilling effect, it depends on the purpose for which the doctor is writing that information down. If the doctor knows that you are going to be posting those records and you have a particular, there are certain sensitive illnesses, which it is not acceptable, it's not legal for that doctor to be disclosing to be shared. HIV is one of them. So, if you communicate with your doctor that you are planning to put those records in a PHR, and the PHR may be one that is a third party entity, it's possible that you have a conversation with your doctor about the fact that you're going to do that, and, "Can you not make some particular notes?" But I would think that—and I don't know that much about the ethics for the physician—the physician has to put in his or her records what accurately represents his or her treatment of you. I think there are conversations that doctors have that are sort of a sidebar, for instance, with insurance companies: "Can you code this as an X because this is how I will receive, how it gets under my insurance plan?"

So those sort of sidebar conversations do occur, but as for whether the doctor is going to somehow change what is reflected in his or her records, I don't think that would be within the ethical bounds of what is appropriate. Will they think twice about writing something in a record because they know that they could be exposing something? It's possible, but I think that really is an issue that is probably not entirely appropriate for the doctor to be engaging in.

QUESTION: As a follow up, doesn't that diminish the value of that doctor's records?

MELANIE TEPLINSKY: Let me take a stab at this. There are two kinds of records. There are personalized health records and electronic health records. And personalized health records are the records that you yourself choose to put in a cloud or wherever else that belong to you. Electronic records are the doctor's records, and doctors typically claim ownership of them. So, to the extent that the doctor has a duty of confidentiality to the patient, if the patient is putting the records online, there's no issue because the patient decided to put those records online. It's a consensual decision. To the extent that the doctor holds the records, the electronic health records issue, that's a separate issue with a whole host of other policy issues. But the doctor's speech wouldn't be chilled in that case because there is no giving of the doctor's records to a third party. The doctor's records are being held by the doctor; they're just in electronic form. So, I think they're very distinct issues.

WAYNE ROSENKRANS: When you're going to flip it around a little bit, does your doctor know what's in the medical record? And can he interpret what's in the record? And I mean that not sort of frivolously for two reasons. One, as genomic, medically

useful genomic information becomes available—and we're getting more and more—most physicians that are practicing today cannot interpret that information. It's an appalling statistic. It used to be six medical schools in the entire country actually taught a class in genetics, much less genomics. I don't think it's quite that bad anymore, but at one time it really was there. And then you look at the business plans for some of the DTC genomic, consumer genomic groups. I'm not going to talk of them by name, but the expectation is that you buy your sequence from them. For that portion you order, they send you a report, and you are urged to share that report with your physicians. Ninety-five percent of physicians in America cannot interpret that report, so it really does become sort of meaningless information.

There's another sort of interesting build on the personalized health care side as well. Cleveland Clinic and Mayo Clinic are experimenting with it as well, something called a tethered PHR, which is actually a patient portal basically into their electronic health record. And rather than having two completely separate, one is linked to the other one. It's a very interesting concept, but they are dealing with issues of, "Where's the cut? How much data is shared?" And part of that is if a Cleveland Clinic patient leaves Northern Ohio and goes to San Francisco, and that patient wants to take his or her records along, which is really a lot of what was intended, does that elicit a different level of download into a protected area on your thumb drive or something like that, that you take with you to your other physician? But all these issues are generating some very interesting solutions as well. There's a tool called Archimedes, which is actually available from the American Diabetes Association website. It's sponsored through Kaiser. If you're a Kaiser patient and you have diabetes and your physician is thinking about putting you on a new diabetic therapy, you can go on to Archimedes, push a button, give it some information about who you are, and the Archimedes tool, which is basically a disease model, goes out and pulls your electronic medical record data from Kaiser, plugs it into the model and spits back data to you as a patient in a digestible format of what you can expect from that new drug therapy.

And when you start to think about if that became very widespread—and Cleveland Clinic is experimenting with something along the same lines—you have this incredible potential for the consumer and the patient to really take some ownership, and we start to get toward participatory care, but then you run into all these other issues which become very, very difficult to negotiate. One of my old mentors was a gentleman named Dr. George Post, who was head of R&D at Smith Kline. Back in the early nineties, I kind of asked him this question, and what he told me and what I think might actually come out is, "Where is the greatest benefit?" If the ethics and the privacy considerations get in the way of deriving benefit, ultimately they will work out, but there will be a lot of chaos in between. I think we are just starting to tip into the chaos side.

MODERATOR (Lindsay Wiley): Thank you so much. I hope you will all join me in thanking our panel.