Panel 3: Moving Forward: The Goals of Personalized Medicine and Consumer Participation

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OPENING REMARKS FROM ROBERT DINERSTEIN*

My name is Bob Dinerstein. I’m the director of the clinical program here, as well as director of the Disability Rights Law Clinic. I’m proud to have this last panel with Donna Cryer and Amy Miller. We’re going to hear first from Amy, who is the public policy director of the Personalized Medicine Coalition, and then we’ll hear from Donna, who is described as a passionate advocate for personalized medicine and serves on many boards.

REMARKS FROM AMY MILLER**

Thank you very much for the introduction. I am Amy Miller, the “passionate” public policy director of the Personalized Medicine Coalition (PMC). As Wayne Rosenkrans said, I guess I’m the scientist on the panel. I’m a National Institute of Health (NIH) trained researcher and left science to do policy and have been in policy since. I think that I want to start today by saying, I’ve never spoken to a group of law school students. I remember the first time I spoke to a group of medical school students. I was very nervous, so I just want to let you know: I don’t have a medical degree, and I don’t have a law degree. Keep that in mind. At PMC, we work to break down barriers to personalized medicine. Throughout the day, you’ve heard different barriers, probably mostly the regulatory and reimbursement barriers, but there are other barriers. And I’ll get to those in a minute. But I want to start in a way I don’t usually start, and that’s with a story.

At PMC, we had a bit of a wake up call this week. We received an email from a woman, who the executive director of the Personalized Medicine Coalition has known for a long time. The email said, “I’ve written this Op-Ed. I’m trying to get it published. I’m having trouble. Can you help me out?” And it was about her dying wish—she was dying of cancer. And Edward Abrahams, president of the Personalized Medicine Coalition, said, “Yes, absolutely I’ll help you out. I’ve got some press connections at these entities. Plus, we have a newsletter. We’ll publish it in the newsletter no matter what. Let’s see what we can do.” She got it published on Forbes’ online blog. It also will be in the next upcoming issue of Forbes and in our newsletter. She died the day of Health (NIH) trained researcher and left science to do policy and have been in policy since. I think that I want to start today by saying, I’ve never spoken to a group of law school students. I remember the first time I spoke to a group of medical school students. I was very nervous, so I just want to let you know: I don’t have a medical degree, and I don’t have a law degree. Keep that in mind. At PMC, we work to break down barriers to personalized medicine. Throughout the day, you’ve heard different barriers, probably mostly the regulatory and reimbursement barriers, but there are other barriers. And I’ll get to those in a minute. But I want to start in a way I don’t usually start, and that’s with a story.

* Robert Dinerstein, JD, Professor of Law and Director of Clinical Programs, American University Washington College of Law. Robert Dinerstein is professor of law, director of clinical programs, and director of the Disability Rights Law Clinic at the Washington College of Law, where he has taught since 1983. Professor Dinerstein was the law school’s associate dean for academic affairs from 1997-2004. He specializes in the fields of clinical education and disability law, especially mental disabilities law (including issues of consent/choice, capacity and guardianship), the Americans with Disabilities Act, Civil Rights of Institutionalized Persons Act, legal representation of clients with mental disabilities, the interaction between disability and the criminal justice system, and disability and international human rights. Mr. Dinerstein was appointed by President Clinton in 1994 to serve on the President’s Committee on Mental Retardation and he has consulted for the World Health Organization regarding the revision of mental health laws in Ghana and Malawi. Prior to WCL, Mr. Dinerstein worked as an attorney in the U.S. Department of Justice’s Civil Rights Division, Special Litigation Section, where he handled federal court cases on the rights of people institutionalized in mental hospitals, institutions for people with intellectual disabilities and juvenile institutions, prisons, and jails. In addition to the Disability Rights Law Clinic, which he founded, he teaches a seminar on law and disability and has taught interviewing and counseling, legal ethics, the supervised externship seminar, and the criminal justice clinic (which he directed from 1989-1995). He currently serves as chair-elect of the AALS section on law and mental disability as well as the secretary of the section on disability law. He has an AB degree from Cornell University and a JD degree from Yale Law School.

** Amy Miller, PhD, Vice President, Public Policy, Personalized Medicine Coalition. Dr. Amy Miller is the vice president of public policy for the Personalized Medicine Coalition (PMC), which represents a broad spectrum of academic, industrial, patient, provider, and payer organizations that seek to advance the understanding and adoption of personalized medicine concepts and products for the benefit of patients.

Dr. Miller works with these communities to reach consensus on policy issues impacting personalized medicine and share those views with policy makers. Before joining the PMC, Dr. Miller worked in the office of the Director of the National Institute of Mental Health where she served as a liaison among the scientific community, the legislative branch, and the consumers of mental health care and their families. A former AAAS fellow, she also served as a domestic policy advisor to Senator Jay Rockefeller. Dr. Miller received a BA from the University of New Orleans and holds a doctoral degree in human development from the University of Connecticut.
it was posted online, February 9th. It kind of shook us up at PMC. We do have consumer advocates, who are part of what we do, but mostly it is scientists and industry members and some academic members. It shook us up to have a consumer advocate reach out to us and say, “This is my dying wish to have my Op-Ed published,” and then die on the day it was published.

You can probably tell I’m a little emotional about it. Her dying wish is what we exist to do, which is break down barriers to personalized medicine and her specific call was for policy makers to break down barriers like was done for the Orphan Drug Act. So she was asking Congress and personalized medicine entities to make more personalized medicine products happen. She had benefited from one called Herceptin, an anti-cancer agent that she says made her life last a decade longer than it would have otherwise. And she died at 41, and she said, “I want others to have this gift of a decade that I had, and I also want there to be more personalized medicine products, not just this one, Herceptin.” You’ve heard of others like Gleevec. And there her dying wish is our mission. That was pretty interesting, so I’m glad Wayne Rosencrans defined personalized medicine.

When you speak to a group of MDs, they say, “Oh, we’ve been practicing personalized medicine since the dawn of time.” And then we have others who want to debate: Is it personalized medicine? Is it individualized medicine? Is it personalized health care? Whatever, we got stuck with personalized medicine, so we’ll go from there. Personalized medicine is targeting medical treatment to individualized patient characteristics. That’s the definition I work with. And why do we want to do personalized medicine? I was talking to my husband about Adrianna, the woman who passed away, her wish, how we can get there faster, how we can shake up the system and move this along, especially with the split Congress and especially when it’s kind of technical and “niche-y.” And he said, “Well, you know, you talk about medicine today as kind of random and kind of not scientific. You know, you go to the doctor, they give you a pill, it doesn’t work, you come back, get another pill, or a newer pill. And you keep doing that.” He said, “That’s ghastly. We’re going to look back and say that’s like bleeding with leeches.”

I’m thinking that yes, one hundred years from now, people will consider that trial and error medicine is like bleeding people with leeches. It’s ghastly; it’s illogical; and it’s definitely not scientific. So why do we have this push for personalized medicine? It’s because we want more effective cures sooner rather than later. We want to avoid all of the cost and quality issues that come with trial and error medicine. We can save the health care system money. We can skyrocket the quality of health care and the quality of patients’ lives. Not to mention, we can extend life. So this is why we want personalized medicine. I mentioned that PMC exists to break down barriers. You’ve heard some of them, and I’m just going to go through my list so you know what I focus on. One is business model barriers. This is what Adrianna was specifically focusing on. She was saying drug companies develop drugs. They go through this drug pipeline, and then they are sold to everybody. Now, for personalized medicine to work, a drug company needs to partner with or own a diagnostic unit and develop those together. And then those two things have to go through the regulatory path at FDA, which has two separate groups of people that don’t particularly like each other and don’t particularly talk all of the time.

Then, when you go to pay for it, usually people pay for a drug based on what it costs to develop it, plus a little more. But with diagnostics, you heard Wayne Rosenkranz talk about the stack, and if you make your test better, you’re penalized by getting paid less. That’s if it’s even covered at all. As discussed by the fist panel, sometimes they’re not even covered. Well, what does that mean for personalized medicine when you’re trying to develop the drug? You also have to consider the business model barrier with pharmaceutical companies being very large and established and having a history of buying and selling diagnostic units. And then you have diagnostic companies who tend to be small, entrepreneurial, and to meet up with “big pharma” to develop a business model, and it’s not working for anyone.

We also have comparative effectiveness research—which Wayne alluded to briefly as a federal effort to say we have to pay for what works. And then there’s a parenthesis, for the most or for whom, depending on your slant. And at PMC, we advocated successfully for a comparative effectiveness policy on health care reform that would recognize personalized medicine. And that’s in implementation right now. I’m a little worried that maybe we are going to pretty standard CER [comparative effectiveness research], what works best for the most. Are you going to pay for the blue pill or the red pill? It turns out most people do well on the blue pill, and the blue pill’s pretty cheap. So that’s all that we have now is blue pills. But what if the blue pill does not work for you? Do you not get your extra decade of life? This is a real question.

We also have some education issues. There’s consumer and physician education. But we need to think about how to get personalized medicine into actual practice. For example, warfarin testing is a business model barrier. You’re taking away profits from hospitals to do a fifty dollar test or maybe a one hundred dollar test. And doctors are very comfortable with the way warfarin is dosed right now. Traditionally, age, sex, gender, weight, and things like that account for 20 percent of initial warfarin response. Having the genetic indications, that’s another 20 percent. So you’re doubling your predictive power. It sounds good to me. It is rat poison. I know Wayne said that like it was a joke, but it’s not a joke—that’s what it is; it kills rats.

So, we need to think about how to convince physicians that yes, it’s a little different, it’s a little something new, but you’re doubling your predictive powers, so why don’t we use that? And we need to educate them a little bit about personalized medicine. Maybe it’s premature, but my grandmother had a lot of trouble with warfarin dosing and was on it forever. And my aunts are from Louisiana—not the healthiest group of people. But my aunts were talking about what if we have to go on blood thinners with all of these heart problems and blood pressure. I told them that there’s a fancy-pants new test that can help you get to warfarin dose faster than Mimi, my
grandmother. And they asked, “Is my doctor going to give it to me?” And I said, “No, you’re probably going to ask for it.” And the look of absolute horror on their faces was quite comical. But many patients are not used to having a dialogue about knowing what works best for me, and tell me if this is going to work best for me.

Now, the irony is that we have a lot of problems with patients taking the drugs they’re supposed to be taking. I think it’s because inside they know it’s kind of trial and error. It’s random. There are no real facts about how this is going to respond for them. There’s a lot of power in saying, “This drug might not work for everyone. But it will work for you. And we know this because X.” I know you’ve already heard a lot about regulation and reimbursement issues, but I think the time is right for these issues to be solved. We have more and more personalized medicine products, a pharmaceutical industry that is shedding jobs, and a pipeline that’s drying up. I feel like there’s a lot of finger-pointing about who is responsible for the pipeline drying up: pharma points to FDA, and FDA points to pharma. I think everybody needs to point at science. The science is moving it towards personalized medicine. I think all of the easy molecular entities were discovered, and now there are more targeted therapeutics because we know more about science.

Now we need the regulatory system to catch up. We need the reimbursement system to catch up. We need the medical care system to catch up. So, that’s what I spend my day doing. Thank you for inviting me here today. I look forward to your questions.

REMARKS FROM DONNA CRYER***

There’s a blessing and curse to being the last speaker of the day. At its best, I could come off looking wise and sage and summarize this and give you the most poignant take-aways as possible. But, all my best lines have been taken already. And certainly following Dr. Miller is always a hard act to follow.

We have a robust personalized medicine practice. Our president is here today, and he’s a pharmacist and has extensive training in genetic diagnostics and with payers. We have a chief medical officer who is actually a geneticist by training and did some very early work in pediatrics and lipid metabolisms and genetic pathways and things like that. And I don’t think that they chose me or made me come to this because I’m a lawyer and they wanted me to speak to my people.

I think it’s really because I’m the closest to an actual consumer that there is in the company. The rest of the company is burdened by knowledge. Clearly Dr. Miller is the scientist on our panel; I am not. So as today’s presentation is “Drugs, DNA, and You,” we’ve come to the “You” part. How do we get “You” to really enjoy all of the benefits of personalized medicine that we’ve heard today? What does it mean to a consumer to be participating in what we’ve recognized to be a robust and growing field? So I think that, first and foremost, consumers are confused, and my remarks, you may decide, reflect that confusion, but that means I’m exactly on point and accurately representing how most consumers feel about personalized medicine. First of all, the field can’t even decide on a title—there is no nomenclature, and as we know as lawyers, words matter. Do you call it “personalized medicine”? “Genomic-based medicine”? “Genomics medicine”? “Preventive medicine”? “Predicative medicine”? “Precision medicine”? “Participatory medicine”? “Performance medicine”? Please decide for the consumer because we need to know.

It was interesting and sort of validating to hear my husband, the geneticist and chief medical officer of the company (yes, it’s a little nepotism HR trick you can really only do once) remark after reading in this week’s most recent issue of Science a commentary that the human genome has not, in fact, been sequenced. How many of you have read in newspapers that the genome has been sequenced and, thus, everything else will follow in due course? Well, someone finally said the emperor has no clothes, and the human genome has not in fact been sequenced. It’s an outline, and there are some gaps. When my husband, a geneticist, was confused as to that fact and someone else pointed out what he believed was not true in the consumer because we need to know.

I don’t think that this is going on. Their aunts in Louisiana are wondering what this means to them. I think the role of all of us today is to really figure out what it means to them. So I thought, as a way of summary, to put together very simple graphics. I went to law school a long time ago. I think we had PowerPoint, but not really. You certainly didn’t get it for moot court, so this is my one slide. As part of the profession that created the filibuster, I could talk for at least three or four hours on this one slide, but I won’t. I did want to point out, usually I like to be part of the first panel because part of patient advocacy is putting patients first. I’m glad to go last because I think it better makes the point that so many things need to happen.

*** Donna R. Cryer, JD, Chief Executive Officer, CryerHealth. Donna R. Cryer is chief executive officer of CryerHealth, a health care consultancy based in Washington, DC, providing advocacy and alliance development expertise to top pharmaceutical, biotech, and diagnostic companies, as well as the largest patient and physician associations in the United States and abroad. She is dedicated to ensuring that the voices and views of patients and physicians are heard in health care decision making. A liver transplant recipient, Mrs. Cryer is a frequent blogger on patient advocacy issues under the name, DCPatient. She has been named to a five year term as a Patient Representative to the U.S. Food and Drug Administration and elected as the first patient to be chair of the board of the American Liver Foundation. An alumna of Harvard and Georgetown Law, Mrs. Cryer has been featured on CNN, Fox News, CBS Evening News, and NBC News. Her recent speaking engagements have included National Institutes of Health, American Association for the Advancement of Science, American Academy of Nursing, World Health Innovation and Technology Conference, and Princeton Medical Center. She serves on the advisory committees for the Women’s Health Institute at Howard University and the Institute for Patient-Centric Design, the board of the Mid-Atlantic Chapter of the Health care Businesswomen’s Association, and is a member of the Women Business Leaders of the U.S. Health Care Industry Foundation, the American Society of Association Executives, and the Virginia State Bar.
before we actually get to the consumers actively understanding and engaging personalized medicine.

So we need industry innovation; we need a reimbursement framework that makes sense and values the innovation; we need physician adoption of these tools; we need a consensus about privacy and ways that this information will be used; and then we need some type of standardized education for consumers so that they can integrate this into their daily lives. All of that needs to happen before we can really talk about personalized medicine being a reality in practice.

I think amongst all of the definitions consumers or patients think about it in at least these terms: getting the right drug to the right patient in the right dose at the right time of disease progression. As Dr. Rosenkrans on the last panel pointed out, personalized medicine is perceived particularly from the consumer’s standpoint and much more than just a gene-based therapy. Consumers have some vague notion if you at least relate it to CSI, but for the most part, it really is thinking about a personalized service, personalized information, a tailored diagnosis, a solution—whether it’s a pill or an intervention—that’s right for me as an individual, and delivery of that in a service model that recognizes my humanity and dignity as a person, as a whole person, and not just a list of symptoms or a collection of data.

I think when consumers and patients talk about personalized medicine, they’re really integrating all of these factors into their common definition. As you can see from the slide, the primary hurdles to having personalized medicine in active practice are primarily about basic knowledge of genes and genomics and trust in the system. There are ethics issues, privacy issues, and just sort of personal-cultural issues in a transformation in how we understand medicine that need to take place as well.

So a little bit on each piece of the framework: industry innovation.

We’ve had fabulous speakers today on that, but I just wanted to make the point from a consumer's perspective that it’s hard for them to distinguish between diagnostic tests that are done in the CLIA [Clinical Laboratory Improvement Amendments] certified lab—nobody knows what they do, outside of here, those of us who work in this building know what CLIA is. What are well-validated tests that are conducted in CLIA-certified labs versus what you might pick up at CVS? When consumers are discussing it, they’re not really making the fine distinctions between those tests that have gone through establishing a certain level of clinical utility and validity and gone through a regulatory process, and those that are supposed to figure out if you have a naturally happy personality or you’re supposed to be on the caviar diet and eat more red meat. We haven’t really taken the time to explain to consumers the differences between these types of tests, and I think that’s very important. Another important distinction to make for consumers is the difference between risk assessment and relative and absolute risk.

Consumers aren’t really good with math. (Many of us lawyers aren’t either. That’s why we went to law school.) But to be able to distinguish between tests that affirmatively diagnose a disease versus those that give information, such as, “You have a two fold increase of risk for diabetes” is something that needs a fuller explanation to patients in terms of how they integrate that, how they respond to that, and how they integrate that into discussions with their doctors. So the difference between validated diagnostic tests and some home-based tests, the differences between definitive diagnostic tests and risk assessment tests are things that are important to consumers. We had quite a bit of discussion today about companion diagnostics and that language and targeted therapy, so I won’t repeat myself.

On the reimbursement framework—others before me have done a really great job. I think one of the ways that consumers can participate in that process is to help payers to find the true value of a test. I’ve done so as a patient for a test that I’m privileged to use to guide my care and to guide the clinical decisions that my doctors make. There is input from multiple stakeholders about what physicians value in a test, what clinical data they get back, what other members of the scientific community value in a test, but short thought is given to quality-of-life issues or other issues that patients hold dear. My law school experience was shaped by the fact that I had a liver transplant between first and second year. So you think second semester recruiting is hard, try doing it from intensive care.

So I use a test, an immune system assay test. It’s a blood test that gives information back to me and my doctor about how my individual immune system is reacting to the immunosuppressive drugs that I need to take. The Center for Medicare & Medicaid Services (CMS), as we’ve discussed today, didn’t want to pay for the test. Amongst the various arguments about return on investment and code stacking was my ability to let CMS know the impact that it would make on patient care. Yes, it was pennywise, pound foolish for them to not pay a few hundred dollars for a test when they pay thousands of dollars for somebody to be retransplanted, but what I was able to get across was the certainty that it gave to me that my treatment was correct; the faith and the trust that it gave me that the medication regime that I was on was the right one for me; the ability to know that I could avoid potential rejection, potential hospitalization, potential cascades of other medications by using this one test.

And so consumers and patients do have a role in helping to establish the value proposition, if you will, for personalized medicine, particularly in the diagnostic area. Dr. Rosenkrans also talked about physician adoption. I’m very lucky to be married to one of like ten geneticists in the country, it seems. There’s little genetic training in medical school to this day, and there are very few genetic counselors. It was interesting, as we discussed, that payers have funded a lot of the studies that have produced some meaningful effect. For example, Medco Health Solutions recently made a $5 million commitment to open a new school of pharmacy at Fairleigh Dickinson University to make sure that pharmacists have the background and training to deal with this new landscape of genomic-based therapies.

For consumers, it’s vitally important that as much as there are new direct-to-consumer appeals (and I’m all for having an empowered and engaged consumer) we need all of our health care professionals
to really be equipped to understand, to interpret, and to use this new information in guiding our care. So when we talk about consumers specifically as a segment (not industry, reimbursement, or physicians—privacy has been addressed by others) we’re talking about what it would take to have consumer understanding. Scientific and health literacy is low. Numeracy is low. It’s very hard to have consumers deal with and interpret a host of sorts of more common, more accessible health care information or conditions about cardiovascular disease or breast cancer or things without asking them to understand pathways and other things. There needs to be some groundwork laid to be able to discuss genomic medicine or personalized medicine with consumers.

What’s available in the popular media that connects with consumers are things like, “Oprah got her genes tested.” That’s great, and so now we know which tribe in Africa Oprah came from. That’s what consumers know about family history. They’re not thinking really about how family history paired with new genetic information can be used to help fill in the gaps and understand and predict their risk for disease and guide their therapy. I think there’s a bit of calibrating expectations that needs to be done with consumers and patients as well. While on one hand, there’s almost no knowledge of science; there’s a great faith in science and what it can do. And there is a long way to go in terms of using genomic-based therapies that still has yet to be realized. The FDA has only recognized thirty biomarkers as valid to be associated with an approved drug label, so there’s a long way to go, and we need to get consumers on the train now, but we need to calibrate their expectations of when and how [genomic-based therapies] can actually impact their care.

One of the most important things to come from an earlier discussion on consumer engagement and health IT is the idea of informed consent. Engagement is much more than education, but how you truly engage consumers in this? And how do you convince them to consent in, opt in, and fully participate in this process? I think that rolling up all of the other points of information, laying the groundwork now on all of the elements: health, numeracy, this new layer of genomic information, connecting it to relatable events—whether it’s Oprah or CSI—and involving patients in this can provide the opportunity for truly informed consent and having true patient participation in this process. I think the goal should be consumer participation in personalized medicine.

**QUESTION AND ANSWERS:**

**QUESTION:** Question about safeguards for consumers of health care. We’ve heard a lot about the benefits of personalized care, but Dr. DeLoia earlier used the example of a forty-eight-year-old woman with breast cancer, and perhaps chemo she wasn’t even 40 percent, that based on her genetics they don’t think it would be effective. Her doctor thinks that it would be medically necessary. What would be the safeguards?

**DONNA CRYER:** You know, there is at least a perceived—if not inherent—tension between personalized medicine and evidence-based medicine or comparative effectiveness research. I think though—and Amy can speak to this—the work of the Personalized Medicine Coalition has really shown that they’re not in conflict. There will always be outliers. I’m an outlier. I think that an overwhelming number of cases, as we grow the body of evidence and become more comfortable with using evidence-based care, rather than intuitive care, perhaps, is a good description of how it’s been done traditionally. Not only prescribing treatment because you’re in the 40 percent that does well on this drug; but also being able to explain and have a comfort level with the discussion with the patient that you’re, in fact, not in that 40 percent that does well on this drug, and we need to try something else or there is currently nothing else, I think, is probably the more ethical way to go.

**AMY MILLER:** I think we need to add to it the idea that chemo isn’t aspirin. It’s a very nasty drug. When there’s a very good chance this chemo is not going to be helpful to a patient, then you’re saving the patient a very unpleasant experience and the potential health detriments associated with chemotherapy agents down the line. And breast cancer treatment is not so black and white—which chemotherapy agent do we use? Do we use the standard Taxotere, or do you use an AI? Is there a great chance of recurrence or not? Personalized cancer care is way ahead of many other diseases, and it’s not perfect yet, but again, it is a bit of information the clinician takes into consideration. If that woman has a crazy family history of breast cancer, they might be a bit more aggressive than if she’s the only one for example.

**ROBERT DINERSTEIN:** It’s interesting because, when thinking about personalized medicine, we also have to think about the way in which individuals process information and predictions in different ways. I also very much take the point that we’re not very good at understanding math, science, and even why we make decisions the way we do. A friend of mine just got diagnosed with breast cancer. In going over some possible treatment alternatives, one choice presented to her was “if you go this route, you have 25 percent chance of recovery, and if you go this other route, you’ll have 20.” But there was a difference in terms of the side effects. And she told her friends, I’m not willing to go through this kind of bad treatment with side effects just for another five percent increment. But some of her friends, who heard it, said, “My god, why wouldn’t you do anything to increase your odds? I mean going from 20 to 25 percent that could be the difference.” Again, there’s no right answer to it. But what she was saying is based on her own experience about how she could predict she would respond to the side effects. She thought, “I’m not ready to die, but I really want to gauge this as to whether this makes sense for me.” I think that is probably something that takes a while to get used to from the provider end of things and family members and others to say it’s okay to make a different choice.

**AMY MILLER:** I think providers are used to just throwing everything at it. That’s something we didn’t talk about is how providers are incentivized to provide. So throw the gamut at each patient.

**QUESTION:** Looking at this pyramid, I think that reimbursement framework is going to be the toughest thing you have to do to get
this pyramid to really work. So what are you doing to try to get the system to reimburse for personalized medicine?

AMY MILLER: I’m so glad you asked. PMC just published a compendium of the problems that personalized medicine technologies face, specifically at CMS. The reason why we did this is we asked CMS to speak with us at our policy meeting, which had only forty people. It was a closed meeting—no press, nobody outside the family. These two doctors came and basically said some very unscientific things about how all of the data needs to be collected in the over sixty-four population. Well, that’s fine if genes change once you hit that magic number. But they don’t. There’s also an unlevel playing field on how drugs are reimbursed versus devices or medical laboratory developed tests. They were just being so crazy and unrealistic. The looks on the people’s faces in the room were quite outstanding, especially people who don’t usually agree. They all agreed that this was just ridiculous. PMC tends to be a consensus-based organization. When we come up with solutions for policy makers, we like to make sure that they don’t create winners and losers, so we did not go to the next step, which is offering solutions. It was intentional. BIO, the biotech industry organization, did take that next step. They interviewed a whole bunch of experts in the reimbursement paradigm and offered up a little over six but under twelve solutions. Some are unrealistic and some will absolutely make winners and losers crazy, which means the lobbyists aren’t going to let them happen. But there are a few—two or three—that are feasible and realistic if everybody wants to really work on the details and get those solutions offered up. So we are partnering with BIO to work on that. You’re absolutely right: getting the payers to pay is where the buck stops, and it’s hard. It’s hard to speak their language; it’s hard to come up with solutions that work for them. I feel like they need to be a partner too. It was mentioned the data they have control over, and there are some pseudo-payers who are leading the way—the pharmacy benefits managers (PBMs)—they’re starting to do their own research, improve the quality of the care they provide to patients. I hope that, by seeing this demonstrated, private payers will say, “You know what, we do need to partner and come up with some solutions that are going to work for everyone,” because payers will tell you if they were sitting on this. They’d say, “If you promise it will work for people, we’ll pay triple or quadruple what we’re used to paying for a diagnostic.” But I don’t always believe them.

DONNA CRYER: I think you’re right. I think it probably is the hardest nut to crack. It is fascinating to me. The innovation we have seen—in terms of demonstrating the value and quantifying the cost savings from use of these technologies—is by the actual private payers or pseudo payers in the PBM-space or others. And it is frustrating and rather sad that the government is not following suit. As far as what consumers can contribute to this, is certainly heightened interest, a critical mass paying for some of these tests out of pocket, as they are able. But I remember a story that was told to us as a sidebar. Agent representatives operate out of the commissioner’s office of the Office of Special House Initiatives, and it was started really because HIV activists closed the campus of FDA down. It may come to about that for us to really, truly get access to personalized therapies. Consumer and patients must partner with industry in affirming the value of these technologies to the practice of medicine and making the payers respond.

MODERATOR (Robert Dinerstein): Maybe on that note of citizen activism would be a good place to end. Please join me in thanking our panelists.