FEDERAL TRADE COMMISSION INNOVATIONS IN HEALTH CARE DELIVERY Thursday, April 24, 2008 9:00 a.m. Federal Trade Commission FTC Conference Center 601 New Jersey Avenue, N.W. Washington, D.C.

1		FEDERAL TRADE COMMISSION	
2		I N D E X	
3			
4			Page:
5	WELCOMING	REMARKS by Ms. Ohlhausen	3
6	OPENING RE	MARKS by Chairman Kovacic	5
7	PANEL 1:	LIMITED SERVICE CLINICS	16
8	PANEL 2:	QUALITY AND PRICE INFORMATION	82
9		TRANSPARENCY	
10	PANEL 3:	HEALTH IT - PROVIDERS' ISSUES	132
11	PANEL 4:	HEALTH IT - CONSUMER ISSUES	197
12	PANEL 5:	INNOVATIONS IN HEALTH CARE DELIVERY:	
13		PRACTICE AND PROGNOSIS	262
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

1	PROCEEDINGS
2	
3	WELCOMING REMARKS
4	MS. OHLHAUSEN: Good morning, everyone. I'm
5	Maureen Ohlhausen, the Director of Policy Planning at the
6	Federal Trade Commission and I'd like to welcome you to
7	our workshop on innovations in health care delivery.
8	I just want to give you a few administrative
9	details before we start. If you need to use your cell
10	phone, we'd ask that you actually go out through the
11	double glass doors here into the bigger lobby because the
12	noise carries through into here.
13	Also, we do have a WiFi hot spot here
14	accessible at the workshop. So, feel free to use that.
15	And then on security details, if you go outside
16	the building, you are going to need to go back through
17	security to get back in. So, give yourself some time if
18	you need to do that.
19	In the event of a fire or evacuation, you will
20	exit through the main doors here and then we have a
21	rallying spot down at the corner here across from
22	Georgetown Law School on this side of New Jersey Avenue,
23	because we have a checklist of the names of everyone who
24	is here so that we can be sure no one is stuck in the
25	building.

If you spot any suspicious activities, please
 alert Security.

3 During the panels, if you have any questions, in your packet, there are index cards. You can write 4 5 them out and hand them up and a staff member will bring б them up to the moderator. 7 I also want to stress that we have public 8 comments for the workshop that you can submit on our web site up until May 30. So, we can only cover a small 9 slice of any issue in a one-day conference. So, I really 10 11 encourage people, once you've heard what's said here 12 today or you think we should know about other 13 information, to make use of that public comment option. I would also like to thank Microsoft for 14 15 providing the coffee and bagels today. 16 Now, it is my pleasure to turn over the podium to FTC Chairman, William Kovacic. 17 18 19 20 21 22 23 24 25

OPENING REMARKS

2 CHAIRMAN KOVACIC: I want to thank Maureen and 3 her team for putting together a fabulous agenda today. I 4 am especially grateful for the many participants who are 5 here, which is really a Cooperstown quality line-up for 6 the day's program, which I think really ensures just 7 fantastic results.

1

8 I want to talk for a bit about why the agency 9 is having this event. And not so much to describe what I think are the self-evident benefits of discussing these 10 11 issues at this time, but to talk a bit about why this 12 agency is a convener for this kind of program, I think, 13 is highly suitable. I want to focus on the benefits for a few moments of having a dual purpose institution with 14 our design and why this type of program and endeavor, I 15 16 think, helps fulfill the promise that was set for the 17 agency decades ago.

18 As my colleague, Marc Winerman, has pointed out 19 in his research, the notion of combining consumer protection and competition policy functions in one 20 institution was somewhat of a matter of accident. 21 We 22 were really born almost 100 years ago with the expectation that the competition policy and research part 23 of our portfolio would be the dominant element of what we 24 25 do. The focus on consumer concerns and consumer

1 protection emerged really in the first 30 years or so of 2 our operations.

But what I want to point out today is that combination of functions is uniquely useful in the examination of the issues that are on the agenda today, and especially in their capacity to expand the effectiveness of consumer choice and to talk a little bit about the institutional implications of how we should be using our resources.

I draw your attention as well to earlier work 10 11 that has probed, in a very significant way, the health care sector. Looking at both competition and consumer 12 13 protection perspectives, the exceptional paper that was done with the Department of Justice and the FTC -- and we 14 are enormously glad to have one of the major contributors 15 16 to that effort, certainly on our side, the principal 17 author, David Hyman, who's here today on the program --18 and a journal that captures a number of different 19 observations of this kind of work.

I highlight this because I see this workshop as an extension and continuation of an extraordinarily useful line of work, which makes the Commission a convener for the purpose of enriching our knowledge base, something I'll turn back to in a moment, and establishing a context in which specific policy initiatives, enforcement programs, suggested rules, legislative
 guidance can take place.

3 To remind you simply of something I think is 4 well known to this audience, why conceptually does it 5 make a great deal of sense for this agency to have the б health care portfolio that it does? The competition 7 policy focus tends to emphasize increasing the range and 8 variety of choices that consumers can choose from in this 9 sector and others. And the value of the consumer protection program, the complementary dimension of our 10 11 jurisdiction, is to ensure that consumers, in seeking to 12 make choices across an array of different product 13 possibilities, make well-informed choices and make wellinformed choices with respect to those items that they 14 can see very clearly, and perhaps, with disclosure 15 16 requirements or other policy approaches, can have a 17 better basis for choosing, and indeed, in some instances, 18 where they are unable to choose, to ensure that policy 19 surrogates are available to ensure that choices actually 20 made serve their best interest.

Three approaches to expanding the range of choice. Certainly, one is to improve incentives for providers to reduce costs and enhance quality. That is, to give the whole range of the health care sector providers inducements to provide better choices, suppress

1 cost and to improve quality, thus a major focus of the 2 work that the Commission did in the earlier study that I 3 referred to before, was to focus on how that range of 4 price quality options might be increased.

5 A second major focus of what we do is to 6 increase the ability of individual consumers of health 7 care to get better information about prices and quality, 8 one example being the interest that the Commission has 9 shown in increasing the role of hospitals and rating 10 agencies to provide information about quality of specific 11 facilities.

12 And third, to eliminate what we regard to be 13 unjustified public and private barriers to entry into provider markets. The major dimension of the agenda 14 today focuses on relatively small clinics, the use of 15 16 clinics as alternatives. Being sensitive, as we are, to 17 quality-control related concerns, but to recognize and 18 exploit possibilities for innovation in the way in which 19 health care services are delivered.

20 What is the benefit of the unified approach 21 that runs through the agenda today? First, I think 22 combining the two functions gives us a better 23 understanding of supplier markets and consumer behavior. 24 If you look at our resume, going back over a number of 25 years, you will see an increasing amount of our effort is

1 devoted not simply to understanding how the supply side 2 operates, but also focusing on the capacity of individual 3 consumers to correctly comprehend the choices before them 4 and make intelligent selections, and not simply with 5 respect to this workshop, but to others that have focused б on issues such as behavioral economics. You see a deep 7 and abiding concern within this agency of the capacity of 8 individuals to make sensible choices or to rely on 9 intermediaries to assist them in making good choices. 10 The second reason for combining these 11 functions, and I would suggest to you again that when you

12 look at the agenda, you see a synthesis of these 13 approaches, is that it gives us a greater ability to 14 devise more complete policy responses. If it were a law 15 school exam, to make sure that we spot all the issues, 16 and not simply spot them, but address them in a 17 sophisticated A minus to A plus level, of course, all the 18 time.

One example is the use of ever more
sophisticated electronic databases for pooling
information and for disseminating information about
matters, such as patient histories and care histories.
It has given us the ability to understand the benefits
associated with electronic collection and storage and the
retrieval of data. That is, the benefits with respect to

treatment. If instead of simply relying on small isolated pools of experience, you are able to link them and thus derive better conclusions about diagnosing specific phenomena and identifying superior treatment paths. That is simply one of the various areas in which, in particular, the competition policy focus has given us insights into the benefits.

8 But at the same time, the Consumer Protection 9 dimension of what we do has made us quite sensitive to 10 privacy related concerns associated with exactly these 11 phenomena, and not simply to understand in an abstract 12 way that privacy concerns are important, but to focus 13 attention on where responsibility for establishing 14 appropriate safeguards might be vested. That is, to establish a model that considers the relative possible 15 16 contributions of those who provide data, those who collect and assimilate data, those who transmit data, 17 18 those who receive data, and to form sensible judgments 19 about where responsibility can best be placed to ensure that optimal levels of security, in fact, are provided, 20 21 and to assist in addressing the deeper issue of precisely 22 what individual preferences are. So that when we go about setting defaults in the variety of policy 23 initiatives that we choose, we set them in a way that is 24 25 most consistent with what might be regarded as broader

1

social preferences and norms.

2 What does this mean for our program and how we 3 It means that instead of simply relying on a operate? 4 single dimensional policymaking program, we have tried 5 increasingly to use a broad array of policy instruments б that in many ways, again, are faithful to the basic 7 institutional design that put us now approaching our 8 100th anniversary. Law enforcement being particularly 9 important on the competition side to prevent restraints 10 involving supplier behavior that diminished choices; from 11 the Consumer Protection side, especially in health care 12 where we have relied increasingly on competition to make 13 sure that when advertising takes place or other information is provided, that it is truthful and 14 15 comprehensible.

16 On the advocacy side, to rely on the filing of 17 reports, letters to legislators and other policymaking 18 bodies, to diminish unnecessary public restraints on 19 rivalry, to engage more actively in consumer education, 20 especially with respect to privacy. That is, to ensure 21 that individuals take basic precautions with respect to the revelation of information about themselves. 22 То 23 attune them to different choices that they might take with respect to the way in which they provide data, as 24 25 well as their choice among alternative suppliers.

1 And I bolded the point about building 2 knowledge. I would say that the conventional criticism 3 of public institutions dealing with the phenomena we do 4 is that they are too slow and too limited in their 5 knowledge base to make sensible choices. It takes them б far too long, in the exam writing scenario again, to 7 identify the right issues, and then when they have 8 identified them, they do not know enough to come up with 9 a sensible solution, so that you get inadequate results. 10 Our major policy response over the past few 11 decades has been to focus, in particular, on the building knowledge component. To use our own research and 12 13 analysis projects, empirical projects involving things such as authorized generics, a major study that we have 14 underway now, but to engage in a much broader program of 15 16 public consultations. That is, to get the gallery of 17 stars that you have on today's agenda to help teach us 18 about what we should be focusing on and to encourage a 19 conversation that puts us in a position to pursue better policy results and to make this a conscious element of 20 21 what we do. 22 Tim Muris, Debbie Majoras referred to this as 23 competition and consumer protection, research and development. That is to model us as though we were a 24

25 firm that did high technology related work, and

necessarily to do that, has to have a major investment in
 building knowledge, research and development.

To finish on this, I think that, again, the work we have done in the past and the convening of this event, I think, underscores the benefits of having one institution that combines the two basic functions that are a part of our policy portfolio.

8 As a way of extending this, something that I 9 hope to do in the time that I have as chair, is to engage in a fundamental self-assessment of the agency. One 10 11 important dimension of that is going to look at how our 12 work relates to that of other public institutions, 13 including the many public institutions, which in the fragmented, decentralized world of policymaking that we 14 have, share responsibility for making policy in the 15 16 health care sector. To increase the likelihood that in 17 pursuing our own work, that we work much more closely 18 with other institutions whose affiliated decisions have a 19 major impact on the final results. And sometime in the coming month, I will be saying more about exactly how we 20 21 seek to pursue this and not looking at the relatively short-term focus that often accompanies transition 22 reports at the very edges of an electoral cycle, but to 23 look ahead of the kind of agency that we want to be five 24 25 or six years from now. Thus, the FTC at 100, what kind

of institution do we want to have in this field and others when we reach our centennial?

3 And a last thought is that I think a dimension in looking ahead, if I were to add something for our 4 agenda over the future is the benefit of comparative 5 б study. I'd mention two jurisdictions here. That is the 7 Netherlands and the United Kingdom, which to a great 8 deal, stimulated by the report that I mentioned at the beginning of my comments, decided to undertake a 9 10 fundamental reassessment of the way in which they deal 11 with health care issues. 12 I think as a response there are enormous 13 possibilities here for learning across jurisdictions and something I hope to do, especially by the development of 14 this kind of policymaking instrument, this type of 15 16 workshop and seminar, to engage in a continuing 17 discussion with our counterparts who have invested top-18 rate resources into the examination of these issues and, 19 to a decided extent, have tried to integrate these disciplines into comprehensive policy approaches. 20 21 So, I want to thank you once again for 22 participating in this venture, which I hope I have convinced you is absolutely indispensable to the way in 23 which we approach policy today. 24 25 And to turn the session over to Gus Chiarello,

1	who is one of Maureen's colleagues. And by way of self-
2	indulgence, I will simply mention my own pride that both
3	Maureen and Gus, who are featured in this program, are
4	former students which just goes to show you can't ruin
5	really good talent in the classroom.
6	Thank you very much and best wishes for a
7	wonderful event today.
8	(Applause.)
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	

PANEL 1: LIMITED SERVICE CLINICS 1 2 MR. CHIARELLO: Thank you, Chairman Kovacic. 3 I would like to welcome you to our first panel, which is a discussion on limited service clinics. Over 4 5 the past several years, the health care marketplace has б seen the development of small clinics located in retail 7 settings, often staffed by a nurse practitioner qualified 8 to provide diagnostic evaluation and treatment for a 9 limited set of disease states and medical conditions. 10 Located where consumers shop, with early 11 morning and evening hours, these clinics aim to provide 12 quick and competent services with transparent pricing and 13 the greatest possible convenience to consumers. They are not without their critics, however, as some have raised 14 concerns that limited service clinics undermine 15 16 continuity of care provided by treating physicians, lack 17 proper medical oversight, present public health issues 18 and may be subject to commercial incentives that could 19 adversely affect the quality of care.

20 Our panel consists of some of the top experts 21 in this area, and I would refer you to your folders for 22 each presenter's full biography. But by way of brief 23 introduction, to my far left is Mary Kate Scott of Scott 24 Consulting. To my immediate left is William Sage of the 25 University of Texas at Austin. To my immediate right is

Sara Ratner, who is a senior legal counsel of
 MinuteClinic. To Sara's right is Dr. Robert Corwin who
 will present on behalf of the American Academy of
 Pediatrics, and to my far right is Web Golinkin who is
 presenting on behalf of the Convenient Care Association.

6 With that, I will turn it over to you, Mary7 Kate.

8 MS. SCOTT: Thanks, Gus. So, Gus asked me to 9 talk for exactly 12 minutes and I promise to start and 10 finish exactly on time.

11 I want to tell you, two things are going to 12 happen in the next 12 minutes. Two things. The first 13 is, I will provide an overview of retail clinics. The second is, about 330 Americans will phone a physician 14 because they have a common medical complaint and they 15 16 need to see their doctor. Of those 330 Americans, 54 17 will hear something like, no, the doctor cannot see you 18 today, would next week suit, the emergency room is 19 located at, oh, no, the doctor is not accepting any new 20 patients. And these 54 Americans are not the indigent, they're not the uninsured. They're actually Americans 21 22 that have insurance, that are part of the safety net population, that can afford health care, they just cannot 23 24 access it.

25

You know, one of my clients has conference

rooms that have these great signs in them and they say,
please invite the customer to the meeting. So, as I talk
today, as this panel talks, I just encourage you to
invite those people to this meeting, and not just the 54
that heard no, but the 330 that actually might be
interested in hearing about retail-based clinics.

7 By way of introduction, the California Health 8 Care Foundation two and a half years ago approached me to 9 write two reports on retail health clinics. Their 10 interest was in seeing if the retail clinic would improve 11 access for the safety net population. Those two reports 12 subsequently outlined the business model and the second 13 one was an update. Both of those reports are sort of the basis of this presentation. You are welcome to download 14 those either at my web site, which is also in your 15 16 slides, or the California Health Care Foundation web 17 site, CHCF.org, and they are free and downloadable.

18 So, let me jump in. Gus asked me to talk a 19 little bit about an overview of this model, and when I talk to you about the care and the business model, who 20 21 are the operators, who are the retailers, who are the 22 consumers, give you a sense of what the players are in the field and then talk to you a little bit about what 23 will happen in the next, I think, 12, 24 and 36 months as 24 25 retail clinics start to gain traction within mainstream

1

health care.

2 So, a couple of images. Traditionally, retail 3 clinics have been inside retail locations. They are a 4 small location. They are usually 200 to 500 square feet. 5 They are staffed by nurse practitioners and they look б after routine medical complaints. You can see many of 7 them look a lot like this. They have menus and often 8 people call them menus where the consumer can see exactly 9 what they need. So, in other words, it will say something like strep throat or, you know, flu shot. 10 11 A couple of images for those of you that haven't seen them. They are really not spartan. Many of 12 13 them have two rooms. They're quite attractive. Many of 14 them have fold-down beds. 15 So, the most important thing to understand 16 about the model is that it is about limiting the scope of service. If you do that, three things can happen. If 17 18 you limit the scope of service, you can actually provide 19 the right kind of care with the right kind of practitioner. So, you reduce the costs because you have 20 21 a nurse practitioner as opposed to a physician, you have 22 a small space and you have a limited set of supplies. So, the first thing is you reduce the cost. 23 The second thing is you offer the consumer 24 25 convenience, and convenience for the consumer is not just

1 about not waiting, but it is about a guaranteed 2 appointment time, it is about knowing when they will be 3 seen, it's about a convenient location where they live 4 and shop and work.

5 The third thing that you do when you limit the scope of service is you can improve the quality. Someone б 7 on the panel actually recently had back surgery and I am 8 always tempted to ask people who have back surgery, did you go to somebody who has done it 400 times or twice? 9 Which would you choose? Somebody who has done it 400 10 11 times or twice? When you do the same thing over and over 12 again, when you use technology to actually ensure 13 convenience and pace, the technology also allows you to 14 ensure quality.

A couple of my colleagues are going to talk about some of the quality studies, but I would encourage you to have a look through some of those.

18 So, in the original report, I was asked to 19 forecast how many clinics I thought there might be. So, when I modeled this out, I looked at both the demand and 20 21 supply. While you will see some forecasts of up to 10,000 or 12,000, I think a realistic forecast is about 22 5,000 to 6,000 in five years. You can start to see when 23 we first looked at this in January, it was about 62. By 24 the end of last year, there was somewhere around 800, 25

900. We think there is about 1,100 right now. It's
 always hard to keep this slide updated. I would forecast
 about 1,500 by the end of the year.

4 So, who are the players? Well, there's 5 operators and retailers and, increasingly, they are 6 overlapping. There are about 50 operators. They are 7 national, regional and local players and the retailers 8 are also national and regional, and the retailers are 9 grocery, drug and mass merchandise. So, of course, by drugstore, of course, they are in CVS and Walgreen's, 10 11 they are in Rite Aid and Long's and Duane Reed, and 12 they're in Wal-Marts and Targets, and they're in many 13 supermarkets as well, Albertson's and so forth.

A lot of people find it interesting to think about who these clinic players are. The top ten, by the way, of clinic operators represent about 85 percent of the industry. Of that top ten, three are retailer owned. So, CVS owns MinuteClinics, Walgreen's owns TakeCare Clinics, Target owns its own clinics.

20 The next sort of players are the independent 21 operators, and these are folks like RediClinic. You have 22 Web Golinkin who is here from RediClinic. And you've got 23 the other independents, like The Little Clinic, Med 24 Express and Quick Health.

25

The other players are hospitals, and let me

1 talk a little bit more about hospitals because they are a 2 recent entry into this arena, which I think is an 3 exciting trend as we see retail clinics being connected 4 more to mainstream health care.

5 So, these different types of clinic operators 6 have different reasons for being. But, in essence, what 7 they are doing is they are including a service model to 8 ensure that their stores are relevant to consumers. They 9 are saying that if I include service in my retail offer, 10 I can get a deeper relationship with the consumer.

11 Hospitals are a little bit different. 12 Hospitals see this as an opportunity to serve new 13 patients and bring new patients in and serve existing patients. What we are seeing is hospital providers are 14 15 participating either as operators or as partners. So, 16 many hospitals actually affiliate with different clinics 17 and either provide oversight or they provide staff or 18 they provide a brand. But some hospitals are actually 19 operators. So, Sutter, for example.

Another one is the Mayo Clinic. I always love this quote and I know Web is going to talk more about the consumer, but the Mayo Clinic came out and said, "Patients tell us this is what they want."

It is worth noting the Wal-Mart strategy. I think it is really interesting, and it will certainly

change our industry, Wal-Mart announced that they are 1 2 going to have an additional 400 clinics and every one of 3 those 400 clinics are going to be operated by hospitals. 4 So, I think we are going to continue to see more 5 hospitals enter this part of the health-care arena. I would encourage you to watch this particular part because 6 7 I think it will be interesting to see the hospitals that 8 come in as operators and the hospitals that work with 9 Wal-Mart as an affiliate of an existing clinic operator.

10 The consumer satisfaction is incredibly high. 11 Some people say, well, maybe the health care bar is low. 12 I would hate to say that. But what we do see is this 13 really consistent, high satisfaction with these clinics.

14 The other thing that consumers say is they actually really like the idea that the clinic is in the 15 16 grocery store. I think at first, and certainly when I 17 did some early research about two years ago, did focus 18 groups and surveys, I was trying to figure out is this 19 like a substandard that people say, gee, I would really rather have this, but I will accept this? But, in fact, 20 that is not the case. The consumer actually said, for 21 this routine care, I prefer the nurse and I prefer this 22 23 location, because what they are saying is this makes sense within my world and my life. 24

25

I thought it was also pretty interesting how

the consumers said, as I get used to using these clinics,
 I will expand my reasons for using them.

3 So, what will impact retail clinics in the next 4 12 to 36 months? First of all, we are creating 6,000 5 clinics. Now, again, a lot of people will tell you they б are creating a lot more. I think that is a pretty 7 ambitious forecast. It was interesting when I was trying 8 to figure this out, how many would open. One of the 9 people I talked to was Starbucks because I was trying to 10 figure out how fast can you open stores because I was 11 thinking not just the demand, but how possible is it to 12 open this many clinics? 13 But what it really means is we are creating tremendous capacity, and it is new capacity. We are 14 creating about 45 to 50 million visits. Well, if you 15 16 look right now in terms of what we need, we really only 17 need about 20 to 25 million visits. So, we are creating 40 to 45, but if you look at the current scope of 18 19 service, we need 20 to 25. So, what will happen for 20 those additional? 21 What I think we will see is an expanding

demographic, and I'm going to start top left. I think we will see a lot more publicly insured patients. I think we will see a lot of insured patients. I think we will see a lot more well baby things. There will be a lot 1 more things that these clinics will start to do.

2 I think technology is also starting to enter 3 We have seen the first clinics implement the arena. 4 telemedicine within their clinics and they are basically 5 bringing the physician in via telemedicine into the clinic, and I think once you get the physician into the 6 7 clinic, we will see another expanded scope of service. 8 The other thing that technology will also do is 9 it will enable new screening devices, new tests and new 10 drugs. An example of that might be some of the 15-minute 11 infusions and the specialty drugs that can actually be handled in these clinics. 12 13 I personally believe that it actually will remain about common, acute conditions, because that is 14 what I think the consumer is saying that they want to 15 16 see. So, I think that will remain core. But I think as 17 we start to see these clinics expand, to really have a 18 look at some of the technology that will actually drive 19 this expansion is pretty interesting. 20 I have a couple of examples up here in terms of some of the devices that I think might be sold or some of 21 22 the different specialty medications. 23 The demographic appeal, I think, will be really

25 this one to say RediClinic now accepts Medicare. In

24

important. This is an important announcement. I used

fact, many of the clinics are now starting to. This is
 actually creating interesting dynamics, but it will start
 to be, I think, an important demographic.

4 I have done some work with what I call 5 specialist clinics and we are starting to see a number of б the community health care centers looking at either 7 operating or affiliating with different operators, either 8 through voucher systems or actually being a co-branded facility as they think about how to apply either the 9 10 principles or actually operate clinics to serve their 11 safety net populations.

We are seeing employers as well -- and this is going to be exacerbated. I think you have all seen the Walgreen's announcement where they bought Whole Health and Eye Tracts. So, what we are seeing is employers are also looking at using clinics as part of not just acute-care but for preventative programs.

As I mentioned, we have stored value cards. It will be interesting to see how we see state governments respond, not just as regulators, but as purchasers.

There are a number of studies that I would encourage you to have a look at. I know a number of comments are going to be made on those and about the payers as well.

25

My last comment is just about legislation, and,

1 again, other people will cover this, but I want you to 2 think about the buckets of legislation. It's mostly 3 about state legislation and the nurse practitioner and 4 their scope of service and their ownership of the clinics 5 and the prescribing authority. б People always ask me where the reports are. 7 You are welcome to download them, and I'm really happy to 8 take questions. But it's been 12 minutes. Please do not 9 forget those 54 people. 10 (Applause.) 11 MR. CHIARELLO: Thank you, Mary Kate. As Bill Sage makes his way to the podium, I would encourage you, 12 13 if you have questions, to use the cards inside of your folders and please have them filtered up here. 14 15 MR. SAGE: Good morning, everybody. Mary Kate 16 has made it very tough on me. It's hard for a professor 17 to follow someone who kept exactly to the appointed time, but I will do my best. 18 19 I call this presentation a Test Case for Health Care Delivery Innovation and American Politics, which I 20 21 think is really the question that retail-based clinics present for us. To a large degree, I think the 22 23 difference between the way that both Mary Kate and I describe these as retail-based clinics and the title on 24 25 the program, limited service clinics, captures this

political challenge as well as the core delivery
 challenge.

3 Are we going to think about these mainly in 4 terms of what services they provide and how they provide 5 them or are we mainly going to try to apportion them б politically among the different players in the American 7 health care system and try to figure out how these 8 squeeze in without squeezing too many others out? Remember Newt Gingrich? Well, in 1995, Newt 9 10 Gingrich wrote this in Forbes magazine: "One of the 11 challenges I've made to doctors is I said, you're either 12 going to Canada or to Wal-Mart. You can either go to a 13 nationally controlled bureaucratic structure or you can go to the marketplace, but you're not going to stay in a 14 quild status where you have all the knowledge and you 15 16 share none of it."

17 What happened? That's what happened. This 18 isn't Wal-Mart, actually. But the Wal-Martization of health care, if you will, is now a serious issue. I 19 20 think it is interesting to think about this in light of 21 Gingrich's original challenge of Canada versus Wal-Mart, 22 because Gingrich thought that what he was saying was, 23 well, either this is going to be a single payer, nationally controlled, governmentally run and funded 24 25 system or it's going to be private competition in the

1 marketplace.

2 But there is also a fundamental difference 3 between an image of Canada in health care and an image of 4 Wal-Mart or other retail providers in health care, and 5 that is the difference between focusing on the problem of б medical access as a problem of insurance, solvable 7 through things like national health insurance, or as a 8 problem of health care services, solvable by innovations 9 in health care delivery, which is why I am absolutely 10 delighted that we are here talking today about health 11 care delivery. 12 If you look back at the experience of the 13 1990s, or at least consider it the way I look at it, it was in a few different categories. We did okay in terms 14 of the insurance reform aspects of health care reform in 15 16 the 1990s. There was Federal HIPAA, the first major 17 amendment to the ERISA statute having to do with health. There was a lot of reform at the state level in terms of 18 19 individual and particularly small group insurance 20 coverage. We did not do too well at either financing or 21 purchasing. Financing was the idea that we would 22 actually be able to decide how much money needed to go 23 into the system to provide a decent level of care for 24 25 everybody and we did not do that at all. We did not do

1 that well in purchasing. We talk about things like 2 purchasing cooperatives and they're back now in things 3 like the Massachusetts Connector, but we really did not 4 get very far. The best we got, in terms of purchasing, 5 was sort of private purchasing and that was sort of managed care. Then, we thought -- well, maybe we really 6 7 did not think about delivery reform. I spent the first 8 six months of 1993 in the White House working on health 9 care reform. There were 24 working groups in that very 10 arcane and ultimately ineffective process, and I was 11 responsible for four to five of those working groups and 12 there was not a single working group of the 24 that had 13 as its fundamental mission evaluating the way that American health care was delivered or figuring out ways 14 to improve it. We just did not try. 15

Managed care, we sort of said, well, maybe they should try, but then we decided -- what we called patient protection was more important than delivery innovation, so we stopped.

20 So, at the end of the decade, we have 21 absolutely nothing, I think, to show in health care 22 delivery form, and I am hoping that this and future 23 decades will be different.

24 So, why do we get retail clinics? Well, 25 government cost control failed, private cost control

1 failed. We put more cost responsibility on consumers. 2 We did not really listen to what consumers wanted. Then 3 we had a political overlay supporting something which we 4 now call consumer directed health care, which did create 5 some benefits in terms of a new found emphasis on both 6 price transparency and quality transparency and then had 7 a little tax subsidy along with health savings accounts 8 and spending accounts to nudge it. And I think these are 9 the various things, but focusing mainly on the fact that 10 nobody seems to have been able to control costs in 11 traditional ways, either public through government or 12 private through managed care. We're now looking for 13 other things.

What are the characteristics? Mary Kate said 14 this very well. These clinics are associated with mass 15 16 retailers, they lease space, they are small, they have 17 expansive hours, no appointments. They have posted, 18 transparent, consistent prices. They do both what one 19 operator calls "get well" services, basic medical care, 20 and also "stay well" services, basic preventive care. 21 They use mainly nurse practitioners, physician 22 assistants, and they rely substantially on electronic 23 information systems both in terms of record-keeping and 24 decision support.

25

So, let's now step back and look at these in

health policy terms, and we always do this in terms of access and cost and quality, to which many of us add a fourth pillar to the stool which we'll call innovation.

So, access, what are the access potentials for retail medical clinics? Well, lower prices and high convenience improve access at the margin. We all know that. Unlike insurance models of access, this does not really depend on people deciding to enroll in insurance. You do not have the same sorts of take-up problems. This puts care where people live and where people work.

Back in the 1950s, we decided we would protect ourselves from then Soviet nuclear attack by dispersing the American population. Well, we managed to disperse them away from many sources of medical care and also keep them from walking, allow them to get fat, and otherwise make it hard to save on energy.

17 But one of the byproducts is that we do not 18 have health care where people are. When I first got 19 interested in this area, I looked for the basic statistic of where were Wal-Marts, and that's not also where were 20 HEBs or CVSs, just Wal-Marts, and I found out that --21 22 this is about three-year-old data -- 50 percent of Americans live within 5 miles of a Wal-Mart and 90 23 percent of Americans live within 15 miles of a Wal-Mart. 24 25 Not a bad way to get access to services.

Moreover, we always point out the irony of large retailers getting interested in this when they do not always have generous health benefits for their own workers. One of the inevitable byproducts of this movement, I think, is they will have services available to their workers and these large, retail workforces will find their access improved, as well as general access.

8 What are the cost sides? Well, there's a 9 commitment to low point of service prices. These are 10 businesses or at least the host businesses are such that 11 they engage in very aggressive supply chain management. 12 Transparent pricing and predictable pricing, I think, is 13 a huge benefit for everyone. Imagine the uncertainty when you take your car to the auto mechanic, or even 14 worse, when we go to a doctor where we might have to pay 15 16 the bill ourselves. It is great to know what service you 17 are going to receive in advance and how much it is going 18 to cost. And then, at least at the beginning, these 19 clinics had a very simplified administrative model which I think is getting complicated now. 20

21 Quality. In some ways, these are a health 22 services researcher's dream because they are a real-life 23 manifestation of a response to a lot of things that were 24 just theoretical discussions until now. This is really 25 sort of a standardized product that responds to the fact

1 that people now understand that regular medical practice 2 is highly variable, doesn't necessarily adhere to best 3 practices and has major safety lapse associated with it. 4 There is also now an understanding that value 5 for money is not a dirty word in health care. Back in 6 1994, I helped develop a health proposal for an 7 unsuccessful gubernatorial candidate, and the proposal 8 that both I and a McKinsey consultant, also volunteering 9 in the campaign, put together had as its centerpiece "value for money." We were laughed out of the room by 10 11 her political consultants. They said, no one thinks 12 about health care and value for money, especially on the 13 Democratic side.

14 What was Hillary Clinton's first position paper 15 in this campaign? It was health care as value for money. 16 This is now part of the discussion.

I think the trusted brand aspect of quality is really important, and here I think the distinction between Canada and Wal-Mart has incredible importance. One of the problems with managed care is that even if it had a brand name, it was a brand name insurance company, and no matter what you see about good hands on TV, people do not naturally trust their insurance companies.

24 Trusting a service provider is an entirely25 different matter. Many people have very high levels of

confidence in recognized consumer brands. 1

2 Now, an aspect, of course, of quality here is 3 that this does depend -- this model does depend on 4 patients having some idea of what is wrong with them. 5 You have to know basically what service you need and that б this is a service that the clinic is going to provide. 7 And that aspect of patient participation, I think, is 8 essential both to the design and to the operation of the 9 model.

I want to stick to my 12 minutes. I think one 10 11 of the great success areas has been in compliance for antibiotic use. Here, I do not have the data myself and 12 13 I will not overly emphasize, but I think we will be able to see things happening in terms of empirical reports in 14 the next few months which will demonstrate that many 15 16 aspects of retail clinic practice are extraordinarily 17 highly compliant with professionally designed 18 guidelines. I think the key to reducing unnecessary 19 antibiotic use has been the time that providers in these settings can spend with patients, a half hour versus five 20 21 or six minutes for the average physician visit for a 22 simple problem, and the fact that you are really not imposing large direct costs or costs of inconvenience on 23 24 patients.

25

They do not wait, they do not pay a lot, they

do not struggle to get in, they do not take time off work. And at the end of the day, they are much more willing for \$50 to be told, here is what you have, it is not treatable with an antibiotic and here is why and here is the guideline to show it.

б Innovation, though, I think, is the critical 7 aspect here. A lot of the innovation is innovation you 8 have heard described around information systems and 9 decision support and miniaturized diagnostic technologies. These businesses would not exist but for 10 11 the miniaturization of diagnostic technology. But I 12 think the more important innovation is the innovation in 13 terms of suiting the preferences of consumers. And I think here the critical point is that this is continuing 14 15 innovation.

16 Even the most progressive members of the sort 17 of traditional medical reform establishment have always 18 thought about being patient responsive as a one-shot. We 19 know that for the last 50 years, we have not been responsive to our patients, we are going to change, and 20 21 starting tomorrow we are going to be patient responsive. 22 But these host businesses do not think of it as a one-shot, they think of it as a continuous process. 23 24 Every year, they are going to be trying to figure out 25 what consumers are going to be wanting one, two, five
years down the road and anticipate that. And that, I
 think, is a critically beneficial model for health care
 that health care has never even considered.

There are many uncertainties. The referral system for acute and more complicated and chronic care; the patient self-referral aspects are important; the continuity of care issues are important, though I do not think that most consumers in the future are going to want the sort of medical home that has been discussed in the past. They will still want a medical home.

I think the mix of cash and insured businesses is one of the greatest challenges. I think this has been a very clean model when it is brand name trust in a service provider different than an insurance provider.

15 But at the end of the day, I think you have to 16 understand that this genie is out of the bottle and it is 17 not going back. When USA Today published a commentary 18 about a year and a half ago on retail medical clinics, 19 some doctor from Kentucky wrote in in opposition. He wrote this. He wrote, "The American public cannot have 20 21 it both ways. They must decide what is more important, 22 money and time or comprehensive, appropriate care," and 23 he wrote this without a hint of irony.

I think we just have to acknowledge that at this stage in American health care, this is not the way

you run a system where you have to somehow decide that 1 2 money and time are irrelevant and you are going to have a 3 health care system that completely ignores them. We need 4 a health care system that incorporates them. Thanks. 5 (Applause.) MR. CHIARELLO: Thank you, Bill. 6 Sara? 7 MS. RATNER: When Gus asked me to speak, he 8 asked me to describe a little bit about the MinuteClinic 9 model. Right now, MinuteClinic is the largest operator 10 in this space. And to also discuss a little bit about 11 the legal space that we operate in. MinuteClinic was founded in 2000 as QuickMedx 12 13 and converted over to MinuteClinic in about 2002. At that point, we started accepting insurance. This model 14 15 was originally developed as fee-for-service where 16 patients pay cash. One of the reasons is to avoid the 17 bureaucracy created by dealing with insurance companies. 18 But in 2002, a strategic decision was made to get into 19 that space in order to increase utilization and work with a larger population. 20 21 In 2006, MinuteClinic was acquired by CVS/CareMark. Currently, MinuteClinic is operating in 22 about 25 states with 500 and -- this is slightly outdated 23 -- I think 519 clinics today. We operate across the 24 25 country in various markets.

1 Over the past several years, retail clinics 2 have gained a lot of attention in the media. As you can 3 see, it has been featured in articles. It's been a 4 feature article in numerous magazines and there have been 5 interviews on the nightly news. It has gained a tremendous amount of attention. I think the next slide, 6 7 where MinuteClinic was featured as one of the Top 10 8 Innovators in the past decade, is evidence of that. We 9 were featured with Google, the Blackberry. I think this 10 is a pretty important depiction about how retail clinics 11 are viewed.

MinuteClinic's strategic vision has about five components. The first, which is our prominent focus, is providing high-quality care. I think if you are a health care operator, that has to be your foremost concern and you will not succeed in this space without keeping that paramount.

We provide integration around a medical home. You cannot operate in a silo. You need to operate in an area in a way that allows you to integrate with a primary care provider and MinuteClinic does that by providing, within 24 to 48 hours, the medical record created at the visit. They provide it to the primary care physician that the patient selects at the time.

25

We align ourselves around cost-conscious and we

are also convenient. So, we try and keep our costs
 relatively low and we try and locate our clinics in
 convenient locations where patients can access us.

And the last point is that we provide an electronic medical record. It is integrated into our system and it is also provided to the patient so the patient has their own record to take with them at the end of each visit.

9 MinuteClinic has been -- it is a right-sized engineered concept. If you compare it to ER's, urgent 10 11 care facilities and medical offices, the critical difference is that we treat a much more limited scope of 12 13 service and we do not use the capital intensive equipment required in the other settings. We do not have a lot of 14 diagnostic imaging -- we do not have any diagnostic 15 16 imaging capabilities. For services that are required, we 17 would refer a patient to another health-care setting.

18 This slide lists our scope of service. You can 19 take a look at it. But as you will see, there is a list 20 of common illnesses and, recently, we have entered the 21 wellness and prevention space, doing screenings such as 22 diabetes, hypertension, cholesterol and obesity.

There are several components that drive quality in MinuteClinic. The first is the focused range of services. We know what we can treat, but we also,

equally as important, need to know what we cannot treat in order to triage the patient to the appropriate health care setting.

4 We are staffed by board-certified nurse 5 practitioners and physician's assistants. In every 6 market, our practitioners are supervised by board-7 certified medical directors. In certain states, such as 8 Oregon, Washington and Arizona, nurse practitioners have 9 independent practice rights. But even in those states, 10 MinuteClinic does have medical directors acting in an 11 oversight function doing chart reviews and the like. 12 The patient record is then given, as I 13 mentioned before, to the primary care provider at the end of each visit. It is sent usually within 24 to 48 hours, 14 either fax or U.S. mail. 15 16 One of the central components, which I will 17 talk about in the next couple of slides, is the electronic medical record. I think this is central to 18 19 almost every retail clinic and it is critical in today's 20 environment. 21 The last component is the in-network status 22 with most major insurance companies. 23 One of the foundations for this is quality. 24 All of our practitioners are credentialed using NCQA 25 Guidelines. Obviously, this is an insurance standard,

but our feeling is that in order to credential
 appropriately we need to hold our practitioners to the
 same guidelines as our insurance companies do. So, we
 credential using those guidelines.

5 Our practitioners go through an extensive two-6 week training process prior to working in any clinic. 7 Their competency is actually verified at the end of going 8 through that training program and they are actually 9 required to re-certify through every module at the end of 10 each year. So, they are held to a high standard and they 11 are also required to go through updates because, obviously, the medical literature changes, guidelines 12 13 change, and the nurse practitioners need to know about 14 that.

Built into our system are specific guidelines for treating patients, and these guidelines have been developed by ICSI, the American Academy of Pediatrics and the American Academy of Family Physicians. Also, recently, the AMA and AAFP came out with desired attributes for retail clinics with which we comply as well.

22 One of the things that we are most proud of is 23 that, as of August 2006, we are Joint Commission 24 accredited. For those of you who are familiar with that, 25 that is a very rigorous process. If you add a certain

1 amount of facilities per year, you have to go through re-2 accreditation every six months. At this point, we are 3 going through re-accreditation quite often, and it is a 4 difficult standard, but something that we are very very 5 proud of.

б Our EMR is something that is home-grown, but it 7 is a proprietary-based system. It allows for a certain 8 amount of continuity of care to enable the patient's 9 medical record to be transmitted to the primary care 10 provider. Imbedded within it are best practices, and it 11 is a decision support tool that allows the nurse practitioner to basically check off, going through 12 13 certain types of medical history, making sure she takes appropriate vitals, things of that nature. So, it is a 14 decision support tool that we are pretty proud of. 15

16 Also built in with that are circuit breakers. 17 So, if a patient has a 104 fever and there are other 18 indicators that this is not the appropriate setting, our 19 EMR will actually have a pop-up to the practitioner saying a triage is appropriate. I think critical to this 20 21 model is knowing what you cannot treat, and while nurse 22 practitioners are licensed to treat a whole range of services, practitioners coming into this space need to 23 recognize that this model is a lot smaller than what they 24 25 are used to. So, while they are used to treating things

1 that are a lot broader, more complicated, they need to be 2 able to recognize it and then triage it out very 3 appropriately.

4 No paper charts are maintained and privacy is
5 assured through a centralized storage space.

6 Recently, MinuteClinic completed a guidelines 7 study and it was referenced by Mary Kate. From 2005 to 8 2006, we studied pharyngitis and we studied 57,000 cases 9 of it to determine whether or not the practitioner complied with evidence-based guidelines. The guideline 10 11 that we studied was antibiotic use. If a strep test is negative, you do not prescribe an antibiotic unless a 12 13 rapid strep test comes back positive -- I am sorry, if a DNA probe comes back positive. If the rapid strep test 14 is positive, then it is appropriate to prescribe an 15 16 antibiotic.

17 In this case what we found was that there was 18 99 percent compliance, which is higher than any other 19 medical setting. So, the notion that these clinics are 20 causing an over-utilization of antibiotics is just not 21 true.

Drivers of retail clinic effectiveness have been really integrating with the medical community. You can go through these slides, but it highlights what has been successful for MinuteClinic.

1 I am going to actually skip to -- these are all 2 slides that Mary Kate has spoken to as well -- the legal 3 challenges, which has been a critical hurdle for us at 4 this point. We deal with scope of service challenges, 5 scope of practice challenges. One of the most difficult б items in this is the staffing model and how to create it 7 with physician oversight that complies with every state 8 requirement. Texas, for example, has a 20 percent 9 on-site requirement. South Carolina has a three to one 10 physician ratio. It is extremely difficult in creating a 11 consistent business model that complies with every state. 12 So, that has been a particular barrier for us, something 13 that we comply with, but something that is very 14 difficult.

15 Also, in rolling out these clinics are 16 structural issues. Some states prohibit the corporate practice of medicine, which essentially prohibits a 17 18 corporation from engaging in the practice. Only 19 professionals licensed can form a corporation to 20 practice. So, that has been a particular barrier for us and something that we have tried to work around and 21 22 engage local providers with as well.

Facility and lab licensure has been a difficult process. For example, in Pennsylvania, every clinic has to have a lab director. That is not our business, that

is not the space we're in, but it is something that we
 have to comply with, even though we are not a Quest Lab,
 for example.

Some of the other areas, especially being
located in a retail clinic are anti-kickback issues and
self-referral prohibitions, advertising regulations.
There have been regulations promulgated by medical
societies, boards and other local authorities governing
this area which have been particularly cumbersome.

10 There are right now a couple of state-specific 11 issues that are on the table. Some of you know that Massachusetts recently passed a regulation dealing with 12 13 limited service clinics which allows these clinics to operate in the state but under certain guidelines. 14 Illinois, Tennessee, D.C., Rhode Island, New York, all 15 16 have proposals on the table in some fashion to regulate 17 this area. I guess our challenge at MinuteClinic is 18 trying to operate consistently within this highly 19 regulated environment and work with states on how to regulate effectively and not to overly regulate this 20 21 innovation compared to other health care providers in 22 that space. Thank you.

23 (Applause.)

24 MR. CHIARELLO: Now we will hear from25 Dr. Corwin.

1 DR. CORWIN: Good morning. First, a thank you 2 to the Federal Trade Commission for inviting the American 3 Academy of Pediatrics to participate in this workshop on 4 innovations in health care delivery systems. I am 5 pleased personally to be here representing the Academy б and its 60,000 board-certified pediatricians, pediatric 7 surgical specialists and pediatric medical sub-8 specialists.

9 The firm commitment of the American Academy of Pediatrics to the medical home model as the best model 10 11 for the delivery of primary care to children is not new. As early as 1977, over 30 years ago, the first policy 12 13 statement of the Academy about this model was promulgated. In fact, it was titled, "The Unfortunate 14 Fragmentation of Health Care Services for Children in the 15 16 United States." In part, the final paragraph of that policy statement says, and I'll read this part, "In 17 18 addition to responsibility for his or her own patients, 19 the pediatrician accepts the responsibility to improve the quality of the delivery of health care to children in 20 21 the community and to work toward reducing fragmentation, 22 diminishing the barriers to continuing coordinated health care for all children." 23

As we look at the first slide, the attributes of the medical home are listed. The partnership between

parents, patients and pediatricians, the mutual respect 1 2 and trust that define that relationship, that is 3 available 24 hours a day, seven days a week, 365 days a 4 year is ideal and is based in effective and respectful 5 communication on an ongoing basis. It takes advantage of 6 teachable moments in health care delivery whenever they 7 occur. Often, they are during the period of time in 8 these so-called minor illness limited type visits. These 9 are not just about a sore throat. Children do not 10 necessarily come in with a specific initial complaint 11 that is noted. They come in because they are sick, they are ill, they do not feel well. In fact, it is our job 12 13 to try to discriminate what is going on and that is quite an extensive process and takes a great deal of knowledge, 14 15 ability and experience.

16 So, those teachable moments can happen during 17 that period of time and you may be dealing with something 18 you did not think you would when it said earache or sick 19 as the diagnosis to begin with. The shared collaboration and communication delivered by the physician leads to the 20 value of the medical home, as you can see on this slide. 21 22 This value for the patients, parents and health care 23 delivery system has been documented by a number of studies that can be discussed at another time. But the 24 25 Commonwealth Fund, the Center for Evaluation and Clinical

Science at Dartmouth, Barbara Starfield's work at Hopkins
 all speak to this specifically and have some data to show
 that, in fact, the medical home is valuable and, in fact,
 saves money in the long haul.

5 On the next slide, you can see that we in the 6 Academy decided when we learned about this new innovative 7 technology of retail-based clinics to participate to the 8 best of our ability, and we were invited to participate 9 in the Wal-Mart Summit on Health Care Delivery Systems in the summer of 2006. We met, during late 2006 and early 10 11 2007, with a number of the leadership of the retail-based 12 clinics, insurance companies, and discussed our concerns 13 as pediatricians with the fact that children are not small adults, and the kind of care that is delivered to 14 them is different than you would do for adults, and in 15 16 that type of setting that we were concerned about what 17 would happen in terms of the issues that we will talk 18 about in a minute.

All of these concerns were met with understanding and a sense that the Academy has always spoken up for children. In fact, our tagline is "dedicated to the health of all children." So, from our perspective, we are not saying anything new, we are merely iterating and reiterating what we have said for the last 32 years, that the medical home is the best

1 model of care for kids.

2 These are the concerns that the Academy has 3 with retail-based clinics, and it is articulated fairly 4 well in the policy statement that we provided in the 5 handout. However, what I would say is the following, 6 that the first paragraph of the statement that we put out 7 in November of 2006 reads as follows, "The American 8 Academy of Pediatrics opposes retail-based clinics as an 9 appropriate source of medical care for infants, children and adolescents, and strongly discourages their use given 10 11 that the retail-based clinic is not a medical home and 12 leads to these concerns." 13 I think that those concerns are valid. They do have -- it's very good to say that we have electronic 14 health records and, in fact, communication between 15 16 electronic health systems, if it were in its ideal format 17 a decade from now might, in fact, be reasonable. But 18 right now, that is not true across the board. Not 19 everybody has electronic health records. The communication even between electronic health systems and 20 an individual community is quite variable. 21 22 I know in my own community, in Rochester, N.Y., 23 which is a fairly sophisticated medical community, the communication between the University of Rochester, some 24 25 of the other hospitals in the community and various

practices is somewhat limited, even though all of us have access to the web and access to the information. So, I would have that as one concern.

4 The second concern about the communication 5 between a retail-based clinic and the physician, the primary care physician, is excellent unless the parent 6 7 decides they do not want to let that information be 8 transferred. In fact, they have the right not to allow 9 that information to go. They do not want to let their 10 doctor know that they went to a retail-based clinic. I 11 do not know the numbers, I do not know if that is really going to be a big issue, but it certainly is an issue and 12 13 we know people who do that. So, it is transfer for 14 information.

15 The hand-off of information in medicine is one 16 of the biggest places where there are concerns about 17 errors being made and they certainly occur even in large 18 groups. We make a very careful approach to transferring 19 information to each other when we sign out, when we sign in to other physicians, and I must tell you that even 20 with that, there is sometimes miscommunication that goes 21 22 forward.

In pediatrics, especially, when we really have a parent who may be with a child all the time, the primary caretaker. The other parent, a grandparent, some

other person, a nanny who comes in, all of the
 information is not always there at the appropriate time.
 So, the record does stand to help us define that.

4 We also acknowledge that the shifting economic 5 and organizational dynamics of the current health care delivery system will likely support the continuation, the б 7 existence and the expansion of these retail-based 8 clinics. So, in our policy, we are not just putting our 9 heads in the sand, we understand that. However, from our point of view, the bottom line, as we speak up for 10 11 children, is that care delivered in a medical home is consistently associated with better outcomes, reduced 12 13 mortality, fewer hospital admissions for children with special needs, lower utilization and improved patient 14 compliance with recommended care. And all the studies 15 16 that have been done about whether people comply with what they are asked to do, clearly over time with the 17 18 relationship of a team of people in the medical home, led 19 by a physician, in this case the pediatrician, does actually provide superior care. 20

21 So, that is what our message is, and we could 22 go on into a lot of other details, but I am not going to 23 because I want to leave it at this point. I certainly am 24 happy to answer questions later on. But from our 25 perspective it's not that we do not understand that this

1 innovation is going forward, we are just concerned about 2 it from the point of view of what is good for the 3 children in the United States of America. We are 4 dedicated to the health of each child. Thank you. 5 (Applause.) б MR. GOLINKIN: Good morning. So, I think a 7 bigger challenge than Bill had following Mary Kate, who 8 stuck to her 12 minutes, is being the sixth presenter on 9 the same topic. So, I will try to add something to this 10 discourse. 11 My name is Web Golinkin. I am the President of 12 the Convenient Care Association. I am also the CEO of 13 RediClinic, which is one of the larger convenient care operators. But I have got my Convenient Care Association 14 15 hat on today. So, I quess, first of all, just to very 16 briefly reiterate what a number of other people have 17 mentioned, the industry has grown very, very fast over 18 the past year and a half. When the Convenient Care 19 Association was founded about a year and a half ago, 20 there were about 150 retail clinics in the United States. 21 Today, there are close to 1,000. According to our estimates, about two and a 22 23 half million or probably upwards of two and a half million consumers have been treated in retail clinics 24 25 without any safety issues that we are aware of. The

projections, as a number of people have mentioned, are that there will be about 1,500 retail clinics by the end of this year and maybe as many as, I've heard, 5,000 by the end of 2010. I will talk about that a little bit in a minute.

б So, the question is, why is it growing so fast? 7 The answer is really simple, which is, that consumers 8 have embraced it. They need it because they are 9 frustrated by lack of easy access to high-quality, affordable, routine care. I think this problem is only 10 11 going to get worse, which will stimulate further demand, because there is a primary care physician shortage 12 13 certainly in some parts of the country.

14 I do not know if any of you read the article in The New York Times a couple of weeks ago about what has 15 16 happened in Massachusetts where they basically have near 17 universal coverage. The good news is that more people 18 can pay for care; the bad news is that nobody can get an 19 appointment with their physician. There was one family practitioner quoted in that article saying that the first 20 21 appointment that she had for a new patient for a physical 22 was in February of 2009. That is in Amherst, Massachusetts. Not exactly in the hinterlands. 23

24 So, there obviously are problems with access 25 and affordability to routine care that is stimulating

consumers to try convenient care, and as a number of 1 2 people have mentioned, the satisfaction with their 3 experience is at an extremely high level. So, depending 4 on who is counting patient satisfaction or customer 5 satisfaction at convenient care is in excess of 90 6 percent. That is very high for any kind of retail 7 concept, or certainly health care concept. So, it is 8 really consumers that are driving this.

9 If consumers did not like it, did not need it, were not embracing it, there is no way the industry would 10 11 have overcome the many obstacles that have been in its path over the past few years. Now, what has happened is 12 13 that the retailers are embracing it, third party payers are embracing it because they see the opportunity to cut 14 costs out of the system while at the same time actually 15 16 doing something that consumers and their members like, 17 and policymakers are embracing it for some of the same 18 reasons.

19 So, from the industry's point of view, it is 20 all good, right? Yet, my philosophy has always been a 21 little bit like Andy Grove's, which is only the paranoid 22 survive. So, you have to ask the question of what could 23 slow the growth of convenient care? There are basically 24 four things, I think, that could slow the growth of 25 convenient care, and I will go through them with you very

1 briefly.

One is systemic quality issues. I do not think this is going to happen. There have not been any safety issues to date. Will there be incidents moving forward? I think it is likely. There are incidents in the health care delivery system every day. Will there be systemic quality issues with convenient care? I think it is extremely unlikely, and the reasons are manifold.

9 Nurse practitioners and physician assistants who provide treatment at these facilities are arguably 10 11 way overqualified for the limited scope of services that 12 they are allowed to offer. They use evidence-based 13 protocols, they use electronic medical records systems. There are compliance and outcome studies, some of which 14 have been referred to by the other panelists. There is 15 16 physician oversight, there are local referral networks. 17 These companies are in compliance with all the applicable 18 regulations.

All of those things and many more make it extremely unlikely that there will be systemic quality issues. In fact, as some people have mentioned, I think over time it will be proven that because convenient care clinics have the luxury of specialization, if you will, actually the quality of care provided within the limited scope of practice they offer will turn out to be better

1 than at other health care delivery outlets.

2 As far as the Convenient Care Association is 3 concerned, what it has done is publish quality and safety 4 standards. That was really the first thing that we did. 5 Those quality and safety standards or compliance with 6 them is now a requirement of membership, and compliance 7 is now being monitored by a third party. Those standards 8 are actually more stringent than the standards that have 9 been suggested for retail-based clinics by some other 10 organizations.

11 So, number two, what could slow the growth? Shortage or increased costs of nurse practitioners and 12 13 physician assistants, sometimes referred to, although I don't like the term, as mid-level practitioners. So far 14 15 we have found that to be manageable. The reason is that 16 nurse practitioners and physician assistants have found a 17 new career track that they really like. It offers 18 competitive compensation, more autonomy than they have 19 been used to, in some cases, more predictable hours or at 20 least more flexible hours.

21 Recently, there was a study which showed that 22 74 percent of nurse practitioners working in convenient 23 care clinics rated their job satisfaction as very good or 24 excellent. That is a very high level of employee 25 satisfaction, if you have ever run a company or been in 1 an HR department.

2 Longer term, clearly, we have to expand 3 educational capacity for advanced practice nurses. The 4 Convenient Care Association has convened a task force to 5 examine the issues related to ensuring an adequate supply 6 moving forward. I think this is very critical not only 7 to the industry but to the health of our country and 8 population as a whole. So, this issue obviously needs to 9 be addressed and I think it will be. 10 Number three, what could slow our growth? It 11 has been mentioned by a number of panelists, regulatory 12 impediments. They come in various shapes and sizes. 13 There are clinic licensure requirements, restrictions on 14 scope of practice and prescriptive authority, physician oversight requirements. Somebody mentioned the State of 15 16 Texas where a physician actually has to be on-site 20 17 percent of the time that a clinic is open, even though 18 they are not treating any patients. That actually serves 19 zero value for the patient. The oversight physicians 20 that are on-site can be reviewing charts on-line, but 21 instead, they have to take time to go to a clinic and 22 basically sit there, and that takes them away from attending to consumers who really do need medical care. 23 So, there are, in some states, already some 24 25 regulatory impediments that need to be either eliminated

or reduced in order to facilitate the growth of 1 2 convenient care. There is also corporate practice of 3 medicine in some states, New York and California most notably, those are significant barriers as well. 4 There 5 have been bills introduced in a number of states over the 6 past couple of years in an attempt to add regulatory 7 impediments which would slow the growth of convenient 8 care. The one thing that they all share is that they all 9 have failed, and they have failed basically because this 10 is swimming upstream. 11 Consumers, again, need easier access to 12 high-quality, affordable, routine health care. 13 Convenient care clinics are providing that. Payers

14 recognize that this is an opportunity to cut costs out of 15 the system. So, the long and the short of it is, it is 16 just not a politically tenable position to be opposed to 17 an industry that is actually providing not a silver 18 bullet, but a partial solution to what ails our \$2 19 trillion health care system.

20 So, the Convenient Care Association has done a 21 better job over the past year educating its various 22 constituencies, including policymakers and other members 23 of the medical community. One of the things that Mary 24 Kate mentioned is that many operators are partnering with 25 health care systems in the markets they serve.

RediClinic is one of them. Health care systems are
 getting involved in this business directly. I think as
 we move forward and better lines of communication are
 established with other parts of the medical community,
 the kind of integration and collaboration and cooperation
 that needs to happen, will happen.

7 So, number four, what could slow the growth? 8 This falls into the category of, is the business model 9 viable? There has not been too much discussion about 10 this, but it has been noted recently that a number of 11 operators have closed their doors. This is not as easy a 12 business as it seems to be. It takes a lot more capital 13 than you might think. It is relatively inexpensive to open a clinic, it is not clear however how many hundreds 14 of thousands of dollars per clinic it takes to sustain it 15 16 to cash flow break even. A number of operators have 17 underestimated this. They have perhaps counted on 18 opportunities for scope enhancement or expansion which do 19 not really exist to the degree that some people may have 20 thought.

21 You have to remember that the whole value 22 proposition is really designed around the 15-minute 23 visit. If operators add more complex procedures which 24 the result of which is that they are not able to 25 consistently deliver a 15-minute visit, then a convenient care clinic becomes just like any other health care
 delivery outlet and, therefore, would lose its uniqueness
 and its value to consumers. So, there are limitations on
 scope enhancement.

5 There is also the danger of over-saturation, 6 ultimately. If we are talking about five or six or 7 10,000 clinics, how many clinics is too much? Nobody 8 knows the answer to that question.

9 My own view is that some operators will survive and ultimately prosper. I think there will be some 10 11 consolidation in the industry. I think that what will 12 drive survival and ultimate prosperity is really, again, 13 the consumer. There is increased consumer awareness of 14 retail clinics. There is increased third-party payer acceptance of retail clinics, which is both driving 15 16 traffic and purchasing power. There is some creative and 17 appropriate scope expansion. There is more efficient 18 promotion and operations by clinic operators. They are 19 starting to understand things like which promotional 20 vehicles are more effective than others and how 21 labor-management works. They are getting more support from retailers and other elements of the health care 22 23 system.

24 So, what might the future hold? I am going to 25 stick my neck out a little bit, but not very much here.

I think the convenient care industry will continue to expand, but perhaps not at the very aggressive rate that some have predicted. There will be limited scope creep that will be governed by not only nurse practitioner expertise, but the importance of the 15-minute visit.

б I think convenient care clinics will play a 7 very significant role in the future in the administration 8 of broad-based preventive care, which is critical to the 9 health of this country and which retail clinics are in a unique position to provide. Things like immunizations, 10 11 things like screenings, things like smoking cessation and 12 weight management, these are things that can be very 13 efficiently provided in a retail setting.

I think physicians will continue to move up the value chain as they have been. Ultimately, and when I say ultimately, it could be five years from now or 15 years from now, I think the convenient care clinics will be a very important portal into our health care delivery system. Thank you.

20

21 MR. CHIARELLO: Thank you, Web. I would like 22 to thank all of our panelists for what I think has been 23 an entre into what could be a very lively and good 24 discussion on one of the most interesting innovations, I 25 think, in the health-care marketplace. We have

(Applause.)

identified an area where consumers may have seen and may
 have not had services reaching them and there has been
 some market-based solutions and it warrants our
 discussion.

5 At this time, if you have questions, there are 6 some folks around the room that you can pass your cards 7 to and they can pass them on up to me. But I would like 8 to kick it off with something that has been discussed a 9 little bit, especially by the providers and by Dr. Corwin. Let me just throw this out, given that there are 10 11 different retail clinic models and different providers, what is the optimal level of physician oversight that is 12 13 necessary to both make a retail clinic cost-effective but 14 also consumer safe?

15

Why don't we start with you, Web?

16 MR. GOLINKIN: Well, my conceptual answer would 17 be the level that is necessary to both ensure and add 18 value to the quality of the care that's provided. There 19 are -- and this is the unfortunate reality of the situation is that there are these different state 20 regulations related to physician oversight. In some 21 22 cases, there is the site-based requirement that I 23 described in Texas. In other cases, a physician can only oversee a certain number of nurse practitioners. It can 24 25 be as few as three nurse practitioners in some cases or

as many as 20 in others. But none of these regulations
 were based, to my knowledge, on any research into exactly
 what problem are we trying to solve here.

4 That is the kind of rationality that needs to 5 be introduced into the regulatory framework here, which 6 is, does physician oversight add value? We, at 7 RediClinic, believe that it does. And what kind of 8 physician oversight adds value? Is it the chart review? 9 Is it the visit with the nurse practitioner on a regular 10 basis? Is it the nurse practitioner being able to access 11 oversight physicians when they need to? What is it exactly that adds value? Then, once you decide on that, 12 13 then how many nurse practitioners should and/or could an oversight physician rationally be able to supervise? 14

DR. CORWIN: I think there is a variability to 15 16 how people practice medicine. Specifically, pediatrics, 17 as I said already, is different. There are such things 18 as pediatric nurse practitioners and pediatricians. 19 Pediatric nurse practitioners are employed and work with many, many, many pediatricians in the United States. 20 Τn 21 our own group, we have nurse practitioners. We work with 22 them side-by-side as a collegial team delivering care. 23 However, we are there, also. And it is not just superfluous kinds of sitting around; it is while we are 24 25 working when they have a question about a patient, they

come and get us and we see the patient with them and provide on-site expertise for that specific condition. It is not necessary all the time. You never know when it is going to happen because you do not really know what is behind the door when you walk into a room. So, on a regular basis, that is one model.

7 There are other models where there are 8 oversight supervision of nurse practitioners in various 9 settings, and as you have already spoken to, Web, I mean, 10 they are variable depending on the state. Initially, in 11 my youth, I created and founded a nurse practitioner 12 training program at the State University of New York, 13 Upstate Medical University in Syracuse that began as a certificate program in the early 1970s and is now a 14 Master's level program and still exists and turns out 15 16 fine nurse practitioners. This is not about nurse 17 practitioners, their skill sets or abilities. But there 18 are different skills sets or abilities for psychiatric nurse practitioners, family nurse practitioners, adult 19 care nurse practitioners and pediatric nurse 20 21 practitioners.

22 So, when I speak from the pediatric point of 23 view, I am really saying this is a different game and it 24 is not necessarily transferable among the skill sets that 25 nurse practitioners have, the physician assistants have or physicians in general who are non-pediatricians. So,
 that is why I was selecting out the children which is why
 we have stated, as an organization, what we have.

4 MS. RATNER: I think one of the things that we 5 have to look at from a supervision perspective is the 6 limited scope of service that these clinics provide. The 7 nurse practitioners are not doing OB work, they are not 8 doing cardiac work, they are providing a very limited 9 scope of service. So, when we deal with the supervision 10 requirements and work with regulators in a particular 11 state, that is one thing that we always like to stress, because I think there is an expanded opportunity to 12 13 provide more flexible supervision.

14 The other thing that you have to look at is the density of these clinics within a particular market. 15 16 There may be some markets where there are five clinics 17 located within a 10-mile radius. I think supervision may 18 shift in a particular market like that as opposed to two 19 clinics within a 30-mile radius. So, those are different variables that will play on the type of supervision 20 structure that you may want to have within a particular 21 clinic. 22

23 MR. CHIARELLO: Thank you for the comments and 24 questions that are coming in. I will turn this now to 25 Bill and Mary Kate because there is a question actually,

1 Mary Kate, on your presentation.

You said that RediClinic now accepts Medicare and the question is, does Medicare accept RediClinic? And in that framework, let us talk a little bit about pricing and how insurance is playing a role in that. I would like you and Bill to comment on that.

7 MS. SCOTT: It is interesting. The model first 8 started out as cash and then quickly shifted into more of 9 a mass market approach with coverage. So, about 45 10 percent of all visits have some type of insurance 11 copayment. We do not really know a lot about how 12 Medicare is actually going to work and if Medicare is 13 ready to accept these clinics because of the pricing 14 variations.

It is quite interesting. When you work with 15 16 the insurance carriers, the first thing they say is, 17 well, what is the discounted rate? But there really is 18 no room to further discount. So, the carriers struggle 19 with the issue of how do you get someone to plug into a system when there are not extraordinary margins to play 20 21 with? So, it is both a pricing issue, but it is about a 22 systems issue.

I know we have a number of folks on plans and they will talk about that today. But the bottom line on Medicare is that we actually do not know because we have very few of these Medicare patients using the clinics and
 we do not really know exactly how it is going to fit in
 with the Medicare regulations.

4 MR. CHIARELLO: What about other insurance 5 providers? Are most customers -- and maybe you folks are 6 better able to answer that. But are most customers now 7 paying copays instead of full price?

8 MS. SCOTT: The majority of the visits have 9 some kind of copay. What is different from clinic to 10 clinic is some will actually just accept a copay; others 11 actually accept the full payment and then the consumer 12 then has to chase down the insurance company for the 13 reimbursement.

14 DR. SAGE: Personally, I think that the shift 15 to insured business by these operators is completely 16 understandable from everyone's perspective, but is really 17 a huge challenge for the business model. I think it is a 18 huge challenge because of the trust issues around your 19 insurance company involvement. I think it is a huge challenge because I think transparent and uniform pricing 20 21 is one of the things that is very attractive to consumers in the sense of instead of, well, I am not sure how much 22 I am paying or how much it is costing is both an 23 individual consumer competitive problem and a system-wide 24 25 potential competitive problem. I think it is a challenge to the administrative simplification and cost savings
 associated with the original model.

3 If there is a bright side to this, I do think 4 that there are going to be some very interesting things 5 as the Medicaid piece expands. One, I think it is just 6 very good to provide new sources of access to primary 7 care for Medicaid populations. But the other I am 8 actually kind of reminded -- and this is based on the 9 prior question of what happened in California in the 10 1980s. What actually brought down the regulatory 11 barriers to selective contracting was California's 12 Medicaid contracting program, and I could see a similar 13 thing happening here with the scope of practice and 14 supervision requirements around physicians and nurse practitioners where getting Medicaid involvement and, 15 16 therefore, having state legislatures putting their own 17 money at issue, as well as just the political preferences of their constituents will change some of the more 18 19 outdated of those laws.

20 MR. CHIARELLO: From your research, is there 21 evidence that understanding the pricing and the pricing 22 transparency for the consumers is really important? 23 MS. SCOTT: The three things the consumer 24 consistently says they like about the model is the

25 convenience in terms of the waiting. Second, the

1 location, and third, the price transparency.

2 What they articulate is not is it cheap or 3 cheaper, but for the first time they actually understand 4 what they are receiving. Through several focus groups 5 and surveys, consumers consistently talk about the sort б of deluge of bills that they receive that are almost un-7 understandable. The discussion is they have no choice 8 but to pay them because, otherwise, this will affect 9 their credit. They have no idea why they are paying They do not know what it is for. This is the only 10 them. 11 thing that they purchase that they never have understood 12 what the price is going to be and when it actually ever 13 stops being billed at them.

MR. CHIARELLO: Let us shift the discussion a
little bit to some of the legislative and other
regulatory barriers and activities going on.

17 Sara, you had started to address this in your 18 presentation. One question came in asking you to 19 elaborate on some of the initiatives at the state and federal level that are being made to impose additional 20 21 regulations on clinics. In particular, we have seen some 22 proposed rules on clinic design and some geographic 23 restraints on clinic location in some types of stores or based on products that are being sold. So, if you could 24 talk a little bit about those restraints. 25

1 MS. RATNER: I think the one that has been 2 particularly successful is Massachusetts. The regulation 3 that came out last year governing limited service 4 clinics, that is where they got the name, basically 5 codified a series of waivers that were required for these б clinics to operate in Massachusetts. That has been very 7 successful because it has been a series of regulations 8 that have allowed the clinics to operate and allowed not 9 just retail clinics to operate, but any other health care 10 provider wishing to enter this space can fall within 11 those regulations and start a clinic. 12 Other states have put forth bills that are a 13 bit more onerous. Rhode Island and Illinois, for example, are ones that have bills right now that are 14 specifically directed at retail clinics, not just limited 15 16 services clinics, that essentially can prevent this 17 business model from flourishing in the state. There are prohibitions on selling tobacco and alcohol in facilities 18 19 where these clinics operate. There are very strict physician/nurse practitioner oversight ratios. There are 20 21 requirements on having a certain number of restrooms near 22 the clinics. There are hand washing requirements, 23 drinking fountain requirements, all things that add cost to this business model. For an area that has tried to 24 25 keep costs relatively low to provide a vital access

point, these are things that could be detrimental to the
 viability of this model.

3 MR. CHIARELLO: Web, do you have anything to 4 add?

5 MR. GOLINKIN: I addressed this a little bit 6 before. I think at the end of the day, these attempts to 7 slow the growth of retail clinics by trying to throw up 8 regulatory roadblocks will fail because this is an idea 9 whose time has come and it is being well implemented by 10 every operator that I am aware of.

11 The Convenient Care Association, by the way, represents about 95 percent of all the clinics operating 12 13 in the United States. It is frustrating, frankly, to be fighting these brush fires at this point. I think we 14 will win them in the end, but it takes a lot of extra 15 16 energy and attention away from the mission of this 17 industry and the companies in this industry, which is to 18 provide consumers with easier access to affordable health 19 care.

20 What we should really be paying attention to, 21 how do we collaborate with pediatricians and with other 22 members of the medical community to maximize the benefit 23 and the efficiency of the services that we are providing? 24 So, I think it is time for us to turn the dialogue in 25 that direction, which is, how do we collaborate better
1 with other elements of the medical community?

2 We are working, at RediClinic, with physicians 3 every day. We have oversight physicians for every one of 4 our clinics who are deeply involved in the quality of the 5 care that is being provided there. We partner with 6 health care systems in every market we serve, a leading 7 health care system in every market we serve. We are 8 doing our best to reach out to other elements of the 9 medical community. Those efforts are being reciprocated, 10 in most cases. 11 We need to just do whatever we can to continue that trend because that is where the consumer will 12 13 benefit. 14 MR. CHIARELLO: Another person asked a question which is worth noting. The question is, are there any 15 lessons to be learned from retail clinics that are done 16 17 internationally? Some of you may know that the Wall 18 Street Journal recently reported that in the United 19 Kingdom, their pharmacists are now given a somewhat 20 expanded scope of service that they can provide in a 21 similar type of setting that we are seeing in this space. Are there any lessons to be learned from Canada or 22 anyplace else about retail clinics? 23 DR. SAGE: Mary Kate just said to me that she 24

liked the Wal-Mart/Canada position in my presentation

25

1 because she is from Toronto. So, she can answer that.

2 MS. SCOTT: We have seen these clinics in Spain 3 and in Canada and the U.K. The hard part about the 4 lessons learned is that those clinics are actually part 5 of the free access. So, there is not even a copayment 6 for them.

7 I think one of the things that those countries 8 are interested to understand is if they open up a new 9 avenue of care, will it increase utilization? So, I 10 think that is actually a really interesting question and 11 I know that the carriers here in the U.S. are also 12 interested to know, again, will supply actually influence 13 demand?

14 So, the early studies -- but the data are early -- the data show that, in fact, it does not increase 15 16 utilization, that people do not actually go to one of 17 these clinics and then follow up with a visit to the 18 doctor. The early data here in the U.S. seems to echo 19 that, although, again, the data are preliminary and just in one state, in Minnesota. So, I think that is the 20 21 issue to watch.

DR. SAGE: And the only point I would make about international comparisons not limited to the limited service or retail clinics is that when you go country to country and compare health care, what you call

a place and what you call a provider does not matter 1 2 nearly as much as what that place or that person does. A 3 hospital in most of Western Europe is very different from 4 a hospital here. What we call a nurse practitioner is 5 very much what most of Western Europe calls a primary 6 care physician if you look at actually who the people are 7 and what they do. So, I think that is just a good 8 caution on international comparisons.

9 MS. SCOTT: I guess my last point on the 10 international piece is that a number of those countries 11 that have these clinics, if you actually had those 12 routine conditions and went to a physician, you would not 13 see the physician, you would see the nurse. So, for many 14 consumers, this is not a significant difference to go to 15 a different location and also see the nurse.

16 MR. CHIARELLO: From a competition attorney's 17 perspective, one of the interesting developments that you 18 touched on, Mary Kate, in your presentation -- and I 19 would love to hear from everyone on this -- is that what 20 seems to be a market reaction from hospitals and hospital 21 network providers to provide retail clinics, and it looks 22 like Wal-Mart is making the outreach with hospitals and 23 hospital networks. Do hospital networks kind of help alleviate some of the other concerns that are being 24 25 raised by legislation and by other rule-making or by

1 other critics of retail clinics? And are they able to 2 provide a truly viable competitive alternative?

MS. SCOTT: So, hospitals are really entering this retail clinic arena in two different ways. Some of them are operators and some of them are affiliating. I used Wal-Mart as an illustration of a retailer, but, in fact, there are many retailers. CVS actually has a number of affiliations with some of the hospital systems.

9 The hospitals are doing this to serve new 10 patients and bring new patients in. It is almost like a 11 mini-experience of a hospital. Some of them are also 12 doing this to actually serve existing patients. So, we 13 are seeing hospitals respond by putting a retail-like clinic on-site in their own facility and, in effect, 14 diverting patients who come to the ED (emergency 15 16 department in Canada, or ER in the U.S.) into a more 17 appropriate venue.

So, for a hospital, it is actually a pretty 18 19 interesting challenge from a pricing point of view because, in fact, if you go to the ED and you are a cash-20 21 paying person, first of all, you pay an extraordinary sum 22 of money and you are actually very profitable. So, in 23 fact, some of the hospitals are starting to struggle with just how much do I want to divert the patients. Of 24 25 course, many hospitals also struggle with the whole issue

1

of uncompensated care.

2 So, I want to make sure we bring in that sense, 3 I think the reason why hospitals are doing it is too. 4 this is what the consumer is demanding and they believe 5 that they do have a compelling offer. Many of them talk б about continuity of care. Many of them talk about a 7 community presence. I suspect the retailers really enjoy 8 the relationship as do the operators because this 9 actually is attractive to consumers. So, it makes it 10 easier for the consumer to go to a clinic when they see a 11 well-known brand and it makes it easy to make that first 12 foray into that clinic. 13 MR. GOLINKIN: Well, as I mentioned, we have

14 been partnering with -- I really refer to them, which I think they are in most cases, as health care systems 15 16 rather than just hospitals because most big health care 17 systems, a hospital is just a part of what they do in a 18 community. We have seen benefits from these alliances to 19 begin with. We are in Wal-Mart Supercenters today. We 20 are expanding with Wal-Mart. In every case, as we 21 expand, we are partnering with a leading health care system. We see a lot of benefits to the alliances. 22

23 The health care systems provide the state
24 required physician oversight. We believe that they
25 provide a built-in referral network, although that is not

1 the only one we use. I think it is true that the co-2 branding is reassuring to consumers. We feel like it 3 just gives us a better opportunity to integrate more 4 quickly into the medical community in these markets. 5 So, there definitely are benefits. It is a little bit harder and you have to be careful, again, that 6 7 you do not add unnecessary costs to this model. I think 8 this is really something that everybody needs to come 9 back to, which is the value proposition here is 10 convenience and affordability and basic quality within a 11 limited scope of service. The margins are very slim in 12 this business at this point, and anything that you do 13 that adds cost to the model pushes it more in the direction of what is already available and could 14 potentially destroy the model. 15 16 This is not an easy needle to thread. That is 17 why health care reform has been so difficult. I also agree with the comments I think Bill 18 19 made earlier on. The discourse about health care reform 20 in this country has been all about who pays. If you just address that side of it and you do not address adding 21 22 efficiency to the delivery of health care, you are never 23 going to fix the problem. 24 Look at Massachusetts. In their universal

25 health care, people cannot get an appointment. They have

not done anything to address the cost or the access side of the equation. That is not health care reform that is going to work for anybody. It is not going to work for the people who now can pay. It is not going to work for the payers. It is just going to add hundreds of billions of dollars to the health care bill and nobody is going to benefit.

8 So, if we are going to fix this, we have to get 9 serious about addressing innovation in health care 10 delivery. This is not a silver bullet, what we are doing 11 today in the convenient care industry, but it is a 12 partial solution and maybe it stimulates innovation in 13 other areas of the health care system.

MR. CHIARELLO: Robert, the health care system that would be the hospital providers going into the retail setting, does that help address some of the continuity of care concerns?

DR. CORWIN: Well, again, general hospitals, the answer is no. If you are talking about children's hospitals or pediatric emergency set-ups or pediatric urgent care set-ups, the answer is perhaps. But, again, it depends on the vehicle that you are talking about. So, systems alone do not do it.

24 Pediatrics is different. It has been
25 recognized by most hospital systems because they usually

have children's hospitals or separate children's emergency rooms or pediatric urgent care centers that are different than the adult ones. So, in that sense, if we had, in a retail-based clinic, a pediatric nurse practitioner supervised by a pediatrician going forward, that might make a difference.

7 Web spoke earlier about expanding into 8 immunizations as a simple, straightforward, limited 9 service. The answer is it is not a simple, limited, 10 straightforward service because of all the complex issues 11 that have to be dealt with relative to vaccines and 12 children and some of the complications that happen 13 therein.

I can only tell you that on Tuesday of this 14 week, I spent 35 minutes that I had not planned on 15 16 spending with a mom of a one-year-old who was really 17 concerned about the 15-month vaccines yet to come in 18 terms of measles, mumps, rubella, autism and all the 19 complications therein. That took a lot of talking and a lot of thinking to give her stuff to read about and 20 21 material to think about between this visit and the next 22 one so that we would not have to do it again. That comes out of a lot of background and experience that I am not 23 sure that general adult level nurse practitioners have, 24 25 nor even pediatric nurse practitioners.

1 So, in fact, I think when we talk about it, one 2 of the basic tenets of the medical home is immunizations 3 and I strongly feel, given everything that is going on 4 with vaccines in today's world, that that needs to remain 5 within the medical home and it is not something to be б casually done elsewhere, except perhaps for influenza 7 vaccine where, in fact, the efficient delivery system for 8 giving flu vaccines to all Americans is not existent currently. We are going to need to use all of the 9 different settings that we have in order to do that. 10 11 MR. CHIARELLO: I want to thank the panel 12 We have exhausted our time for the panel. I aqain. 13 would encourage those with questions, they will still be here for a little bit after, I assume. There is always 14 going to be the opportunity to submit comments to the 15 16 public record. I want to thank everyone for submitting 17 questions and I am sorry we could not get to all of them 18 in this panel. Thank you again, panelists. 19 (Applause.) 20 21 22 23 24 25

1

PANEL 2: QUALITY AND PRICE INFORMATION TRANSPARENCY

2 DR. COOPER: Good morning, I am James Cooper 3 with the Office of Policy Planning here at the FTC. 4 Welcome to our second panel on transparency.

5 Increasingly, transparency is becoming a 6 watchword in health care reform. The concept is simple. 7 Armed with better data on the relative prices and 8 qualities of competing health care providers, consumers 9 will make more informed choices. This enhanced consumer choice will drive competition, ultimately leading to 10 11 lower prices and better quality in health care. Indeed, 12 as Chairman Kovacic mentioned this morning, this concept, 13 fostering competition by ensuring that consumers have 14 access to truthful marketplace information, is a cornerstone of FTC policy. 15

16 At the same time, however, the effect of 17 transparency initiatives in health care markets remains 18 unclear. For instance, insurance insulates a large 19 proportion of the population from the prices that health care providers actually charge. So, transparency may not 20 21 have a large effect on this segment of the population. 22 Indeed, as one of our panelists will show today, the data seem to indicate that only a limited number of consumers 23 24 take advantage of the price and quality data that already 25 exists.

Also, some have raised concerns over the
 validity of quality measures that exist today. And,
 finally, price disclosures can raise competition
 concerns.

5 We are very lucky today to have such a 6 distinguished panel here to talk about these issues. 7 First up will be David Hyman. He's the Richard W. and 8 Marie L. Corman Professor of Law and Medicine at the 9 University of Illinois, where he directs the Epstein 10 Program in Health Law and Policy.

11 The next presenter will be Maribeth Shannon, to 12 my left. She is the director of the California Health 13 Care Foundation's Market and Policy Monitor Program which 14 promotes greater transparency and accountability in 15 California's health care system.

16 Our third presenter, to my immediate right, is 17 Dr. Nancy Nielsen. Dr. Nielsen is an internist from 18 Buffalo, New York, and she was elected President Elect of 19 the American Medical Association in June 2007.

Finally, our last presenter today will be Stephanie Kanwit. She currently serves as Special Counsel to America's Health Insurance Plans and the Pharmaceutical Care Management Association, which represents pharmacy and benefit managers and their health care partners in pharmaceutical care. So, without any further ado, I will turn it
 over to David to get us started.

3 MR. HYMAN: It is a pleasure to be back here at 4 the FTC. I worked here from 2001 until 2004, and I did 5 about 30 days of these hearings, along with Pat Schulteis б and a group of very talented people. I just wanted to 7 start by telling everybody here these things do not 8 happen and do not run as smoothly as this without an 9 incredible amount of hard work by a lot of people at the Federal Trade Commission, some of whom you will see 10 11 today, many of whom work behind the scenes. So, I wanted 12 to single out Maureen, Dan and James, who have been the 13 public presence, but there are lots of other people who are involved, including Michelle. I would just like to 14 ask the audience to give them all a round of applause. 15 16 (Applause.) 17 MR. HYMAN: Okay, that does not count against 18 my time. 19 (Laughter.) 20 MR. HYMAN: As I said, we did a whole bunch of 21 hearing some years ago, issued a big report that Chairman Kovacic referenced previously. Both Dr. Nielsen and Ms. 22 23 Kanwit testified in those hearings. I do not know how we left Maribeth off. Sorry about that. 24 25 MS. SHANNON: California, just too far away.

1 MR. HYMAN: California. And the striking thing 2 is we did a lot of work on transparency and we said 3 absolutely nothing about retail clinics. So, that will 4 tell you something about the pace of innovation in health 5 care and how confident you ought to be in your ability to 6 predict the future.

7

(Laughter.)

8 MR. HYMAN: That said, let me give you a 9 general overview of the issues on transparency. Where we have been and where we are. Alex Azar used to be the 10 11 Deputy Secretary of HHS. He gave this speech two years 12 ago and I think he nicely summarized it. Our health care 13 system is both price blind and quality silent. People in the system do not have a great insight into how they are 14 doing, let alone people who are the consumers of the 15 16 system or those who are paying for it. That is very 17 unlike every other market, or at least to the degree to 18 which we are price blind and quality silent is very 19 unusual in the health care marketplace. That is why 20 there has been a lot of interest in transparency 21 initiatives.

22 So, let me just give you -- law professors do 23 theories, so let me give you some of the theory for why 24 people think transparency is a good idea, particularly in 25 the health care market. I am going to divide into demand

1

side effects in theory and supply side effects in theory.

2 So, on the demand side, you know, this is 3 pretty straightforward. The purchasers, if they have 4 access to good information, can reward superior 5 performance. They flock to people who provide high-6 quality, low-cost services and they avoid people who 7 provide low-quality, high-cost services. They make 8 individual decisions sorting themselves along those 9 parameters reflecting their own unique preferences. So, that is the sort of straightforward demand side effects, 10 11 expected effects of transparency.

12 There are also two other important components 13 that do not directly relate to purchasing decisions by individual consumers, but nonetheless are very important. 14 We spend a lot of money on health care services. It goes 15 16 in lots of different pots. It would be nice to know, 17 both as consumers and policymakers, first of all, how 18 good or bad a job individual providers of those services 19 are doing and also tell us something about the 20 performance of a very substantial sector of our economy. 21 Fifteen-16 percent of the GDP is going into health care. 22 It would be nice to know that we are getting good value 23 for the money we are spending there.

Now, what about the supply side? Again, in theory, the basic issue, as I said previously, is lots of

people working within health care do not have a great 1 2 idea of how well or poorly they are doing and how they 3 stack up against the competitors down the street. So, 4 more transparency can have supply side effects by 5 informing providers of am I above average as I think I am or am I below average, and if I am below average, what 6 7 are the specific things that explain that? What can I do 8 to do better?

One of the things I tell people when I talk 9 about transparency, which I do a lot, is nobody goes to 10 11 medical school to be below average. That is not the 12 cohort of people you have selected for, that is not the 13 thing that keeps you in that long training period, that is not the thing that gets you up in the middle of the 14 night to answer the questions that your patients have or 15 16 go down to the emergency room to answer the questions 17 your patients have.

18 So, physicians and other health care providers 19 want to deliver high-quality care. Transparency is 20 potentially an important tool with which to provide them 21 the information they need to know to improve.

And the other factor, of course, and it is sort of incidental, consequence of disclosing that you happen to be below average or not where you think you ought to be is it provides a real incentive to do better. Whether

1 it is because of pride or because of the prospect of 2 attracting more patients or being able to brag about the 3 quality of care you are delivering when you go to the 4 doctor's locker room, whatever it is, it is suddenly an 5 encouragement for people to do better.

б That effect, obviously, is going to be more 7 significant if the information is likely to be made 8 public because, suddenly, it is not just you knowing that 9 you are below average or not as good as you had hoped you would be, but everybody else does as well. Then they can 10 11 tease you in the hospital locker room or shun you if they 12 do not want to do business with you. You can sort of 13 think about a variety of things along that spectrum.

The other reason why -- and this is not theory, 14 it is reality -- why transparency initiatives has lots of 15 16 proponents is because of the political economy of 17 transparency initiatives. Even if we cannot agree about 18 how we want to substantively regulate an area of the 19 health care market, across the political spectrum, people can say, I am in favor of transparency. The reasons they 20 might offer for being in favor of transparency may differ 21 22 a little bit, but they can all come out in favor of it.

This is a very long, very heavily footnoted article Bill Sage wrote, who was on the first panel. Law professors do get paid by the footnote.

1

(Laughter.)

2 MR. HYMAN: We respond to incentives as well, 3 and they are transparent.

4 As Bill points out, disclosure laws work across 5 the political spectrum. Conservatives talk about market б facilitation and bootstrapping and liberals favor 7 empowerment and the right to know. You do not have to 8 substantively agree as to how we should regulate health 9 care to think more information has utility, although the 10 reasons you might offer for thinking it has utility may 11 differ.

12 So, what do we know about the effects of these 13 initiatives? Mary Beth is going to talk in more detail about California. I thought I would give you a sort of 14 high-level view of this. The short answer is, there is 15 16 mixed evidence. There is much better evidence for impact 17 of transparency initiatives on the supply side. That is, providers decide to hitch up their socks and do a better 18 19 job than for an impact on the demand side where consumers say, well, I looked at the report card and I am not going 20 21 to my doctor any more or I am going to go to the doctor 22 who is ranked higher. The evidence simply is not there to indicate a significant impact on the demand side. 23

I will talk at the end about some reasons why that might be and ways of thinking about strengthening it, if that is what we want to do. As I said previously,
 there is better evidence for supply-side effects when the
 results are made public than when they are not.

4 Last, an important point, design details 5 matter. What transparency measures you use matter, how 6 you package them and signal the results to consumers and 7 to providers makes a big difference. I will have some 8 slides to show you on that. You might think, well, no, 9 people can sort this out, it should not matter how we 10 frame it. It makes a huge difference how you frame it in 11 terms of how both consumers and providers use it.

12 So, my students now that are starting in law 13 school are 22, 23 years old. They do not remember the Berlin Wall. They cannot remember a time when everyone 14 did not have a cell phone and access to the Internet. 15 16 Alfred E. Newman, what, me worry, from Mad Magazine is 17 someone who I have to introduce them to every year. So, 18 what could possibly go wrong? Well, a bunch of things 19 can go wrong if you do not do this well.

There is some evidence that increased transparency can lead to problematic behavior. How problematic depends a little bit upon your risk tolerance and what direction you think we ought to be going in, but there is evidence of what I think lots of people would say is problematic behavior. Among them, managing to the

measures exclusively. It is not a problem if people 1 2 manage to the measures. The whole point of setting up 3 the measure is because you think it has some utility in 4 assessing quality. But if people fixate on the measures 5 to the exclusion of other things that matter, but are not 6 captured by other measures, that is to the extent we are 7 under-determining our measures, you teach to the test, 8 but you actually have not done a particularly good job of 9 delivering high-quality care.

The obvious response to that is, well, we ought 10 11 to have more measures and then, suddenly, they will be delivering higher quality care. The reality is for lots 12 13 of things we do not have good measures. So, you ought to worry about measures crowding out levels of care that 14 pretty much everybody agrees is the standard of care, but 15 16 it gets ignored or at least slighted in the presence of a 17 dominance of measured measures, if I can use that.

The second kind of problematic behavior is patient de-selection, non-compliant patients, patients with problems that will make an individual provider's record look bad. That is suddenly a patient who a physician who is suddenly being ranked is not going to be enthusiastic about continuing to see.

You also should also worry about using themeasures to frame decisions versus to steer people's

decisions. You do not want to say and embed in the way in which you do a transparency initiative, here is the right thing to do. What you ought to be doing is framing issues for consumers and letting them make their own decisions.

A final challenge is balancing transparency and innovation. If you pick a set of measures and say, this is what we are going to use forever, there may be a bunch of other things that are important. If you do not update, you are not going to capture that. You ought to worry about old measures versus new measures.

12 So, a couple of ways of screwing things up. 13 You can do transparency on something nobody really cares 14 about. You can use bad measures for things that people 15 care about. This is an issue that physicians are very 16 concerned about, especially at the individual physician 17 level.

18 There are complications with how you attribute 19 patients to individual physicians. How big a sample do 20 you need in order to get reliable results? And you can 21 also poorly communicate the results.

Let me show a couple of slides Judy Hibbard showed a few years ago at the hearing to make the last point, because I think it is one people do not focus on, but they really ought to. This is real data, consumer satisfaction ratings and premium costs for a bunch of
 different health plans.

3 Simple question, what is the best health plan? 4 Well, you look at that and you go, I do not know. I do 5 not have any idea. And why don't I have any idea? Because it has been framed in a way that makes it really б 7 hard for you to extract meaning from the chart, partly 8 because the plans are listed alphabetically. All you 9 have to do is group things by price and then you can look 10 at this and say, at any given price point, what is the 11 best health plan? It is suddenly easy to do rather than 12 hard to do. So, framing the information makes a huge 13 difference in its utility. That is at least part of the reason why we have not seen the kind of demand side 14 impact that we would like to see. 15

16 This is, again, real data from Pennsylvania. 17 There have been lots of report cards. And you look at 18 this and you say, well, it is a sea of ink and I cannot 19 figure out what to make of it, and some things that they 20 are measuring, I do not know whether a higher number is 21 good or bad. So, a lot more work ought to go into 22 providing better framed information for people.

I have got a bunch of rules for the road which I will just focus on the last one in 30 seconds. Making information salient to consumers is really important.

1 But providing information, the way in which you do it 2 can make it easier or harder for people to use it, and 3 think about framing and setting defaults rather than just 4 providing information if you are trying to make 5 transparency framework work better. Thank you very much. б (Applause.) 7 MS. SHANNON: Thank you. So, I will just start 8 while we are setting this up, which is I agree with 9 everything David just said. I am going to focus on the 10 supply side issue, though. I agree for transparency the 11 demand side -- excuse me, reverse. I think that there is a lot of evidence that shows on the supply side that 12 13 providers really are influenced by these measures. There is a little bit less on the consumer, sort of the demand 14 15 side. 16 So, what I would like to do just really 17 quickly, these are two web sites the California Health 18 Care Foundation sponsors, one on nursing home care, one 19 on hospital care. We did pay a lot of attention to what 20 research exists about how to make these sites useful to

consumers and how to design them. We did lots of focus group testing, et cetera. So, I will not spend a lot of time on these sites, they are really good. I would encourage you to look at them someday. I have the web addresses at the end, so I will just share those with

1 you.

2 But what I really wanted to focus on today was 3 some information that we have recently done. This report 4 has not been released yet. It will be released at the 5 beginning of May. It is a survey that we conducted with б Harris Interactive to actually look at who, on the 7 consumer side, is using these sites and what information 8 might we provide to make that experience the best it 9 possibly can be.

10 So, this I think probably is not surprising to 11 These are a bunch of cuts for who is using the you. 12 Internet for health care information now. And, of 13 course, you can see here that older, more poorly educated, lower income people have much less access to 14 the Internet. And, of course, when you think about who 15 16 is using health care service, that is the very population 17 we are trying to reach. Unfortunately, the Internet 18 might not be the best way to do it. But the numbers are 19 not zero. I mean, there are some sizable numbers of people, usually in the range of 30 to 40 percent, of that 20 21 population that indeed does use the Internet for 22 services. So, it is not a hopeless cause, but it could 23 certainly improve.

This is just one quick slide to show that things are getting better, that we did in the same survey

in 2004 and then repeated it in 2007. The section here with the red box around it does show that there has been some improvement in people using the Internet to find physicians and other health care professionals. It moved from 19 percent to 26 percent.

б But here we looked at how people are using this 7 information. So, again, we have the 2004 results and the 8 2007 results and we have cut it by whether they are 9 looking for information on hospitals, health plans or physicians. You will see, for the most part, there 10 11 actually hasn't been a huge amount of improvement for 12 2004 to 2007. There are in some buckets, like 13 physicians. There are more people using the Internet to find information about physicians. 14

But what is really kind of frightening here is it drops pretty dramatically in terms of who knows that these sites exist versus whether or not it actually made an impact on their decisions, whether they actually considered a change.

As I was flying out here, I was reading some studies. It is always good to use the airplane to read things. I saw a study done by the group that rates health plans in California or at least provides the web site so people can see those ratings. What they found is that when they publish reports of health plan quality

using NCQA measures and then survey who actually used the 1 2 reports and made a decision, they found that 24 percent 3 ended up changing, but changing to a health plan that had 4 fewer stars and 38 percent of the control group that did 5 not get a report ended up moving to medical groups that б had more stars. So, it is kind of like in the absence of 7 information, people seemed to have been making better 8 decisions than when we actually gave them information.

9 We decided to take a cut and see, well, how 10 about people who really have health care needs, because I 11 was kind of trying to justify these low numbers by 12 saying, you know, but only 10 percent of the population 13 in California is hospitalized in a given year. A lot of people are not terribly concerned about accessing health 14 care information until they need it. So, we actually 15 16 looked at those who had been hospitalized in the prior 17 two years and those who were in poor health. What we found were the numbers really were not significantly 18 19 different. They were almost exactly the same. Again, those people tended not to be changing their decisions 20 based on the information that they found. 21

22 So, let me move a little bit into price 23 transparency issues. We certainly spent a lot of time 24 doing quality measures in California. We actually do not 25 have a lot of price transparency yet. So, we have been doing some research to try and see how we could do that effectively. So, we have been looking at other state's sites, looking at other lessons, doing a lot of research on what might work. And there are three questions I kind of wanted to talk about today.

6 The first is, are consumers willing to pay for 7 better quality? The second is, does transparency work in 8 terms of lowering prices in health care, and then how can 9 we best serve consumer needs?

10 So, the first question, this is actually a 11 slide that comes from Thompson, the health care information company where they actually surveyed 12 13 consumers to see if they were willing to pay for higher quality. Fifty-three percent of the population said 14 15 nope, and largely, these are insured people where they 16 are not as price sensitive as people who are uninsured 17 But still, you know, they were not willing to would be. 18 even spend a little bit more in terms of copays to get 19 higher quality.

20 There was another 26 percent that was willing 21 to pay up to 10 percent more. But then the numbers fell 22 off pretty dramatically after that.

Another piece of information that we looked at, we tried to find whether we could learn something about those who potentially are price sensitive and looked at

self-pay markets. Specifically, we looked at Lasik 1 2 surgery. This is an article that came out of that 3 research that was published in health affairs in 2007, I 4 think February of 2007, where we actually tried to look 5 at this question of, okay, when it is coming directly out б of their pocket, are they price shopping, are they 7 calling around and are they looking at quality information? 8

9 This chart is hard to read. Fortunately, we have three screens which makes it a little bit better. 10 11 But the bars are volume and the lines are price. The 12 line that goes all the way across is for sort of basic 13 Lasik. The line that you will see coming in just in 2004, 2005 is for custom Lasik. So, there is a little 14 bit of a difference in terms of kinds of procedures, and 15 16 in 2004 and 2006, we actually break the bar into those 17 that were getting basic Lasik versus those that were 18 getting custom Lasik.

But what is really interesting about this chart is the price line. So, initially, the price was relatively high, the procedure was relatively new. There wasn't a lot of volume. But then it dropped off pretty dramatically, largely as more providers entered the market, but it did not have any effect necessarily on volume. So, price dropped, but there were not 1

necessarily more people getting a Lasik procedure.

2 What happened kind of was this innovation. 3 Well, let's do custom Lasik instead which had a higher 4 price point. The thing that I think is particularly 5 interesting about this market, the Lasik market, is it is 6 one of the few self-pay markets that we looked at where 7 you actually could call and get a price estimate without 8 actually going in to have an exam done first.

9 On lots of other self-pay markets, plastic 10 surgery, for example, cosmetic surgery, you actually have 11 to go in and have a consultation, and that is a little 12 bit of a barrier for people when they are price shopping.

13 The other interesting thing about this market, 14 other than the fact that you can call and get a price 15 pretty readily, is that people end up not having access 16 to quality information. There is no quality information. 17 For the most part, I think consumers see this as a 18 commodity, that all providers are the same. It is not. 19 I think there is a 7 to 9 percent complication rate with respect to Lasik. So, that is relatively high. I think 20 if I was having Lasik done, I would be concerned about 21 22 quality. But there is not a lot of quality information available about this procedure, so people tend to go with 23 referrals from their friends or from their doctors. So, 24 25 that also, I think, leads to a sort of odd impact on

1 price sensitivity.

2 So, in looking at these different things, one 3 of the things that we sort of become convinced is that it 4 is not helpful to put up sort of hasty price web sites 5 without really looking at what the consumer is going to б use that information for. So, I want to walk through a 7 quick little model of that. This is specific to 8 prescription drug price transparency which is something 9 that we are trying to move into in California. We do not have it yet. So, it is sort of rude of me to criticize 10 11 Maryland when we haven't even done it. 12 But the State of Maryland does have a 13 prescription drug web site. Specifically, I've used Provocol as my example here. So, you can check which 14 drug you want, check which community you are in, and it 15 16 will bring back a nice slide that compares the price for that, for a 30-day supply, at all of these different 17 18 pharmacies that are located in this geographic area. So, 19 you would do this and you would do this and you would look at it and you would say, \$154 at Happy Harry's seems 20 21 to be the best price. I didn't make that name up. True 22 pharmacy in Maryland. It seems to be the best price. I 23 will go there.

24 But what this site does not do is really 25 recognize the fact that it is more than just a brick and mortar pharmacy market, that you can actually go on the Internet and you can find a cheaper price. In this case, if you go to drugstore.com, you will indeed find a cheaper price. This ends up being \$4.86 a pill, which is slightly better than the Happy Harry rate.

б But, interestingly, on this web site it also 7 brings back information about generics. People may 8 specifically want the brand name drug, but they may also 9 be persuaded by the difference in price if they move to a 10 generic. If you just give them price on brand name, they 11 do not have the opportunity to look at that. So, on this web site it brings back both and you can see there is a 12 13 pretty dramatic price drop if you decide to go with the 14 generic here.

But what this site does not even do, which I think is the most interesting to consumers, is link in another market, which is if you go to Wal-Mart, you can actually get it for \$4 for a 30-day supply, which is a significant savings over the \$154 I think you would have gotten if you just looked at the Maryland site.

21 So, one of the things we're encouraging the 22 State of California to do is combine all of those 23 markets. It is not just brick and mortar pharmacies. 24 There are lots of places that people can get drugs these 25 days and make sure people know what all their options are, including things like the mass-market stores, Target
 and Wal-Mart, that offer these special generic programs.

3 So, just in conclusion, I guess I want to make 4 a couple of comments. One is it is important to combine 5 quality information with price. I think Lasik is an 6 example where you have easy access to price information, 7 but not quality, and it is hard for people to make a 8 decision and that sort of influences the market.

9 But then, in addition to that, I think if you 10 are going to do price, it is important to sort of look at 11 who your audience is, both in terms of the supply versus 12 demand split that David had talked about, but also even 13 looking at consumers and what their ultimate needs are and where else they may have as options to shop for 14 health care services. I would be happy to take questions 15 16 at the end.

17

(Applause.)

DR. NIELSEN: Good morning. Nice to be here.
I agree with everything they just said. But I am not
going to sit down yet.

The AMA absolutely welcomes the opportunity to be here. We were in this business of trying to improve quality, and I want to focus a lot on quality in the beginning, long before the FTC got interested, long before anybody talked about pay for performance. 1 Beginning in 2000, the AMA founded and has continued to 2 staff the physician consortium for performance 3 improvement and the whole goal of that was to bring all 4 of the specialties together, along with consumers and 5 employers, and look at and define what are the right quality measures that are going to make the biggest 6 7 difference in the health of the people that we care for. 8 So, we are not new to this game at all.

9 In fact, we have developed well over 200 10 measures and that forms the basis of over 80 percent of 11 the quality measures that Medicare is using presently for 12 quality reporting for physicians.

13 We believe absolutely that more information, 14 good information, is better for patients. We also know 15 what can happen when the information is not accurate, not 16 reliable, and we also know exactly the information that 17 Maribeth has presented, which is consumers have not paid a lot of attention to these physician ratings, and we 18 19 think that is a really good sign of good judgment on their part, and we will explain why in just a minute. 20 21 The reason is that there is an absolutely

flawed methodology. In some cases, different health plans were using different quality measures. Often those were dictated by employers, not the plans themselves. There was an employer whose wife was diabetic and, so,

1 the boss wanted 16 diabetic measures, did not care a lot 2 about congestive heart failure or childhood immunization. 3 That does not make a lot of sense and the health plans 4 legitimately complained. 5 Risk adjustment has been a major problem in that if one reports on physician performance based on the 6 7 patient -- assuming that every patient is equal -- it is 8 going to look completely different. A physician who 9 treats patients with pneumonia may be treating a 20-year-old perfectly healthy individual, and on the 10 11 other hand, the next day or even the same day may be treating an 80-year-old with congestive heart failure and 12 13 diabetes, and the outcomes are going to be different. So, risk adjustment of the patients is really very, very 14 15 important.

16 One of the concerns that we have had is the 17 inaccuracy of the ratings on physicians. This is 18 important. I think the poster child for this was in 19 St. Louis. Let me give you an example that you will resonate with. Washington University in St. Louis is 20 21 perhaps one of the premier health systems in the country 22 and, in fact, my recollection is only four of the faculty were rated by one plan in the highest quality. 23

24 But what they did not say, and what consumers 25 had no way of knowing, is that most of the faculty at Wash U. in St. Louis were not ranked highly because they
 did not have enough numbers to qualify to be ranked, but
 there was no explanation of that.

4 The concern about unnecessarily disrupting a 5 patient-physician relationship is really very important. Inaccurate ratings -- and physicians have legions of 6 7 stories to tell you about this. For example, I live in 8 Buffalo where there are three major health plans and I 9 can tell you that I have gotten quality report cards from all three on the same condition, and it depends on which 10 11 one you want to believe. Part of that is a lack of numbers, just not aggregating the data. Part of it is 12 13 just flawed methodology. So, the methodology is very important because bad information does not help 14 consumers. What it does is it creates confusion and 15 16 chaos.

17 We are very concerned about the lack of appeals 18 that physicians have to correct data. Let me give you an 19 example. If I got a mammography rate report card from a plan that showed that I had a mammography rate for my 20 21 eligible female population of 88 percent, I would be very 22 concerned about those 12 percent who did not get their I would also know, as the plan might not 23 mammogram. know, that one or two of those patients, in fact, might 24 25 have, when they were with another plan earlier, so the

current plan does not even know this, they might have had
 a bilateral mastectomy because they already had breast
 cancer. So, it is a matter of trying to make sure that
 the data are accurate.

5 The unintended consequences, I think David 6 focused on absolutely well and we would agree with all of 7 that.

8 The concerns of physicians is when what is used 9 with this information is exactly what David talked about, 10 and that is, steering people instead of framing 11 information so that consumers -- we call them patients. 12 Doctors tend to refer to them as patients. So, I am 13 sorry at the FTC, you will just have to translate 14 consumer every time I say patient.

We think that patients are smart enough, if given the information framed properly, to make their own decisions. We think narrowed networks have served a purpose for health insurers but not for patients.

Well, this leads us to several seminal events.
The first was the groundbreaking settlements that
Attorney General Cuomo in New York, my home state,
reached with insurers. It is our understanding that this
came to his attention from consumers themselves because
physician rankings were being put out in the public media
and they had very big concerns about it and did not trust

the rankings. When the Attorney General looked into it,
 it was clear that there was no transparency and the
 accuracy was questionable.

Now, why do I say that? It is because when anyone, whether it was a patient or a physician, questioned the ranking and the methodology used to reach the ranking, the answer was but it is proprietary, we cannot tell you. So, there was no way to counter that data. So, consumers went to the Attorney General who had their best interests at heart.

11 There was no oversight. There was concern that 12 the profit motive, which clearly any business such as a 13 health plan must have, might be what was driving this more than quality. We were very concerned about that. 14 Physicians have been terribly concerned about that. We 15 16 worked with the Attorney General, as did consumer 17 organizations, to make sure that going forward, under the terms of the settlement, there would be no physician 18 19 rankings on cost alone. It had to be done in conjunction with quality. 20

21 Why is that? Well, think about it. Is that 22 what consumers want to know? You already heard from 23 Maribeth the answer to this, but let me frame it in the 24 way that Attorney General Cuomo framed it in a press 25 conference. He said, if you have the diagnosis of
cancer, are you looking for the cheapest oncologist? Is
 that what you want? I think that really puts the issue
 squarely front and center.

4 For example, it may be that a family, a young 5 family might have certain interests, are they getting the б immunization for their kids, can a sick child get access 7 to the pediatrician? Someone with a much more complex 8 disorder might have a different set of needs. The value 9 is in the eye of the beholder and the beholder here that 10 we need to be concerned about is the patient, or in FTC 11 language, the consumer.

12 The National Quality Standards, very, very 13 important that these be evidence-based. The AMA has been front and center, has been at the board of the National 14 Quality Forum and in the forefront of the AQA that I 15 16 believe you will hear about from Stephanie in a minute, 17 along with the plans, trying to make sure that the 18 ratings that are used, the quality measures that are used 19 in those ratings, are nationally agreed upon and are evidence-based. 20

21 And, finally, this is very important to 22 physicians. That there be an adequate sample size to 23 make a logical conclusion by a consumer, that the risk 24 adjustment be there so you avoid some of the unintended 25 consequences that David described.

1 Interestingly, attribution, this is one that 2 makes doctors crazy. Let me tell you about this. There are "proprietary rules" that are available that take an 3 4 episode of care and attribute that episode of care in a 5 variety of ways to physicians. Sometimes it is the 6 physician who orders the most percentage of the total 7 cost. Sometimes it is the person who operated on the 8 patient. Sometimes it is the primary. It makes doctors 9 crazy because it is not transparent and, again, when 10 asked, one has been told it is proprietary. 11 The settlement language is important. It forces the plans -- and some of these signed on under 12 13 duress, others signed on voluntarily. We are happy either way. Some of them have even voluntarily agreed to 14 roll it out nationwide. We like that a lot. It 15 16 discloses the limitations of the profiling. That is only 17 honest. It is not good enough to be transparent about 18 flawed methodology. It is not. There is a process for 19 patients to complain. There is a process for physicians to appeal incorrect rankings based on data that is flawed 20 21 and, importantly, there is oversight from an independent 22 rating examiner. 23 Now, that was the basis that was then expanded

23 Now, that was the basis that was then expanded
 24 into what has now been released as the patient charter
 25 for physician performance measurement. This was

1 spearheaded by the Consumer Purchaser Disclosure Project 2 by consumers and employers based on the work done in New 3 York with the Attorney General settlements. It clearly 4 used that as the template, and this is a request to plans 5 across the country to voluntarily sign on to the 6 principles that I have already described. It is 7 voluntary. The big difference between this and what 8 happened in New York is there is no oversight. There is no legal enforcement arm, and that is actually important. 9 10 So, the Attorney General settlements are 11 binding only in New York. The charter, on the other hand, is voluntary. We need to work on the transparency, the 12 13 accuracy, the criteria used in the program review. With that, we very much welcome the dialogue 14 that is about to follow, and the AMA thanks you very much 15 16 for allowing us to appear here today. 17 (Applause.) 18 DR. COOPER: As Stephanie gets her presentation 19 ready, I would just remind you, if you have any questions, you can write them down on the card and FTC 20 21 staff will be around to pick them up. 22 MS. KANWIT: I am Stephanie Kanwit, good I am Special Counsel for America's Health 23 morning. Insurance Plans, which is the trade association based 24 here in Washington, just a few blocks down the street, 25

1 for 1,300 of the health insurers, life, long-term
2 disability, et cetera, et cetera, in this country. We
3 are working really hard on this issue of transparency and
4 have been for about five years now. So, I am thrilled to
5 be here talking about it.

б In my paper, I outline in great detail -- but I 7 want to just hit the high points so we have time for 8 questions. Basically, my paper talked about three buckets of material. First of all, I talked about the 9 10 critical principles that quide our members as we work to 11 assure transparency, and I want to define what that That means to us, how do we get consumers or 12 means. 13 patients, as Dr. Nielsen said, and she's right, reliable and useful data to help them choose physicians and 14 hospitals that deliver value-based care? Value-based 15 16 care.

17 Number two, my number two bucket is examples of
18 initiatives, and Dr. Nielsen alluded to one of those,
19 AQA, which we are very proud of.

20 Number three, I want to issue a caveat as a 21 reformed antitrust lawyer about the possible 22 anti-competitive aspects of transparency. When is too 23 much information going to harm the competitive market, 24 going to chill innovation? A very, very critical issue 25 and an issue that we currently are lobbying on extensively. I hate to use that word "lobbying." But lobbying on, talking to state and local regulators all the time about do not do this. Think about what you are doing when you are mandating too much information. It is not going to help consumers and, in fact, it may chill the competitive marketplace.

7 In terms of AHIP's principles, again, in detail 8 in my handout -- and Attachment A to the handout, we are 9 very proud of because it is a statement of our Board of 10 Directors from November '07 -- again, that is not the 11 beginning of when we started working on it -- embodying 12 some of the principles that Dr. Nielsen talked about. 13 How do you work with providers to assure that you have accurate measurement and performance-based criteria to 14 evaluate? For example, on paying for quality, paying for 15 16 performance kinds of issues.

17 So, what our principles talk about are uniform 18 approaches, as Dr. Nielsen talked about to the disclosure 19 of useful, relevant, understandable information. How do you assure that those are going to be advanced while 20 21 still preserving competition? How are you going to do 22 those measures and still recognize the importance of linking quality and cost of care? And sometimes cost is 23 kind of the wrong word. We should also be talking about 24 25 value, value of care. It is not just the absolute

numbers, as you saw from Maribeth Shannon's charts, et
 cetera. It is not just, do I have to pay a \$40 copay?
 It is value. Is that consumer, that patient getting
 value in that particular instance?

5 Developing tools, again, in our principles to analyze high-utilization, high-cost services. Recently 6 7 The Dartmouth Atlas came out with high-cost services for 8 patients in their last two years of life in Medicare. I 9 do not know whether you saw the data, but it made the National Press. The data were astounding in the sense 10 11 that the Mayo Clinic was I believe about half the price of UCLA in terms of how to care for patients in the last 12 13 two years.

14 That is what Dr. Wennberg and Dr. Fisher talk 15 about in terms of the geographical disparities that we 16 are dealing with in this country. How do we get costs 17 under control and still deliver high-quality medical 18 care?

All right, in practice, a couple of initiatives that we are doing right now. Again, the one I mentioned and everybody keeps mentioning it, it is the AQA Alliance. Do not ask me what the acronym stands for because we have changed it. We are working with all sorts of physician groups including, I am proud to say, the American Medical Association. Dr. Nielsen is head of

1 one of our reporting work groups. Those groups include 2 the American Academy of Family Physicians, AHRQ, which is 3 the Federal Agency for Health Care Research and Quality. 4 What are we doing with AQA? We are doing 5 nothing less than building the infrastructure for a 6 consumer health care information system that we can use 7 in local communities throughout the country, both in 8 terms of quality and in terms of cost, that 9 infrastructure. 10 So, to date -- and we have much more 11 information if you need any of it -- the AQA has approved 12 218 quality clinical performance measures, 218. So, one, 13 for example, I just looked up this morning to give you an example. What percentage in a practitioner's practice of 14 patients 18 or older with heart failure and a left 15 16 ventricular systolic dysfunction were prescribed beta 17 blockers? That is just one measure. How do you measure 18 physician performance? That is one of them. 19 We have got 218 quality measures. We, the whole group, is also looking at cost and working on cost 20 21 measures. We have also rolled out pilot programs in six 22 different areas in the country and are working on that

with a group called Better Quality Information. Truly, everybody, if you go on Google or any of the sites and you start going into the web site and seeing what all

these -- the BQIs, the AQAs, you will get tons and tons of information about all the initiatives that are going on there, but in our health insurance sector, in the provider sector, in the government sector, like AHRQ. CMS is doing this with Medicare in terms of hospitals, as many of you know. It is just amazing.

7 What else, the initiatives? Dr. Hyman alluded to this in terms of the demand side. When you are a 8 9 member of many of our health plans, big and small, you 10 can go on the web and find individually-based 11 information. Price data on physicians, quality data on physicians, access to quality and price, hospital 12 13 information. I need hernia surgery in Cleveland. What is it going to cost me because I am insured by Aetna and 14 I am using Dr. X? That material will be on that web 15 16 site. Is it 100 percent of our members who have these up 17 on web sites? No, but it is an astounding number and we 18 do believe that consumers need to be -- what's the right 19 word -- incentivized to use this very, very useful 20 information.

There are also, as I point out in my paper, regional health initiatives out there. For example, the Massachusetts Health Quality Partners that get together and put this kind of information on web sites so people can understand what their options are.

1 And last but not least, the issue that, again, 2 we could talk about for three hours this morning, which 3 is, how do we reward quality care by providers, by 4 hospitals and doctors? This is not just "pay for 5 performance" but the principles that go into that. Again, I would refer you to an Appendix A, Attachment A 6 7 to my testimony here where I talk about some of the 8 principles that we try to work with our health plans to 9 adopt.

10 For example, Dr. Nielsen referred to the 11 opportunity of giving clinicians and physicians the opportunity to comment on measures. That is in our 12 13 principles. To review and comment on the results before performance information is made public. So, we are not 14 going to put on the web site Dr. X's information before 15 16 that doctor or that hospital is given the opportunity to 17 comment on that.

18 Last but not least, in the short time, I just 19 want to, again, do a red flag on an issue that is dear to 20 my particular heart, which is this issue of how do you 21 make the information useful and enough but not so much 22 that it chills competition? What I talk about in the paper is the problems involved. Namely, you want to make 23 24 sure that transparency does not involve inappropriate 25 government regulation that stifles the flowering -- I use

that word in my paper, it is a little much -- of various transparency initiatives before they have had the chance to benefit consumers. How do you keep from having practitioners not use the material out there, because we are all dealing within a certain corridor, because that is what the regulation allows? Why not let competition flourish?

8 Secondly, how do you keep governments, state, 9 federal, local from mandating what I called the wrong 10 kinds of information? In other words, information that 11 is not only useless to consumers, that does not help 12 them, but, in fact, harms competition.

13 Just one quick example, last year we fought against -- fruitlessly, by the way -- a New Hampshire 14 initiative where the Department of Health and Human 15 16 Services here put on its web site provider by provider 17 information about what our health plans were paying 18 providers. We said to the Department, wait a minute 19 here, you are violating rules of trade secrets, of proprietary information. But, more importantly, on 20 21 transparency, why does a consumer in Hanover, New 22 Hampshire, who needs an orthopedic surgery procedure, 23 need to know what Aetna is paying an orthopod in a different city for a different procedure? Doesn't that 24 25 consumer really need to know information about his or her

1 procedure? What the copay might be? What the deductible 2 might be? If I go out of network and do not use a 3 network doctor or hospital, what am I going to be paid? 4 Those are the kind of issues. 5 I hope in the question time you will ask me to б comment on Dr. Nielsen's comments about Andrew Cuomo's 7 investigation in the State of New York because, 8 basically, we health insurance plans say that is the 9 wrong way to go, that you do not want that kind of law 10 enforcement activities by a state official. The way to 11 go is what the AMA is doing with us right now like AQA. 12 Let's work together to develop uniform performance 13 measures and make consumers aware of what is happening 14 out there. Thank you.

15 (Applause.)

DR. COOPER: Thanks, everyone, for great DR. COOPER: Thanks, everyone, for great presentations. Before we get started with some specific questions, we have a very limited time for lunch here. I thought I would turn it over to the panelists here to see if they had any reactions or any comments to what their colleagues have said up here. David?

22 MR. HYMAN: Yes, just very quickly. I would 23 agree with Dr. Nielsen that risk adjustment is important, 24 but it is important for outcome-based measures of 25 quality. It is really not a significant issue for

process-based measures, and I am happy to talk about that after if people want to understand the difference. But the overwhelming majority of quality measures that are out there, that have basically been validated, are process-based measures. So, I do not want to give people the wrong impression about the impediments.

7 The second point is to understand that the 8 perfect can be the enemy of the good and to realize that 9 there are trade-offs with any transparency initiative. 10 Then the question is, what is your risk tolerance for 11 transparency initiatives that are less than perfect, but 12 nonetheless can help drive improvements on both the 13 supply and the demand side?

The last point is, I want to certainly agree 14 with everything Stephanie said about the anti-competitive 15 16 consequences of overly intrusive transparency 17 initiatives. I actually worked on the letter that we did 18 here that went to the Rhode Island legislature on that, 19 that was sort of the FTC's major initiatives in that area. So, let me stop there. 20 21 DR. COOPER: Maribeth? MS. SHANNON: I would like to make two 22 comments. One is following on some of Stephanie's 23 comments about health plans tailoring price information 24

25 to the specific benefits available to an individual, I

1 think that is a really important point about price 2 transparency. Where quality is pretty consistent no 3 matter what your insurance card says, that is not so true 4 for price, obviously. So, quality measures, I think it 5 is appropriate for state agencies or CMS or other kind of 6 global groups, non-profits such as ours, to do quality 7 because quality is consistent across patient 8 populations. But when it comes down to price, the best 9 people to provide price are those who know what the 10 deductible and copays are and can make that specific to 11 an individual.

12 With regard to the uninsured, I think the most 13 important piece of information you can give the uninsured is how they can negotiate for price. We have just added 14 on our hospital quality web site a link to discount care 15 16 policies at all the participating hospitals so that an 17 uninsured person actually can go and understand what 18 options might be available and the raw price at a 19 hospital is much less important than what they might be able to negotiate. 20

21I think that is it. I will just leave it at22that.

DR. COOPER: Dr. Nielsen?

23

DR. NIELSEN: Thanks very much. First of all,
on the uninsured, I think that is terrific what you are

doing in California because the uninsured are often left alone and unable to negotiate this and unable to negotiate any discount prices. So, anything we can do is helpful. It would be really much more helpful if everybody were insured, though, wouldn't it?

б In terms of David's comment about the risk 7 adjustment, he is absolutely right about process 8 measures. There is no question on quality measures for 9 process. You do not need to risk adjust. Where that becomes critically important, though, is when you have 10 11 cost of care measurements or what is termed "efficiency measures." There you really do need to factor in the 12 13 risk adjustment.

14 Then, finally, on Stephanie's point, I know that they do not like the Cuomo approach. That is, of 15 16 course, why the health plans were not unhappy about the 17 patient charter which is voluntary. From a physician's standpoint, we are all for cooperation and collaboration. 18 19 That is what we think we should be. We think we should get away from this gotcha mentality and collaborate to 20 21 try to get every patient the care that they need.

But let me just promise you absolutely that if voluntary does not work, we will go to every Attorney General in the country for enforcement if we have to. We hope it does not come to that, and I think the patient

1 charter is a good foray to begin.

25

2 MS. KANWIT: On Dr. Nielsen's point of 3 voluntary versus non-voluntary, my objection to Attorney 4 General Cuomo's procedures here is not particularly that. 5 And, again, I commend the AMA for working with us the way б it should be done, which is the cohesive, cooperative, 7 collaborative kind of thing. 8 You have Attorney Generals who in, say, New 9 York's case -- I'm just using an example -- running for 10 governor, thinking about running for governor, perhaps, 11 using a law enforcement action where he or she is 12 claiming antitrust, consumer protection issues and doing 13 it on a state-by-state basis, which is a problem, by the way, for our national health plans, our national 14 employers. Remember, we have a voluntary employer-based 15 16 health care system which that causes problems. And then, 17 with rhetoric, hitting it out of the ballpark, again, as 18 opposed to working in a collaborative manner. 19 So, the question is not voluntary versus nonvoluntary, it is whether you want to make this a law 20 21 enforcement effort that, to some extent -- again, I am 22 using the same word -- chills the ability to innovate in 23 the area of aggregation and reporting. DR. COOPER: Thanks. Like I said, we have a 24

very brief amount of time here. But one question I had

1 goes more to the value of price transparency to
2 consumers. We have mostly a third party payer system
3 where most people have insurance. Therefore, most people
4 are sort of insulated from the actual prices they paid,
5 and even for high-deductible health plans, the out-of6 pocket price they pay is already going to be negotiated
7 by whatever their carrier is.

8 So, I guess my first question is, how much do 9 prices vary within a given market for the type of 10 services that consumers would buy, you know, primary 11 care? How much do they vary so if they had perfect 12 transparency, would they see a large variance in prices? 13 And, second, how valuable is it to consumers 14 now, given that most are sort of divorced? They don't do

15 the negotiating. Most of the negotiating still occurs 16 between health plans and providers.

17 MS. SHANNON: What we found is that there is 18 actually, at least in California, huge variation in price in the absence of transparency. One of the interesting 19 phenomenon is when you make price transparent, because 20 21 providers do not want to compete on price and consumers 22 do not necessarily want -- they are not as cost-sensitive 23 for all the reasons we just mentioned, that what tends to 24 happen is when you make price transparent with regard to 25 health care services, you reduce variation in price, so

the most expensive people do sort of put a limit or a cap on what they charge, mostly because it's hard for them to get health plan contracts if their price is such an outlier.

5 But what happens at the bottom is that the 6 lower price providers sort of see that they have room to 7 increase their price and it is not going to hurt their 8 competitive position. So, price transparency tends to 9 reduce variation but doesn't necessarily reduce mean 10 price.

11

DR. COOPER: Yes, David?

12 MR. HYMAN: The other point is to understand 13 the pricing in health care is totally screwed up. Because the list price is paid by essentially no one 14 except for the uninsured occasionally, if they have an 15 16 asset that can be seized in collection. This is why we had these lawsuits, these unsuccessful class action 17 18 lawsuits against hospitals several years ago, alleging 19 that they were in breach of their obligation as non-profits by charging the highest prices to the people 20 who could least afford it. 21 Regardless of the substantive merits of that, 22 as a legal matter, I think it points to a sensible 23

24 intuition, which is in the absence of price transparency, 25 when people with bargaining power can negotiate huge

1 discounts off a list and the only question is how big is 2 the discount, pricing transparency will have exactly the 3 effect Maribeth alluded to, which is decreasing variance, 4 but it won't necessarily drive the consumer purchasing 5 behavior you might expect in other markets where б individuals are footing the bill directly. 7 MS. KANWIT: Which is why you need to combine 8 the cost with a value as well. It is not just a cost 9 issue. DR. COOPER: Okay. That actually raises 10 11 another question. David says pricing is screwed up here. Is price a signal of quality in health care markets? 12 13 MR. HYMAN: No. DR. COOPER: Everyone? 14 MS. SHANNON: A universal no on that. 15 16 DR. COOPER: That was pretty easy. I want to 17 go to a couple of audience questions here. First, how is 18 information technology facilitating or impeding the 19 collection and dissemination of relevant health care 20 data? Is the current state of IT and its adoption adequate to the task? 21 22 MS. KANWIT: Aren't you doing a panel on this 23 this afternoon? DR. COOPER: That's the afternoon. 24 25 MR. HYMAN: I guess the short answer is it is

1 very important to have a good IT backbone in order to 2 collect the information, particularly the quality 3 information. The challenge is most of the information we 4 have about health care performance is insurance claims 5 data, which is tremendously useful for some purposes and б completely worthless for others. So, the entire focus of 7 the afternoon is the need to create the IT backbone and 8 figure out how to get standardization across it and 9 encourage people to invest in it.

10 One of the things about health care as compared 11 to lots of other sectors in the economy, there is a 12 significant under-investment in IT and the retail clinics 13 are, in lots of ways, the salient exception to that.

MS. KANWIT: Exactly. And IT needs to be inter-operable. We want IT that works for consumers across the country. PHRs, personal health records, et cetera. Very, very critical.

DR. NIELSEN: I agree with that. The reason that providers are slow to adopt this is there are no standards. People who have invested then find their systems outdated, unable to communicate with their hospital, the pharmacies, et cetera. So, we really do need a concerted effort here.

DR. COOPER: Another audience question here,
with regard to the AQA. Are hospitals involved in this

1 and why isn't there more transparency in this project?

2 DR. NIELSEN: There is a companion organization 3 called the Hospital Quality Alliance and it does for 4 hospitals what AQA does on the non-hospital side, not 5 just Ambulatory -- it used to be called the Ambulatory Quality Alliance. We decided it is more than ambulatory. б 7 Then there is a coordinating body called the Quality 8 Alliance Steering Committee that brings them both 9 together.

MR. HYMAN: Yes. The HHS also runs a web site 10 11 that might be worth looking at called hospitalcompare. 12 gov, where you can type in your zip code and compare your 13 hospital's performance along a number of measures. There is similar information available for nursing homes, home 14 health agencies, dialysis centers. The Federal 15 16 Government has made a major push in this direction in 17 recent years.

DR. COOPER: If you would indulge me, just one more question and then we are a little over budget here. What is the future of consumer-driven or value-driven health care? I mean, that's kind of a popular phrase or a popular term these days. If we start moving toward the consumer-driven health care model, what will the role of health plans be in the future?

25

DR. NIELSEN: Let me start from the physician

1 standpoint. We think consumer directed health care is 2 the way to go, but I want to expand it beyond what you 3 think I am talking about. I am not talking about more 4 cost shifting to consumers. We are talking about letting 5 consumers, our patients, have more information, be able б to judge value based on what they value and, frankly, I 7 think what will happen -- and this is just Nancy speaking 8 here, okay -- what I think will happen is insurance will 9 -- the health plans will market retail to individuals 10 rather than wholesale to employers when that happens in a 11 big way, and we think that would be healthy. 12 MS. KANWIT: But there are many, many products 13 involved in HSAs. There are tons of them. Congress has, 14 what, five of them on the books right now, James, I think, which is a lot of products. We are big 15 16 supporters, but I do not think it is ever going to 17 replace the system of group health insurance that you get 18 through an employer or Taft-Hartley Plan. By the way, it 19 is much easier to administer that kind of group plan as 20 well.

21 MS. SHANNON: There is a really interesting 22 experiment going on in Minnesota right now. There is a 23 web site called carol.com that allows people to go in and 24 look at packaged prices for services by individual 25 provider entities in Minnesota. So, I would encourage

you to take a look at it. It is a really well-designed site. It actually looks like a Target ad. It has got a little woman shopping with a basket like as if you could buy health care just like you can buy toothpaste. So, it is a really interesting site.

6

DR. COOPER: David?

7 MR. HYMAN: Yes. If I was good at predictions
8 I would be working for a hedge fund instead of a tenured
9 professor of law. But nothing ventured.

10 Look, I think consumer-directed health plans, 11 depending upon -- or HSAs, if you want to give it the statutory name, combined with a high-deductible health 12 13 plan, I think will be with us unless Congress wipes them out, which may well happen. You never know. But I do 14 not think it is going to capture more than probably 10 15 16 percent of the market, even in the most optimistic of 17 circumstances.

And then the question is, well, what will its 18 19 impact be not just on those 10 percent, but its spillover 20 effects on other people? One of the things you see 21 across competitive markets is you do not need everybody to be perfectly informed for the market to work 22 23 effectively in creating the right incentives for the suppliers of whatever services. None of you know who 24 25 makes the spark plugs in your respective cars, but it

1	nonetheless works because somebody cared enough to get it
2	right. So, a relatively small percentage of motivated
3	people can make it run. Whether it will be HSAs or some
4	other version I think remains to be seen.
5	DR. COOPER: Anything else? Okay, thanks a
б	lot. This was a great panel and thank you all for
7	participating.
8	(Applause.)
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	

1 PANEL 3: HEALTH IT - PROVIDERS' ISSUES 2 DR. GILMAN: For those of you who are just 3 joining us for the afternoon session, welcome to the FTC, 4 and for the rest of the folks, welcome back. We had a 5 good morning session I thought and I am looking forward 6 to this afternoon's panels. 7 This is, I think, an exciting time for health 8 IT. On the one hand, there has been a proliferation of 9 utilities and systems in recent years, including electronic health records, personal health records, 10 11 electronic prescribing and the integration and flow of 12 increasingly rich sorts of health information. Health IT 13 has been seen to have the potential to, for example, greatly reduce medical errors and administrative costs 14 now attributed to incomplete, hard to access or faulty 15 16 paper records. 17 At the same time, the adoption of health IT, 18 the interoperability of heath IT systems and the 19 integration of health information has, in many places, lagged behind expectations. Many have raised concerns, 20 21 too, about practitioner and consumer knowledge, 22 expectations, costs and protections. 23 We have a terrific panel here today I think, for a discussion of providers' HIT issues and, in fact, I 24 25 think the next three panels will work very well together.

1 The following panel will have some emphasis on consumers' 2 issues, and then we will have a very interesting wrap-up 3 In the interest of time, I will refer you to our panel. 4 supporting materials on the web site for panelists' 5 biographies and supporting information. But I would like б to address briefly our panelists before kicking things 7 off. 8 First off, we have Jamie Ferguson, the Executive Director for Health IT Strategy & Policy at 9 Kaiser Permanente. 10 11 Immediately to my left, we have Deven McGraw, 12 who is the Director of the new Health Privacy Project at 13 the Center of Democracy and Technology. 14 Dr. Kevin Carr is here, Physician Senior Manager for Clinical Transformation Health Care at 15 16 BearingPoint. 17 And to his right, Paul Uhrig, General Counsel 18 and Executive Vice President of Corporate Development, as 19 well as the Chief Privacy Officer, for SureScripts. 20 Also, Dr. Doug Wood, who is Vice Chair of the 21 Department of Internal Medicine and a practicing cardiologist at Mayo Clinic, in Rochester, Minnesota, as 22 23 well as the Chair of Mayo's Division of Health Care Policy and Research. 24 25 So, I think it is a very good group. I will

1 leave it to Jamie Ferguson to kick things off.

2 MR. FERGUSON: Thanks, Dan. I am going to 3 start out here, and I think the handouts should be 4 outside by now. I noticed they were not here earlier 5 this morning for this particular slide deck, but they б will be available. 7 I am going to start out with -- it is on this 8 screen over here, but it is not on these screens. 9 Unfortunately, the computer screen here in front of me is blank as well. So, I cannot see what the slides are. 10 11 However, basically, the first couple of pages of the handout are talking about Kaiser Permanente. We 12 13 are a very large integrated delivery system. We have over eight and a half million active members currently. 14 We also have in our electronic medical record systems 15 16 records of over ten million patients. 17 And now the microphone is out. Okay. Yeah, 18 this is the IT panel, right? 19 So, in Kaiser Permanente's integrated delivery system, we have multi-specialty group practices 20 21 representing all medical specialties, and we primarily 22 operate in 10 states across the country. 23 So, there are also some facts on the slides that talk about the scope and scale of our operations. 24 One of the key things that I will talk about a little 25

more later is the fact that we have now over two million of our members who have chosen to go online, activate, and use their personal health record and are actively online with their Kaiser PHR.

5 The other thing I want to talk about, though, 6 is, more broadly, what are some of the general areas of 7 health IT? So, when we say health IT, what do we mean? 8 Is it just health medical records or is there more to it? 9 Certainly, in the electronic medical records arena, we would add in to that same bucket, clinical decision 10 11 support that aids the actually clinical decision-making. 12 There are also other kinds of electronic health records 13 systems, laboratory records, health plan records, personal health records. We would also add into this 14 category health records exchange systems and patient 15 16 identification systems.

17 But then there are a lot of other different kinds of health IT that are used in the clinical arena. 18 19 There are clinical ancillaries and other kinds of clinical information systems, such as labs, radiology, 20 21 image management systems. There are also terminology 22 services so that things can be properly understood, and there are a lot of clinical analysis and reporting 23 24 systems.

25

There is a different category, also, in

biomedical devices. A lot of network connected devices, whether wired or wireless, now exist and are used commonly both in the inpatient ambulatory settings, as well as home health. That would then include a lot of consumer devices that are network connected, as well as certain kinds of durable medical equipment.

7 The next category is population health, and 8 population health is not just public health reporting, 9 which is moving to an electronic basis, but also 10 registries such as disease registries, immunization 11 registries, and there is a lot of statistical analysis and reporting such as quality of process, quality of 12 13 outcomes and health disparities analysis that would count 14 in the population health area of health IT.

15 Then, finally, I think the administrative and 16 financial sector of health IT also is very important. 17 That includes billing and claims systems, information 18 derived from claims, scheduling, and other kinds of 19 administrative systems. So, when we talk about health 20 IT, it is all those different things, it is not just the 21 EMR or the PHR.

There are a few different things, also, that make health IT truly unique compared to other kinds of IT and other kinds of data systems and record systems. One is the absolute permanence of your health record. There

1 is no equivalent of bankruptcy to wipe your health record 2 clean. There is also a unique attachment of your health 3 data to an individual person. So, where you hear about 4 privacy concerns of consumers that might relate to things 5 like denial of coverage, it comes frequently or usually 6 from this unique attachment of those records to the 7 individual.

8 Also, these individual health records may 9 relate to family members, so information about a person's 10 health history also can relate to the genetic information 11 of family members.

12 Okay, back online. Thank you. I will try to13 get the slides to catch up here. There we go.

Also, in terms of the complexity of health care 14 data, for example, the industry data model for financial 15 16 services is well understood. It has been relatively 17 stable for a couple of decades. If you look at the 18 number of unique information concepts for financial 19 services and compare that to the number, at a similar level, the number of unique information concepts for 20 health care, you find that it is not just 30 percent or 21 22 100 percent more in health care. It is between three and four orders of magnitude more. So, the degree of 23 complexity really is quite different for health care. 24 25 And then there is also a unique set of concerns around

personal privacy that relate to both medical practice and
 liability.

3 Now, in Kaiser Permanente, we have a lot of 4 experience with all these different kinds of health IT. 5 I am not going to go through it in detail. It is really б in the handouts. But that sort of covers the gamut. 7 What I will say also about that is that, again, our 8 electronic medical records system is, I believe, the 9 largest deployment of electronic medical records in the 10 private sector and, certainly our two million plus active 11 users of the personal health records system have found some benefits from that. 12

13 One of the things I was asked to address was some of the cultural changes that attach to the use of 14 health IT. We have certainly had some cultural change on 15 16 the physician/clinician side in terms of collaborating 17 across different medical groups in order to define the 18 end state of how they want these health IT systems to 19 work and working together to get there. We have also had a cultural change on the part of individual members. 20

So, the individuals who use the personal health records system have found that some of the things that they use the most are the secure online communications with their provider. They use the online appointment scheduling. They like to look at their online lab

results. They like to do their prescription refills 1 2 online. So, this close connection with their physician 3 in a secure way online is one of the key things that 4 really makes that go. 5 And then sort of the next frontier for us is a health records exchange with other entities. We are 6 7 looking forward to participating in the National Health 8 Information Network for the secure exchange of health 9 records with other provider organizations for shared care 10 patients, and we are also looking forward to a further 11 rollout of the National Health Information Network. 12 There is a slide in here on interoperability. 13 I am not going to go through it really, again, in detail. But what I will say is that interoperability is certainly 14 a requirement for making health IT go. 15 16 I think I have mentioned already that Kaiser 17 Permanente is involved in the National Health IT Strategy 18 in terms of our deployment of electronic medical records, 19 the National Health Information Network, as well as common standards. 20 There is a list in here of the different areas 21 22 of current oversight of health IT. The only thing I will mention here is that the HIPAA privacy rule, which is 23 mentioned on here, really is the primary way of 24

addressing those concerns about some of the unique nature

of health IT that addressed some of the consumer concerns
 I mentioned earlier.

3 And then, I serve on a number of different boards and standards bodies, both national and 4 5 international, for health IT, and I can truly say that 6 this issue is one that has been raised in every one of 7 those forums. The distinguishing part of this issue is 8 that there are operators of persistent stores of health 9 information, of medical records data, that have basically 10 different sets of rules that they play by. So, this has certainly been brought up. This is not something that 11 Kaiser Permanente is taking an advocacy position on, but 12 13 it is something that has come up in every forum that I have ever participated in. 14

15 Then, finally, it is really all about finding 16 balance in health IT. So, we find that there are 17 different needs of the different stakeholder groups that 18 we need to balance. We find that when consumers take 19 control over their sharing of their health information, that has to be balanced with the need of that information 20 21 for proper clinical decision-making. And, also, there is 22 not always transfer of liability for those decisions when the decision rights transfer to the individual. 23

24 We also find that in terms of innovation, both 25 in terms of time to market and advancing the deployment

1	of health technology in the medical practice area, there
2	are two different areas that need to be balanced.
3	Obviously, the security and privacy is something that I
4	know was on sort of part of the morning agenda. There
5	are certainly needs in the security and privacy that need
6	to be paid attention compared to innovation and time to
7	market, but also cost and affordability needs to be
8	balanced against the rollout of these advanced
9	capabilities.
10	DR. GILMAN: Thank you.
11	(Applause.)
12	MR. FERGUSON: Sorry about the technical
13	difficulties there.
14	(Laughter.)
15	DR. GILMAN: Our next speaker is Deven McGraw
16	from the Center for Democracy and Technology.
17	I apologize for the technical difficulties.
18	For those people who missed it, we have supporting
19	materials in hard copy on the tables as you come in or as
20	you go out, and these things will be available from the
21	workshop web site as well.
22	MS. McGRAW: Thanks, Dan. I want to start by
23	thanking Jamie for going first. I am never good with
24	resolving the technical issues.
25	Again, I am the Director of the Health Privacy

1 Project at the Center for Democracy and Technology. We 2 do believe that health IT has tremendous potential to 3 improve health care quality, reduce costs and empower 4 consumers. But we are very concerned about the privacy 5 and security issues and the scant progress that has been 6 made in resolving these issues. So, the aim of our 7 project at CDT is to develop and promote privacy and 8 security policy solutions for personal health 9 information, largely in an online context. In our view, 10 in fact, resolving privacy and security is an enabler to 11 advancing health IT.

12 The survey data is very clear that the public 13 wants electronic access to their personal health information, but the survey data is also very clear that 14 people have significant concerns about the privacy of 15 16 their medical records, particularly in electronic form 17 and where the data is going to move online more freely. 18 Without privacy protections, people are likely to engage 19 in what we call privacy protective behavior where they are reluctant to share with their doctors full 20 21 information about their health care conditions or lying 22 about them or paying out-of-pocket to avoid creating a 23 record for a payer to access. So, we really do need to be able to build trust in these systems in order to move 24 25 them forward, and failing to do so will amount to a

failure to really grab these opportunities and engage the
 full benefits of the technology.

3 Technology actually can enhance privacy, but it 4 also magnifies the risk. So, you have tools like 5 role-based access, encryption and audit trails at your disposal that can actually make an electronic record more 6 7 protective than a paper record. But, at the same time, 8 the aggregation in computerized format of the personal health information means that the risk is magnified in 9 the absence of strong privacy and security safequards, 10 11 and you do not have to look too far to find lots of 12 examples of thousands of records going out the door with 13 one stolen laptop or the inadvertent posting on the web site of personal health information by either a provider 14 or a holder of that data. 15

16 Again, for the most part, these are not 17 malicious acts, but they happen. And, again, if we do 18 not have the right protections in place, it really does 19 deepen the consumer distrust, even for people whose 20 individual information is not the subject of a breach, 21 because this sort of compounded effort about hearing about this over and over and over creates the chilling 22 23 effect that keeps people from trusting in these systems. So, what do we mean when we say health IT? 24

25 Jamie did a nice job of going through really actually

more examples of what we mean by health IT than even I have covered on here. But I am going to go ahead and do this slide anyway because it is sort of pertinent to some of my later discussion about what we might need to do with privacy and security.

б Electronic health records held by providers and 7 health plans, commonly called EHRs or EMRs, and those can 8 typically be within one institution or be shared among 9 institutions and physician providers, for example, within a system, and then there are also, as I will talk about 10 11 it in a minute, efforts to link systems together within states, within regions, and then the whole idea is to 12 13 wrap it all up in the National Health Information 14 Network.

15 Some of the more interesting models are what we 16 are calling the consumer access models, like the personal 17 health record and what is called a patient portal. 18 Patient portal is essentially giving the patient the 19 right to get information that comes from an electronic health record or an EMR that is held by a provider. 20 Tt 21 is not typically a snapshot directly into the record, but 22 involves things like the ability to access lab test results and to be able to get summaries, scheduling 23 appointments online, secure emails with your providers, 24 25 et cetera.
1 But there are also the personal health records 2 which are modeled as belonging to the consumer and a place for the consumer to store, access and use health 3 4 information about them. There are models being offered 5 by employers -- Dossia is one of the ones that has 6 received a lot of press. They are also being offered by 7 vendors. Microsoft, Google, WebMD, and providers and 8 plans. As Jamie mentioned, Kaiser provides a personal 9 health record for beneficiaries. 10 Again, these are -- the distinctions get 11 blurred because the market is innovating actually quite quickly here. But essentially most of these, the 12 13 personal health records, are built on the model of the

consumer. That is information that the consumer 14 15 controls. It might not all be populated by the consumer, 16 but the consumer typically can add information into it 17 and then either claims data can be pushed in, if it is 18 offered by the plan, or if there is a linkage between the 19 personal health record who provides the web-based platform and the provider, then sometimes clinical data 20 21 can be pushed directly into it as well.

I already mentioned the networks of systems largely happening at the provider level called health information exchanges or HIEs or RHIOs, regional health information organizations. You cannot survive in health

care without throwing in at least 10 to 12 acronyms with
 anything that is new, and this is no exception.

You foresee the networks actually also being able to interact with the consumers' personal health records, too. So, really, the possibilities, if you think about it, are maybe not endless, but certainly even beyond what is on the market now and likely to be on the market in the next two years.

9 So, what are the existing privacy protections that we have? Well, there is HIPAA and then, of course, 10 11 there are stronger state laws, which are not preempted by HIPAA that typically follow the data. But the problem 12 13 with the HIPAA privacy rule is that it only covers certain entities. So, it covers providers and it covers 14 health plans and it covers this thing called a health 15 16 care clearinghouse that most people do not know what it 17 is.

And then to the extent that these providers get into business arrangements with entities whereby that entity is providing a service to the provider and needs to handle personal health information as a result, those business associates are covered, too, but only to the extent of their contractual provisions. They are not directly covered.

25

So, there is a gap here, and the gap is

1 particularly glaring when you talk about the consumer 2 access technologies and also these networks as well. 3 Where a PHR is being provided by a health plan or by a 4 provider, then arguably, that would be covered under 5 HIPAA. But, otherwise, the extent of coverage is through 6 the privacy policies and practices of the organization 7 that is providing the personal health record to the 8 consumer.

9 The real regulatory authority is with the Federal Trade Commission. So, we are very glad to have 10 11 this opportunity to talk to the FTC today about the need to use its authority under the FTC Act to enforce the 12 13 privacy and security policies and practices that these companies develop, and maybe even consider developing 14 model privacy and security practices. Because while 15 16 there are -- actually, some of the bigger companies are 17 doing very well in this space in terms of privacy policies. There is also lots of evidence that other 18 19 providers are not.

Alterum, which is a health research firm, did a study back in January of 2007, which is just over a year ago, for the Office of the National Coordinator for Health IT, which is the entity within HHS that is charged with moving health IT forward nationally. They basically looked at the privacy policies of about 30 different PHR

providers matched up against various criteria that ought 1 2 to be in a privacy policy, like how or what are we going 3 to use the information that you put in there. What they 4 found was that, for the most part, the basic criteria 5 that ought to be in a privacy policy were largely 6 missing, and only one of the entities that they looked at 7 -- now, again, there are some really good actors in this 8 field -- but only one of them had in their policy what 9 they were going to use the health information for.

10 On the other hand, about half of them said that 11 they had a policy in there about what they would do about 12 cookies that they would collect on you and non-personal 13 data, but not anything having to do with the very 14 personal health information that was in the record 15 itself. So, it is really a glaring absence.

16 Jamie mentioned in his presentation the need to 17 make sure that HIPAA extends to these organizations, but 18 I want to present a different way of looking at this 19 because HIPAA was really designed to govern how providers and health plans, traditional actors in the health care 20 21 system, use health information and that they get to use 22 it without patient consent for treatment, payment and a 23 host of activities that are called health care 24 operations.

25

If you contrast that with the personal health

1 record, which is about giving the consumer a tool that 2 they can use to access their health information, that 3 they are going to potentially populate with information 4 of their own, like maybe their blood glucose monitoring 5 levels or their fitness activity, and you juxtapose that 6 against a regulatory framework that allows for use of 7 information for a whole range of purposes without consent 8 and it is not the right fit. Whereas, you know, when you 9 look at the privacy policies which are actually, for many 10 companies, going beyond what is in HIPAA, it seems as 11 though the FTC ought to consider what its role will be, 12 again, under the Federal Trade Commission Act, and 13 looking at whether these companies are actually doing what they promise in their policies and practices. 14 15 So, one thing I want to mention, the Health 16 Privacy Project has developed some employer best 17 practices. They are on my slides. I am not going to 18 have time to go through them. But the other thing that I 19 wanted to mention is that the Markle Foundation, Connecting for Health, has had a work group looking at 20 consumer access services, and they will actually shortly 21 22 be coming up with a common framework which is going to 23 have both privacy principles as well as technical recommendations to offer for consumer access technologies 24 25 that organizations can use in developing their own

policies and practices and that, quite frankly, the
 Federal Trade Commission could use in looking at ways to
 make sure that consumers are well protected in this
 space.

5 And, so, in conclusion, for privacy to enable 6 health IT, we really have to enable privacy. Thank you 7 very much.

8

(Applause.)

9 DR. GILMAN: Next we have Dr. Carr from 10 BearingPoint. While he is getting ready, for those who 11 missed the spiel in the morning, we will take questions. 12 There are index cards in your workshop folders, and if 13 you think of questions as the presentations go forward, 14 you can jot them down and they will be collected at the 15 end of all the panel presentations and presented.

16 Thanks.

DR. CARR: Well, we have a very short Conversation today. I am originally from the South and I talk really slow compared to many of our panelists and I tend to talk a lot. So, what I am going to try to do today is really focus in on one particular area of health information technology, and that area is provider adoption of health information technology.

24 Many of us here in the room today on the panel 25 and also outside of the panel, spend all of our waking days and nights trying to dream up how we are going to get providers to adopt technology and how we are going to make them change their processes, get down to the dirt and make patient care safer and improve quality of care and improve efficiency. I think that is a really good thing to do. There are obvious benefits to health information technology.

8 But one of the things that we do not always do 9 is apply the same rigor to change management among 10 physicians that physicians actually apply to their care 11 of patients every day. When a patient comes into a provider office, many times those providers have in the 12 13 back of their mind a designated, a very rigorous approach to managing change within their patients. But many 14 times, on the organizational side of those provider 15 16 organizations, we do not have the same rigor of managing 17 change among those providers.

18 So, we are going to go through a little 19 scenario. So, let's have a scenario where we have an elderly patient who has been smoking for the past 30 20 21 years, and he comes in to the office and we talk to him 22 and find out that he has been smoking for the past 30 years. One of the first questions we would probably ask 23 is, on a scale of one to ten, how would you rate your 24 25 willingness to stop smoking? The patient may say a one.

1 Then the provider would then say, well, why not a zero? 2 There are some patients that would probably have said, 3 well, I would have said a zero, but you did not give me 4 the option of a zero. So, therefore, I said a one. But 5 most patients would start saying, well, the reason I did б not say zero is because my wife does not like the smell, 7 it makes the sofa smell really bad, and when my 8 grandchildren come over, then she says that me smoking 9 around them makes them more likely to have some type of lung disease and also smoke themselves. 10

11 So, what that patient is doing is actually 12 moving through a different stage of change. So, when the 13 patient first came in, they were in pre-contemplation. So, at that point, we found out they were smoking. 14 But when they came into the office, they had absolutely no 15 16 desire whatsoever to stop smoking. None, not even 17 thinking about it. They were there because somebody made 18 them come.

19 So, as you start moving them and start having 20 the patient explain why they want to stop smoking, then 21 you are moving them along the continuum over to 22 contemplation. So, you have two reasons now that that 23 patient should stop smoking. You got the it makes 24 everything stink and that you want to make sure that the 25 family is in a safer environment.

So, as you start moving along the continuum with that patient and developing a plan, you know the first thing you have done is stage the patient, stage the readiness for change, and then started moving them towards the planning phase and then action and then maintenance.

7 So, when you sat down with the patient to 8 counsel them about smoking cessation, the first thing you 9 do is not sit down and say, well, you smoke, so let's put 10 you on medication, start it for seven days, you take his 11 medication for seven days and then you stop after the 12 seven days and then continue it for three months. That 13 is not going to work. Providers know that is not going to work. But many times we do that with providers. 14 We say, as an organization, we are at the planning or action 15 16 phase and, so, we are going to come into your office, 17 install an electronic medical record, but you, as an 18 individual provider, may be at a completely different 19 stage.

20 So, the challenge I think is often trying to 21 figure out an approach that actually stages those 22 providers so that we can apply that same rigor that the 23 providers apply to their patient care every day, to 24 installing and getting them to adopt an electronic 25 medical record. Because most of the resistance is not

1 actually around the technology itself. It is not around 2 the network. Providers tend to assume that that is going 3 to work. Especially in a larger organization, they are 4 going to assume that that is going to work. In a smaller 5 organization, they are not going to buy an electronic б medical record unless they know it is going to work, 7 unless they are sure. So, then it really comes down to 8 how ready and willing am I to change the things that I do 9 every single day.

10 So, some of the benefits of staging the 11 providers and putting them into categories is that it is 12 a scalable approach. As a provider, most providers are 13 not going to spend every minute of their day going out 14 and getting other providers to adopt health information 15 technology.

So, you have to have an approach that allows other non-clinicians to work with those providers and bring in clinicians when needed so that you leverage the experience on the team and you can kind of go out en masse to a larger group of individuals.

So, if you are able to stage the providers in actually using terms that providers are used to using every day, then your learning curve for the physician temps that are actually on the team that usually do not have a lot of administrative experience in the past, they come onto a project and somebody says, we want to groom you to move into administration, so we are going to move you into this project as a position temp for electronic medical record implementation, but they do not really know how to manage change of an organization.

б If you allow them to use terms and techniques 7 that they actually use for their patients every day, then 8 you can flip it around and apply it to the providers, 9 then the learning curve is a lot lower. So, they can go in and say, okay, if somebody kicks me out of the office, 10 11 oh, you are in pre-contemplation, you are obviously not 12 thinking about moving to the electronic medical record 13 any time soon. What you need is education. You don't need me to come back in and start working with you on a 14 plan for how you are going to implement the system. 15

16 It also allows you to be able to start creating 17 subcategories of physicians. So, why is someone in pre-18 contemplation. There is a reason. Is it because they do 19 not believe that the technology is going to meet the benefits that have been proposed to them in the past, or 20 is it because they just really, from a technology skills 21 22 standpoint, they have never turned on a computer in their 23 life, they hate Googling things on the internet. There are a lot of different reasons that they could be in pre-24 25 contemplation. So, it allows you to then say, okay, you

1 are in this category and this is why, so we can develop 2 an individual action plan for you as opposed to a larger 3 organization.

4 So, really the goal of change management among 5 physicians is really to take out the uncertainty and б skepticism, so move them from pre-contemplation and 7 contemplation over to planning and action, which is 8 commitment to the project. Because without individual 9 commitment to the project, you are not going to have department commitment and you are not going to have 10 11 overall organizational success.

12 So, these are a few examples of provider 13 staging touching points that you can use within an organization. So, one of them is a project kick-off. 14 So, if we were all providers in a room working for a 15 16 health system, and I was giving you a little information 17 about our electronic medical record installation and 18 everyone in that room was just nodding their heads going, yeah, this looks like a really good idea, paying 19 attention, you would probably say that leads to the 20 contemplation phase if not the planning phase. 21 22 But if everybody is having like little secret

23 conversations over to the side, you really have to pay 24 attention to that. It is telling you something and many 25 people do not want to listen to that.

1 There are also online and paper readiness 2 assessments that many times get you down to the 3 department level. But, increasingly, we are getting to 4 the point where we can actually identify with a readiness 5 assessment those individual characteristics and stage б them at the individual level as opposed to the department 7 level. So that we can then go in before we hit the door 8 with a lot of information in our back pocket about that 9 provider. Also, physician championed road shows, on-site pre-training, et cetera. 10

11 The interesting thing about Go-Live support is that, in my experience, I have had about 5 percent of 12 13 providers that would not budge from pre-contemplation and contemplation over to planning. So, when they went live, 14 it was really, really painful, and anybody in the room 15 16 that has gone live with an electronic medical record in 17 an office where the provider was not really on board, it 18 is extremely, extremely painful because everything is 19 wrong, even if it is not.

But there are still techniques to get them to move into planning relatively quickly. But the thing that I want to point out is that if you apply a rigorous technique, it is really only about 5 percent that you cannot get to budge. It is not 70 percent, it is not 60 percent, it is not 80 percent. We are at a point right

now where we only have about 20 to 30 percent adoption of electronic medical records. So, we need an approach that gets 100 percent. The only way that we are going to get to 100 percent is to stage the providers and then communicate to them specifically based on their stage.

б So, the next couple of slides are just a couple 7 of examples of tools that we use right now in our mock Go 8 Live. We go out to the individual, allow them to answer 9 questions around their processes, get them involved ahead 10 of time and then map them out so that they know in 11 advance what their processes are going to be post Go-12 Live. So, you take that cynicism and skepticism out of 13 the picture and get their commitment early on.

14 Just to move to the last one, if you start thinking of smaller provider offices, it is interesting 15 16 because you would hope right now that there is an 17 adoption gap. Hopefully, that adoption gap is going to 18 narrow over time. So, the way that we can start looking 19 towards the future is to start identifying where, as a group, are small offices. So, looking at HIMSS Analytics 20 21 data from 2007, provider offices with 25 providers or 22 less are 50 percent most likely to identify themselves as not automated and without plans. So, they are early on, 23 they have not budged. They are probably not going to 24 25 budge unless we send them the right message.

I I believe that we are not sending them the right message right now and, so, that is part of the reason that they are not moving along the continuum. Thank you.

6 DR. GILMAN: Our next speaker is Paul Uhrig 7 from SureScripts.

(Applause.)

5

8 MR. UHRIG: Hello, everybody. I was asked to 9 come here today to talk about SureScripts and what we do 10 with the providers. There are some very familiar faces 11 in the audience, so for those of you who have heard this 12 before, you can pull out your Blackberrys. But for the 13 rest of you, hopefully this will help inform your 14 discussions as to the role of the FTC.

15 First, who and what is SureScripts? 16 SureScripts was created in 2001 by the pharmacy industry. 17 We were created with the goal of basically improving the 18 prescribing process by moving physicians and pharmacies 19 to a true e-prescribing process. We are an LLC, but we 20 essentially operate as a non-profit. Our goal is to 21 drive down prices and to drive down the cost of this 22 service to the industry. We are very much a neutral entity in the sense that we have similar contracts with 23 all who want to contract with us. We want a level 24 25 playing field, and we have rules in our system, for

instance, that prohibit advertising or commercial
 influence at the point of care.

An essential tenet for us is that a patient should choose the pharmacy and the provider should choose the therapy without what I will call undue influence from commercial activities. So, we have rules in our system to ensure neutrality and this balanced playing field.

8 We are essentially the intermediary. So, what 9 we are not is we are not a vendor of software to 10 physicians, we are not a vendor of software to 11 pharmacies. We are the intermediary that connects all 12 the physician systems with all of the pharmacy systems. 13 So, we are the behind-the-scenes network.

What we essentially do is on the physician 14 side, contract with the vendors, so the Mckessons of the 15 16 world, the AllScripts of the world, the Doctor Firsts of 17 the world, entities that license to physicians electronic 18 prescribing systems or more robust EMR systems. We certify their software to connect to the pharmacy health 19 information exchange. So, we look to security measures, 20 privacy measures, standards. This is all standards space 21 as I will talk about a little bit later. 22

23 We look to see that the systems will, in fact, 24 if a message is designated to go to the Walgreen's on 25 19th and K, that it will get to the Walgreen's on 19th

and K, or if a reply is going back to Dr. Smith Jones, it
 will, in fact, get back to Dr. Smith Jones.

On the pharmacy said, we contract either with pharmacies that have their own proprietary systems or with pharmacy management companies, again like the Mckessons who license software to the pharmacies. We do the same thing on their end. We certify their systems for connectivity, ensuring privacy, security and that the correct technical implementation is in place.

At a high level, how it looks, very simply a 10 11 physician has his or her handheld device or a laptop computer, pulls up the application, enters in the 12 13 patient's name, the drug to be prescribed, the dosage, the directions and the pharmacy to which the patient 14 wants to go. Hits the send button and it goes through 15 16 the system to the pharmacy that was selected. It arrives 17 at the pharmacist's computer so that the pharmacist can 18 then dispense the drugs. E-prescribing is not computer-19 generated faxes. There are a lot of doctors who hit that send button and say, I e-prescribe. But what actually 20 21 happens is it gets converted to a fax and shows up at the 22 fax machine at the pharmacy. That is not e-prescribing 23 in our mind.

Ours is true EDI transmission. It is bi directional so physicians can communicate with pharmacies

also in terms of refill requests and other information.
 So, it is very much a bi-directional system, again all
 standards based.

4 There has been substantial growth in e-prescribing since inception. We really went live in 5 б The AMA estimates there are about 563,000 office-2004. 7 based physicians. About 35,000 of them are actually e-8 prescribing today. You will see the growth chart there. 9 That is the number of physicians who are beginning to e-prescribe. Obviously, with only 6 to 7 percent 10 11 e-prescribing, there is still tremendous growth and need for additional physicians to adopt and use the 12 13 technology.

Our focus has historically been on the high prescribers. Our goal has not been to necessarily have every single doctor on the system because for some doctors, it just may not be as valuable as with others. So, our focus has been on the high prescribers, those who send, obviously, the most prescriptions.

20 On the pharmacy side, there is much greater 21 connectivity with the pharmacies. There are about 57,000 22 pharmacies in the country, 40,000 of them are connected 23 to the health information exchange. So, about 97 24 percent of the chain pharmacies are connected and are 25 e- prescribing and about 27 percent of independent pharmacies are connected and e-prescribing. So, our goal
 and our challenge is to increase the connectivity with
 the independent pharmacists.

4 In terms of transactions, there has also been 5 substantial growth in just the past year, but, obviously, 6 there is a long ways to go. Last year about 35 million 7 prescription transactions went through the system. It is 8 estimated there are about one and a half billion 9 transactions that are capable of being e-prescribed. So, 10 to date, that is probably about 2 percent. So, there is 11 obviously still a lot of room for growth in order to have this more fully deployed throughout the country. 12

13 Looking at some of the biggest factors that influenced e-prescribing in our view in 2007 would be, 14 15 one, regionally based programs. This is where 16 collaborations come together of various stakeholders and 17 they work together to either coordinate or create 18 programs to drive e-prescribing in a local area. 19 Those efforts tend to work very, very well. So, examples would be the Massachusetts ERX Collaborative or the Semi 20 21 Henry Ford Collaborative in southeast Michigan, or E-22 Prescribe Florida that has just started. So, those 23 groups bring together payers, governments, quality organizations, vendors and other stakeholders to really 24 25 focus on a particular area to drive e-prescribing.

1 Secondly is just the involvement either of the 2 federal government or the state governments to help drive e-prescribing. So, you obviously have the MMA and 3 4 activities under the MMA, standards adopted by health and 5 human services under Part D. You have a range of state 6 executive orders where governors have either created 7 targets or created government agencies or departments of 8 agencies or allocated money to drive e-prescribing. 9 Those efforts have often proved very fruitful. It is not 10 a coincidence that when you look -- just last month we 11 had what we called a Safe RX Award where we announced the top states in e-prescribing, and it is not a coincidence 12 13 that Massachusetts was the winning state because it has the Massachusetts ERX Collaborative, it has executive 14 orders that are driving connectivity in the state. 15

16 The third driver would be where the technology 17 vendors are actually spending time with their customers 18 on e-prescribing. Not to speak ill of vendors in any 19 means and not to paint them with a broad brush, but many vendors, once they license the system to the physician, 20 21 they move on to the next physician to license the system. 22 What we find is where the vendors actually work with 23 their clients and with the physicians to provide 24 training, to provide support for e-prescribing, that has 25 an impact on the physician actually adopting and using

1 the technology.

2 What else can happen to help drive utilization? 3 First, the Drug Enforcement Agency does not permit 4 e-prescribing of controlled substances. That has proven 5 to be a significant barrier. Physicians want one process, one application, one process to e-prescribe. 6 7 They do not want to have to use paper for one and use 8 electronic for another. Some physicians do not even know 9 off the top of their head which drugs are controlled 10 substances. Some of the Schedule IIs are obvious, but 11 some of the others may not be as obvious. This has proven time and time again to be a hurdle. So, movement 12 13 by the DEA who has been considering the issue for some time to allow e-prescribing of controlled substances we 14 think would have a significant impact on utilization. 15 16 The Kerry Bill, the E-MEDS Bill up on the Hill, 17 which provides incentives to physicians who e-prescribe 18 through grants and increased compensation when they e-19 prescribe, and starting in 2011 or 2012 would provide penalties if they do not e-prescribe, would also be a 20 21 driver.

Then, finally, health plans focusing on adoption programs, providing incentives to physicians through compensation and reimbursement, are also drivers of e-prescribing.

1	One thing that is not on here is the consumer
2	angle. What you will see starting actually in the next
3	few days is a campaign focused on the consumer.
4	Obviously, if your doctor e-prescribes you know because
5	you did not get that piece of paper. But many consumers
б	do not know what e-prescribing is. You will start seeing
7	in a few days a campaign based in pharmacies and
8	physician practices announcing that they e-prescribe,
9	informing the consumer what the implications are and what
10	it means to them, that their prescription will get a head
11	start to the pharmacy. So, you will see that and
12	hopefully that will be a driving force.
13	I am going to run through rather quickly a
14	couple of the myths about e-prescribing. One is that it
15	is expensive. If a physician actually wants to start e-
16	prescribing, there are free systems available. Now, a
17	great benefit to e-prescribing is that it would be
18	integrated in EMR, you have decision support, clinical
19	alerts, and that is more expensive. But the reality is
20	if you really want to get to step one, there are
21	inexpensive systems, and admittedly affecting workflow
22	has a cost in terms of human capital, but it can
23	obviously be done.
24	E-prescribing violates HIPAA, also a mythy All

24 E-prescribing violates HIPAA, also a myth. All 25 these systems are in compliance with federal law and state law. Obviously, there is an important debate going
 on now, as Deven was talking about, whether HIPAA is
 sufficient in today's world, but looking at the state of
 HIPAA today, these systems are all compliant.

5 E-prescribing is more secure, in our view, than 6 paper. The systems are secure, so, in our view, it is 7 more secure than a paper-based system.

8 There are no standards is another myth. All of 9 this is standards-based, the NCPDP standard, adopted by 10 the MMA to apply to the Part D Program. So, it is not a 11 question of no standards. The standards have been in use 12 for years and have been adopted by Health and Human 13 Services.

E-prescribing does not facilitate data mining. Our organization transmits data from one provider to another. That is it. Period. End of story. Deidentified data is not used, there is no data mining, we don't transfer it to anybody else other than the providers for a patient's care.

Then finally, e-prescribing does, in fact, have the support of many consumer and patient advocacy groups. Just a few weeks ago, the organizations listed here indicated their support for e-prescribing as it is implemented. Thank you very much.

25 (Applause.)

DR. GILMAN: Finally, we have Dr. Wood from
 Mayo Clinic.

3 DR. WOOD: Good afternoon, everyone. Thanks, 4 Dan, very much for the invitation to come. I hope that 5 in this last presentation before we go into the б discussion, I might be able to synthesize a bit of what 7 each of the presenters before me has done talking about 8 specific pieces of care and to share with you what I 9 think might be the promise of virtual medicine or 10 electronic practice and then where some of the 11 preemptions might be. Some of them already have been 12 shared with you from the perspective of technical issues 13 and concerns about privacy and regulatory issues, but at the end, as we contemplate this, I think it may become a 14 15 bit more personal than some of us perhaps have thought. 16 From my perspective, as a practicing physician, 17 there are many opportunities for us to interact with 18 patients that go beyond the traditional method of seeing 19 a patient in the office, sitting down and taking an exhaustive history, doing an exhaustive examination, 20

sometimes, at least in my practice that is what I am accustomed to, and instead, beginning to meet the needs of patients in different ways by delivering care to them when they need it and really how they need it and where they need it and increasingly at a cost or price that is

1 affordable.

2 So, those of you who were here this morning 3 heard about price transparency and things like that, 4 those are all drivers of what we need to do. 5 Particularly, this needs to be built, from my 6 perspective, on the capability of applying these tools to 7 facilitate direct interaction with patients, as well as 8 direct interaction with other physicians who are caring 9 for patients. In so doing, there is virtually nothing, I 10 think, that we cannot do this way except potentially for 11 those things that require direct procedural intervention. 12 But in my experience in working in rural Minnesota, we 13 can even do interventions that are supported by networks that allow us to do cardiac procedures in hospitals, for 14 example, that do not normally have cardiac surgical back-15 16 up. 17 Mayo has approached this problem for the last 18 several years. I am going to show you two screen shots, 19 one from a patient portal, which is this one, and one

from a physician portal. These are both password protected. We found the need to develop them mostly on our own, because we have not found opportunities with partners who can help develop them with us.

24 But I have highlighted here on the patient 25 portal one that we call Ask Mayo and Appointment Manager,

1 and it gives patients actually a specific opportunity to 2 interact with their health care provider in a number of 3 different ways, including leaving messages for the nurse, 4 asking for consultations, electronically arranging 5 appointments and even talking to a person who might б provide them specific help in navigating what is a 7 complex system. So, the Mayo Clinic is a big, big 8 system. It has got a lot of strange rules, and if you do 9 not know the rules, it's hard to get through those, hard to navigate them on the web site. But you could ask your 10 11 particular manager to help do that and solve some of your 12 problems perhaps more effectively.

Now, this is the physician portal. It also is one that is intended to allow flexibility in approach. Both of these portals, by the way, are password protected. So, in particular, they are looked at as an opportunity for us to truly be a partner with both the patient and the referring physician.

19 I have highlighted here the concept of patient 20 reports. One of the great difficulties we have in modern 21 medical practice is that when a consulting organization 22 like the Mayo Clinic sees a patient for a specialty 23 consultation, you then may wait for the mail to carry a 24 consultation report back to a referring physician, which 25 may take weeks and months. There are circumstances,

obviously, with electronic approaches where we could 1 2 provide much more timely information and, in fact, for 3 some physicians who may not have already an existing 4 electronic medical record, by using web-based 5 applications, we can ship back to them information that б they can at least convert into a usable electronic record 7 that they can work from. And I will tell you a little 8 bit about how we are doing that in a minute.

9 Now, Mayo has the opportunity, too, that it is 10 a highly integrated system and we have had an integrated 11 electronic medical record, which has had its share of problems because it didn't really match the physician 12 13 workflow. But be that as it may, we have it, we use it. A few years ago, we started building on it in our 14 Division of Primary Care Internal Medicine, which is here 15 16 signified by PCIM. The idea here was that we would 17 change the mode of consultation support. So, rather than asking for the traditional face-to-face consultation, the 18 19 primary physician could decide, I would like that cardiology consultation delivered virtually. I have a 20 21 question I would like to ask and I do not think it needs 22 the patient to go see the cardiologist, I am going to 23 order that.

We have started actually in cardiology,
endocrinology and gastrointerology and hepatology, which

1 is GIH, because that was where most of these 2 consultations happened to be. We had the principal of 3 the common medical record to build on. We found that the 4 uptake was a little slow, gradually increasing. I will 5 come back to some of that information a little bit later. We then decided to see if we could extend it way far 6 7 away, so we developed a specific link with the United 8 Arab Emirates, and then we have also developed a 9 satellite-tele video link to support that. And in 10 between, we have developed some relationships with some 11 of our own system hospitals in Minnesota that allow us to 12 transfer real-time hemadynamic data, voice data, electro 13 cardiographic data, video transmission and audio, and at the same time, permit remote cardiac catheterization and 14 cardiac interventions. So, there are lots of those 15 16 particular things that we have undertaken.

17 We have also looked at this from the 18 perspective of improving patients' ability to care for 19 themselves. So, we are delivering in our primary care practices web-based interactions that can be done both 20 21 with pdf file transmissions and from the perspective of 22 providing virtual consultation support to rural practices 23 in Minnesota who do not have an EMR. Finding ways that they can send us simple questions, scan documents, a few 24 scanned laboratory results, and if they need to, store 25

1 and forwarding electronic images.

Now, in Minnesota, about 54 percent of the patients are cared for by physicians who work in systems, but there are still a large number, nearly half of the physicians in the state practice in small groups of two to four, half of the population is in rural Minnesota and most of these practices do not have an electronic medical record.

9 So, in particular, one of our test beds here was to work with a small group of family physicians in 10 11 Proctor and Two Harbors, Minnesota, and Duluth, 12 Minnesota, which is about 250 miles from Rochester. So, 13 most patients who might hear from a physician, you need a consultation with a specialist, are not going to really 14 think about Mayo as an option unless it is something 15 16 really serious. Something closer usually is what comes 17 to mind.

But we proposed this approach by saying to the family physicians, we would like to provide you an option to ask a question that you might not otherwise think of in as simple a way as possible. They said, yeah, but we do not have an EMR. Okay, well, we can solve that problem.

24 So, you just tell your nurse what question you 25 want answered, she writes it down on a piece of paper,

scans it, creates a pdf file, ships it to us by the 1 2 electronic portal for physicians you just saw. It is 3 opened by one of our specialists who then looks at the 4 question and can then review, again, the scanned 5 information, if there are some laboratory tests, and 6 provide an answer. It takes usually less than 15 minutes 7 to do this. Traditionally, if I would do this in a face-8 to-face consultation, it would take me 40 minutes. That 9 is what we allocate, mostly because there has to be the time to do all of the other sorts of documentation that 10 11 may be totally unnecessary, but are necessary only from 12 the perspective of billing.

Now, in that circumstance, I can rapidly deliver an answer to the primary care physician who can apply that to the patient, hopefully improving their care and doing so in a much more convenient fashion.

Now, as we begin to look at the results of that kind of intervention, we found that generally the patients that used this approach were satisfied with the answers they were getting and they generally rated the explanation that they were getting from their primary care physician about what the specialist said as being excellent to very good.

24 So, one important observation here is you do 25 not necessarily need a specialist to always deliver the

1 opinion. The specialist, in particular, can facilitate 2 the work of the primary care physician quite readily. 3 However, when we tried to ask people about their 4 preference, still despite their rating their experience 5 pretty satisfactorily, there was not a lot of interest in б rapid uptake among patients. I think some of the 7 evidence that was shown this morning from California is 8 kind of interesting in that regard as well. So, that, 9 plus what Dr. Carr shared a little bit earlier, I do not 10 know where most patients are perhaps in this context, but 11 maybe there is something that we will have to do together 12 and it might be some form of group therapy.

13 At any rate, we have also tried, as I mentioned earlier, to extend this to patient care, where we can 14 have patients begin to become a more active partner in 15 16 their own care by providing some web-based algorithms for 17 them to make decisions. Now, years ago, we used to do 18 this somewhat by phone. But, now, we can provide 19 algorithms that patients can use, and this is a screen shot of one which is aimed at urinary tract infections. 20 21 But if you are a patient of one of our primary care 22 physicians, you can access this information via the web. 23

23 Now, you can do it by phone if you want to, as 24 well, if that is your preference. You can go through the 25 exact same approach with a nurse. She will use the exact

same script. Hopefully, if you did it with a physician,
 you would follow the same script as well.

3 Now, this is relatively simple but there are 4 some things that are a bit more complex. This is a 5 little busy and I apologize, but what this is a common 6 problem for anti-coagulant management. It begins then to 7 give the patient and the physician an algorithm that they 8 both know that they can follow. This is, in fact, how we 9 think we will create greater safety and reliability in 10 the system.

11 Now, the promise of virtual medicine from our perspective is more than simply automation, but in 12 13 providing greater connection to specialty and primary care, better management of our physician workforce. Many 14 of the concerns that we have heard in Minnesota, 15 16 especially about the shortage of physicians, we think 17 would be mitigated by applying this kind of technology. 18 In fact, we believe that many of the assumptions that 19 have been made about shortages based on current medical practices are probably severely flawed. 20

You have heard already today about some of the limitations which have been articulated. There have been payment concerns that have been identified this morning. Licensure issues were not talked about very much. We have heard a lot about technical limitations.

1 Dr. Carr talked about physician adoption. Our 2 experience says that there are some patient adoption 3 issues. Now, as we have looked at this in a couple of 4 different places, in a highly integrated system in 5 Rochester, Minnesota, the Mayo Clinic, and a small rural practice, the physician adoption issues are pretty much 6 7 the same and the patient adoption issues are pretty much 8 the same. It may be that we will need, again, sort of a 9 combined approach, perhaps group therapy, that will be based on the development of a trust that, in fact, these 10 11 tools do work, they are better, you do not always have to see the doctor, you can get lots of things done and begin 12 13 to deliver. 14 But until we do that, I think the greatest preemption is going to be personal rather than technical 15 16 rather than legal rather than regulatory. 17 So, with that, Dan, it is back to you and, 18 hopefully, a good discussion. 19 DR. GILMAN: Thank you. 20 (Applause.) 21 DR. GILMAN: Once again, we are glad to have 22 questions from the audience both during the session and If people want to write them down on the 23 afterwards. index cards, staff will collect them and send them 24 25 forward.

1 While that is happening, I would just like to 2 kick things off by going down the panel and asking 3 whether any of our panelists want to sort of pick up on 4 comments made by their colleagues here at the table. 5 MR. FERGUSON: I will pass it off to Deven б first. 7 MS. McGRAW: Well, you did have to go first 8 last time, Jamie. 9 I think that I would submit the point that you 10 raised about the patient reluctance that was raised in 11 the last presentation. I do think it is somewhat due to 12 the mistrust in the systems that have to do with privacy 13 and security. Even if you look at the urinary tract questionnaire that was just on the screen, that is 14 information that folks are typically comfortable sharing 15 16 with a doctor, but they want to know for certain that 17 that information is not going to get in someone's hands 18 for unauthorized or inappropriate purposes. 19 DR. CARR: I think I would say that the concept of doing patient group therapy sounds like a lot of fun. 20 21 So, any time you are willing, I am willing. MR. FERGUSON: One comment that I would make on 22 the patient adoption issue is, we have had certainly a 23 very rapid sign-up for our personal health record. I 24 25 think at year end we were at 1.7 million, we are now well

over 2 million. So, over 100,000 people a month are 1 2 choosing to go online and activate their personal health 3 records. So, this is very rapid, given that really we 4 have just announced that all the capabilities are 5 available nationwide within the last couple of months. б MR. UHRIG: Well, I quess just picking up on 7 the same theme, there is a concern about privacy and 8 security. I think the key is also education of the 9 benefits, of the convenience that come with it, and there 10 is no doubt privacy and security are paramount. What we 11 are finding is that when the patient realizes, one, that 12 it is a secure system and the benefits, they will start asking their physicians, in our case, do you e-prescribe, 13 14 and drive the system that way. 15 DR. WOOD: I have nothing else to add. 16 DR. GILMAN: Okay, thanks. Maybe to kick 17 things off, I would like to make an observation and put a 18 question to the panel. The observation is that we have a 19 wealth of experience here in implementation, implementation of HIT systems, whether for electronic 20 21 prescribing or whether more complex systems for providers 22 or implementation at the practice level. In that regard, 23 there has sort of been a broad concern with interoperability of HIT systems, interoperability between 24 25 different utilities within institutions, of course, but

also interoperability more broadly in health care between
 providers and patients within institutions and between
 institutions, within states and among states, and I
 think, a broad recognition that there are some big gaps
 here.

6 So, for the panel, what do you see as the main 7 stumbling blocks to successful interoperability and to 8 put it slightly a different way, for both innovators and 9 policymakers looking for marginal improvements or 10 breakthroughs, where is the low-hanging fruit and where 11 might we be say five years from now?

MR. FERGUSON: Well, certainly in terms of 12 13 interoperability, there have been truly great strides made in just the last few years as a result of the 14 programs of the Office of the National Coordinator. 15 So, 16 we really think that this has fundamentally changed the 17 marketplace. We have seen much more competition among 18 vendors of electronic health records systems as a result 19 of publication of these consistent standards for the top use cases for which health IT is used, which is labs, 20 21 medications, demographics, e-prescribing, and so forth. 22 So, the fact that these standards are being

23 recognized by the Secretary of Health and Human Services 24 really has had a great impact on the activity in the 25 marketplace both in terms of competition and adoption.
DR. GILMAN: Any others?

2 MR. UHRIG: In terms of barriers, I guess cost 3 is always one that we certainly hear, real or perceived 4 cost. You always have the debate, why do I have to pay 5 it because it is everybody else who benefits, so they 6 should pay. So, it is always the allocation of that. 7 In our world, for us, whether it is for the 8 physicians or independent pharmacies, it is also where

9 they are located and who is going to go first and who can 10 I speak to, in the sense, oh, you know, imagine the first 11 salesman for the first phone, there was no one for them 12 to call. So, how do you make the first sale? This is 13 sort of a similar concept. We are overcoming that.

And then in sort of rural areas, you just have issues of connectivity. Even in today's world we hear, well, we just do not have the internet connection or whatever in certain rural areas to be able to communicate. So, those are all things we need to deal with.

20 DR. CARR: I would say that I agree with the 21 comments about interoperability standards being key to 22 moving forward. There are a couple of things that -- in 23 my past life I worked on a health information exchange 24 and there were two things that really jumped out at me 25 that were very surprising. One of them was that vendors 1 spend a lot of money developing software and 2 interoperability is not always beneficial to them in the 3 We have to consider that when we are talking market. 4 about interoperability. If I am the leading vendor in a 5 particular market and then I suddenly become interoperable with all of the other software within small 6 7 physician offices, then I have lost the ability to sell 8 to those smaller offices within that particular market.

9 The second thing which was very surprising to 10 me is that I spent a couple of years implementing 11 electronic medical records on the inpatient side at a 12 hospital and we spent \$20 million doing that. One of the 13 things when we started to work on interoperability with a competing hospital across town, we found that the CFO, 14 one of the reasons they signed off on it was because it 15 16 gave, in her opinion, a competitive advantage over her 17 competing hospital across town to have an electronic 18 medical record capturing the data, being able to report 19 off of the data and providing it to the providers within the community. 20 21 So, because of that perception of a competitive

22 advantage, it was somewhat challenging to convince her 23 that it was a good thing for patient care.

I do not think that is uncommon. I do not think that she is the only one. So, we should not 1 crucify her. But it is something that we have to 2 acknowledge. It is a fact. It is out there. It is in 3 the market. Because when you are spending \$20 million on 4 technology for your hospital, then somebody has to give 5 you a compelling argument. One of the arguments that the 6 vendors are giving you is that it is a competitive 7 advantage. We need to get to the point where it is just 8 a must-have. Everyone has it and it is not a competitive 9 advantage.

10 DR. GILMAN: Another thing that has been 11 interesting is sort of from different perspectives, consumer advocates, providers and also IT providers have 12 13 spoken about the importance of building trust among 14 health care consumers and others. Some of you have struggled with this, some of you identified it as an 15 16 ongoing problem. Where do you identify special models of 17 institutional success in this area and how do you see 18 these successes being replicated? What is the mechanism 19 for that?

20 DR. WOOD: At Mayo, this has been a significant 21 concern for us since the nineties actually because in 22 Minnesota, privacy legislation was passed then that was 23 specifically aimed at making sure that patients 24 understood how their medical record information might be 25 used, including for point of care activities, as well as

potentially for research after the episode of care.

2 We actually did some focus surveys, starting 3 with some quantitative research and then following it 4 with some qualitative research with people coming to 5 Rochester from out-of-state, from communities more than б 100 miles away from us, and then from people in our own 7 community. A lot of our practice actually comes from 8 outside Rochester, Minnesota. But what was rather 9 interesting was that regardless of where people were 10 coming from, their greatest concern about privacy 11 actually had to do with their privacy locally and it did 12 not make any difference to them whether it was electronic 13 or not in terms of how the record was handled.

14 The idea that they articulated was, a neighbor of mine may still sometime be able to see my protected 15 16 health information in the course of their work. So, the 17 solution for us was to make sure that we made it very 18 clear to patients that we have a strong policy, that we 19 enforce it strongly and immediately and that they always had the opportunity to come to us with a complaint or a 20 21 concern. But we felt it imperative to make sure that it 22 was clear to patients that their personal information, 23 even though you can make a strong argument that electronic modes are more secure than what our paper used 24 25 to be, it was still important for us to make sure they

understand what our commitment is and that we, in fact,
will stand by that. It is an institutional policy for us
that if you, as an employee, inappropriately access a
record, we have a very strong audit trail. If that
happens, there is disciplinary action and it is usually
pretty swift.

7 DR. GILMAN: Great. We have several questions 8 from the audience. One is directed to Dr. Carr. What is 9 the right message to get providers to adopt health IT? 10 DR. CARR: We will pay for it all, et cetera. 11 No. I think it does depend on the stage of change for 12 the provider. If you look at someone that is in pre-

13 contemplation, they are going to probably have multiple 14 different reasons for being in that particular stage.

15 I will give you a couple of the incorrect 16 messages to start off with. One of them was based on an 17 experience that I had in my previous life before joining 18 BearingPoint, where we installed an electronic medical 19 record at a couple of offices and then that software was purchased by another company, which then merged with 20 21 another company. Probably not what you want providers to 22 be fearing is that their vendor will be bought by someone else and then merge with someone else within the next two 23 years. They had three owners of their EMR software 24 25 within a two-year period of time. Not what you want to

hear. So, we need to tell providers that they are going to have a stable system that will be around with the same or similar owner over a long period of time because they are practicing for longer than a couple of years and they are looking to invest for longer than just a couple of years.

7 The other thing is the cost, but I do not think 8 that the cost is going to be enough. If you look at just 9 larger organizations that are implementing an electronic 10 medical record, there are providers within that 11 organization that are resistant to having an electronic 12 medical record in their office, even if the organization, 13 as a whole, pays for it and it does not impact their income at the local level. So, the things that those 14 larger organizations have to do is they have to convince 15 16 them that they are going to be supportive, that they are 17 going to come in and develop a specific action plan that 18 is specific for them as an individual, identify their 19 issues and address their issues. I think that until we start doing that with smaller office physicians, then we 20 21 are not going to get the adoption rate that we are 22 getting in the larger offices.

23 So, the organizations are doing it, but there 24 is nobody really out there doing that type of work with 25 the smaller offices. 1 DR. GILMAN: This is a question addressed to 2 Dr. Wood and Paul Uhrig. I hope that I can read all of 3 it, but it does seem to be relevant to other panelists as 4 well, so maybe we can start with the two of you and then 5 move along. This asks, how do you lower costs by 6 reducing duplicative lab tests, unnecessary services, et 7 cetera, without sharing information on a more global 8 scale?

9 Hospitals share information with other 10 hospitals about how certain -- I do not know, certain 11 documents are treated -- diagnoses are treated and study 12 the outcomes to determine the most effective treatment. 13 To this end, why are we not data mining e-prescribing 14 info to learn how we are treating people so we can 15 examine how smart our current protocols are?

16 DR. WOOD: I would say there are a couple of 17 different ways you could conceive of lowering costs 18 without actually sharing information. Clearly, the 19 immediate opportunity is that when you are confronting a patient as a physician who has been seen elsewhere, 20 21 knowing exactly what was seen is extremely helpful and it 22 sometimes can be absolutely diagnostic. I could share with you many stories of situations where patients bring 23 with them their CD of their CT or their MR where we 24 25 immediately look at it and make the diagnosis, and it was not made elsewhere simply because these are the kinds of
 things we deal with. They are rare for other people,
 common for us. So, it makes much more sense for us to
 have the information and make the diagnosis.

5 But that aside, there are lots of circumstances where in medicine we do lots of testing that is somewhat 6 7 traditional. It is not evidence-based and it may not be 8 based on good judgment. So, having electronic solutions 9 that will get you good guidance, either guidance that you can get if you have time, but better yet, especially in a 10 11 very busy primary care practice, point of care clinical decision support. 12

Lab tests are usually not the big cost. So, if you are not certain as a primary care physician and you had the ability to do a quick virtual consultation to a specialist and say, this is the problem, what do I do next, that could probably save you lots of unnecessary testing.

In our experience with working with this small group that is north of us a few hundred miles, at least 60 percent of the questions that we answer are ones that are like that and they do result in a reduction of costs directly that way. So, those are two very good ways you can do it without actually sharing lots of information. Sharing knowledge becomes important.

1 MR. UHRIG: From my perspective, I guess there 2 are two things about costs. One is just I mentioned cost 3 and that is just the transaction costs. That will be 4 lowered just by virtue of scalability in our system. So, 5 the more people who are connected, the more people who 6 are transacting, the greater the scale. So, our costs 7 will go down and that will be passed through to those who 8 pay the fees.

9 Just the sharing of the information, if I 10 understood the question in terms of overall costs in 11 terms of health care, obviously, e-prescribing will lower overall costs just in terms of the ability get the 12 13 clinical alerts, payer information to the extent there may be sharing of medication history so the proprietor is 14 better informed of what the patient is taking. Those are 15 16 all things that will improve the health system and drive 17 down costs.

In terms of data mining, my suggestion was not that it should not happen or does not happen, but along the question of trust of what people do with information, the point is, in our world, it is not a means for data mining to occur. That is just something that we are very clear about to increase trust in the system.

24 MS. McGRAW: Can I make a comment about it? I 25 think the questioner really points out the host of

benefits that we can gain from moving to electronic health records systems, whether it is through eprescribing, personal health records, electronic medical records. The ability to reduce duplicative tests, to stop harmful drug interactions, to get decision support tools that guide us towards more evidence-based decision making, all of that is good. Absolutely.

Again, it is our position that workable privacy and security protections that still allow for the appropriate uses of that information will actually help enable all of that to happen.

12 DR. GILMAN: There is a question about the move 13 to interoperability and whether maybe it is misplaced when so few providers have EMR systems that can work for 14 them in patient care. Maybe people can comment on that. 15 16 I think another wrinkle to this might be just to add some 17 detail. Certainly, we have representatives here of 18 institutions that have done quite a bit to integrate 19 different systems, sometimes developing things to a great 20 extent in-house. Where in the course of this development 21 did you start to see real and clear benefits to different 22 steps along the way? How did you measure these? To what extent do you need integration between different systems 23 to sort of make the case for adoption? And how is this 24 25 information disseminated in the larger market?

1 DR. CARR: So, for the interoperability versus 2 an EHR, I will start with that one. One of the 3 interesting things that I found working with a number of 4 small physician offices in Connecticut, we were moving 5 forward on a health information exchange that also 6 supported electronic medical records in each individual 7 office. So, the concept was you had a health information 8 exchange, agreed to participate in the health information 9 exchange. You also had an electronic medical record.

10 One of the challenges to that was that we could 11 get to the point where we could afford the software, but it was extremely, extremely challenging for us to support 12 13 the infrastructure for interfacing all of these systems. Each system was proprietary. The standards were not as 14 far along as they are right now. So, for each physician 15 16 office, it was double the price of the implementation for 17 You had the software cost and then you had the us. 18 interfacing costs, which were double what the actual 19 software cost the office. So, that is a huge barrier that needs to somehow decrease over time. 20

I think if we do not have standards-based interoperability, then we are never going to get to the point where those interfaces, that communication between your practiced management system and your electronic medical record system and the hospital IT system actually

becomes cost-effective.

I do not think it is an either/or. I do not think we should approach this problem as an either/or. I think it is that, yes, you are right, whoever asked the question, that we do need electronic medical records. I think that we have to have a balanced focus on both.

7 MR. FERGUSON: If I can add something, I think 8 that I would address that question in part by saying it 9 depends which part of the health care sector you are talking about. So, if you are talking about the 10 11 fragmented fee for service non-system of care, there I 12 think that the interoperability in terms of the basis for 13 certification provides the fee-for-service providers with a sense of not necessarily guaranteed, but a sense of 14 comfort or trust that they are buying the right product, 15 16 that they are spending their limited resources on things 17 that they can use to get to a very basic level of 18 coordination of care for their patients, whereas in the 19 integrated, more systematized part of the sector that we operate in, some of the very early benefits that we got 20 21 were much more about being able to consistently employ 22 evidence- based clinical guidelines on a very consistent 23 basis right away.

24 So, I think the answer, both in terms of 25 benefits and drivers, depends on sort of what part you

are talking about.

2 DR. WOOD: Well, there is also the interface 3 between say the small, private, fee-for-service and 4 the -- I would not say private necessarily, but an 5 organization like either yours or Mayo Clinic, and that is the intersection. So, if we are going to start -- the 6 7 reason to have to interoperability is when you start to 8 transfer information, especially images, you really want 9 to make sure that you know that the image you have is of 10 the patient you are trying to provide an opinion about. 11 So, there would have to be some standards about how those images are transmitted, marked, labeled and manipulated 12 13 for just a single practical thing. But that is replicated in several different things. So, I think 14 15 there is this intersection that is also very important. DR. GILMAN: One of the three clocks in the 16 room tells us we have a couple minutes left. Maybe there 17 18 is time for one quick question. The question says -- I 19 do not know what the information on this is -- in some locations, the top hospital has been unwilling to share 20 21 its EMRs because of fear that they will lose business, 22 how do we overcome this? I do not know if other people share that assumption or observation, but to the extent 23 24 that you can speak to it.

25

MR. FERGUSON: I am not sure how to address

1 that.

2 DR. CARR: Well, I have had that situation, 3 actually come up. It is extremely, extremely, extremely 4 challenging. The only way that I have been able to 5 overcome it in the past is to -- the project that I had 6 where we actually addressed that issue was an 7 under-served project where it was not around their 8 fee-for-service patients, their Aetna or their United Health Care patients, it was around the under-served 9 10 patient population which was about 15 percent of the 11 population in that particular community. 12 So, people tend to have a heart, otherwise they 13 would probably not be sitting upright. I think that you have to approach them as an individual, as opposed to a 14 CEO or a CFO, and say for this particular community, we 15 16 need to do this for our patients and get them out of 17 their daily mind set of what they are doing, crunching 18 the numbers, et cetera, but really find something that 19 the only way you are going to get people to change is to really either hit them in the heart, hit them in the 20 pocketbook, or in the face. 21 22 So, that is what has worked for me in the past, 23 is to have an under-served focus and really focus on 24 that.

25

MS. McGRAW: Well, speaking of the pocketbook,

this occurs to me as one area where the major purchasers of care, your employer, community and also the consumers can really have a big impact in terms of driving communities to move towards these system.

5 A single provider might have a very good 6 business reason to be worried about business going out 7 the door and, therefore, not want to make an investment 8 in these types of technologies. But the improvements in 9 health care quality and the cost reductions that the 10 system overall, that are there as potentials, are going 11 to drive the other actors in the system, consumers and purchasers, again, if we set up the right conditions for 12 13 all of this, to actually be on the demand side for moving 14 some of this.

15 MR. FERGUSON: Just to add sort of one final 16 comment on that one, I think what both of these comments have pointed out is the fact that there is no billing 17 18 code for it. I am sorry, but health care has been 19 extremely responsive to economic incentives. It just that it comes back to that basic financial question. 20 DR. GILMAN: Well, I want to thank the 21 22 panelists. We have a short break now. If we could adopt this central clock as a benchmark and be back here at 23

24 2:45, according to that device, for the next panel.

25

MS. OHLHAUSEN: And we do have the WiFi

1	password available now. So, I am going to give it to
2	Michelle because it is a little long to read out. So, if
3	anyone still wants it, it is here. So, see you all at
4	2:45.
5	(Applause.)
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	

1 PANEL 4: HEALTH IT - CONSUMER ISSUES 2 MS. RICH: Hi, welcome to our afternoon panel 3 on health IT and consumer issues. Actually, we have 4 been hearing about consumer issues all day. It has just 5 been bursting forth in every panel. Consumer trust, 6 privacy, security, HIPAA. But this is our opportunity to 7 really drill down on those issues with some experts on 8 them. We are going to discuss some of the benefits. 9 Again, we have been hearing about that. But some of the 10 benefits of electronic records to consumers, the benefits 11 that are provided, the consumer issues that are raised, 12 including notably privacy and security issues, and try to 13 solve the problem here today of how to balance those or at least start talking about it. 14

We are very pleased to have here to discuss these issues five wonderful panelists. Let me introduce them now and then they will each take five or ten minutes to talk and then we will be able to discuss some of the issues among themselves.

20 We have Thomas Berg, who is the general manager 21 of the IS Strategic Relations of the Marshfield Clinic in 22 Wisconsin. Mr. Berg has hands-on experience with 23 development of electronic health records systems as well 24 as compliance with HIPAA requirements governing the 25 privacy of the records.

1 Susan McAndrew, who is the Deputy Director for 2 Health Information Privacy of the Office of Civil Rights 3 at HHS is here. She is an expert on the requirements and 4 scope of the HIPAA privacy rule as well as HHS's efforts 5 and priorities with respect to implementing electronic records systems. 6 7 Pam Dixon is the Executive Director of the World Privacy Forum. Pam is a leading advocate on 8 9 consumer privacy issues generally and has particular expertise and interest in areas of electronic medical 10 11 records and medical identity theft. 12 Amalia Miller, Assistant Professor of Economics 13 at the University of Virginia. Amalia has done substantial research in the health, health policy area, 14 including research on the benefits of adopting electronic 15 16 health records and the inhibiting effects of some state 17 privacy laws on such adoption. 18 We are hoping for a spirited debate on both 19 sides of the issue here. 20 And George Scriban, Senior Manager for 21 Microsoft's new consumer health records platform, 22 HealthVault. George has personal experience in developing this personal health record product as well as 23 in addressing the privacy and security issues it raises. 24 So, we will take five or ten minutes each to 25

1 set it up and then we will chat.

2 MR. BERG: Good afternoon. Gee, I could hardly 3 remain in my seat during this last presentation. I feel 4 privileged kind of because I got a good leg in the 5 provider side and I am going to kind of bridge into the 6 patient concerns. 7 If you take a look at Dr. Wood's clinic and you 8 drive two hours east, you will arrive at Marshfield 9 Clinic. We see Dr. Wood's helicopter come into our heliport almost daily and I think, gosh, they must have 10 11 really a sick patient over there to be bringing him here 12 to Marshfield. 13 (Laughter.) MR. BERG: But, anyway, we have just finished 14 up on a three-decade journey to move from the paper 15 16 record to the electronic health record. So, I am going 17 to tell you a little bit about that, frame that up, where 18 we are, and then I want to switch gears and say how we 19 are using this to help the patient, the consumer, and we

are going to focus in on just one very small -- it is actually a big cost item, diabetes, and what we are doing with that data.

23 So, let's see, moving on here, just a little 24 framing us up, we are about 100 years old. We have 25 roughly 800 of our own physicians, we have got another

400 non-Marshfield Clinic physicians that are also using the system. Within our region, the purple area, that is about a footprint about the size of West Virginia, we have 45 centers and we are moving into some dental practices as well. We have about two million patients in our electronic health record. We do research and we educate doctors.

8 IT at Marshfield is over four decades old. We 9 have about 400 people in my department. Half of them are 10 developers. Our first module of the electronic medical 11 record went live in 1985 with laboratory results. Every 12 laboratory result generated in the system at all 45 of 13 those clinics still remains online.

Fourteen years ago it became impossible to practice medicine at Marshfield without using the computer. All documents were generated by the computer and had to be electronically signed.

18 We are an integrated culture in that all specialties and subspecialities in our hospitals use the 19 20 same electronic health records. We have had extremely 21 strong, and are fortunate to have, leadership support. Three to 4 percent of our total budget for the last four 22 decades has gone into IT development. The physicians, 23 for four decades, have been committed to building an 24 electronic health record. 25

1	We are internally developed. We are CCHIT
2	certified. We are chartless. This is us before, we had
3	miles and miles of files. And, today, this is being
4	converted into a sleep laboratory.
5	(Laughter.)
6	MR. BERG: We waited very impatiently for a
7	device we could carry. You will see Dr. Stalmus here has
8	a device in his hand, it has all the power of your
9	desktop PC. It is a PIN-based operating system from good
10	old Microsoft. This was the huge enabler for us. We did
11	not want to provide each provider with five systems, one
12	in each of the exam rooms, one in his office, and then a
13	mobile device for them to take on the road and take home.
14	This one device goes with them, it stays logged in no
15	matter where they go.
16	Most physicians have this on their bed stand at
17	night when the phone rings and they are on call. That
18	system is live in their home. They see all the images,
19	laboratory. Anything that the nurse is talking about
20	with them, they have those images at their bedside. That
21	was a huge selling point.
22	We have about a quarter of our devices, 2,600
23	of these devices are in the hands of our health care
24	teams. So, that means not just the provider carries
25	them, everybody on the health care team carries these

tablets or convertibles and the communication goes back
 and forth.

3 Dr. Stalmus here, on a need to know basis, he
4 has a complete medical record on over two million
5 patients in his hand.

б In the absence of interoperability standards, 7 we are listening for somebody that wants to communicate. 8 We can communicate if somebody is listening. However, I 9 think the big problem with interoperability is the state 10 providing me a legal infrastructure in which I can talk 11 to other group practices in my state, and when I want to send a patient to Mayo, I do not want to have to go and 12 13 broker a relationship with Mayo, I do not want to have to broker a relationship with Duluth Clinic. I need a 14 SureScripts broker that we all can talk to in the state. 15

16 In the absence of this, we have done a technology adoption, HIE. What does that mean? This is 17 18 our campus at Weston. On that campus, we have Marshfield 19 Clinic, we have Ministry Health, that is a totally separate legal entity, we have St. Claire's Hospital, yet 20 another totally separate entity, and in the middle, we 21 22 decided to form a fourth entity to house ancillary services like radiology, cath lab, laboratories. Very 23 expensive stuff to replicate. 24

25

So, on this campus is one electronic health

record. If we back up here, we have a real cooperative, 1 2 aggressive relationship between these two. We 3 aggressively compete for the same patient. We are in the 4 same business. But we cooperate on the back end in that 5 all the data on that patient goes into the same 6 repository, so that no matter where the patient goes in 7 the system, either one of our systems, they have a 8 complete medical record.

9 Now, this came up in the last session about why 10 aren't people sharing the medical record. We are a not-11 for-profit. It is a mission-driven system and the 12 mission is to serve patients. You cannot serve patients 13 by sequestering their data. So, we ask other people to 14 use our intellectual property and pay for it, but it is 15 working well.

Now, we are going to switch gears, we are going to talk about leveraging the health care technology to transform health care for chronic disease. We are going to focus on diabetes. And the message here is, you cannot influence what you cannot measure.

21 We are taking a warehouse look at the data. I 22 will explain this. It is a little busy. Each one of 23 these are dots. Each dot is a patient. We have 13,350 24 diabetics in our system that we are trying to manage. 25 There are 11 things that have to happen or that should 1 happen to adequately manage a diabetic.

2 Eight of them are processes. These things here 3 in yellow, blood pressure, hemoglobin, A1Cs, these need 4 to be done at a certain time in the life of the patient. 5 If they have an active foot problem, that foot exam maybe б needs to be done every month or every two months. So, 7 there is eight processes, things that need to be done to 8 take care of the patient. This is not rocket science. 9 If my doctor had only me as a patient and I had diabetes, I would get perfect care. But he has 2,000 patients and 10 11 there is 17,000 in the system and there is two million patients in the system, you drop through the cracks. 12 13 Eight of those processes have outcomes. So, the laboratory and the blood pressure, they have to be in 14 control. So, back here, at the 5,000 foot level, these 15 16 patients down here are patients with no measurements out 17 of control. Up here, nothing is going right for these 18 patients, they are probably not coming in. 19 So, we can take a look at the data at the system level. We can drill into a division, that happens 20 to be the blue dots. Now, the division director is only 21 looking at 3,800 diabetics. We can look at a clinic 22 within that division. Now, this clinic only has 373 23 diabetics. So, the clinic manager focuses on those. 24 In

25 that clinic, we have physicians. This physician has 122.

1 And we can look specifically at any patient, any dot that 2 a patient represents here. Here we have a patient, a 3 71-year-old, last seen almost a year ago, 11 out of 11 4 measurements are not at goal.

5 How come? Now, you take that data -- so, we 6 have had it at the system, the division, the clinic, and 7 now we move it into my practice. This is the data for 8 Dr. Penniman. We scrambled the names, but these are the 9 patients that he has that are not in control, he needs to 10 get the patients in, he needs to order the labs, he needs 11 to do what is necessary to get that patient into control.

Now, at the individual patient level, the doctor has a view on his dashboard. It's called preventive services. So, we have immunizations, we have early detection, and we have here's our eight processes because this is a diabetic. We pull out those things that need to be done, very visible at the top, and the physician then can address those.

We also then move this to the patient. They can log into the portal, they can see what is overdue on either preventive services or, if they are diabetic, what diabetes services are overdue. Click on the hemoglobin AlC, they can graph their hemoglobin AlCs, they can reorder their medications, they can make appointments. So, the results, there are lots of graphs

1 showing results, but this one probably says it best. 2 Back in 1974, we had 355 all cause admissions for 3 diabetic patients. At the middle of 2007, we had dropped 4 that to 311 admissions per thousand. Remember, we have 5 17,000 patients. So, 44 admissions per thousand. These patients are feeling better. It is costing the system 6 7 \$18 million less to take care of these patients. It is a 8 real win-win situation. And I am over time, stop.

9

(Applause.)

10 MS. McANDREW: Good afternoon. I, too, was 11 intrigued by the number of HIPAA references that were in the prior panel, and I will try to keep on time. 12 I want 13 to really just emphasize a couple of key points about HIPAA and the electronic health effort and personal 14 health records in particular, and that is that the 15 16 Privacy Rule, the current HIPAA Privacy Rule, is very 17 relevant to the operation of electronic health records 18 and even personal health records that are in existence 19 today, and they do that in a couple of ways, which I will 20 get to.

Equally important is to know that my office, the Office for Civil Rights, is at the table and actively cooperating with the other offices in the Department, primarily the Office of the National Coordinator, as well as the Advisory Committee, the American Health

1 Information Community, AHIC, and other federal, state and 2 private sectors, stakeholders in this effort to make sure 3 that the mapping of privacy to the new risks and 4 opportunities of electronic health records and personal 5 health records in the future is going to happen in the 6 right way and achieve the right balance.

7 What the Privacy Rule does today is -- often we 8 spend a lot of time fighting the battle that, you know, 9 HIPAA is not the obstacle, privacy is not the obstacle to electronic health records, to personal health records. 10 11 It is an important consideration. Assuring privacy is 12 key to getting this done. It is not a barrier, it is a 13 facilitator to getting what we want out of these electronic health systems. Hopefully, I do not have to 14 spend my time convincing this audience that privacy helps 15 16 and HIPAA helps.

17 In terms of what HIPAA does today, it will vary 18 in a couple of ways depending on what a PHR does. This 19 is just an early idea of some of the functionality that one may have with respect to a personal health record. 20 21 It can substitute for the clipboard or the creation of a longitudinal health record, aggregating the medications 22 23 and the doctors and the allergies and the health care encounters. It can provide a mechanism to facilitate 24 25 communication between the patient and the provider. It

can help with administrative functions, operational
 functions like appointments, refill reminders and things
 like that. It can also connect the consumer with tools
 to improve their own understanding of their disease and
 access to information on providers or care alternatives,
 or just general information in terms of their illness.

7 Not all PHRs will have all this functionality. 8 Hopefully, in the future, PHRs will have this 9 functionality and more. So, right now, how HIPAA interacts with these PHRs will depend on which of these 10 11 functionalities are involved. It will also depend, to a large extent, on who is offering the PHR. We know today 12 13 there are some health care providers, covered health care providers from the HIPAA point of view, that are offering 14 a PHR that is linked or tethered. I think is the term of 15 16 art, to their electronic medical record. Health plans 17 clearly are in this field in offering their beneficiaries 18 personal health records.

We know that outside of the health plan there are just employer consortiums that are coming together to offer their employees personal health records, and then clearly, Microsoft, Google and others are marketing personal health records directly to the consumer. In addition, again, depending on what

25 functionality is involved in that personal health record

1 will depend on what kind of information and what kinds of 2 information sources are necessary in order to feed that 3 personal health record.

4 But the way that the Privacy Rule is relevant 5 today, regardless of who is the offerer or what information is involved, is that certainly with regard to 6 7 those personal health records that are being offered by a 8 covered entity today, a plan or a provider. HIPAA 9 certainly will obey the rules of the road with regard to 10 the privacy protections of the information in that 11 personal health record. The offerer is covered, the PHR is simply another way of sharing information with the 12 13 individual or potentially with others. So, it is all subject to the HIPAA protections for that information. 14 That information clearly is protected health information 15 16 under the rule and how that information can be shared 17 with others would be subject to HIPAA disclosure 18 permissions.

Now, HIPAA being the baseline in most cases,
that in no way precludes the provider or the plan from
offering the consumer, in the context of a PHR,
additional or more restrictions on that information. For
instance, the general concept of most personal health
records is that it will be consumer controlled. So,
while the HIPAA Privacy Rule may allow, in the case of a

1 record, that the provider today has to disclose that 2 information say for public health purposes, it would be 3 perfectly permissible, under HIPAA, for the covered 4 entity to provide a personal health record and then 5 promise the individual that the information that is in б that personal health record can only be used and 7 disclosed as that consumer wants it to be. That 8 information would not be subject to the permissions that 9 the provider has with respect to the medical record that 10 they maintain separately.

11 So, that is the way that HIPAA would apply with regard to the records today. When an employer or another 12 13 vendor is involved in the offering of the personal health record, they typically will not be covered by the HIPAA 14 rules in the way that a provider or a plan provided 15 16 record would be, but, nonetheless, HIPAA is relevant to 17 even those personal health records to the extent that the 18 arrangement, with regards to that personal health record, 19 relies on a HIPAA-covered entity, a HIPAA provider, as being a direct source of information input into that 20 21 personal health record, as opposed to relying solely on the individual. So, the usual HIPAA disclosure 22 provisions would apply to the release by the provider of 23 that consumer's information as it gets transmitted into 24 25 the personal health record.

1 So, HIPAA is relevant today. HIPAA is going to 2 be and remain relevant in the future despite probably the 3 chagrin of several. But, no, HIPAA will still be around, 4 even when the world is fully connected in electronic 5 health records, I am sure. б What HIPAA will be dealing with or the privacy 7 concepts that we will be dealing with in the future 8 clearly go to certain gaps in the current HIPAA coverage. 9 Clearly, many of the actors involved in EHR systems, network systems, as well as personal health records, are 10 11 not covered by HIPAA and have no direct liability to consumers under federal law or at least HIPAA. 12 13 So, there are various discussions going on in terms of how to require liability or how to place 14 liability or even if liability should be placed on these 15 16 providers. Most recommendations are saying that there 17 should be some sort of level playing field here with 18 regard to personal health records and that all should be, in one way, shape or form, subject at least to rules of 19 20 the road equivalent and as stringent as HIPAA, and in many cases, perhaps more stringent. 21 22 With regards to many of these entities under HIPAA are business associates today, there are many 23 concerns about how the business associates rules are an 24 awkward fit for all of these and they certainly do not 25

create a level playing field between these entities
 participating with this information as a business
 associate versus how a covered entity directly providing
 these services would be governed.

5 I will not get into preemption. I would just 6 say, briefly, that there are many additional 7 opportunities here, which we are also actively looking at 8 in terms of how these opportunities meet with current 9 HIPAA requirements, including the benefits of a personal 10 health record in being able to provide an individual with 11 access to their health information 24/7, instead of just through a written request to the covered entity and then 12 13 you wait 30 days and maybe you get the information and maybe you don't. 14

15 But instant access whenever they want it, 16 whenever they need it, the ability to migrate this 17 information as seamlessly as possible to other providers, 18 the ability to create, for their own use, an aggregated 19 health record, and the ability to be a more full participant in their own care through the access to this 20 21 information. Now, clearly, all of this requires 22 interoperability, it requires portability, it requires security, and it definitely requires privacy. 23 So, with that, I will thank you for your 24

25 attention and look forward to your questions.

(Applause.)

2	MS. DIXON: Good afternoon. I would like to
3	thank the FTC for tackling this topic. It is not an easy
4	one. And I would like to thank them for inviting me.
5	So, I am just going to dive right in. For
6	those of you who are not familiar with the World Privacy
7	Forum, we are a nonprofit public interest research group.
8	We like to focus on in-depth more longitudinal work in
9	the area of privacy. We work in the area of health care,
10	also various technologies, especially internet-based, and
11	a couple of other issues.
12	So, when I was thinking about this workshop,
13	what I kept thinking of and kept going back to is, where
14	is the Archimedean point? In other words, is there a way
15	that we can look at this issue and then, all of a sudden,
16	magically understand the whole thing? Yeah, right.
17	Well, there is a couple of things. I was here
18	this morning and I am very happy that I was. So, I have
19	a couple of broad things I just want to say. So, the
20	first thing is I think that we can definitely say that
21	one Archimedean point is delivery reform. I was
22	fascinated with these like MinuteClinic, these are new
23	to me and I had not really noticed them. So, I think
24	that is very interesting point of reform. I think that,
25	very broadly, it is very fair to say, though, that most

of the current health care reform focuses on modernization efforts that are, in fact, focused on health care information technology. That is a neutral statement. I am not saying it is evil, I am not saying it is angelic. I am just saying that is what it is.

б Basically, what this has involved is basically 7 doing this reform through highly technical standards. 8 You have heard people talk about interoperability quite a 9 That is an important outgrowth of this. Basically, bit. 10 of course, the Holy Grail of this is to come out at the 11 end of the process with a national health information network that is interoperable, with a health care 12 13 exchange that is interoperable and with this thing called a comprehensive, longitudinal EHR or EMR, depending on 14 your terminology. I am going to get to that because I 15 16 think we have heard EHR, EMR, PHR a lot today. So, I will define that a little bit. 17

18 But I am actually going to take a little bit of 19 a different tack here. I am using a different Archimedean point. I know that we are talking about 20 21 reform here, but what I want to do is talk about cost. 22 So, I am using a broader conceptual model, and my model is cost and I want to talk about the cost of privacy. 23 So, while understanding that there are really two very 24 25 broad ways of looking at this topic today, delivery

reform and health care information technology reform, I
 just want to pull the curtain up just a little bit and
 add privacy cost into that mix, because a lot of times it
 is lost in the conceptual model.

5 So, to do this I am going to basically give 6 three snapshots of one picture. Snapshot number one, 7 medical identity theft. So, Sue was actually there when 8 this happened. In 2005, I was asked to testify before 9 the National Committee on Vital and Health Statistics on 10 my geeky opinion on what constituted the big risks to 11 any potential national health information network, and they gave me too much time. If Maya Bernstein is here, 12 13 she gave me too much time to think about this. So, I had a couple of months. This is a problem because I started 14 thinking about it and going, hmm, I wonder what this is. 15 16 I thought, I wonder if medical identity theft exists in 17 the system, similar to financial identity theft.

18 I Googled it, nothing, zero entries. Then I 19 started looking at cases and it was like, oh, okay, it does exist. So, basically, after doing some research, it 20 became quite clear that this was a significant potential 21 22 risk to any national health information network. So, I presented that to the NCVHS and said the following, 23 really there should be no national health information 24 25 network without mitigation for medical identity theft.

Well, that did not happen.

2 But anyhow, let me talk a little about what it 3 Medical identity theft is essentially when someone is. uses health care information or basically any identity 4 5 information for the purpose of acquiring medical goods or services. This is not a credit card shopping spree. 6 7 But, basically, the big core harm here -- and I will skip 8 to this slide. The core harm here really is is that 9 these people who have had this happen to them, their lives are utterly wrecked. We work with them all the 10 11 time. And the core harm is actually changes to the 12 medical file.

13 So, when a fraudster comes in and starts working to acquire medical goods and services, they do 14 15 not just get the medical goods and services and leave, 16 they change peoples' medical files in the process and 17 that has impacts for the victim themselves, they end up with conditions that they do not have. We just had a 18 19 woman who almost had her children taken away from her because she was supposedly addicted to methamphetamine. 20 21 Well, she wasn't. She had to do a DNA test to prove it was not her. So, this is the kind of things that happen. 22 If your medical records become really polluted with this 23 stuff, it can be just a huge problem for these people. 24 25 So, basically, in terms of where is the risk
in an electronic system, going back to the cost of 1 2 privacy, basically the health care sector is not at all like the financial sector. The financial sector invests 3 4 about \$15,000 per person in IT. The health care sector 5 invests about \$3,000 per person in IT. It has got a 6 trust architecture. Basically, you go into a doctor's 7 office and you are who you say you are. You are a 8 patient to be treated, you are not an entity to be 9 background checked.

10 In terms of people working within the health 11 care provider, you have doctors and nurses who are, themselves, part of the trust architecture. They need to 12 13 have access to those records and legitimate access. So, what on earth do you do with fraud in a trust 14 architecture? Well, we have not done anything yet, that 15 16 is the problem. There is a real profound risk here in 17 electronic structures and medical identity theft and we have seen that. The National Health Information Network 18 19 pilots, I have talked to just about all of those folks involved with the pilots and not one of them really even 20 knows what medical identity theft is. None of them have 21 22 mitigated for it.

Some EHR systems are better than others, for
example, putting red flags on this. But others do not.
Insider access is the most significant threat

here, something called clinic takeover where someone just 1 2 buys a clinic and just collects patient information, does 3 fake billing and then makes two million bucks and moves 4 on their way. The most recent case of medical identity 5 theft as an insider job was just announced a couple weeks 6 ago. New York Presbyterian Hospital, an insider gained 7 access to nearly 50,000 patient records and sold them. 8 He has been indicted.

9 So, this is a privacy cost. Can it be fixed? 10 Yes. Has it been? No. Do we need to? Yes.

11 Personal health records, next item. So, 12 definitions, I definitely want to talk about this. So, 13 EMR basically stands for electronic medical record. This is conceived of as a comprehensive longitudinal record 14 that incorporates many, many different things. It is 15 16 interoperable and it goes to many different providers and 17 places. It is interchangeable. It goes through public 18 health systems. Public health data is added to it and extracted to it. It comes back as smarter record. 19 This is the Holy Grail record, the EMR. 20

The EHR is typically an electronic health record, which is a term of art which has different meanings, but most people take it to mean the record that a single hospital has for themselves or a single clinic. You have an EHR. Sometimes you can exchange those, but

usually -- like Kaiser has an EHR. It is a very large
 set of EHRs with about two million people, but it still
 is an EHR.

4 Then there is PHR, personal health record. So. there is a lot of interesting controversy about personal 5 health records. Basically, you can have a personal 6 7 health record that is done through a covered entity under 8 HIPAA, like Kaiser, or even have a commercial PHR, which 9 is done under a non-covered entity which is like Microsoft. And there are many, many types of PHRs. I am 10 11 going to leave it to you to define PHR as a platform. It is just a term. People will say we have a platform, not 12 13 a PHR. This is just a semantic term, but it is all about 14 the same thing.

15 Basically, here is my complaint about these 16 systems. Here is the privacy cost. When consumers 17 approach a PHR, they really do have in their minds that 18 this is just like what has been before. So, on the left 19 you see what has been before. The Hippocratic Oath, dating from the 4th Century, do no harm. Codes of 20 Medical Ethics. 1803, Thomas Percival. Basic tenets of 21 22 bio-ethics. The AMA, dating from 1847. Privilege laws in many states, dating from, for example, 1828. You have 23 record keeper torts, you have malpractice liability for 24 25 confidentiality violations and, of course, you have

various legal confidentiality standards for researchers,
 but also for HIV, AIDS, genetics, and also HIPAA. HIPAA
 is just one piece of all of this.

4 But if you go over to a commercial PHR, a 5 non-covered entity or a non-medical sector personal health record, you have -- basically, I just took one 6 7 privacy policy and kind of mapped it to what we are used 8 to in the health care sector and you have a disclaim of 9 liability. You've got an exclusion of remedy for patients in the terms of service and you have a privacy 10 11 policy that requires indemnification from the patient, if 12 they use that. So, this is a sea change for patients and 13 the big complaint here is I do not think that they know that this is happening. So, it is kind of the wild west. 14 It is not that there is no sheriff, it is that they do 15 16 not even know that it is the wild west.

So, my last example, and this will be very 17 18 quick, just a minute or two. The third view of a privacy 19 cost is direct to consumer marketing. This is a very broad topic. I am just taking one slice of it which is 20 21 direct to consumer genetic testing and consumer-initiated 22 genetic testing. There are many possible examples. 23 Weight loss is one of them. But here you have got a cost that is really high. The core harms here that you are 24 25 looking at is significant data leakage and the potential

for subsequent secondary use and, of course, the
 potential for lifelong impact because genetic data can
 apply to you for your whole life and also the life of
 your blood relatives potentially.

5 But here is the deal. When I say direct to consumer genetic tests, the Federal Trade Commission, the 6 7 Department of Health and Human Services, and the CDC have already issued a consumer alert about direct to consumer 8 9 genetic tests. This was a couple years ago. It was a 10 very rare joint alert and it was prompted by the 11 Secretary's Advisory Committee for Genetics Health in Society. There was so much concern about DTC genetic 12 13 tests that they were like, hey, we have to do something.

14 Now, this consumer alert focused on a really important aspect of this and that is that certain tests 15 16 are just simply fraudulent. So, this is one of the 17 costs. Direct to consumer genetic testing opens a whole 18 brand new avenue for fraud, frankly, for fraudulent 19 genetic tests. They found one, it is called Ferrari Hair Testing. You send in a hair and it tests your hair to 20 see if you can take this magic potion and have your hair 21 I mean, this is ridiculous, but this is the kind 22 grow. of genetic test that people are selling. 23

24 So, the problem is that will bad actors selling 25 snake oil genetic tests tarnish a whole really exciting

1 field? That is a cost. But the privacy cost is really 2 important to also think about, and that is this. When 3 you look at the privacy policies of DTC genetic tests, a 4 lot of times they will retain for themselves the right to 5 use the information for marketing purposes. As stunning 6 as that is, it actually gets worse. They also retain for 7 themselves the right to patent anything from your genes 8 that might possibly come up, and typically, they also 9 retain, even the larger companies, retain for themselves the right to do GWAS testing, genome wide association 10 11 studies tests, and most consumers do not know what these things mean. So, this is a privacy cost. 12 13 So, these are three costs, and what I would say 14 is this. Oh, here are some resources. You can look up 15 some of our reports. 16 I think that the cost of not reforming the 17 health care sector is extremely high. But I think the 18 cost of reforming the health care sector also is high. 19 The key for all of us is going to be to say, okay, let's balance these costs and come up with a good solution. 20 21 Thank you. 22 (Applause.) 23 PROFESSOR MILLER: Hi, it is really great to be I will tell you up front that everything I am 24 here.

25 presenting today is not stuff that I have done on my own,

but this is joint research with a colleague of mine,
 Kathryn Tucker, who is a professor at the MIT Sloan
 School.

4 What I want to talk about today is kind of two 5 parts of a bigger research agenda that Dr. Tucker and I б have to try to think about electronic medical records and 7 thinking about the causes and consequences of the 8 diffusion of electronic medical records. Both of the 9 papers that I am going to talk about today, very briefly in ten minutes, are going to be quantitative, empirical 10 11 studies that use national data from the U.S. over a 12 period of close to a decade, if not more than a decade, 13 looking at this diffusion and trying to understand some of these trade-offs between privacy protection and 14 technology diffusion. 15

16 So, in some sense, I think of it as maybe 17 causes and consequences in that we are going to look at 18 what effect -- the first paper I will talk about looks at 19 what factors influence a hospital's decision to switch over to computer records and to adopt this electronic 20 21 medical records technology, and the second set of results 22 that I will try to talk about quite briefly will look at 23 the consequences of that diffusion, and in particular, we quantify some of the health benefits in terms of quality 24 25 improvements in maternity and infant care.

1 So, our first question that we were thinking 2 about was a research question thinking about electronic 3 medical records. Now, as everyone here knows, electronic records are a technology, a system that combines hardware 4 5 and software that allows health care providers to really 6 accomplish two goals. In our mind, we split it into two 7 functions. One has to do with the recording and storing 8 and managing of information internally, the sort of 9 stand-alone provider benefit and then there is this other 10 potential benefit that may not be fully realized but this 11 benefit that comes from the exchange of information from sharing across different providers. These are issues 12 13 that have already come up today.

So, these second benefits we call network 14 benefits. And as economists, you think about these 15 16 network benefits fitting into what we think of as classical externalities, so positive externalities, and 17 18 this is a situation in which one person makes an 19 investment and bears a cost, but there could be positive spillovers to other people who are not also sharing in 20 21 the cost.

22 So, what happens in these cases, classically, 23 is that we have under-investment. So, if we think about 24 EMR today in America among hospitals, it is under 50 25 percent, even though the technology has been around since

the seventies. We think that it could be a case of network externalities that are not being realized. So, that is sort of one of the things that we have in our mind is a framework of what might be explaining this slow diffusion.

б Now, we combine this idea of a network 7 externality with the idea of privacy protection and, in 8 particular, the privacy protection that we are looking at 9 is state privacy laws. So, we have heard about HIPAA, we heard about the federal law, which provides basically a 10 11 floor of privacy protection. However, states have the rights to have laws and they have passed laws that 12 13 supplement federal protection and provide stronger protection. So, in our data set we have 50 percent of 14 15 states, during the period, there is some switching, some 16 states add laws, some states remove laws, but about half 17 of the states have some kind of protection that applies 18 to hospitals, limiting their ability to disclose private 19 information that could restrict the exchange of medical information. 20

So, I talk very quickly, but if people havequestions, they can ask me later.

23 So, our research question was, we are thinking 24 about this privacy protection and we are wondering, is 25 this going to be something that is going to promote

diffusion of technology, is this going to help EMR or is 1 2 it going to be something that slows the diffusion? 3 Actually, both of the stories have already kind of come 4 up today through some of the other discussions. On the 5 one hand, you might think that it would promote б diffusion. If consumers are very concerned about 7 privacy, they might need that extra reassurance. So, it 8 could be that living in a state with strong protection of 9 your privacy is going to make consumers less worried and, 10 therefore, make providers feel more comfortable and give 11 them incentives to adopt.

12 Alternatively, it can go to the other way. Ιf 13 there are these positive spillovers, these positive 14 network benefits where one hospital adopts and can share information about their patients with other hospitals, 15 16 which could be particularly important for emergency 17 situations or patients with chronic conditions, we might 18 think these benefits would be impeded or reduced by some 19 strong privacy protection. And that is the question, empirically, that we set out. We take it to the data and 20 21 we ask the question.

22 So, our background motivation, sort of we got 23 interested in this for a variety of reasons. One of the 24 big reasons was we think that EMR diffusion is really 25 important. It has been argued that there could be great

1 benefits from increasing diffusion of EMR. We cite this 2 number, the 44,000 to 98,000 deaths per year from this 3 very well-known IOM report that received a lot of 4 attention and there are some estimates done by the Rand 5 Corporation and other groups that have estimated 6 potential cost savings from EMR adoption as high as \$100 7 billion. So, we are talking about large numbers both on 8 the quality side and the cost side, so we think it is 9 important. I will let you read the quotes from Newt 10 Gingrich and Hillary Clinton on your own. 11 So, we think that there is a real importance to

12 this technology and to understanding what affects the 13 diffusion and then we are concerned or we are wondering what is the effect of privacy laws going to be in 14 promoting or inhibiting this diffusion. So, there is 15 16 this national target of having national EMR by 2014, and 17 that is not just national EMR, but that is actually an 18 integrated system which is even farther from where we 19 are.

There has been a lot of debates and discussion talking about privacy concerns, and what we found kind of missing from a lot of the public discussion, especially if you think about the public sort of media discussion, is there is not a lot of conversation about these potential trade-offs between privacy and diffusion. 1 There has been some outside evidence, there is a lot of 2 anecdotal evidence where people have expressed concern 3 about possibly strong privacy protection inhibiting 4 technology diffusion, and a particular case that comes to 5 mind is the collapse of the Santa Barbara County Health Information Exchange. One of the reasons that was 6 7 claimed for that collapse that happened in 2007 was the 8 difficulty, the costs associated with complying with 9 costly state-mandated privacy filters.

10 So, there is sort of anecdotal evidence that 11 privacy costs may be inhibiting adoption, but there is really a lack of quantitative evidence and research. So, 12 13 that is sort of where we come in. In particular, we are 14 showing potential costs from strict privacy protection 15 that might extend beyond electronic medical records. So, 16 for today's audience it is really all about electronic 17 medical records, but you could think that a lot of these issues would apply to other technologies, other 18 19 technologies that are interactive, that are not necessarily just in a medical setting. 20

So, the data that we use is from the HIMSS and we have the 2005 data. This data set, for people who are not familiar with it, it is a survey done of hospitals and it contains a really rich amount of information about the hospitals and about their technology adoption

1 decisions. So, some samples, these are not real data 2 points, obviously. It is confidential data. But a 3 sample set of information that we use would talk about 4 where the hospital is located, what kind of software they 5 have and what vendor they purchased it from and when they б bought it. So, we have this information on about 4,000 7 hospitals in the country. We match this data with the 8 data set by the American Hospital Association. When it 9 comes down to sort of observations that we actually know 10 whether or not they adopted EMR and when they adopted, we 11 have about 3,000 hospitals.

12 The one thing I want to say is that EMR 13 adoption is about 50 percent in our sample among hospitals. It is lower than that nationwide. Our sample 14 does not include very small hospitals, rural hospitals 15 16 that are not part of larger hospital networks. So, all 17 the results that I am going to talk about really just 18 apply to hospitals really with more than 100 beds or the 19 hospitals that are part of bigger networks.

20 So, this is a picture from the HIMSS data 21 looking at the patterns of new EMR adoption over time. 22 Now, that big bump at 1992 is really just all adoption 23 between 1970 and 1992. It is not a real jump in '92. 24 What you see is a little bit of maybe what would suggest 25 kind of a traditional diffusion path where we see increasing adoptions, although it does appear there is a decline after about 2002, 2003, which might suggest some leveling off, which could be a concern since our current level is still quite low.

5 So, this is what we are explaining over time. We also put that together with data about these state 6 7 privacy laws that I was talking about and we have data 8 from 2002, '99 and '96. So, we sort of had three point 9 in time observations of which states had protection that 10 required hospitals to limit their disclosure. Now, to be 11 clear, for people who kind of think about privacy laws, especially medical privacy law, there are a lot of 12 13 dimensions in which these laws can vary and we are just focusing on one narrow thing. We just say there is a law 14 or not based on whether or not hospitals are limited in 15 16 their ability to disclose information.

17 This is a map from 2002. You can see there is 18 no obvious red state blue state thing going on. States 19 all over the country have these laws.

20 So, a summary of the results, I do not have 21 time anyway, so I am not going to talk about the 22 statistical details of where these numbers come from, but 23 they are in the paper and I will put a plug in for people 24 who are interested to look and see where this stuff is 25 coming from. But what we do find is there is a

substantial effect, a significant, substantial effect. 1 2 We are finding that hospitals located in states with 3 strong privacy protection are 24 percent less likely to 4 adopt than hospitals in other states. We use a natural 5 experiment framework where we are going to argue that б this is causal effect. This is coming from differences 7 in taste for privacy that are causing states to adopt 8 these privacy laws. We do not think that it is some other omitted factor that is driving this relationship. 9

We also find evidence of network effects where 10 11 hospitals are actually responsive to the decisions of 12 other hospitals in their local area and they are more 13 likely to adopt when other hospitals in the area adopt. We estimate that effect to be at 6 percent. That is 6 14 percent in states that do not have strong protection. 15 Ιf 16 you go to a state that has a strong privacy law, that 17 effect goes away entirely. There is no correlation at 18 all. So, this hospital responsiveness only happens when 19 hospitals are able to freely exchange information or at 20 least have that potential to exchange information.

21 Other evidence that we show in the paper, we 22 actually look at the type of EMR that hospitals are 23 adopting. So, you can buy your system from a lot of 24 different vendors. Some vendors have openly and publicly 25 committed themselves to interoperability and to make

1 their systems comply with existing standards. Other 2 vendors have not done that. They have taken a more 3 proprietary closed loop approach. So, what we find is 4 that privacy laws not only reduce overall adoption, they 5 are also shifting adoption towards more closed loop 6 proprietary systems. They are making hospitals care less 7 about adopting compatible systems and we think that that 8 is because they are reducing that potential for 9 information exchange. So, the first paper shows that 10 there is potentially some real reductions in privacy 11 laws.

12 I really would love to talk to you more about 13 the second paper because it is near and dear to my heart. I will just tell you the bottom line punchline is that we 14 then use these privacy laws as a natural experiment for 15 16 which hospitals are going to be more likely to adopt 17 electronic medical records and try to quantify the benefits on an observable, measurable health outcome. 18 19 And that outcome that we look at is neonatal mortality 20 and infant death rates. The U.S., as many of you know, 21 is actually ranked very poorly in international 22 comparisons. This is a big public health concern, or has 23 been for a while. There is also substantial racial 24 disparity.

25

What we find there -- I will just skip to the

1 conclusion there. Our conclusion is that we actually 2 find that when a hospital adopts health information 3 technology, in particular, electronic medical records or 4 an RIS system for managing their radiological 5 information, those two systems are going to actually б reduce infant mortality in the county where that hospital 7 is located by between 5 and 18 deaths per 100,000 live 8 births.

9 So, comparing that to the average mortality 10 rate, it is about a 1 percent reduction. So, one 11 hospital adopting electronic medical records, we are not 12 going to expect a huge effect. It is not going to make a 13 huge difference. But if we were to quantify it, we would say it is about a 1 percent effect. What is very 14 interesting to us is that those gains are twice as large 15 16 for reducing African American deaths than for white 17 deaths.

And in the paper and in our discussion with 18 19 people, we have thought about what might be driving that. One potential explanation could be something about 20 21 standardizing care and providing a more standard form of 22 care that is going to maybe influence African Americans more than whites. It is also worth noting that African 23 Americans are at a much higher risk of having adverse 24 25 health outcomes, especially infant mortality rates are

1

nearly twice as high.

2 So, this could be an important benefit, not 3 just in terms of improving overall health, but also in 4 terms of reducing a racial disparity that still exists in 5 the country.

б So, finally, when we do a cost effectiveness 7 calculation of kind of figuring out what would be the 8 dollar value per infant life that we saved, how much 9 money do you have to spend in an EMR system to save a 10 baby, we come up with an estimate of about \$450,000. 11 That is assuming that none of that investment in EMR 12 actually lowered administrative costs or had any other 13 benefits at all. If we only said what is the EMR cost benefit for saving an infant life, we get \$450,000, which 14 is really a lot smaller, a lot lower than most values 15 16 that economists, who are the only people who do this kind 17 of thing, would put on the value of a human life. So, 18 those estimates are much larger. So, it suggests that 19 maybe even from a cost effectiveness consideration, this is an important technology to consider. 20

Finally, just to remind you of the first part, we documented that privacy laws are actually inhibiting network benefits in the diffusion of electronic medical records. As a kind of interpretation, we would say that there are a lot of reasons why privacy protection is important and it may be a good thing for a lot of
 reasons.

3 However, it does seem to be having this 4 negative effect in terms of slowing diffusion, and this 5 is a trade-off that we want to consider. This is important to consider not just in thinking about whether 6 7 or not you should have strong privacy protection, which I 8 do not think is the key question. But more when we are 9 thinking about designing the right kids of privacy 10 protection, if you are not even thinking about this 11 trade-off, you are not going to be worrying about 12 diffusion. So, we may need to think about policies that 13 are going to balance these goals of spreading EMR and protecting patient privacy. Again, just a plug in terms 14 15 of how this has broader applications to other types of IT 16 Thank you. 17 (Applause.) MR. SCRIBAN: I think I forgot one of the 18 19 important two laws of public speaking, never follow lunch 20 and do not follow a polished lecturer. 21 So, I am the senior product manager for 22 Microsoft Health Vault. It has been gratifying to see 23 Microsoft's name invoked a couple of times here throughout the sessions of the day. So, it is 24 25 interesting that towards the end of the day we are going

to try and give you your first glimpse of what it is that
 people are talking about when they talk about Microsoft
 entering the consumer health care space.

4 Let me step back a little bit and talk a little 5 bit about some of the insight that went into what Health Vault actually is, why we designed it the way we designed б 7 it, the purpose it serves, the function it serves within 8 the consumer health care world. I like to think of the 9 problem in terms of where are all the fragments of, personally, my health care identity. So, just to make 10 11 this personal, I moved to Puget Sound in August of 2007 12 to join Microsoft and work with the Health Solutions 13 Group. In doing so, I actually left behind a pretty significant chunk of health history not only for myself, 14 but for my family, my wife, my two sons. That is all 15 16 sitting someplace in a suite of providers somewhere in 17 Manhattan, probably in Midtown. I have established a whole bunch of new silos now in Puget Sound on the east 18 19 side in Seattle.

20 So, clearly, when you think about who knows you 21 as a person, as a patient, as a consumer, all of your 22 providers know a little bit about you, and they can range 23 anywhere from very large-scale providers, hospital 24 systems to ambulatory care centers, right down to solo 25 practitioners.

1 Obviously, my plans, and I have been through a 2 lot of them since I have moved here to the United States 3 from Canada, my plans each know a little bit about me for 4 a limited time and so do all of the associated pharmacy 5 benefit managers and PDMs out there. The pharmacies that б fulfill, they know a tiny fragment about me. I am sure 7 my employer knows a certain amount about me, or my 8 employers in the past do now as well. The state might 9 know something about me. And if I am a self-managing 10 patient with a chronic condition, my devices, my 11 spirometers, my peak flow values, if I am managing my 12 weight, my smart scale knows a little bit about me; if I 13 am managing my diabetes, my blood glucometers know a 14 little bit about me. These are all silos of information that build up over time and they wind up remaining 15 16 unconnected.

17 If you want to take this down to almost a 18 microcosmic level, think about what happens within each 19 provider facility or within each one of these silos, there are multiple silos within the silos. As anybody 20 21 here who works in a hospital environment will tell you, 22 not all of these systems even internally talk to one another. It would be nice to have a place under consumer 23 24 control where we can all aggregate that information, all 25 of the stuff that we think is important about us from a

health care standpoint, put it someplace so that we can 1 2 present the information that is most critical to our care 3 to the caregivers at the point that care is being given 4 regardless of whether or not the individual care 5 providers and all of the individual players within the б health care ecosystem have brokered connections with one 7 another in advance of us showing up, before we get that 8 kind of coordinated health care. That is essentially the 9 insight that drove Health Vault.

10 We saw that, by and large, consumers are 11 already acting as aggregators. It just so happens that they are under-powered, nobody is investing in tools to 12 13 help them. It all works on paper. If I am really diligent, maybe I keep all of the statements of benefit 14 from my insurance company or if I am super obsessive 15 16 compulsive, I would keep all of the slips that come with 17 all of the prescriptions for my family, and if I am a 18 real go-getter, I go around to every provider that I have gone to and, theoretically, I am entitled to a copy of my 19 complete patient record from them. 20

But in the end, even if it all works, it is all on paper, so really what do I get from it except the ability to lug a suitcase full of stuff from my house to the next doctor? Well, actually, first, I would have to copy it because I wouldn't want to bring along the

originals. Then, the doctor has to sort through all this
 paper and figure out what is going on.

3 So, Health Vault kind of addresses this from a 4 -- the idea behind Health Vault is to address this with 5 technology, which is something that Microsoft is really 6 good at, solving information problems. Health Vault 7 essentially is a place where consumers can collect and 8 store all of this stuff, and it is provided by Microsoft 9 as an online utility.

10 But it is more than just storage. In order for 11 this information to be useful, to have value, to be really meaningful to you in terms of changing the way 12 13 health care is delivered to you, it also has to have an API, interfaces that allow third parties like hospital 14 clinical systems, HIT systems, pharmacy benefits 15 16 managers, their systems to read and write data into your Health Vault record. So, it is not just a place where 17 consumers can store stuff, it is also a platform on which 18 19 third parties can develop and deliver interesting and valuable health services. 20

21 So, taking all of those silos, all of those 22 islands of information, here we have a hugely -- if this 23 is hugely simplified, you do not want to see what the 24 reality actually looks like. This is a hugely simplified 25 graph or picture of what Health Value -- the purpose it

serves. It is a central place. One thing I do not like about the graph is that the actual consumer is not represented. So, picture a person actually at the computer sitting on top of the vault, which some people say looks like a washing machine, typing away on the computer and managing their Health Vault record.

7 Around them, all of the plans, physicians, 8 hospitals, employers, pharmacies and devices, which sort 9 of sit in the top right-hand corner, all of these sources 10 of data are exchanging information with your personal 11 Health Vault record and that enables -- sort of the 12 interesting piece that does not exist is in the lower 13 right-hand corner, all of these consumer services that could help you manage a condition, lose weight, just keep 14 track of your family's health or keep track of your 15 16 health over time. So, we are trying to enable a whole 17 new ecosystem of interesting and valuable health care 18 stuff to happen based on your personal health 19 information.

20 So, one thing that I want to talk about, and 21 some people have called it a semantic difference. I 22 partly agree. It is kind of a semantic difference. But 23 one thing I want to make clear is that Health Vault is 24 not a PHR, per se. Health Vault is sort of the bottom 25 half of a PHR. It is the place where the data gets

stored, but it is kind of independent of the applications
 that sit on top of it, which is to say you could build a
 PHR that uses Health Vault as where the data is kept.
 You could also build health risk assessments, condition
 management applications, even fitness management and
 coaching applications on top of Health Vault.

7 The point is, in fact, that it is a portable, 8 consumer-controlled layer underneath all of these 9 applications that affords you the portability, the 10 ability to take this data and move it say from New York 11 to Puget Sound and use Health Vault as a conveyance between various providers and sources of data and people 12 13 providing applications. So, it is a way to store and 14 share data.

15 If you go to healthvault.com, you can see some 16 of the partners that are already building interesting stuff on top of Health Vault. Here I have kind of two 17 18 sample applications that sort of give life a little bit 19 to what I am talking about. The American Heart Association has written this interesting little 20 21 application called the Blood Pressure Management Center 22 that leverages Health Vault. So, essentially what it does is it allows you to consent to the AHA Blood 23 Pressure Management Center application to look inside 24 25 your Health Vault record, your specific Health Vault

record or Health Vault record that you control, and it will read blood pressure measurements, aerobic session activity, height, weight, some basic information. It has to disclose to you ahead of time exactly what information it is going to take a look at and you approve that or authorize that access which you can revoke at any time.

7 The Blood Pressure Management Center does some 8 very nice, interesting visualizations that show, over 9 time, these are where your blood pressure measurements 10 have been, are these within the recommended ranges, yes 11 or no, particularly for your age or height or weight?

12 On the lower right-hand side is an example of a 13 provider integration with Health Vault. We are currently working with Medstar Hospital system here in the mid-14 Atlantic region. If you are a cardiac patient being 15 16 discharged from either Union Memorial in Baltimore or 17 Washington Hospital Center, you can now get your 18 discharge summary into your Health Vault record as a CCD, 19 which is kind of cool. And it is just a very basic first step in putting information into the hands of consumers 20 so that they can go out to the hands-on local care 21 22 providers that they work with more frequently than they 23 do with Medstar and share and exchange that information with them, coordinating care between physicians in the 24 25 field, primary care physicians in the field and the

1

specialists at the hospital.

So, I want to take a little digression here to
talk a little bit about what we consider to be the
primary design principles of Health Vault, kind of keys
to what we feel are going to be its success.
First is that the platform has to be security

7 and privacy focused, which should come as no surprise. 8 Inclusive of industry standards. So, we have heard 9 interop come up an awful lot today and this is our nod 10 towards that. And free for users and developers. So, 11 speaking in terms of the economic model of exactly how 12 you get diffusion of this, we want to lower the barriers 13 of entry or certainly the financial barriers of entry and 14 adoption here.

15 So, let me talk first about security and 16 privacy focus. This is near and dear to my heart because 17 I was primarily before launch tasked with coming up 18 specifically with our security and privacy policies 19 around Health Vault. The way we did this was kind of 20 interesting because it was kind of the first time that we 21 had done this within Microsoft. The way we decided that 22 we would go about crafting the privacy policy for Health Vault was first to take a baseline of what our corporate 23 privacy practice is, and we have a corporate privacy 24 25 group within trustworthy computing. We have acronyms,

too. CPG with NTWC. That cares very deeply about this
 stuff. We set that as our minimum bar baseline.

Then, of course, we took a look at the regulatory environments, state and federal, and not just in the United States, but globally because, of course, we have ambitions to roll Health Vault out globally, although no times and plans declared yet. That brings a whole swath of other interesting regulatory hurdles, if you will, into the mix.

10 Then we reached out proactively to a lot of the 11 privacy advocates, either specific health care privacy advocates or people who looked at privacy online and 12 13 digital privacy more in general and health care as a sideline. What we found is actually only now is there an 14 increasing knowledge on both sides of the camp that, in 15 16 fact, there is common ground between them and common 17 territory that they should be looking at. So, that is a 18 sure sign of a new field of endeavor when even the 19 advocates said there was not really somebody right in the middle who cared about online health privacy for a long 20 21 time.

We reached out to them and sanity checked all of our assumptions against what they saw as best practice and what defended the patient best. We arrived at basically four simple privacy promises that we make on

1

the very front page of healthvault.com to our users.

2 First is that the Health Vault record that our 3 customers create is controlled by them. It is theirs. 4 They decide what information goes into their Health Vault 5 record. They decide who can see and use that information on a case-by-case basis. We, as the stewards of their б 7 health information, just assume that nobody wants that 8 information used for commercial purposes, that we would 9 have to ask ahead of time and they would have to explicitly consent in order for any commercial use to 10 11 happen there.

12 And, of course, the security policies that 13 underlie go even deeper still, and I would be glad to 14 talk offline about kind of the operational security that 15 we have put into supporting these. But our effort has 16 been basically to err on the side of consumer empowerment 17 and err on the side of transparency.

18 So, for example, if you have a Health Vault 19 record, you could pop into your Health Vault account at 20 account.healthvault.com, and take a look at a complete 21 audit trail of everything that has happened with your 22 Health Vault record. So, you can take a look at the life cycle of any individual piece of data, be it a blood 23 pressure reading or a bit of medication history dropped 24 25 in by your pharmacy benefit manager. You can see exactly

when that data was created, the value it was when it was created, has it been altered over time, if so, what was the alteration. So, we keep a complete audit trail and make that available to the consumer.

5 Obviously, we expose every trust decision that 6 a consumer has to make about authorizing an application 7 to have access to their Health Vault record and we are very clear to our third-party developers that they must 8 9 ask for the data that they feel is absolutely necessary 10 for their applications to run because we want to give our 11 users the ability to grant the minimal amount of privilege possible of access to their individual health 12 13 record.

I am sure we will dig deeper into privacy and 14 security over the rest of the panel, but in a nod to 15 16 interoperability, from the get-go, we have committed 17 Health Vault to speak health care the way the rest of the 18 health care industry speaks it, which means that we have 19 publicly committed to supporting any meaningful industry 20 standard in health care. That means whether or not it comes from a standards body or it just happens to be a 21 22 form of transacting in health care data that happens to be widely adopted but is, nevertheless, sort of private 23 24 and proprietary.

25

So, we have done an awful lot of hard

1 integration work integrating with clinical systems, with 2 HIS systems that hospitals and doctors use. We have also 3 recently announced an initiative that commits Microsoft 4 in the other direction to be very explicit and clear 5 about how Microsoft speaks health care to the rest of the What we are doing is we are basically releasing 6 world. 7 the full Health Vault set of interfaces, the Health Vault 8 protocol, if you will, under what is called the open 9 specification process. We have used this with other 10 standard protocols in the past.

11 Essentially what we have done is we are in the process of clearing all of the intellectual property that 12 13 underpins the Health Vault XML interfaces and basically making an irrevokable promise that we will not pursue 14 intellectual property patent claims for anybody who 15 16 implements the specification as we specified. We will 17 make that specification public by the fall of 2008. 18 Essentially it means anybody can recreate the Health 19 Vault service if they so desire, which is interesting because it gives a lot of longevity to Health Vault 20 21 applications.

Finally, of course, we are supporting community-based projects -- this is interesting only for you open source folks out there -- community-based projects around implementing Health Vault in developer

1

environments other than Microsoft developer environments.

2 One last point I wanted to make is that Health 3 Vault -- what we want to do is we want to see wide 4 adoption. We consider this as sort of a competition 5 against paper. What we want to do is drive a little bit б of behavior change on the part of the consumer to see 7 this as a tool that works for them. To that end, there 8 is no cost associated with obtaining a Health Vault 9 account and a Health Vault record, there never will be. 10 We do not license the software development kit. So, our 11 third-party developers do not have to pay money in order to develop Health Vault applications. That is free. 12 The 13 only bar they have to meet is the privacy one that we set on behalf of our customers. 14

So, that is a quick introduction to Health Vault, about as fast as I have made one yet. So, I look forward to your questions.

18 (Applause.)

MS. RICH: Thanks very much to all of you. I wanted to have time for some questions and also some audience questions. Why don't I start with the big question, which is -- I think we have heard all day and also in this panel about all the benefits that can be derived from electronic health records and that have already been, and we have also, though, heard about

privacy concerns, surveys show that consumers are 1 2 concerned about whether their data will be protected. We 3 have seen a good many breaches involving medical data, 4 and consumer fears as well as medical identity theft 5 could actually affect data quality which could affect 6 whether electronic medical records are actually providing 7 the benefits we had hoped. But, meanwhile, Amalia talked 8 about the inhibitions potentially from privacy laws.

9 So, what is the right balance? I think it 10 would be a mistake to say no electronic health records 11 because privacy it is too important and also to say 12 privacy is inhibiting the uptake of medical health 13 records, so forget about privacy, and Amalia recognized 14 there is a value to privacy. So, what is the right 15 balance and how do we get there? Sue?

16 MS. McANDREW: I think that is, of course, the 17 conversation that is now going on and will continue to go on amongst the variety of stakeholders in terms of 18 19 advancing the goal toward nationwide access to electronic health information by 2014, which is the current 20 21 administration's goal. I will say that it was not an 22 easy balance to strike back in 1999 and in 2000, when 23 essentially those same issues were being debated in the environment of HIPAA. 24

25

At the time we heard that privacy is going to

shut down health care as we know it today, privacy is 1 2 going to shut down research as we know it today, privacy 3 is going to shut down public health as we know it today. 4 In fact, we made some hard decisions, but I think we came 5 up with a workable balance and there was nothing shut б down. I think probably those same hard decisions are 7 facing those that are trying to move forward this 8 electronic health record initiative, and given input by all the stakeholders, that they will come to the table 9 10 and those decisions will get made.

11

MS. RICH: Pam?

MS. DIXON: Thank you. There are a couple of things. I think that we can all affirm the benefits of modernization of the health care sector. That is absolutely undeniable. But I think that we need to also affirm the benefits of privacy protection, especially in the area of consumer trust.

18 Something I think that is very intriguing is 19 that -- and I alluded to it in the beginning of my talk -- which is right now the modernization effort is really 20 21 focused on health care information technology and the 22 standards setting process. I think that there is an opportunity to find a balance between the cost of reform 23 and the cost of privacy in finding broader, conceptual 24 25 models. We do not have the time to go into this, but I

think, for example, HIPAA is a compliance model and it is fine. But we have this problem of medical identity theft, about a quarter of a million people every year are falling victim according to the FTC's number. That is a lot of people, that is a lot of bad data. That is a lot of people who get improper medical treatment.

7 So, how do we fix that? You do not fix it by 8 going back to paper. I think one of the things that we have to do is kind of -- we had this pendulum in the 9 health care sector. It went way over to one side, going 10 11 technology, technology, technology as a cheerleading 12 mantra, and I think we are just now starting to come back 13 and say, oh, you know what, there might be some things to mitigate. I think just the fact of coming back more to 14 the center and starting to look at some of these other 15 16 costs, I think that, in and of itself, is going to be 17 very, very helpful.

MS. RICH: Amalia, I assume you want to answerthis one.

20 PROFESSOR MILLER: Well, of course my answer 21 has to start by saying I do not have an answer. Maybe I 22 will hide behind being an academic and say, it is not my 23 job to make policy decisions. I think that there are 24 important trade-offs and it is not obvious what the 25 optimal level is. When we find these cost of privacy

laws, I just want to emphasize, it is the effective state 1 2 protections that go above HIPAA. And if you look at the 3 raw data, which we were just talking about, there does 4 seem to have been an increase actually in EMR adoption 5 shortly after the privacy rule from HIPAA went into 6 effect. Some people theorize that maybe that was a 7 result that maybe HIPAA promoted some adoption of EMR by making HIPAA compliance easier to demonstrate with an 8 9 electronic record than with a paper record. So, there 10 might have been a one-time kind of boost.

11 These stricter state privacy statutes, the 12 problem with them may be the fact that they are stricter, 13 the problem may be that they are inconsistent across the 14 country and that there is a patchwork. It could be that 15 there is room for a national standard. It could be that 16 we want to consider these stricter ones.

17 In terms of the sort of downside that we are 18 finding from privacy protection, I just want to clarify 19 or make it really clear that it is not privacy protection at all. I do think it is going to be some necessary 20 21 condition. It is a sort of situation where if you rely 22 on consumers to know when their privacy has been breached, that is the kind of difficult situation for 23 24 consumers. There is some role for government oversight 25 to ensure the protection. I think that the question is,
1 of course, how to design smart policies, and I think when 2 we are doing this, it is good to be aware of exactly what 3 those costs are.

4 So, not just to think privacy versus EMR, but to get into the more specific details of how are we going 5 to promote diffusion. It could be that strong privacy 6 7 protection combined with more efforts to promote 8 technology diffusion is a solution. That is the kind of 9 thing that sort of taxpayers have to decide, how much money do they want to put in. These are not things that 10 11 cannot be traded off, either politically or economically.

12 So, I am not going to tell you where to decide. 13 I am sure we all have opinions. My goal is to sort of 14 put some more facts out that people may not have been 15 aware of.

16 MR. SCRIBAN: I want to dive into this. I am 17 going to be radical and say, I do not think there is a 18 problem, and here is where I am coming from. First of 19 all, I am in one of the strict states that have strict laws, I am not developing a system for multiple states, 20 21 and I know what HIPAA is. So, if I put privacy advocates 22 and attorneys on my development team and if I know the specification up front, it does not add that much more 23 cost to the system to do it right. 24

Now, if I am a vendor like GE or Epic or

25

1 Cerner, who is developing for 50 states and territories 2 in foreign countries, that becomes a much bigger problem 3 because they have a much wider target to hit. But if 4 nationally we could standardize on a set of what is right 5 for the patient, then it should not be hard. It is not 6 going to add significantly to the development costs to 7 develop it if you know in advance what it is you are 8 trying to develop to.

9 MS. RICH: That sort of segues to one of the 10 questions that was asked by the audience which is, Tom, 11 how did you make a decision 14 years ago before it was 12 fashionable to move over to the electronic records?

MR. BERG: It was actually 35 years ago. I don't know if anybody knows Warner Slack. He is kind of the icon of the medical record. He trained in Wisconsin. Some of the docs early on at the Marshfield Clinic said, when we first got our computer system, this is going to change everything, this is going to be very important. Our first computers came in the late seventies.

We had diagnoses coded on paper and some of the doctors said this is going to be important for research, so they entered all of this coded diagnosis data all the way back to 1960 even. It is rare to find that kind of dedication in physicians that kind of got it a long, long time ago.

1 MS. RICH: Do the patients express concern 2 about privacy? Is privacy something that comes up a lot? 3 MR. BERG: Yes, there are questions and we have answers for them. We can show them exactly who looked at 4 5 their record, what they looked at and when they looked at it. In the old paper world, it was nice, if I am holding 6 7 my record here, there are 10,000 people back home that 8 are not at this because there is only one copy. 9 The bad thing in the electronic world is that on a need to know basis, 10,000 people may have access to 10 11 a portion of my medical record. I got to know who is looking at it, what they are looking at, when are they 12 13 looking at it, did they have a need to know, did they have a need to be in there. 14 15 Biometrics, you can steal my log-in, but can 16 you steal my thumbprint? I mean, even that is not 17 foolproof. But we need good biometric authentication and 18 verification of users. That needs to be part of it and we are not there yet. But it really does need to be part 19 of it. 20 21 MS. RICH: I would love to explore that, but we 22 are running out of time. I want to get to another big

question that has sort of come up throughout the day which is, there has been a lot of discussion of the fact that HIPAA covers certain entities, but it does not cover

1 a lot of PHRs, including you guys, and what to do about 2 that. There has been some allusion to maybe the HIPAA 3 standards should be applied to them, but then Deven, in 4 the last panel, was saying, well, it is apples and 5 oranges a little bit. Those standards were designed for 6 health care providers.

So, let me get thoughts about what should we do besides using FTC enforcement, which I saw all through the -- when it is a clear violation of the FTC Act. What should we do to address non-HIPAA covered entities who are operating in this space?

12Pam? You haven't spoken recently.13MS. DIXON: Yeah, I do not have a dog in the14HIPAA race, so I will start and everyone else can jump

15

in.

16 I think actually the question goes beyond HIPAA, I really do, and that is why I did that chart. 17 I 18 think one of the significant issues here is to get beyond 19 saying, oh, HIPAA covered or non-HIPAA covered. HIPAA 20 covered or non-HIPAA covered is an extremely important 21 consumer consideration because with HIPAA consumers they 22 have a baseline that they do not really understand but they know something is there. 23

24 But without HIPAA what happens is that that 25 right side of the chart that I showed, it changes all the time. Depending on which privacy policy you are looking at, the chart will change. So, consumers do not have a clear expectation of privacy or they should not. They do not really know what they are going to get. You can have a bad actor, you can have a good actor. It is really dependent.

7 So, the question is what becomes the new 8 baseline? I think that there is a camp that says HIPAA 9 should be the baseline that covers everyone. But I have 10 to tell you there is some controversy there because the 11 second you apply HIPAA to, for example, Microsoft or 12 Google, then you have public health carve-outs, and there 13 are a number of people who vehemently oppose having a public health carve-out in a commercial company. I think 14 15 that there would be some lawsuits based on that. So, 16 that is one issue.

17 But the other issue is exactly on the other 18 side. Is it ethical for us to build data silos that do 19 not have public health data reporting? So, these are both very clear, very good arguments, and I am afraid 20 21 that I do not have an answer yet to this, but I can tell 22 you that I think we absolutely have to crack open a new 23 book and find a new path. I am not so sure that old pathways are going to get us where we want to go. But 24 the one thing I will say is this, I think it would make a 25

1 lot of sense for consumers to have a known quideline that 2 they can depend on and I do think that the medical ethics 3 that are in the health care sector are extremely 4 important, even going back to the Hippocratic Oath. 5 If you have a whole bunch of third parties, and I am going way beyond PHRs here, if you have a whole б 7 bunch of third parties that are beholden to SEC filings 8 and stockholders, this is a fundamental difference 9 between a patient-doctor relationship. I think we are going to have to work that out. I do not know the 10 11 answer, but that is the crux of what we have to work 12 out. 13 MS. RICH: Sue, do you know the answer? MS. McANDREW: I do not know the answer. I do 14 know what is being talked about and it generally falls in 15 16 three buckets. 17 One is HIPAA is the solution. We should make 18 all of these entities, in one way or another, 19 HIPAA-covered entities are somehow subject to HIPAA and 20 there are other variations on the theme. It gets very 21 Baroque. But there are certain potential regulatory 22 fixes that one could look at under HIPAA to extend its reach, but many of these areas would still, I think, 23 probably require some sort of statutory or legislative 24 25 fix.

1 Even if your bottom line is we ought to find 2 homes for all of these people in HIPAA, I would say in 3 finding a HIPAA home for all of these people or some sort 4 of HIPAA liability for all of these players, it is not 5 necessarily the case that the same disclosure or even the 6 rights requirements would necessarily apply in these 7 different contexts. It seems to me quite conceivable 8 that, say with regard to a personal health record or some 9 concept of a record that is consumer-controlled, that we 10 could find a different balance to this public health 11 disclosure or research disclosures and provide a 12 mechanism for making that information consumer-controlled 13 without impinging on public health access to other kinds of electronic records maintained more in the provider 14 world. So, that is one possibility, is some variation on 15 16 HIPAA coverage.

17 The other thing that is talked about is some 18 other kind, and this is clearly a statutory issue, is 19 some sort of overarching legislative fix or some sort of more uniform legislation on the protections of medical 20 21 information no matter where it resides. So, depending on 22 one's proclivities and thinking of how likely it would be to get statutory HIPAA legislation, getting statutory 23 universal medical information protections is on the far 24 25 side of that.

1 The other solution that comes up in many 2 conversations is some sort of marketplace within a 3 network kind of protections which would be to participate in a network sharing, you have to sign up for or you have 4 5 to promise to abide by certain rules of the road. So, your price of entry into a network sharing situation 6 7 would be promises that you would do X, Y, Z, even if 8 there is no HIPAA requirement or other federal law 9 requirement that you do X, Y and Z. So, this would mean 10 a contractual relationship or some sort of partnership or 11 other kinds of agreement among parties to this network sharing, and this can be controlled, to varying degrees, 12 13 by federal standards or other kinds of federal sanctioned 14 participation. 15 Probably more achievable because it would not 16 necessarily require a statute. Push back generally tends to be then how enforceable, what are the enforcement 17 18 mechanisms for those promises for the consumer, and how

19 can the consumer fully participate in and feel 20 comfortable in what those promises are that are going to 21 be part of this network sharing?

22 So, those are the most commonly discussed 23 solutions to this coverage issue and the pros and cons. 24 MS. RICH: And there are bills in Congress, 25 right?

1	MS. McANDREW: There are a variety of bills,
2	some strictly in the HIT construct, there have been a
3	couple more broader privacy bills that have been dropped
4	in the hopper. I have not seen anything that goes as
5	global as a whole new legislative regime for handling
6	privacy or security in the medical world in general.
7	MS. RICH: Okay. Well, we are out of time. We
8	have a million questions, so I guess feel free to come
9	up, many of them are for a particular panelist, and talk
10	to our excellent panelists today. Thank you very much.
11	(Applause.)
12	MS. RICH: I guess it is a break until 4:30.
13	Then we will have our final panel.
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	

PANEL 5: INNOVATIONS IN HEALTH CARE DELIVERY:
 PRACTICE AND PROGNOSIS
 MS. OHLHAUSEN: I would like to thank everyone
 for sticking with us to the end here. I think it has
 really been a very interesting day full of lots of
 information.

7 This final panel, which is called Innovations 8 in Health Care Delivery: Practice and Prognosis, is 9 going to try to step back a little bit, reiterate some of 10 the big themes that we have heard today and touch on a 11 lot of the points that have already been raised, but give 12 some additional perspectives.

13 In the interest of time, I will just refer you 14 to the full biography for all of our very well-qualified 15 panelists. It is in your packet of materials and it is 16 also on our web site. So, I will just give very brief 17 introductions.

We have, all the way on my left, Robert M.
Kolodner, M.D. He is the National Coordinator for Health
Information Technology at the Department of Health and
Human Services.

Immediately to my left is Mark Dente, M.D. He is the Vice President for Health Care Solutions and Integrated IT Solutions with GE Health Care.

25

Turning to my right is Tony Trenkle. He is the

Director of the Office of E-Health Standards and Services
 at the Centers for Medicare and Medicaid Services in the
 Department of Health and Human Services.

And then, on my far right is Professor Joy
Pritts, the founding Director for the Center of Medical
Record Rights and Privacy at the Health Policy Institute
at Georgetown University.

8 What we are going to do is short presentations 9 by the panelists, followed by I hope what will be a 10 lengthier discussion. I wanted to remind the audience 11 that if you want to submit questions, write them on those 12 index cards and send them up here.

13 So, Dr. Kolodner.

DR. KOLODNER: Good afternoon. It is a pleasure to be here. I know a number of my fellow panelists have been here and will be reacting to some of the things. Unfortunately, I have not been able to get here before, so I will react to their reactions a little later.

I am going to quickly go through a number of slides. If you have epilepsy, you may want to look away from the screen, just painting a picture of kind of the big picture of some of the things that are going on in terms of the activities.

25

So, first of all, just emphasizing while we are

1 talking here, at least in terms of the innovation for 2 health IT, that it is not about the technology, it is 3 about the health and well-being of individuals in 4 communities, and the information that we are looking at, 5 and I think you have heard it on a number of panels, б serves multiple purposes. It serves not only health care 7 and empowering individuals to improve their health, but 8 also population health and things that help them as 9 individuals in a community but also help the communities 10 as well. It is when we get to that population health, in 11 particular, that a lot of the issues of privacy and is 12 that information really protecting the privacy that comes 13 up particularly acutely.

The health information needs to serve both of those purposes as it is moving. So, I think it is very easy to have it serve one or the other and that really sub-optimizes and we will be paying for that at a much higher level.

19 Secretary Levitt talks about value-driven 20 health care. So, what my office is responsible for is 21 helping to set the strategy and coordinate the activities 22 in the public and private sector regarding connecting the 23 system, that is the health IT piece, but dropping in 24 health IT it is not a magic bullet, whether it is an 25 electronic health record or otherwise, you really need to

have ways of driving that forward and having that
 properly used, particularly electronic health records
 used by the providers.

4 Just to refresh for those who may not be 5 familiar with health care and wondering why we are so far 6 behind, even Peter Drucker talks about the fact that the 7 large health care institutions may, in fact, be the most 8 complex organizations in history, at least in human 9 history. One of the things is that not only have we not succeeded here in this country, but the vast majority of 10 11 countries around the world are still struggling with 12 this. So, it is not as if somehow we have not done 13 something that everybody else is doing that is easy.

Tom Garthwait and, actually, Secretary Levitt made a 14 similar statement that we are going to move forward and 15 16 it is going to be messy at first and then we continue to 17 move forward. If you think about the way that we make 18 progress, the Internet and other things, we do not get it 19 perfect. In fact, if you wait to get it perfect, you are waiting too long. So, there will be some mistakes as we 20 21 go out. What we have to do, though, is to make sure that 22 some of these, particularly in the area of privacy and 23 security, is not the place where we make mistakes. But some of the technology, some of the communication, some 24 25 of the standards will not be quite right when we first

1

roll it out and do not be surprised about that.

2 The National Coordinator position was set up in 3 2004 with an Executive Order by President Bush. David 4 Railer, my predecessor, was the first National 5 Coordinator. He talked about having an interoperable б health IT infrastructure and, in addition to the 7 Executive Order, President Bush talked about having a 8 goal that the majority of Americans will have electronic 9 health records enabling their health care by 2014, a tenyear goal. Some people said, well, why is it taking so 10 11 long? Those of us who were involved in it said, how are we going to get there that fast? When you have health 12 13 care delivered in about 400,000 individual cottage industry sites, it is not easy. But it is not about the 14 15 technology. It really is to improve the quality and the 16 efficiency of health care and to enable individual 17 consumers to manage their health. That is really what we 18 mean by the National Health IT Agenda.

Now, there are a variety of collaborations that are going on. You have the HHS view of the world. There are all these different agencies that are a part of it. Tony is looking to see if I have changed my slide, and I have. You have other feds who also recognize that they play a role, and you see here a number that are listed. We are all about the individual. So, we have a

group that looks at the architecture, the federal health architecture. There is another subgroup that does health IT policy and Jody Daniel leads that group. In addition to what is going on at the federal level, we also have a few things that are going on at the state level because that is actually where it is being delivered much as us feds may not always want to acknowledge that.

8 Then there are things that we need to do that 9 just did not exist before to move forward these 10 initiatives, things such as harmonizing standards and 11 beginning to get certification of products, having a 12 governance that is part of it, and also, beginning to 13 move on a network.

14 Different people mean different things by health IT. You see here my take on it. The first three 15 16 being the things that might be considered applications 17 and electronic health records getting the most play. But the personal health records we will talk about in a 18 19 second, I think you talked about earlier, may actually be the disruption there. Then having public health, 20 21 population health information systems as well. 22 Then there are the geeky things below it. You 23 need to have standards and you need to have a network

25 standardized information. But I think that personal

24

combining or connecting these isolated islands of

health record area is one that we need to really pay
special attention to. The question is, how do we enable
that and enable consumers or individuals to manage their
health and move forward and also be able to meet the
population needs and the public health needs that we
have? Not a trivial issue, but certainly doable.

7 Within our office we have been doing a variety 8 of activities. When I came to the office there was this 9 whole long list and people said, well, wait a minute, you got to set some priorities, how can you do it all? We 10 11 realized that what we were doing was addressing five areas, five components that we thought all needed to be 12 13 addressed, because if you leave one out, then we are not 14 going to get to where we need to get to.

First is, you need a governance. There is so much to do, what are you doing first, second, third, and who is deciding that? That really needs to be a multi-stakeholder. We started with an advisory group, the Secretary of HHS, Secretary Leavitt. We are now moving it out as a public-private entity in the private sector, but, again, the public sector is part of it.

22 We also need to have policies, especially 23 privacy and security policies, but also ones having to do 24 with licensure and cross state licensure. We need to 25 have interoperability standards, but not sitting on a shelf. We need to have them in products and certify that
 those products, in fact, have those standards and other
 functions.

4 We need to have a network that connects these 5 and not creating a new network, but riding over the б internet. The internet is inherently not secure, as many 7 of us know, from the viruses and the other things that 8 are going on. But this is really using technology to 9 create a secure connection over the internet. Then we 10 need to make sure we have adoption of these interoperable 11 health IT technologies that are part of it. And, again, it is about health, not about illness and moving forward. 12

13 So, when we go forward, it is not going to be a straight line. We are going to go very slowly at first 14 15 and it looks like nothing is happening, just like when 16 you are planting a garden or a field. Yet, there is a 17 lot going on underneath and when you do it right, it 18 comes forth and it grows very quickly. My estimate is 19 that we are going to see that upturn not yet, but somewhere in the 2009-2010 time frame, when you have 20 enough of the standards, enough products, enough adoption 21 22 and the network has actually been shown to work and building trust in that privacy and security. 23

Following that tipping point, then you get the adoption by the providers. Sometime later, you actually

get the transformation, just as riding a bike, you do not 1 2 do your tricks when you first get the bike, it is after 3 you are comfortable with it. So, we expect the same 4 thing to happen. At least from the experience that I had 5 in VA, we went through seeing that gap between when you б first used it and then when people really started to do 7 things and especially when the patients themselves 8 started to use the technologies.

9 So, how good are we doing? Well, in 2005, we 10 had about 9 percent adoption of what we call a minimal 11 functionality of electronic health records. In 2007, we 12 went up 50 percent, but 50 percent still only takes us to 13 14 percent in this country. So, it is not very high and 14 there are comparable statistics for the hospitals.

15 To pull it together then, what is this going to 16 look like? This is where we are going in the future. You have communities that connect through health 17 18 information exchanges or RIOS. So, they connect to the 19 doctors and the hospitals and the pharmacies and laboratories. You may have some communities where there 20 is a dominant integrated delivery network and one main 21 22 provider that dominates. You are also aware that there 23 is some work either in the health bank area or commercial 24 companies offering personally controlled health records. 25 Then you have us feds who also need to connect and we are all over the country and the idea of having to connect
 differently in each community would be impossible to
 sustain and the cost would be enormous.

Also, community health centers. We need to make sure that as we move forward we are not increasing the disparities and we need to pay special attention to make sure that we are addressing these groups. We need to mobilize this health information. If you think about the number of providers you have seen and that you may be seeing now, do they know what is going on? Mine do not.

11 So, what we want to do is take, which is there, 12 put some standards and specifications and agreements 13 across there and really that is mobilizing that 14 information and connecting them securely, and honoring 15 the privacy of individuals as well.

16 This year we expect it to be a banner year. We 17 will be launching this AHIC 2.0 that is out there, the 18 governance, releasing a strategic plan shortly, have a 19 privacy and security framework, working with the states on privacy, releasing more standards that are recognized, 20 21 getting what we call a dial tone over the network. We 22 will be doing the trial implementations and how to go operational very shortly, and getting increased adoption 23 over time. So, this is really what we see as 2008. 24 25 By the way, this is something that looks a lot

1 like the Gardner Hype Curve, if you know what that is. 2 It is the stages that an idea goes through. This one 3 happens to be from a textbook in 1979 that cited 4 something in the early 1950s, but the idea is the same. 5 Whatever idea we have, whether it is are you really going to have an HIN that works, are you really going to have 6 7 privacy that works, are you going to have the HRS? They 8 go through first the resistance, then the 9 over-enthusiasm, then it is going to fail and then, 10 ultimately, it actually does work and you figure out what 11 it is. So, when you hear these things, figure out where 12 in the curve it is. By the way, presidential campaigns 13 and candidacies go through the same thing. So, you can apply this to an awful lot of things. 14 15 If you want more information, go to our web 16 site at hhs.gov/healthit, and I look forward to the 17 conversation at the end of this. Thank you. 18 (Applause.) 19 MS. OHLHAUSEN: Mark? 20 Thank you. You are all hard core. DR. DENTE: I appreciate and thank the Federal Trade Commission for 21 allowing myself to come in and share the view, frankly, 22 23 from a tactical point of what we are doing as GE. We talked today about a lot of abstract 24 25 concepts. We heard some great examples of Marshfield

Clinic and others, Mayo, that are really on the street 1 2 doing things. Then my perspective is going to be, gee, 3 now that we think about all this, and frankly, it is the 4 end of the day, so I want to end on some really 5 outstanding work that when we really get it right and we б bring together information and we think about patient 7 care and the safety of our patients, we can have a 8 wonderful impact. The backbone of that is IT. 9 Just to let you know, there are two competing 10 schools within GE. We spend about \$2.6 billion a year on 11 our own health care costs. So, we are motivated. As Jeff Emwalt will clearly let us know as often as he can, 12 13 we do have to get this right. We have to get it right for our own patients, our own families. 14 15 So, I always like to go around, it is the end 16 of the day, anyone here that is a physician that is left? Clinical staff? Okay. Lawyers? 17 18 (Laughter.) 19 DR. DENTE: Aw. 20 UNIDENTIFIED FEMALE: We have stamina. DR. DENTE: Who is a patient? So, it is the 21 22 old joke, but we are all patients at the end of the day. Even though there are folks like our organization that do 23 have shareholders, they are run by physicians. So, there 24

are a number of clinical people within our organization

that this is our medical specialty, clinical informatics, and we drive and get up and work every day to do the best we can to provide tools that we know will affect the lives of our patients around the world.

5 Unfortunately, when we think about all this, look to the left, look to the right, one of us is going 6 7 to have cancer. Fifty percent of us will die after our 8 first heart attack. As we all start to age, about 20 9 percent of us will develop Alzheimer's disease. So, when 10 I say that I use this as a context of what we need to be 11 doing and what we need to be thinking about when we balance the need for connectivity, interoperability, 12 13 information, with the rights of all of us to have a patient privacy. 14

I want to differentiate between identifiable patient data versus de-identified data, because we did not even touch on that topic at all. I think there is absolute violent agreement on the identified data. Patients should have a lot of control over that and we really need to make sure about that.

21 When it comes to anonymized information, our 22 colleague from Marshfield put up that slide that showed a 23 distribution. Is it reasonable for him to put up that 24 slide and say, gee, I have to go consent every patient 25 whose dot was on that slide because it is all anonymized

information? So, again, just use that as a context. It
 is late in the day, something to think about.

We are also not doing that great. So, these are some of the national standards. The Rand Corporation actually published this one. About 54 percent of the time we are kind of getting it right now. So, it is not like there is not room for improvement. There is a lot of room for improvement.

9 There is a challenge out there. Every eight years, the knowledge of medicine doubles. Every eight 10 11 years, I know half as much as I needed to know to practice medicine. Look, my brain does not work that 12 13 great at 10 minutes of 5:00 in the afternoon on a Thursday, never mind the fact that all I have to do to 14 stay current, there was another article, that is, you 15 16 read 22 articles a day, 365 days a year and you could 17 stay current, doctor.

18 Well, you know what? I have my own stack of 19 articles, personal stacks of articles, once they get 20 below about the top inch and a half, they are never going 21 to get read and my wife is the first one to point that 22 out to me.

So, how do we actually do that? It is throughinformation technology.

25

Rob, you pointed out wonderfully that you got

going. So, GE believes in Lean Six-Sigma. So, Six-Sigma 1 2 is let's take out every defect, our jet engines are 3 running at literally like 14, 12 sigma, right? They are 4 really reliable. Medicine has a lot of room for 5 improvement in that area. But you know what, we cannot б build nirvana. So, Lean says, we should just get going. 7 It is not going to be perfect right now. There is going 8 to be iterations and we are going to have to iterate, but 9 that is okay because we are putting a stake in the sand 10 and we are moving. 11 So, let's talk about some success. 12 InterMountain Health Care is a great partner of ours.

Mayo is a good partner of ours. In fact, Marshfield, your colleagues over at the Ministry of Health are great colleagues of ours and use our technology. We are very fortunate to have a really rich depth of institution. We have a lot of information coming out here.

18 So, out at InterMountain, we did something 19 about acute respiratory distress syndrome, about ventilator management. This could have easily been 20 21 around Woffren (phonetic) Care and the cytochrome P450 22 and how do you use a genomic test. But what this found is they took the survival rate -- and this is bad, okay, 23 24 this is bad because everyone kind of treats a ventilator 25 differently. It is a little bit of voodoo. There was

1 really no real metrics involved out there.

2 By the way, the paper protocol is what you see 3 down here. Just remember what is on page four about 4 three-quarters of the way down at 2:00 in the morning. 5 So, if you do not think you need IT to help you manage these situations, right? What we did is the б 7 InterMountain folks got the survival rate up to 44 8 percent. And by the way, the best possible care using 9 protocols and guidelines and best practices, by definition, is the least cost of care. They actually 10 11 saved about \$120,000 per case. Same thing on cardiology. On that other slide, about 50 percent of the 12 13 time we are getting it right. Let's talk about an ACE inhibitor prescribed on discharge after an MI. We should 14 all be doing this. Well, nationally, it is about 54, 57 15 16 percent of the time. InterMountain was at about 65 17 percent of the time. After putting in a protocol, an IT-18 driven protocol, that got it up to 95 percent of the 19 time.

20 Well, first of all, they drove down the 21 readmission rate to 38.5 percent. That is 551 patients. 22 That is marvelous. That is what we are doing in this 23 room. This is what we all worked towards is to develop 24 these technologies that really have this great effect on 25 care. That is 331 people that are alive every year. Last year, this year, next year. That is what technology
 can do.

Just to show you this graph shows you cost of care and quality of care. So, you can spend a whole lot of money, California, Texas, Florida, and frankly you are not really ranked that well in terms of quality of your care. Or you can actually be like Minnesota and Utah, that have some of the least expensive care going and the best quality of care going.

10 I will challenge and say both systems are IT 11 savvy systems that leverage information technology and 12 clinical decision support. So, evidence-based medicine, 13 clinical decision support. In fact, these are some of the numbers that were published in the Dartmouth Atlas, 14 that just by adopting the Rochester standards and the 15 16 Salt Lake standards, you could see this reduction in cost of care. 17

18 Well, we also talked a lot about getting to the 19 patient. Again, we could have hours of conversation 20 about how to do that through web portals, through 21 personal health records, through frankly NBC, Universal and iVillage and how do we reach out to a patient on 22 23 knowledge about gastric reflux disease and a research study we did with AstraZeneca to increase patient 24 25 compliance. But what it really comes down to is thinking 1 about interoperability standards.

2	So, we talked today about in fact, one of
3	the presenters said, gee, there are some vendors out
4	there that are really closed. Well, I am here at now
5	almost five minutes of to say we are not one of them. We
6	are driving interoperability. It is the wave of the
7	future, it is where we all need to be. We are proud of
8	what we do in adopting standards. It is about
9	connectivity. And you know what? It is damn good
10	business. I am a doc and I am telling you it is damn
11	good business.
12	You think about DiCom, we talked about that,
13	how do you bring images across? Well, it is a standard
14	that is called DiCom that does that standard exchange.
15	GE helped develop that standard. We gave it away.
16	By the way, we took a business that was like a
17	\$60 million a year business to a couple billion dollar a
18	year industry. A rising tide floats all ships.
19	So, as we think about patient privacy, as we
20	think about consumerism, as we think about what we have
21	to do to drive care and quality of care, it is consistent
22	that we can get out there as an industry, as individuals,
23	and work collaboratively.
24	The Marshall Clinic person was spot on in
25	saying it is not expensive if we have the standard up

1 front. You want to give us a standard on privacy, we can 2 develop to that standard. What gets expensive is, gee, 3 50 different states change the standards as well as 14 4 countries and the next thing you know, it takes millions 5 and millions of dollars worth of IT resources to rebuild 6 these systems.

We are going to have a wonderful discussion for
the rest of the afternoon. I am going to pass this on,
and thank you.

10 (Applause.)

11 MR. TRENKLE: I want to spend just a few 12 moments talking about some of the things that CMS is 13 doing, but also, because I have been here all day, just 14 tie it into some of the overall themes that we have heard 15 today. We are a small health care organization.

16

(Laughter.)

17 MR. TRENKLE: Actually, about 30 percent of the 18 costs are Medicare in this country, and if you add in Medicaid, it is closer to 40 percent. We are also a 19 major policymaker. We also have the largest store of 20 health data in the world. So, I think if you look at all 21 22 these different roles that CMS plays, we have a big role 23 in this effort. I think Rob has said this as well, this is all personal as well as policy or a business issue. 24 25 But, also, if we do not get this right in the

next 10 to 15 years, when the silver tsunami of baby boomers comes through, they will wreck the system and we have wrecked a number of systems on our way to old age and we will continue to wreck them. So, we need all the help we can get.

б But I think the key point here is that there 7 are a lot of efforts that are going on. As you heard 8 today, a lot of things need to be balanced against 9 privacy and security needs. As Deven said earlier, it is not something that is an either/or, it is something that 10 11 has to be worked together. One complements the other. 12 If you do not have the privacy and security in place, you 13 will not get the health IT gains that you want to get 14 because it will be held back.

15 What we do at CMS is we support a lot of the 16 work that Rob and his shop are doing at the Office of the 17 National Coordinator. But the way we look at E-health 18 strategies is it is a combination of things. It is not just policy, it is not just technology, it is not just 19 standards, it is not just collaboration, but it is all of 20 21 these things and all of them working together to develop 22 an overall strategy to support large-scale health care 23 IT.

Our priorities, it is funny, I did this before today's discussions, but a lot of these themes came up 1 today, things such as value-based purchasing and 2 transparency, promoting standards in interoperability, 3 insuring privacy and security safeguards, and then the 4 game changers, we heard Paul Uhrig talking about e-5 prescribing, we heard a number of people talking about б EHRs and people talking about PHRs. As I said, Kerry 7 Weems is our administrator and he calls these game 8 changers because they do have the ability to change the 9 game, but we have to work them in the right way.

As we go through some of these processes at Medicare, a lot of the cautions that we have heard from the privacy advocates say what we find are true, some of the things we found with some of these vendor PHRs, they need a lot of work. People say something meets privacy and security, but what do privacy and security mean to different people?

17 I think one of the problems with defining 18 privacy and security is that it does mean different 19 things to different people. One of the things I look at 20 is the Medicare beneficiary. The 75-year-old on Medicare 21 has a very different idea of privacy and security than 22 the 18-year-old who is text messaging and doing a lot of 23 things on the web today. So, how do you define what privacy and security means as you go through it? It is 24 25 very difficult.

E-prescribing is a good example. We heard some 1 2 of the discussion about data-mining, some of the other 3 types of activities that are going on with e-prescribing. 4 But as we see in the slide here, there are a lot of 5 benefits. Providers see it as a way of reducing medication errors. Millions of adverse drug events occur 6 7 each year. Many of these could be prevented by large-8 scale adoption of e-prescribing, access to medication 9 history.

10 There is a lot of relation to fraud and 11 tampering that obviously can occur with e-prescribing, 12 but e-prescribing can also prevent a lot of that.

13 For the consumer, there are a lot of benefits. Reduced waiting time and the handwriting are certainly 14 15 two of them. There is an opportunity to get more generic 16 drugs. There is an opportunity, of course, to have less 17 medication errors. There are a lot of things that can be 18 done if we do this right. With CMS, we have been a 19 leader in promoting standards adoption. We have been spending over the last several years, as part of the 20 21 Medicare Modernization Act, in the Part B drug area, we have put forth a number of e-prescribing regulations with 22 standards and we will continue to do that education and 23 24 outreach and promotion adoption are all key areas within 25 the e-prescribing area with CMS.

1 Personal health records are something that we 2 are very interested in. You can see some of the 3 benefits. I think we have talked about a lot of them 4 today. The issue of communications between the provider 5 and the patient. As beneficiaries, we have a large б number of people not only who have a stake in it as 7 beneficiaries, but a lot of them as their care providers, 8 as children of the beneficiaries. So, the whole issue of 9 how can personal health records assist in that.

10 Chronic care, the largest share of costs in the 11 Medicare program, I think it is something like 75 percent 12 relates to chronic care conditions, how do we use 13 personal health records to help with that? So, we see a 14 lot of potential there.

15 A lot of the personal health record vendors 16 want Medicare data, how do we provide that in a way that 17 we ensure privacy and security? How do we promote and 18 support the standards that Rob and his team are putting 19 together? And how do we deal with certification issues, and when I say certification, I do not mean it in the 20 sense of necessarily the Certification Commission, but a 21 22 75-year-old's interest in usability is far different than a 35-year-old's interest in usability. How do we deal 23 with that? How do we deal with these disparities issues 24 25 that come up with personal health records?

1 We want to make sure that as we promote the 2 adoption of personal health records, it extends beyond 3 just the people who can deal with personal health records 4 on a regular basis, but those who do not generally use 5 technology as a regular part of their lives, and tied to б that and certainly a key role for us working with the 7 Federal Trade Commission is beneficiary outreach and 8 education. How do we educate consumers, particularly in 9 our population, of the benefits as well as some of the 10 concerns around personal health records? 11 Another area we are working very closely on 12 with Rob's office is electronic health records. The role 13 of CMS is really to promote electronic health records, but promote adoption and implementation, but also 14 interoperability. But ours is not to go out and buy 15 16 electronic health record systems, but it is actually to improve quality and efficiency, how do we utilize them to 17 18 improve the health care system? 19 We have a major initiative going on over the next five years that will involve thousands of practices 20 that will begin to start out in phases over the next 21 22 several years, and we hope that that will not only promote the growth of electronic health records, but also 23

improve the growth of quality and other types of health

25 care improvements.

24

So, this pretty much covers my initial remarks.
 I am looking forward, as are Mark, Rob and Joy, to
 addressing the questions that come from the audience.
 Thanks.

5 (Applause.) б PROFESSOR PRITTS: Good afternoon. I would 7 like to thank the Federal Trade Commission for inviting 8 me to be here today. I know that I am the only thing 9 standing between you and leaving, which always puts the last speaker in an awkward position. But I actually 10 11 really like, batting clean-up because you get to respond to what everybody else has said during the day. 12 13 I am not going to have a PowerPoint presentation for you because I find myself to be 14 technologically challenged and unable to speak and click 15

16 at the same time. I also wanted the ability to kind of 17 respond to a lot of what went on here today. The theme 18 of our panel here is practice and prognosis. There has 19 been a lot of talk today about the new way, earlier, of delivering health care and the focus in the future on 20 21 more quality and price transparency of health care, which 22 is one of the essential components of what we call consumer-driven health care. 23

24 Something that was not talked about much I 25 think today was that one of the new ways of practicing health care is also paying for that health care with the development of health savings accounts, which will have a large amount of health information in them. In addition to that, we have talked a lot about new ways of storing, managing and transmitting health information.

6 All of this is very exciting and I am here to 7 tell you that the consumers do get this. As has been 8 stated earlier in the day, they understand that there are 9 a lot of benefits to moving health information into an 10 electronic format. As a matter of fact, a lot of them 11 think it already is in an electronic format. But they 12 also understand that doing this poses some risks.

13 The patients and the consumers who are the most 14 likely to adopt this technology are not your teenagers 15 who are posting all their personal information on 16 Facebook and then are surprised to find out when an 17 employer or their parents look at that information. How 18 did that happen? That is not the market for most of this 19 technology that is developing.

The people who are looking at this are somewhat sophisticated. They understand the risks of sharing their health information and how it might possibly be used against them, and they will not adopt it if there is not adequate trust that their information will be kept confidential.

1 There are a number of polls that have shown 2 this. They show it repeatedly over the years. What do 3 patients want? They want some degree of control over 4 their information. They want to know who looks at it. 5 They want to know why they are looking at it. They want б to know when they looked at it. They want to be ensured 7 that their information will not be shared or used 8 inappropriately, and they want to be sure that if 9 somebody does that that there is appropriate redress for 10 that.

11 I worked with a group out of Michigan that did 12 a study on the Veterans Administration and the Veterans 13 Administration actually went to the veterans and said, we would like to use your health information for research 14 purposes, what do you think of that? This is a group of 15 16 people that, in some ways, has been marginalized by the United States. They are elderly, a lot of them are poor. 17 They get their health information from the federal 18 19 government and some people think that might not be the 20 best, although people in the know know that that is some of the best health care that they can get because it is 21 22 electronic. But they were very attuned to the benefits 23 of their information which was electronic and the potential threat to this. 24

25

What I would say to you is that if your average
person who is like 70 years old and is sitting in a room and probably does not have a computer at home gets this, your average consumer does get it.

4 So, the question is, are these needs for 5 privacy and control and trust in the information, are б they being met? I think that part of the problem with 7 that is that they are not being fully met because all of 8 these new emerging models do not really meet the 9 traditional lines of our sector-driven regulation. When is information, protected health information, when is 10 11 this information financial information? When is it protected by state law? When is it just protected by the 12 13 HIPAA privacy rule? When does it fall between the gaps? And if you think it is difficult for businesses to figure 14 15 this out, you should try being a consumer and having to 16 figure this out and think, if something happens, who do 17 you call, who do you complain to, how do you get redress?

18 Fitting these new models into the existing 19 regulatory structure does not necessarily work well. I 20 think we have had some discussion about that today. The 21 HIPAA privacy rules is fairly limited in its scope as to 22 who it covers now and it is designed for people who are 23 currently the core stakeholders in the system to control that information, where some of these other models are 24 25 designed for the patient to control that information.

1 The market has responded to this to some degree 2 in ways that go beyond what a lot of regulations require. 3 They say they will keep the information private, that 4 they will not sell it, that they will not give access to 5 other people, without the consumer's permission. The б problem with that is what does that mean in an electronic 7 environment when we all know how we interact with the 8 web? You get on the web, you see a privacy notice. You 9 scroll through it until you get to the bottom and you 10 click accept. So, what does that really mean and how 11 protective is that? So, that does not really work very 12 Now, because I get to talk well in many ways. 13 about prognosis, I think I will probably go a little bit beyond that. Being an academic, I get a little license 14 to climb up the ivory tower. And because I am in the 15 16 Health Policy Institute, I do get to talk about policy 17 because that is what I do on a daily basis.

I would encourage us to revisit, to a certain 18 19 extent, the sector-driven approach that we have taken to addressing health information in this country and that we 20 21 should require everyone who touches health information in 22 a commercial context to abide by the fair information practices. I do not think that you need to disturb the 23 existing framework to do this. The regulations written 24 by HHS and those written by FTC all incorporate fair 25

information practices. There are some regulations that
 govern other people who hold health information that do
 not and they really should.

I would also encourage in my wish list that we have one central clearinghouse where consumers could file complaints and where they could be routed to the appropriate agency, at least at the federal level.

8 I have a web site that deals with patients' 9 access to their own medical records. Not a day goes by 10 when I do not get a phone call and these people do not 11 know who to call or how to get responses to the 12 information or who really has -- you know, this is my 13 problem. Is this covered by HIPAA? Who do I complain 14 to? They really do not know.

15 I believe it was Sue earlier who said this is 16 beyond anything we could hope for in regulation, but I 17 would like to point out right now that genetic 18 information, the Non-Discrimination Act, which has been 19 kicking around for 15 years, looks like it is going to be 20 passed this week. So, hope does spring eternal.

Lastly, I would like to address one issue that was raised today, which is the cost of privacy. I would like to flip that on its head and talk very briefly about the cost of not protecting privacy. As Pam Dixon talked about, there is a financial and health care cost that

incur costs in not protecting privacy. But there have 1 2 also been a number of surveys done by the California 3 Health Care Foundation that show that when privacy is not 4 adequately protected, approximately 8 percent of the 5 population engages in privacy protected behavior. They б do not go see their doctors, they give them mis-7 information, and this is bad not only for the patient, 8 but for the public health in general and it has a real 9 cost, although it is hard to calculate. 10 So, with that, I would like to thank you all 11 for staying and turn it open to discussion. 12 (Applause.) 13 MS. OHLHAUSEN: Well, thank you very much to all of the panelists. You have definitely done a good 14 job touching on the broad array of issues that we heard 15 16 from today and trying to synthesize some of these things. 17 One of the questions that I wanted to kick it off with is 18 a general question to the panel. Just kind of stepping 19 back and saying, where the greatest benefits have come in 20 innovations in health care delivery, where has the greatest progress been made so far? Is it in types of 21 22 systems, such as, for example, the Veterans 23 Administration that is virtually integrated or limited service clinics that did not start out in a paper world, 24 25 or does it involve the type of information, like the

1

2

e-prescribing or it is a certain kind of data or radiology or something like that?

And does that tell us something? The places where the greatest progress has been made, does that tell us about how to proceed in making progress in other areas? Anybody want to try?

7 DR. KOLODNER: Having lived through the VA as 8 it went through its various iterations from also being 9 this side of the barn to just being able to publish some 10 documents, just getting the information to move in a way 11 that does not give the doctor just a big chart with a 12 text blob, but being able to have it be available, 13 whether it be in an institution or whoever is seeing that person, gets you started. I think that at least gets the 14 continuity compared to places that have paper records and 15 16 find them 60 percent of the time or 70 percent of the 17 time.

Now, if you do that for people who are chronically ill and you just give a PDF of the things to the doctor, sees a stack of one, two, three, four inches, at that point they panic and a lot of the pushback about electronic health records is, wait a minute, how am I possibly going to look at this?

24 So, the next stage is how do you just take it 25 and represent it very simply? You could have thousands, tens of thousands of blood pressures and glucoses, you can easily review it. But if you tried to do it with paper or if you tried to do it with just sending a text blob, that is not going to get you there.

5 So, what we find is it is an incremental б movement, you begin to see is it the drug-drug 7 interaction and having some allergy or drug-drug 8 interaction pick-up, that is certainly something. Is it 9 a few alerts? Yes, we know that that is important. But that really changes the workflow. So, you have a whole 10 11 change in health care that needs to occur and that is on the health care side. 12

I think what we are just beginning to get an inkling about is when you actually give tools to the individual and you begin to engage them actively, and there is a body of literature that talks about the activated patient. That really seems to make a big difference in terms of people beginning to take responsibility.

20 DR. DENTE: Agreed. So, it is not about a 21 specific type of technology, it is the aggregation of the 22 longitudinal patient record and the data points that come 23 about from that.

I like to think there are revolutions in health care. The first revolution in health care was Dr. Wash 1

Her Hands, okay? A revolution.

2 The second revolution, we have this thing 3 called an antibiotic and the microbial theory of disease. 4 The third revolution, we are in it right now. 5 It is information technology and its impact on the 6 delivery of care for our patients. So, a 7 transformational change is thinking about aggregation of 8 data so we can actually treat our patients in real time. 9 It is not uncommon. The statistic you gave is right on. 10 Many times when your doctor is seeing you in a paper 11 world and seems very interested in what is going on, a 12 third of the time that paper chart is not there. We do 13 not know where it is, but it is not where it needs to be. So, we kind of know that IT will do that. 14 15 The other thing IT will do is sophistication 16 and how do you filter all this information to 17 appropriateness is through clinical decision support 18 engines. Well, now there are some informatics things

19 that have to happen under the hood. We have to get a 20 consistent vocabulary. So, if I say hypertension and you 21 say high blood pressure, how does the computer know the 22 difference? What are the ontologies out there that get 23 it consistent, so this stupid computer that only knows a 24 zero or a one can give a rules engine? But when you do 25 that, a wonderful benefit is something called signal detection. So, we can talk about patients, one aspect, a
 wonderful aspect of empowering the patient.

3 The other aspect that is really exciting, 4 though, is thinking about looking at large data sets and 5 looking for low signal detection. So, pharmaco б vigilance, pharmaco surveillance. How do we think about 7 and look for the Vioxx before it occurs? 8 So, I can tell you that because we were able to 9 aggregate anonymized clinical data, once we knew the 10 questions to ask, we are doing that work right now. 11 Those are the really exciting things that IT is going to 12 bring to us in the future. 13 MR. TRENKLE: I think there are a variety of things and I think that Mark and Rob have touched on a 14 number of them. Also, I think the whole issue of point 15 16 of care is changing, too. We saw the example this 17 morning with the clinics and the care they are offering, the personal health records and the remote monitoring, 18 19 how that will change the whole definition of care and 20 where it is done. I think that is a real major 21 innovation that we are seeing occurring over the last several years and it will continue to accelerate. 22 23 PROFESSOR PRITTS: I would like to answer that

question from a slightly different perspective and say that I think the greatest progress made is within organizations where the health care provider is also the
 health care payer. Because that way your market is
 aligned and the entity that is investing in the
 technology is also reaping the benefits of that
 technology. For example, the Veterans Administration,
 Kaiser Permanente.

7 So, one of the issues that comes up a lot is 8 that providers end up paying for these systems up front, 9 but that the financial benefits go to the health insurer. 10 DR. DENTE: I just want to actually echo that. 11 This is a serious discussion point that we have to have. 12 I just want to actually touch on one quick 13 point from this morning. So, I am actually a resident of Massachusetts. I live outside of Boston. And the 14 statistics you heard about not being able to get a 15 16 primary care physician is a very real, serious problem. 17 When I graduated from Boston University 20 something odd 18 years ago now, every other one of us went into some type 19 of primary care, internal medicine, pediatrics, family practice. Now, it is down to one out of four. There are 20 21 reimbursement issues. These young folks are coming out with hundreds of thousands of dollars in debt. 22

23 So, while we try to figure out how to drive 24 down costs of the overall cost of care, we also have to 25 recognize that we have to be able to attract the best and

the brightest into this profession and be able to
 reimburse them and compensate them so they can, frankly,
 pay off the cost of becoming a physician in this day and
 age.

5 DR. KOLODNER: By the way, I just want to 6 emphasize, Joy was talking about this idea of aligning 7 the payer provider incentives. What it also attests to 8 is that those institutions that are not in that 9 situation, who have become premier users, have overcome even more. So, it is a special tribute to them as well. 10 11 MS. OHLHAUSEN: That actually sort of answered 12 most of a question that I was going to initially direct 13 to Tony, which was, how do payment and reimbursement issues affect innovation in health care? 14 I did not know if you had anything additional you wanted 15 16 to add. MR. TRENKLE: Well, I think obviously the 17 18 reimbursement system has to be modified over time. But one of the things that, of course, we face with Medicare 19 is the fact that a lot of ours is in statute. We have a 20 21 number of limitations that we have to deal with. The 22 private sector is moving along, in a lot of ways, faster than we are. But it is a tough issue to deal with 23

24 because, obviously, everything that you change creates25 another impact. When you change the payments, it creates

some incentives in one way and creates some disincentives
 in other ways.

3 So, how you do that is a very difficult task. 4 I think we heard that from one of the panels this morning 5 with the whole transparency area. When you start looking 6 at quality measures, what are the right measures to deal 7 with and how do you broadcast those measures and results? 8 It is very critical. So, I think the reimbursement is 9 similar. How do you deal with reimbursement in such a 10 way that it promotes better health care as opposed to 11 just promoting certain types of technology that may or 12 may not produce better health care results?

13 DR. DENTE: The other part is it may not be a 14 one-payer system. So, we need to not just look at what we can think of ourselves, but let's also look at what 15 16 the world has done. So, clearly, there is the Canadian 17 system and the U.K. system. But I have also had the good 18 pleasure of spending a fair amount of time in Japan and 19 they have the insurance unions which are basically private insurance companies and their cost of delivery of 20 21 care is considerably less than ours. Yet, they are 22 really kind of non-profit entities versus for-profit entities. 23

24 So, there are different ways that we can look 25 globally for folks that have solved or at least addressed or tried to address some of these problems. We do not
 have to reinvent the wheel.

MS. OHLHAUSEN: I have an audience question which is addressed to Joy initially, but I would also like to open it to the panel as well. But they are asking, do you have anything to say about enforcement of current privacy laws, just having a law or rule on the books is not enough?

9 PROFESSOR PRITTS: Well, that is actually very 10 true, that just having a law -- and the longer I am in 11 the policy world, the more I realize that there are a lot of regulations at both the state and the federal level 12 13 that are intended to do good and that are never really followed or enforced. The enforcement at the federal 14 15 level, right now, is interesting because it depends on 16 who you talk to. If you talk to people in the industry, 17 they will tell you that everybody is scared to death that 18 they are going to get sued or prosecuted under HIPAA and, so, they will not exchange data. If you talk to the 19 health care consumers and consumers organizations, they 20 will tell you that the enforcement is not enough. 21 22 So, the truth is probably somewhere in the

23 middle there. It probably would be beneficial to know a 24 little bit more about the kinds of complaints that are 25 being filed by entities that are not even covered by HIPAA because I think that accounts for a lot of the volume that does not trigger any kind of enforcement activity. But the figures that are thrown around to many people indicate to them that enforcement is not what it should be. But it is hard to know that without knowing more detail about who is complaining and what they are complaining about and those kinds of things.

8 I mean, it is written into the regulation 9 itself. That is one of the things I think most people do 10 not understand is that -- the enforcement regulations are 11 written so that HHS must try to bring people into 12 compliance before they access civil penalties.

13 MR. TRENKLE: Joy is correct. I am actually responsible for HIPAA security enforcement, so we work 14 very closely with the Office of Civil Rights who does the 15 16 privacy enforcement. The way HIPAA was written is it is 17 a complaint driven process and a lot of the complaints 18 that come in on the privacy side, certainly many more 19 than come in on the security side, are improper disclosure type of arrangements. Somebody working in a 20 21 medical facility snoops at some records, things of that 22 sort.

But the issue that we run into is given the way it is, you have to do a corrective action plan. There are a number of steps that come in. One of the things

that we are doing on the security side is we are actually going out and conducting compliance reviews now and what we are trying to do is get some of the information out there on the security side and, certainly, we have worked with OCR as they are doing on the privacy side.

б Some of this is outreach and education, as well 7 as compliance, there are a lot of people out there who do 8 not understand what is covered by HIPAA both on the 9 privacy side and security side. But it is an evolving 10 and iterative process. I do not know how many people are 11 aware, but the enforcement rules only went into effect two years ago, 2006. So, it is still a very new process 12 13 even though HIPAA has been around for some years now.

But part of the problem, as Joy says, is a lot 14 of these are not covered entities, and in the new world, 15 16 we have to figure how to deal with that. One of the 17 efforts that is going on at the department that Sue 18 mentioned was looking at ways to crosswalk what is under 19 HIPAA now and what needs to be done to cover some of these gaps that are going on. That is certainly, 20 obviously, a place where the FTC can be beneficial as 21 22 well.

23 MS. OHLHAUSEN: Then on sort of a very 24 FTC-centric kind of thing, we have heard a lot today 25 about the role of consumer education. What I wanted to

1 find out is what, in particular, do you think this
2 consumer education should say to consumers to help these
3 innovations get more disseminated and increase the uptake
4 rate for consumers or their comfort with the new models
5 that are in the market or coming?

б DR. KOLODNER: I think, first of all, as much 7 as we talked about some of the statistics that Mark 8 showed in terms of quality of care and the error rates 9 and how poor it is compared to things that we normally would expect it to be, I think consumers, for the most 10 11 part, are not aware of it. There is no way that we are going to be able to improve that without the support of 12 13 information systems.

Clay McDonald, back in 1976, published an 14 article talking about the non-perfectability of man and 15 16 that you need these reminders. So, it is not a matter of 17 what somebody wants to do, it is just what you are 18 capable of doing as you stuff in the information. What 19 Mark did not mention is that while you are doubling every eight years, you are also finding that half of what we 20 21 thought was right is wrong. So, you are having to try 22 and decrement that while you increase the other. It is 23 incredible. So, you cannot do that without the supports. I do not think that consumers understand that 24 25 or they would demand that they would not go into a

hospital unless they had the bar code checks for the
 medication and other kinds of things for the information
 and the ability to connect. So, I think that is a major
 part.

5 DR. DENTE: I think that is one aspect of it. The other aspect of it is with the proliferation of 6 7 personal health records, I think that there was a 8 panelist that kind of stated, you know what, HIPAA may 9 not be perfect, but at least somebody kind of goes, I 10 know there is something that is already in place and I do 11 not think the consumer truly understands the difference 12 between a tethered personal health record and a 13 non-tethered, where it is -- I do not know if she is still here, but the wild, wild west. Perfect, perfect 14 statement because it is the wild west. You have good 15 16 companies that have great morals and ethics and they have 17 wonderful policies. And then there can be Joe and Jim 18 with a visual basic manual who built a personal health 19 record that are ripping people off.

20 So, I think to say how do you extend maybe 21 HIPAA in some manifestation to at least cover this until 22 we come up with something iterative, you know, Lean Six 23 Sigma. Let's look for Nirvana, but you got to get going 24 with something. I think if you have that approach and 25 then an educational campaign. This is about educating people to understand what we currently do and what the advantages of IT is, all the way through, you really better understand that there is such a thing as a non-tethered personal health record where all bets are off.

6 DR. KOLODNER: Well, playing off that and also 7 the rule of the FTC, and this was the discussion that the 8 American health information community had about the 9 personal health records, extending HIPAA requires 10 legislation. It is written in statute and so Congress 11 has to act to cover these type of entities. That is one 12 of the rulings.

13 But there is something. If you can, in fact, say there must be a fear of privacy notice and 14 understandable. Then if there is a violation, FTC can 15 16 step in and you can take action rapidly. So, there are 17 things that we need to do, but it also means working 18 together to make sure that the notice that is there is as 19 clear, as some people have talked about, as the soup 20 What is in it? Can they get to it? As opposed label. 21 to the scroll through, the stuff that even many lawyers 22 cannot understand as they go through it.

I think that there are things where coming up with such a simple, clear type of way that needs to be posted, and you say be wary if it is not posted, and then

if there is a violation, there is a way of taking quick
 action.

3 MR. TRENKLE: I would agree with Rob. I think part of the benefits and part of the problem with the 4 5 internet is the explosion of information, but not just the explosion of information, but the explosion of 6 7 information that no one knows the quality of the 8 information you are getting. So, to have a trustworthy 9 source, such as the FTC, that could explain some of the 10 privacy issues in easy to understand language and then, 11 as Rob said, require on the various PHR vendor sites, language or something like the soup can, as you 12 13 mentioned, so you know how much sodium is in the soup if you have high blood pressure, if you know how much fat is 14 in the hamburger meat or whatever. 15

I mean, I think that type of, I do not want to call them standards, but criteria posted on these sites, it is easy to understand, that people can measure one against the other and realize what they are getting. That whole education process has a long way to go and I think the FTC could play a key role with that.

PROFESSOR PRITTS: I guess the point I would like to make about consumer education is that it should not -- and I think this has been inferred by the prior speakers -- is that it should not be just designed to

1 encourage people to adopt these systems, but it should be 2 truly educational about here is the good, here is what 3 can happen to your information. 4 People have, as somebody said earlier, a wide 5 range of privacy thresholds that they are comfortable б with. If they truly understand how the information is 7 used, people will make different decisions. 8 MS. OHLHAUSEN: Well, with that, I want to 9 encourage -- we have come to the end of our time here, but I did want to encourage everyone, if there are things 10 11 you did not get to say or the audience did not get to 12 raise, we do have a public comment period that is open 13 until May 30th. If you go to the web site, ftc.gov, and go to the web site for this workshop, there are 14 15 instructions on how to submit that. 16 I would appreciate it if you would join me in 17 thanking our panel here for their remarks. 18 (Applause.) 19 MS. OHLHAUSEN: With that, the workshop is concluded. 20 (Whereupon, at 5:34 p.m., the workshop was 21 22 concluded.) 23 24 25

1	CERTIFICATION OF REPORTER
2	
3	MATTER NUMBER: V0800051
4	CASE TITLE: NEW METHODS OF HEALTH CARE DELIVERY
5	DATE: APRIL 24, 2008
6	
7	I HEREBY CERTIFY that the transcript contained
8	herein is a full and accurate transcript of the notes
9	taken by me at the hearing on the above cause before the
10	FEDERAL TRADE COMMISSION to the best of my knowledge and
11	belief.
12	
13	DATED: MAY 14, 2008
14	
15	
16	ROBIN BOGGESS
17	
18	CERTIFICATION OF PROOFREADER
19	
20	I HEREBY CERTIFY that I proofread the transcript for
21	accuracy in spelling, hyphenation, punctuation and
22	format.
23	
24	
25	ELIZABETH M. FARRELL