UNITED STATES OF AMERICA FEDERAL COMMUNICATIONS COMMISSION AND FOOD AND DRUG ADMINISTRATION

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JOINT WORKSHOP PROMOTING MEDICAL TECHNOLOGY INNOVATION THE ROLE OF WIRELESS TEST BEDS

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TUESDAY MARCH 31, 2015

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The Workshop convened in the Commission Meeting Room at the Federal Communications Commission, 455 12th Street, S.W., Washington, D.C., Karen Onyeije, moderator, presiding.

PRESENT:

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- KAREN ONYEIJE, Moderator, Chief of Staff, Connect2HealthFCC Task Force
- BAKUL PATEL, Associate Director for Digital Health, Center for Devices and Radiological Health, FDA
- PHIL RAYMOND, Wireless Architect, Philips Healthcare; Chair, Wi-Fi Alliance, Healthcare Marketing Task Group
- HAZEM REFAI, PhD, Professor, University of Oklahoma; Founder and Director of the Wireless Electromagnetic Compliance and Design Center

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* Present by teleconference

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1 P-R-O-C-E-E-D-I-N-G-S 2 (9:08 a.m.) 3 MS. ONYEIJE: So my name is Karen 4 Onyeije. I am the Associate General Counsel of 5 the FCC, one of them. I also serve as Chief of Staff of the Connect2HealthFCC Task Force and we 6 want to welcome you to today's FCC/FDA Workshop, 7 Promoting Medical Technology Innovation, the Role 8 9 of Wireless Test Beds. 10 This workshop is just another step in 11 the ongoing FDA/FCC collaboration and leadership 12 in promoting innovative medical technologies. It 13 has been organized by the Connect2Health Task 14 Force, the FCC Office of Engineering and 15 Technology and our good friends at the FDA Center 16 for Devices and Radiological Health. 17 We're really fortunate this morning to 18 have with us key members of the leadership from 19 both of those agencies, both the FCC and the FDA, 20 to offer greetings to all the discussants and 21 participants this morning and to kick off today's 22 endeavor.

1 As I said, we have a very aggressive 2 agenda planned, so I'm not going to take a lot of time on these sort of preliminaries. It's just 3 4 my distinct pleasure to introduce The Honorable 5 Mignon Clyburn, Commissioner at the FCC. She's a champion of health IT issues here at the 6 7 Commission. Please join me in welcoming Commissioner Clyburn. 8 Thank you, Ms. 9 COMMISSIONER CLYBURN: 10 Onyeije. And one of the reasons why I've lasted 11 so long in D.C. is because I know my place, and 12 so I say that because the chairman of the Federal 13 Communications Commission just walked in. There 14 was no way Karen, Ms. Onyeije, sorry, this being 15 formal proceedings, could have seen him. 16 So at this point, I present to most 17 and introduce to just a few the Chairman of the 18 Federal Communications Commission, Mr. Tom 19 Wheeler. 20 CHAIRMAN WHEELER: Now, you just stay 21 up, you just stay right up here. You just stay 22 because I'm not going to be long, number one,

applause, applause, applause I'd say. 1 2 (Laughter) 3 CHAIRMAN WHEELER: I do want you to 4 know the reason I was late walking in here is I 5 have just come from the doctor's office, okay, where I gave blood, something that we need to 6 7 work on the technology so that we can do it without the stick. I'd like that. 8 Okay. 9 And the doctor's office, I know this 10 will surprise you all, was backed up, which is 11 kind of a microcosm for everything that's going 12 on today and some of the great promises of health 13 care futures, particularly driven by wireless 14 devices. 15 I want to be real clear about one 16 thing. This lady is the reason that we are here 17 today. The driving force behind the mHealth 18 Initiative, the Telehealth Initiative, here at the FCC has been Commissioner Clyburn. 19 20 And we are all incredibly grateful to 21 you, Mignon, for your leadership in this and for 22 continuing to drive this forward to bring

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1 together the kind of group that we have today
2 because, you know, we've all lived through
3 watching how mobile has changed businesses,
4 changed the way we interact in our daily lives
5 and you scratch your head and you say, you know,
6 you ought to be able to do that same kind of
7 thing in health care.

8 But delivering health care is not the 9 same as delivering a voice call. Delivering 10 health care is not the same thing as delivering 11 Angry Birds.

And so what's great about what you have put together today is to bring together these kinds of experts to talk about the importance of test beds and the importance of making sure that we take advantage of this great revolution and get it right.

So thank you, Commissioner Clyburn,
for all of your leadership and thank you to
everybody who has come from FDA and elsewhere to
participate in this.

COMMISSIONER CLYBURN: Thank you, Mr.

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Again, let us welcome and thank the 1 Chairman. 2 Chairman. None of this would be possible without his leadership, his budget allocation and I am 3 4 appreciative. And I believe, and probably, 5 that's important and I'm going to ask for something else so I'm going to be very nice to 6 7 him today. One of the things that I want to make note, and maybe you do this on every birthday. 8 I 9 believe this is your birthday week. Am I right? 10 CHAIRMAN WHEELER: Next week. 11 COMMISSIONER CLYBURN: Next week? 12 Okay, well, we'll start early. We'll send out a 13 happy birthday to him right now. I knew it was 14 close to mine, hint, small hint. You guys missed 15 my birthday. 16 But anyway, seriously I would like to 17 thank the Connect2Health team for everything that 18 they are doing to bring about awareness and focus 19 on this very important role of wireless test beds 20 throughout history. 21 The medical field has gone through 22 several transformations thanks to the work of

innovators, researchers, entrepreneurs and many
 of you in this room.

Take for instance the discovery and 3 4 invention of the x-ray machine. Remember the x-5 ray machine? Prior to x-rays, there was no way to look inside of the human body for diagnosis or 6 treatment except for cutting a patient open. 7 With this invention, all of a sudden 8 9 there was a new non-invasive way to diagnose 10 injury and disease. Eventually this discovery 11 would also lead to improved ways to treat 12 patients by helping visualize doing surgery or 13 other interventions. 14 In today's digital revolution, health 15 care is in the midst of yet another remarkable 16 transformation. Dr. Eric DePaul, one of the 17 nation's most innovative thinkers about the 18 digital future, has said, "Nearly everything we 19 can do in medicine can be done remotely."

If you take a moment to really think about it, the implications behind that statement is huge. It indicates an extraordinary shift in

the way health care is being delivered and received.

At the center of this shift are 3 wireless medical networks and devices. In the 4 5 same way that x-rays use an invisible property in order to produce incredible changes to medicine, 6 wireless networks, also invisible to the naked 7 eye, power devices that are transforming health 8 9 care. 10 Today's innovative technologies are

10 completely changing when, how and where medical 11 care takes place. Virtual doctor's visits and 13 wireless monitoring devices allow the consumer a 14 more convenient way to get the care they need and 15 to get that care when they need it.

In addition to convenience, these innovations are also making it possible to reach people that previously had been difficult to reach.

Health disparities based on geography or socioeconomic status are being bridged through technologies that make health care more

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accessible and less expensive.

2	Health care providers are also seeing
3	a shift in the way they diagnose and treat
4	illnesses with the help of wireless technologies.
5	For example, patients are being sent
6	home from the hospital sooner after surgery or a
7	major illness with the help of in-home monitoring
8	systems. Physicians can continue to keep track
9	of recovering patients at home instead of keeping
10	them in the hospital or a clinic.
11	As this transformation of the health
12	care system continues to evolve, we owe it both
13	to the consumers and the clinicians to continue
14	to ensure that medical devices are safe and
15	reliable.
16	We must, therefore, take into account
17	the need for wireless coexistence. Wireless test
18	beds are a critical piece of ensuring safe,
19	reliable technologies.
20	And I am grateful for all of the work
21	that Connect2Health Task Force, OET and their
22	partners and our partners at the FDA have done to

make this workshop a success.

2	I would also like to thank all of the
3	moderators and speakers who have graciously
4	joined us this morning and look forward to
5	hearing your thoughts and perspectives. Some of
6	it will be remotely for me.
7	But as a final thought, I will say
8	that just as individual musical instruments come
9	together in an orchestra to create a symphonic
10	beauty, individual medical devices must work
11	together on wireless networks to create a
12	transformed and improved medical health care
13	system. Working together we can ensure that that
14	orchestra of wireless devices coexists in
15	harmony.
16	Thank you very much for allowing me to
17	make these welcoming remarks and I'll turn it
18	over again to Karen. Good morning.
19	MS. ONYEIJE: Thank you so much,
20	Commissioner Clyburn. I think that analogy to a
21	symphony is going to be with us throughout the
22	day. Thank you.

1	Next, it is my pleasure to introduce
2	Dr. William Maisel, Chief Scientist and Deputy
3	Center Director for Science at the FDA Center for
4	Devices and Radiological Health. That's a
5	wonderful mouthful, Dr. Maisel.
6	Dr. Maisel provides strategic
7	leadership in developing, implementing and
8	executing the Center's broad national and
9	international biomedical science programs.
10	He is a board-certified cardiologist
11	so he knows what he's talking about. He's a
12	prolific researcher and an author with a focus on
13	device innovation and medical device safety and
14	effectiveness. Please help me welcome Dr. Maisel
15	to the podium.
16	DR. MAISEL: Thank you very much, and
17	let me add my welcome to those we've already
18	heard this morning and it's great to see such a
19	terrific turnout for what we consider a very
20	important workshop today.
21	And really before going any further,
22	I want to acknowledge our FCC colleagues for not

only their cosponsorship of this workshop but 1 2 also really a very collaborative and constructive relationship with FDA and FCC over the past 3 4 several years. 5 I think together we recognize the importance of bringing together communications 6 technology with those of medical devices and 7 really the transformative impact it can have on 8 9 health care. 10 And perhaps a little bit, even more 11 exciting than that is that these innovations are 12 really no longer the stuff of fantasy. They're 13 no longer the science fiction novel or the movie. 14 They're here today and we're living and breathing 15 them. There are many devices that we see at 16 17 FDA but that more importantly are out to 18 consumers and patients. 19 We have continuous glucose monitors 20 that not only provide information to pediatric 21 patients but can transmit wirelessly to the 22 parents so that they have peace of mind and can

monitor their children's glucose.

2 We have implantable cardiac devices that automatically and wirelessly transmit data 3 and information to health care providers. 4 We have surgical sponges in operating 5 rooms that can help OR staff monitor the presence 6 of sponges in an operative field and help make 7 sure that there's no sponge left behind. 8 We 9 really have these amazing transformative 10 technologies. 11 In many respects these examples don't 12 really do justice, though, to the amazing 13 opportunity that lies before us and there are 14 really an unlimited number of devices and 15 possibilities to help consumers and patients and 16 I think that's, in many respects, why we're all 17 here today. 18 And it would be remiss of us if we 19 didn't also take a moment to think about the 20 manner in which these technologies are changing 21 health care delivery. 22 It allows patients to be treated at

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home instead of in a hospital which certainly is 1 2 important for their happiness and well-being and quality of life. 3 It helps physicians monitor patients 4 5 outside the hospital in a different health care environment than normally they would be. 6 7 And so thinking about how to approach making sure these technologies deliver on their 8 9 promise is really part of what we're here to 10 discuss today. 11 At FDA we've taken what we believe is 12 a balanced approach to the participation in 13 helping get these products out to patients, an 14 approach that both promotes innovation and 15 protects patient safety, trying to strike that 16 right balance and getting good, high-quality, 17 innovative products out to the American public as 18 quickly as possible. 19 And you can see this approach in our 20 actions that many of you are familiar with, our 21 mobile apps final guidance published in September 22 2013, more recently our medical device data

systems final guidance related to the hardware
 and software products that transfer, store,
 convert and display medical device data. We've
 really tried to take a smart, narrowly tailored
 approach to getting these innovative products out
 to patients.

7 It's also important, however, to 8 recognize, and I think many of the people in the 9 room today do, that we also face a number of 10 challenges in evaluating these products, and when 11 I say we, I mean the collective we, not FDA but 12 the entire community.

And we certainly have challenges that remain and there are challenges in the convergence of communications technology, coexistence and establishing test beds for the evaluation of wireless medical devices.

And as we discussed at the outset, it's great to bring together the community, not only FDA and FCC but many of the smart people in this room to help us figure out the next steps and solve some of these challenges that lie

before us.

2	Some of you may know that today is Dr.
3	Peggy Hamburg's last day as FDA Commissioner and
4	we will miss her but in many respects it's really
5	a fitting day to have a meeting like this.
6	It was under Dr. Hamburg's leadership
7	that the collaboration between FDA and FCC really
8	entered its next stage of really close
9	collaboration and working together and we've
10	really very much adopted her vision and approach
11	to how we think about regulating technologies
12	like this.
13	And she made some comments at an
14	FCC/FDA cosponsored event back in 2010 and I'm
15	going to read you a quote because I thought it
16	was very apropos of what we're experiencing
17	today.
18	She said, "At the FDA, we view every
19	issue through the lens of public health. Our
20	ultimate goal is a balanced approach, an approach
21	that meets the unique challenges of the 21st
22	century while prioritizing health and well-being

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1	above all else. I know it's a tall order, but
2	it's what the American people demand and it's
3	what we must deliver."
4	So Dr. Hamburg's words from nearly
5	five years ago really couldn't ring more true
6	today, and so on behalf of FDA and our FCC
7	colleagues, I really want to welcome you and we
8	look forward to a productive discussion.
9	MS. ONYEIJE: I like that, no sponge
10	left behind. In the spirit of no speaker left
11	behind, we're going to shift gears and talk just
12	for a few minutes about the FDA and the FCC's
13	interest in wireless coexistence issues
14	generally, wireless test beds more specifically.
15	And we have Julie Knapp who is the
16	Chief of the FCC's Office of Engineering and
17	Technology, and Bakul Patel, who is Associate
18	Director for Digital Health at the FDA Center for
19	Devices and Radiological Health. Julie, take it
20	away.
21	MR. KNAPP: Thanks, Karen. When the
22	program was being organized and they said, Julie,

you're going to get to speak after Chairman 1 2 Wheeler, Commissioner Clyburn and Dr. Maisel, I said talk about tough acts to follow. 3 4 So one of the more gratifying parts of 5 our jobs as public servants is to do things that truly make a difference in improving people's 6 7 lives and perhaps one of the areas that is most compelling is where we do things to improve 8 9 health care. 10 And as I was thinking about my remarks 11 for this morning, I was struck by how long we've actually been working on some of these issues 12 13 including the one that is the subject of our 14 workshop today. 15 It reminded me of the show Glee. With 16 Glee, if you missed some episodes, the show 17 always began by telling you, to set you up for 18 what you were about to see, here's what you 19 missed on Glee. So if you haven't been following 20 real closely about wireless test beds, here's 21 what you missed on wireless test beds. 22 The FCC and the FDA have been working

together for many years on a variety of issues
 that intersect at the crossroads of our
 responsibilities, the FDA for overseeing health
 care and medical devices and the FCC for
 overseeing use of the airwaves, the radio
 spectrum.

7 An entire chapter of the Commission's 8 March 2010 National Broadband Plan, Chapter 10, 9 was devoted to how we could promote broadband as 10 a tool to improve health care.

In July of 2010, and this is what Dr. Maisel had referred to, the FCC and FDA conducted a workshop to gain a better understanding of the convergence of communications technologies and the challenges that they face.

At the time, FDA and FCC formalized our working relationship through a Memorandum of Understanding that is intended to promote collaboration and ultimately to improve the efficiency of the regulatory processes that apply to broadband and wireless-enabled medical technologies.

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1	Then, in June of 2012, the FCC
2	Chairman Julius Genachowski assembled a group of
3	the nation's leading wireless health care
4	technology experts from industry, government and
5	academia for a summit on mHealth.
6	The outcome of this event was the
7	creation of a task force by the participants to
8	develop concrete recommendations to accelerate
9	the adoption of mHealth technologies.
10	The task force made its
11	recommendations later that summer, including the
12	recommendation to promote the availability of
13	wireless test beds.
14	In response, the chairman said the
15	Commission would consider an order to streamline
16	the FCC's experimental licensing rules to promote
17	and encourage the creation of wireless device
18	test beds to improve research, development and
19	deployment of mHealth technologies. The Order
20	was adopted by the Commission in early 2013.
21	And just to show you how closely we've
22	been working together between FCC and FDA, I'm

doing the first part of this presentation and Bakul's going to pick it up from here to bring it home.

And with that, I'd like to introduce
my good friend Bakul Patel who's the Associate
Director for Digital Health, the Center for
Devices and Radiological Health at FDA.

8 MR. PATEL: Thank you, Julian. In 9 Season 2 this is what you saw in Glee, which is 10 also a four-letter acronym.

11 So while all that was happening, we 12 also, as part of Section 618 of the FDASIA which 13 is Food and Drug Administration Safety and 14 Innovation Act, Congress asked FDA, FCC and ONC 15 to work together to come up with a proposed 16 strategy for health information technology.

So taking a step back, so it's almost
like Glee where you go from one scene and one
plot to another plot, so we did that.

As a result of that, in the report we saw highlighted the need for testing, not only during the making of the product but also during

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the design and development, implementation,
 customization and post-deployment of products
 into the health care setting.

We thought, and we highlighted in the report, that it's as important to test the product before it reaches the users, is as important to test them in the environment that it's going to be living into.

9 So with that whole concept, and this 10 is what you, this is what Julie mentioned as well 11 as testing and what you missed in wireless or why 12 we are thinking about wireless test beds is to 13 simulate or emulate the environment, these 14 products, as technology converges from, you know, 15 from medical devices that were non-connected to 16 connected using wireless versus all other 17 technologies into an environment, how can we 18 actually look at what are the needs, what are the 19 thinking behind what should be considered in the 20 development of the products and also how can we 21 make it transparent for just not the makers of 22 technology but also users of this technology?

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So I'm not going to speak any more 1 2 because we have a whole day set up to sort of identify those needs, identify what things are 3 4 happening in this area and also, at the end of 5 the day, sort of figure out where do we go from 6 here on. 7 So there will be a Season 3 and not only a Season 3 but also Season 4, but as 8 9 Hollywood does it, only thing we're missing 10 between seasons is the theme song for the shows. 11 So having said that, this is what you 12 missed for wireless test beds and I'm going to 13 turn it back over to Karen to kick off the 14 workshop. 15 Thank you so much. MS. ONYEIJE: A11 16 right, so we're done with all the preliminaries 17 and now the work of the day begins. 18 I'd like to invite the moderators and 19 discussants for Session 1 to come up and get 20 seated on the dais and I'll provide just a few 21 instructions while they are taking their places. 22 We are working on getting some

programs for you. We had some technical
 difficulties on that front and you'll get those
 shortly.

When you get them, you will see that Session 1 is titled Defining the Need and Scope of Wireless Medical Test Beds, and we have an illustrious group of discussants assembled this morning and they are going to consider the question of how wireless test beds can contribute to the overall health IT ecosystem.

11 They're going to ask questions and 12 answer them hopefully. Are there new issues 13 emerging that make these test beds more or less 14 important? And it's going to be a really 15 fascinating discussion. I'm very much looking 16 forward to it.

17 One housekeeping note. For those of 18 you who are joining us online, and this is being 19 aired lived on the FCC's website at fcc.gov/live, 20 you can join the conversation and follow using 21 the hashtag test beds. We'll also be accepting 22 questions for each of the session participants

through Twitter using that very same hashtag. 1 2 All right so, Julian and Steve, the 3 floor is yours. Thank you. 4 DR. GOLDMAN: Okay, now we just would 5 like to share with the panel the critical information that the light doesn't turn on when 6 7 the mic goes live. Okay, good to know. 8 MALE PARTICIPANT: 9 DR. GOLDMAN: Good morning, everyone. 10 Karen, thank you very much. It's an honor to be 11 here. 12 Our panel has spent considerable time 13 trying to formulate a cohesive coverage of this 14 topic area for Session Number 1 to help set the 15 stage and to generate questions and provide 16 background on what led up to this session on 17 wireless medical device test beds, and there was 18 an evolution and we'll go through that a bit when 19 we begin the slides. 20 But first I would like to introduce 21 our panel members just by name and you'll hear a 22 little bit more about them and, of course, there

are extensive bios in the handouts which are 1 2 being reprinted I understand, so stay tuned for the larger packet. 3 4 So why don't we go through and have 5 everyone introduce themselves, mention their name and organization first. 6 7 MR. BERGER: I am Steve Berger with TEM Consulting. 8 9 MR. TEVIS: Rick Tevis from Geisinger 10 Health System. 11 MR. RAYMOND: Phil Raymond, Philips 12 Healthcare. 13 MR. JACKMAN: Shawn Jackman with 14 Kaiser Permanente. 15 MS. MCDERMOTT: I bet you can guess 16 this but I'm Kerry McDermott with the Center for 17 Medical Interoperability, and I just have to say 18 I'm particularly proud to be an FCC alum today. 19 Had the pleasure of working with these fine folks 20 over the past five years so this is a day of 21 nostalgia for me but I'll try not to make it all 22 about me. Thanks.

MR. WITTERS: I am Donald Witters with 1 2 the Center for Devices and Radiological Health. DR. GOLDMAN: And I am Julian Goldman 3 4 with Mass General Hospital and Partners 5 HealthCare System and the Medical Device Interoperability Program. 6 So I think we'll begin with the 7 Several of us have just a few slides and 8 slides. 9 we'll get that going here. 10 So a bit of history, several years ago 11 a group was formed by the FCC called the mHealth 12 Task Force. 13 The mHealth Task Force was initiated 14 by Chairman Genachowski as I recall and brought 15 together a diverse group from hospitals, industry 16 and others to discuss and examine mHealth, 17 something that was still a topic. It was unclear 18 what the "m" stood for, mobile, medical, you 19 know, that was the stage that we were at that 20 point. Even that wasn't completely clear. 21 So we convened the group over some 22 period of time and came up with recommendations

which you can find online on the FCC website and 1 2 the recommendations are here. Now, the idea of a test bed did not 3 come out of the mHealth Task Force. 4 In fact, it 5 had been under discussion within the FCC for some time. 6 7 I remember Julie Knapp talking about this meeting with several groups that were 8 9 looking for ways to innovate with medical devices 10 and primarily that work focused around research 11 spectrum allocation if memory serves, but I don't 12 want to put words in Julie's mouth. 13 That idea was matured through the 14 mHealth Task Force and you can see the 15 recommendations here. They're all contained in a 16 single slide. 17 And I'll read just a small part of 18 this. It says, "Specifically, we recommend that 19 the FCC encourage and lend its expertise to the 20 following initiatives. "Creation of national centers with 21 22 equipment, expertise, licenses, and support

staff.

Identification of tools and consensus
standards to monitor and assess the performance
of wireless technologies in healthcare
environments.

6 "Easier access to spectrum or rules 7 for healthcare that feed the quest for 8 interoperability, for example, separate medical 9 spectrum with more capability, rules for more 10 protections on critical care spectrum, emergency 11 situations communications."

Next, "Encouragement for innovation of technology and other tools such as standards or publications," and finally, "Encouragement of newer technology, for example, cognitive radio, and applications that are built on a risk management approach."

18 Those recommendations were published 19 on the FCC website that were concluded in 2012 20 and then the Consumer Advisory Committee, an FCC 21 FACA Number 7 started and then the FACA picked up 22 the recommendations from the mHealth Task Force

as you can see in this final slide.

2 This was modified a bit in the final version but these are the recommendations of the 3 4 Consumer Advisory Committee that were made by the 5 committee to the FCC, again, revisiting and underscoring the importance of moving forward 6 with the workshop on test beds. 7 And so this is some of the work that, 8 9 you know, was the groundwork for this and I'm 10 really excited that we're finally here today 11 after all this preparation. 12 So I'd like to thank the FCC and the 13 FDA for kicking it off, and let me pass the baton 14 to my co-chair. 15 Okay, thank you. MR. BERGER: Let me 16 go ahead and put the first slide up. I thought 17 the most useful contribution of my time is to 18 throw some rocks and stir up some trouble if I 19 can, so let me do my best. 20 What I'd like to do is go through a 21 set of issues and there's been a lot of work it's 22 been said that's gone before but I think these

are connection points and axes that's worth 1 2 revisiting and saying where are we, how are we doing? 3 4 So to start with, what's the problem

we're trying to solve? And I think it's clear there's multiple problems. You can't solve 7 something you're not focused on though.

So are we trying to quantify the 8 9 operational reliability of medical devices? 10 Alternatively are we trying to spot the potential 11 impact of those devices on the installed base, 12 what's already out there, as new technologies 13 enter the health care delivery system? Are we 14 trying to gain insight into the deployment 15 Is the combined system ready to take in process? 16 a new technology?

17 And in the interest of causing 18 trouble, let me suggest that potentially the best 19 use of the test bed would be to never allow it to 20 run a test.

21 So is the test bed best a place and 22 organization to do testing, or is it a function

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and process that engages with the larger system for developing medical devices delivering health care?

And potentially if you didn't allow 4 5 the test bed to ever run a test, it would have to think more about how it engages the system, where 6 and when are the critical decisions made and how 7 does it influence those, which very possibly 8 9 spends more time trying to influence chip and 10 component designers to do the things that 11 consequentially result in improved health care 12 delivery and performance of medical devices.

So some connection points. We clearly observe there's this huge, attractive pull to the dominant networks and to the dominant RF protocols.

17 The problem is we want medical devices 18 to perform at higher levels so how do we sort 19 through that? There's a lot of good reasons for 20 health care devices to operate in the dominant 21 networks but then we want them to have higher 22 levels of performance.

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How do we stay in touch with the RF 1 2 environment which is constantly changing? What's the bridge to research to compliance testing? 3 4 There's multiple examples of coexistence testing 5 taking multiple millions of dollars to perform and with good reason. I think that's called 6 7 research. That clearly isn't affordable on a 8 9 every product basis so we need to trim that down, 10 automate the tests and what's the test bed's 11 purpose in getting it down to an affordable level 12 of testing to predict an individual device's 13 operational performance? 14 Correlating field results to what 15 happens in the test, hopefully that is well 16 understood. 17 This is one that is unusually 18 difficult but we're naturally attracted to 19 Gaussian distribution normally distributed 20 events. We can look at what's going on. We can 21 run statistics and figure out what the worst case 22 is.

How about those low probability/high impact events that are non-Gaussian? What are we doing about those? And I'd suggest that that deserves some time of its own. They will happen. They do happen. They have impacted our society significantly.

7 And then does the test bed include 8 consideration for all the people who will engage, 9 both the professionals who will use the equipment 10 but those who will be receiving the benefit of it 11 and particularly people with disabilities who 12 commonly then bring their adaptive technology.

13 And there is a history of recreating 14 old problems because the people who make 15 decisions on new technologies are unaware of the 16 diversity of human population and human needs 17 and, therefore, over and over again we end up 18 doing things like recreating hearing aid 19 interference, interference to different kinds of 20 medical devices. So some issues to throw out 21 there and hopefully kick around some today. 22 DR. GOLDMAN: So we can pass the baton

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1	down to those who have slides and then we'll go
2	fill in with the verbal comments only. Kerry.
3	MS. MCDERMOTT: I don't think anyone
4	else has slides.
5	DR. GOLDMAN: Oh, okay. Thought we
6	had more slides. All right, we don't have more
7	slides. So we have a number of comments that the
8	panelists are prepared to make to kick off the
9	conversation and who shall we go with? I see
10	Phil and then Kerry. Is that right?
11	MS. MCDERMOTT: What about ladies
12	first? I'm just kidding. I defer to the
13	judgment of the moderator.
14	(Off mic comments)
15	MR. RAYMOND: I was just going to
16	start with maybe view this from the medical
17	device manufacturer and where test beds and where
18	a program like this could fit in.
19	From a medical device manufacturer
20	standpoint, we obviously do extensive testing as
21	part of our quality system, as part of verifying
22	interoperability with all the various networking

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vendors.

2	As much testing as we can do in our
3	labs, in our environments, it does not 100
4	percent correlate to the performance of our
5	devices in a hospital network.
6	There is a gap there and, you know,
7	it's a challenge we face as a medical device
8	manufacturer working with the hospitals to
9	understand that gap, to understand their
10	capabilities and what they can test to.
11	And work with them and it's a
12	continue. It's not a one-day, okay, we tested.
13	It works. All good. You'll be good to go for
14	tomorrow and the next month.
15	So filling that gap in with a test bed
16	certification program that can have some, take it
17	the further distance. I don't think we ever get
18	away from a hospital having to have its own
19	testing capabilities, have its own networking
20	competencies around wireless connectivity.
21	But having this test bed
22	certification, whatever we end up calling it,

where this goes is a key component, in my 1 2 opinion, of addressing and filling in that gap between the medical device manufacturer and the 3 4 hospital. 5 Kerry. Thank you for DR. GOLDMAN: your patience. 6 MS. MCDERMOTT: You know that's hard 7 Anyway, I think there is a good 8 for me, so. 9 articulation of the problems presented. 10 I'd like to just paint this in a 11 slightly broader picture for folks as we think 12 about test beds and the strategic role they might 13 play for the health care industry. 14 So if you think about what health 15 systems are facing today, they have to deal with 16 evolving business models and care models, so 17 we're moving towards population health management 18 and transitioning care from inside the, sorry, 19 from inside the hospital to outside the hospital 20 walls, to the home. We're trying to focus on 21 having more personalized care for individuals. 22 Health systems are working to adapt to

out-based payment models and making a transition to value. They have to deal with coordinating care across disparate delivery sites and with other entities.

5 They're focused on leveraging data 6 analytics and engaging individuals in their care 7 and making sure they maintain a satisfied and 8 motivated clinician workforce, and in order to 9 support all of this, the underlying technologies 10 must work as expected.

11 So we find ourselves, as Phil started 12 to note, where, you know, the people buying, 13 deploying and using these technologies need to 14 have confidence that it's all going to work 15 together safely and securely, and test beds can 16 really help with that, especially as a resource 17 for solving shared technical challenges.

So given the proliferation of wireless devices in the health care setting and the changing nature of what constitutes the health care setting, wireless is an indispensable utility.

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You know, this is a huge 1 2 infrastructure challenge as you're managing various networks for specific purposes, but the 3 4 clinicians aren't thinking about what network 5 something is on or whether they're using a regulated or an unregulated device. 6 7 You know, they are just needing the system as a whole to just work and so I think we 8 9 have a real opportunity to talk about how we help 10 the system as a whole just work. 11 DR. GOLDMAN: Thank you, Kerry. So if 12 I can, I think Phil brought up the notion that 13 the testing predeployment and at the point of 14 manufacturer development does not guarantee 15 success once it's deployed. 16 And Kerry pointed out the importance 17 of it just working. And so I'm not sure who 18 should best speak next to this. Okay, here we 19 go. 20 MR. JACKMAN: So at Kaiser Permanente, 21 to give you a view of this very problem, what I 22 face on a daily basis is my job is to provide a

reliable and safe wireless network for general use.

I don't put a customized wireless network for each product we put into the environment. We need a general utility, and because of that, I literally am faced with the challenge of taking in a different medical device every day.

You know, I'll get a phone call. Hey,
Shawn, I just bought this device. I'd really
like to, can we go ahead and put that on our
wireless network? I'm happy to help you. Let me
understand, you know, what it is. Oh, wait.
Which protocols are you using with this device?

15 It is the maturity in the marketplace 16 isn't where it needs to be, just put it that way. 17 So it forces me to build a very expensive 18 wireless test bed. It's in the hundreds and 19 hundreds of thousands of dollars, what I've put 20 into this in order to get to that general utility 21 network to have a safe and reliable experience. I don't know if I should be in the 22

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business of doing that. There's a level that 1 2 I'll always need to do because our environment is, you know, you could argue there's going to be 3 4 some unique characteristics about it. 5 But, gosh, it would be sure nice to have something, a place, as Stephen put it, to go 6 for medical device manufacturers, infrastructure 7 vendors to have an ecosystem to test these 8 9 products in. 10 I would argue the equipment vendors, 11 listed medical device manufacturers, they do a pretty good job of testing their product and 12 13 their product in isolation. 14 They can't predict every type of 15 environment that's going to be out in the 16 customer world. I mean, their expertise is in 17 the devices, not running a hospital wireless 18 network. That's my job. 19 And we have, I think, over 70 20 specifically certified wireless devices. How 21 those interoperate, right, coexistence, some of 22 them have, you know, different level performance

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requirements than others.

2	So a voice call running on WiFi,
3	that's real time. You would have to, that could
4	be care team communication for acute care to deal
5	with, you know, our sickest of patients. I'm
6	very, very concerned making sure that is as
7	reliable absolutely as possible. So it takes so
8	much detail to go test these things out.
9	And I'm excited about the topic today,
10	wireless test beds, so I'm just trying to frame
11	the perspective that folks like, you know, Rick,
12	myself, Calvin, that we have to provide a general
13	utility network, and the problem I think was
14	pretty well articulated.
15	DR. GOLDMAN: Shawn, thank you. I
16	wonder if, so that, your problems could
17	potentially be unique to the West Coast because
18	it's so far from here.
19	MALE PARTICIPANT: That's right.
20	DR. GOLDMAN: But maybe we could hear
21	from Rick Tevis to see if there are problems like
22	that in rural Pennsylvania.

MR. TEVIS: We do. We do have the 1 2 same issues. It's hard to 3 MALE PARTICIPANT: 4 believe. 5 It is. It's amazing. MR. TEVIS: It's congruent. You know, it's not just data 6 7 anymore. It's not benign data. You know, we're talking about patient information here and if we 8 9 lose it, we change it or delay it, we're not 10 going to get the desired outcome that we need. 11 And things that keep a clinical 12 engineer up at night are coexistence, 13 interference, loss of data. So I depend on these 14 guys. These guys are the guys that put my 15 networks together. 16 But at our end, the test bed needs to 17 be as hostile as possible. You know, within our 18 four walls, we really, really have a hostile 19 environment. 20 You know, we have argon coagulators, 21 ESUs. We're very, very good at generating our own spurious emissions. You know, we have lead 22

walls, doors, WiFi clock systems. We pretty much 1 2 have a torture chamber for WiFi systems, you know, built within our system. 3 4 And you add that into the rural 5 component of it. You know, we're working with 30- or 40-year-old copper that doesn't work, much 6 7 less having any wireless capabilities, so we have a whole other spectrum to go there. 8 9 But, you know, like I said, these are 10 the guys that help provide me the information I 11 need but, you know, I'm the end user I feel like 12 and we need the test bed. The hostile 13 environment test bed, you know, is the final 14 piece. 15 So thank you and Phil, DR. GOLDMAN: 16 I think, wants to comment that this is the FDA's 17 fault. 18 (Laughter) 19 No, if you think about MR. RAYMOND: 20 it, so Shawn's doing testing. Rick's doing 21 testing. They're not necessarily collaborating. 22 You make the joke about distances but

that points out, well, gee, if the hospitals are 1 2 realizing that they need to develop their own test capabilities, why not? They're probably 3 4 duplicating efforts. Why not bring that out into 5 the community in some type of test bed? So I think that's fundamentally part of the challenge 6 7 and part of the solution. Right. 8 DR. GOLDMAN: Thank you. So 9 I think we haven't heard from Don Witters at all. 10 I was trying to goad him into, you know, 11 responding but --12 MALE PARTICIPANT: Sorry, Don. 13 MR. WITTERS: Thanks, Julian. I was 14 just going to point out a few points that I put 15 into the short abstract which I submitted. 16 First, wireless technology has been 17 around for decades. It has evolved into a 18 communication system which is what we're focused 19 on for use in health care and is widely used as a 20 means to communicate not only patient 21 information, signals from the patient, but also command and control of various medical devices, 22

both within and outside. So it's used widely and
 it's become a lot more widely used in a larger
 and larger group of medical devices and
 functions.

5 We began many, many years ago 6 cooperating and communicating with the Federal 7 Communication Commission when some problems were 8 seen back in '99/2000 with wireless medical 9 telemetry. We came together very quickly with 10 the industry and the broadcasters on that and 11 came up with ways to resolve that issue.

12 In the meantime, of course, things 13 have developed a lot quicker in computers and 14 that's enabled much of the wireless health care 15 infrastructure to develop to where it is today. 16 We have not been standing still.

17I participate as a co-leader of18Association for the Advancement of Medical19Instrumentation standards group for wireless20coexistence of medical equipment.

21 Our drive is really risk management, 22 how to manage the risks that are appropriate to

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that use of the device and also in the world that these devices operate in, which these days is pretty much you can guarantee that there are going to be a lot of other wireless in that area at the same time and in many cases using the same, exact technology.

Coexistence is something we found as
a fundamental piece of our guidance for wireless
medical devices and we expect manufacturers to
perform some assessment of that, and as
appropriate to the risk, testing for that.

12 What I was thinking today about what 13 the gathering is about is really to flesh out a 14 little bit more what do we mean by a wireless 15 test bed? Who would use this? What would it be 16 consisting of? It could go all the way into the 17 hospitals or the health care, into those 18 facilities or at least simulate those facilities. 19 It could be, and is already, utilized 20 by the manufacturers as Phil was talking about 21 and by the computer industry who have been using 22 this type of approach for many years and also

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bridging it out into wider and wider areas, 1 2 perhaps coming up with ways or more simple ways 3 that it could be done in situ. 4 One of the groups that Steve didn't 5 mention but he is the chair of a ANSI-certified C63.27 group working on wireless coexistent 6 7 standard right now. We're communicating, cooperating, 8 9 because he's my co-chair on the AAMI group as 10 well, to develop documents, to develop tools that 11 are really needed. 12 How does the wireless test bed fit 13 into that? How would we utilize it? Who would 14 utilize it? How could we make this a resource 15 that even the smallest companies in the medical 16 community could utilize to some extent, all 17 questions that I am hoping we'll be able to 18 discuss in this session and the later sessions as 19 well. Thank you. 20 DR. GOLDMAN: Thank you, Don. 21 (Off mic comments) 22 Okay. Yes, let me throw MR. BERGER:

out a question picking up on some things Don
 commented on.

The longer I look at coexistence, it's clear it's a probabilistic issue. Wireless is going to work famously some places and then you can find places there are problems.

7 Ultimately it's a risk assessment 8 issue. What that gets down to most fundamentally 9 is what's an acceptable level of risk and how do 10 we even discuss that in a wider forum? Let me 11 just throw that out.

12 MR. WITTERS: What I drive for when I 13 look at these is risk management. So risk 14 assessment is a part of that, but risk management 15 means going the next step which is what the folks 16 from Kaiser and the other hospitals do to 17 understand what they're dealing with and how 18 important it is in the scheme of what the 19 treatment is for the patient and manage that in a 20 way that is reasonably safe, reasonably effective 21 and does the job they need it to do in those 22 situations.

For example, some things, perhaps 1 2 administrative information, may not be as critical to get there as timely as other 3 4 information like a ECG, for example, or the 5 patient is having a major problem and we need to get to them. 6 7 This goes not only in the hospital but into the home as well. Patients are increasingly 8 9 being monitored at home and for good reason 10 because it's more comfortable. There are many 11 positive ways of looking at that. 12 How can that be assured that that's 13 going to work reasonable in an environment of 14 people who are not technically that savvy in this 15 area? In fact, the group that is relatively 16 small compared to the group that are patients and 17 users and facilities. 18 So what kind of tools can we help to develop that will push that forward, that will 19 20 allow them to have an assurance but also give 21 them a tool if they desire to work in other 22

environments and allow them to do something

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perhaps simple that they could do themselves? Do we need that? I don't know. I just throw that out there. How much of these test bed and where are they needed are good questions.

5 Let me just ask for a DR. GOLDMAN: clarifying question. So, Don, are you referring 6 7 to tools that would be applicable prior to deployment, during development and assessment of 8 9 technology, or for monitoring performance post-10 deployment to detect and perhaps to help analyze 11 sources of interference and degradation of 12 performance?

13 MR. WITTERS: I'm opening it up. I'm 14 not focusing in particularly for my perspective 15 on any one. I think initially the idea is at the 16 development and design of the equipment and the 17 testing for the equipment before it goes to the 18 hospitals.

But also we must include the larger sense. There may be simple things that could be developed that would be straightforward for the hospitals that would allow them to look at this

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and examine it and mitigate if they need to. 1 2 Perhaps they need to create separate networks of a certain type of technology with a 3 4 certain level of quality of service that they 5 need for their operation. And that may differ from organization 6 7 to organization. You may not need that in a home but perhaps this is a critical patient that has 8 9 certain things that they need to monitor. It 10 really is a risk management overall type of 11 aspect. 12 There's other issues, and I think 13 maybe Kerry was leading into this, of 14 interoperability. 15 Coexistence and interoperability are 16 two various things that need to come together I 17 think in a way that makes this whole area more 18 cohesive, more consistent, more coordinated, all 19 along the spectrum of device design, device 20 deployment, device use, device longevity, which 21 is another thing. 22 We all know how longevity is in

computer world and in the things like smartphones and other technologies. Medical devices, some of them don't have that kind of turnover. They last for decades and they do their job very well and very safely.

How do we tie those in and when they
become wireless and they potentially use an older
technology that's continuously changing and still
maintain that degree of safety and effectiveness?

10 MR. BERGER: Don, let me ask, is an 11 implication of your comments that perhaps as 12 important or even more important than testing 13 individual devices, a test bed should be testing 14 the risk management systems, its ability to deal 15 with events as they arise?

MR. WITTERS: I'm not sure how this would work out. I think this forum should give us a better idea, especially in some of the panels that are coming, where these things might be developed.

21 Some might be quick, some might be 22 slower, some might not take hold at all but we

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need to go forward. We need to innovate. 1 This 2 is a challenge and the opportunity that many have been seeking to have a forum that allows them to 3 4 push these things forward. DR. GOLDMAN: I'd like to ask a 5 question of the panel. The title for this event 6 7 is Promoting Medical Technology Innovation, The Role of Wireless Medical Test Beds. 8 9 Medical technology innovation, you 10 know, from my perspective working at Mass General Hospital and Partners HealthCare, there have been 11 12 many times when we would have liked to use new 13 technology, new equipment, new devices but we run 14 into the challenge of assuring that they will 15 function in the environment and they won't cause 16 interference with other devices.

And there's a high cost to that
assessment and sometimes it's quite difficult.
The security component fits in, as does the
interoperability component, and later today, Rick
Hampton from our institution will address this in
detail.

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1	But for the moment, I wonder if the
2	panelists could comment on, from their
3	perspective, what is the barrier to innovation
4	that not having test beds presents today?
5	MR. RAYMOND: Barrier? How about a
6	tool to address the barriers? The wireless
7	complexity in hospitals and the home and in
8	between is only going to increase. You start
9	talking about wireless sensors, wireless
10	wearables. It's not slowing down and it's only
11	accelerating.
12	Risk management is a tool that's been
13	talked about here that can help formulate and
14	create a vehicle for addressing these challenges
15	because, as pointed out earlier, and, Julian, to
16	your question earlier, it starts at the
17	development phase, through the deployment phase
18	and then a maintenance phase. You know, change
19	control, change management, those type of things
20	are all, can be part of a risk management
21	process.
22	So to enable all these technologies,

to enable wireless wearables and the innovations that there's a lot of brain power in the industry working on, it has to be safe and effective, and you want to talk about a barrier, well, talk about patient safety.

And so you have to keep those in back of mind as you're developing these and as you're bringing these systems out, as you talk about whether it's security or interoperability or interference.

But those can all be barriers if they don't work appropriately, if you don't meet the clinical use to the safe and effective use of these type of devices and that will just stall and inhibit innovation.

16 DR. GOLDMAN: Kerry. 17 MS. MCDERMOTT: Thanks. Yes, I would 18 say absolutely, full agreement there. And I 19 think it's worth stressing the point that when we 20 think about test beds and the results that they 21 will deliver, those results have to be relevant 22 to me, to my health care organization, assuming a

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test bed is in service of the health care 1 2 organization, or if we're saying test beds are in service of medical device manufacturers, then it 3 needs to be relevant to them. 4 5 I don't think those are mutually exclusive choices but there's a real decision in 6 7 who the real customer of the test bed is. And I love what you said before about 8 9 the hostile environment test bed. You know, yes, 10 I hope somebody's tweeting that, you know, 11 because you need to test in the environment of 12 intended use and, to the other point, at the 13 system level, not just at a component level. 14 So one-off components doing what 15 they're supposed to do, that's great but it's the 16 integration and interoperation of those 17 components, that's what really matters. 18 MR. JACKMAN: I'd like to add some 19 comments to that. I think you're spot-on. A lot 20 of times when you -- What I find is the more 21 traditional approach is people test the 22 infrastructure and they constantly look up at the

They're looking at the antennas and 1 ceiling. 2 when there's a problem they look back up at the ceiling. Well, maybe I can change these things 3 4 and so they constantly look to the 5 infrastructure. I submit that that's rarely actually 6 Usually the problem is with Mr. 7 the problem. Baker's wireless devices over there. 8 9 The devices, we all have smartphones. 10 Well, hopefully most of us do. We've probably 11 all experienced those devices not working well on 12 WiFi. 13 And I have physicians, nurses, other 14 hospital staff that they look at their smartphone 15 -- Shawn, come on, right? I just want to use 16 this. You know, I wanted to, can I connect into 17 our unified communications infrastructure, can I 18 do all that, you know, all of that new stuff that 19 I saw in the marketing material, right? It's 20 supposed to be able to do all that, right? 21 There isn't a knob I can turn on the 22 infrastructure to make some of these devices

I've tried. I've tested 39 different code 1 work. 2 versions for one particular smartphone, still for it to fail 39 times. So the system is so 3 4 important and it has to be the same 5 infrastructure for medical devices, for the care team communication. 6 And then there's this little thing 7 called guest WiFi. It's not a little thing. 8 9 It's an expectation. Again, Shawn, come on, 10 right? We want to have all the members and, you 11 know, health care members and guests that come in 12 and let's just take care of them. Let's give 13 them free WiFi. 14 Well, coexistence with that, with the 15 wireless medical telemetry, you know, the WiFi 16 variance of that, right, because that seems to be 17 the momentum that the device manufacturers are 18 qoing. That's an interesting topic. It really 19 is the system. 20 And you have to look at it -- So I 21 have 1,000 or so facilities with Kaiser 22 Permanente. I work really hard to make sure

there's one configuration out there and one of
 everything. Gosh darn, that's hard, especially
 across so many facilities.

So now you look at it. So when you paint a bridge you start on one end, right? Start going down on the end. Let's say it takes you, you know, three to five years to get there.

8 Well, you know, I'm going to start, 9 start going back to the beginning. Well, as I go 10 back to the beginning, I'm a year into it. I 11 still have four more years to go.

12 So I have two types of wireless 13 infrastructures out there, and if I just upgrade 14 the infrastructure, those devices are all going 15 to work fine, right, because they worked good on 16 the other one. No, right? Maybe their adapters 17 are changing.

So it's not just about putting it in
the first time. It's about a life cycle. You
have to address the devices and the applications
based on their intended use.

Don made a good point about a

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clinical device that Rick has. He may have a
 device that he just needs to check in once a day
 and just to see if is there, maybe update some
 information-only logs, nothing that's going to
 affect the clinical device and its intended use
 with the patient. I'm going to look at that with
 a different lens.

8 Then if somebody says, you know, the 9 next version of the Philips telemetry product and 10 hey, Shawn, you can go ahead and put this on WiFi 11 too, I could. I absolutely could.

12 The intended use of that is, gosh darn 13 it my lens on that device is I have to make sure 14 that device is never down. So then you think 15 about it, right, and it's one infrastructure.

16 Intended use, I guess I really want to 17 reiterate there is a point that we have to look 18 at it as we're testing these things. There's an 19 intended use of the device.

Talked about everything from, you
know, information only to the other extreme, the
physiological monitoring, to, you know, devices

and the different types of infrastructures we 1 2 have out there.

And then there's the life cycle, how 3 4 we make sure when we put it in it stays good 5 because our users, that's their basic expectation, is that it will work and it is safe 6 7 and it's reliable.

DR. GOLDMAN: I have a commercial 8 9 comment here to make, just a short break to let 10 everyone know out there in radio land as they 11 used to say, that it's possible to submit 12 questions with hashtag test beds. Is that with 13 an S, test beds? Then the questions are picked 14 up here.

15 Also questions can be emailed. Just 16 look at the FCC.gov website for the email 17 information and, of course, people here in the audience should just step up to the mic at any 18 19 point if they have questions.

20 And I'll start off with a question, 21 but I'm just going to speak. I'm not going to 22 tweet it. So, Don, you mentioned remote control

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of medical devices which I thought was
 interesting. You commented ever so briefly on
 that.

Could you add some detail, a little bit of richness to that? What kind of devices? Are you seeing specific devices that are being remote controlled? I imagine insulin infusion pumps are an example but perhaps --

9 MR. WITTERS: I am not aware of an 10 insulin pump that's actually remote controlled in 11 some sense. There could be. There is a 12 difference between remote control and closed 13 loop.

14So there are some systems that are15utilizing wireless technologies to close the loop16to sense and then provide the necessary therapy.17This has been common in pacemakers for many, many18years. Now it's finding its way into other19systems.20Insulin pumps, for example, for

21 diabetic patients who need them, have wireless 22 communication and are making their way into a

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sensing and then providing the kind of therapy, 1 2 but they're not quite there that I understand. Remote control, perhaps you've heard 3 4 of and you utilize the remote teleradiology-type 5 issues, so you can have physicians and radiologists in one part of the globe basically 6 7 examining these kinds of images and issues in some other remote place. The military, of 8 9 course, does a lot of this. 10 The surgical types of things are not 11 typically, as far as I have seen, remote control 12 but there are surgical systems that utilize 13 wireless somewhere along their communication. 14 They send out information and are connecting. Ι 15 need to know what this patient is. I need to 16 know what they're on. I need to have that 17 information right here. There's a lot of 18 innovation there. 19 I would like to throw out, again, just 20 a challenge also. Where do we think, or at least 21 where the panel thinks, the wireless test beds 22 should be and who do they think they might be

1 targeted to, because I see a spectrum of where 2 this kind of tool, and that's what I'm going to 3 call it, a tool, could be used but needs to be 4 tailored to.

5 The ones that Steve talked about that are very expensive to do are very rigorous and 6 7 there are test labs who do those now and FCC has promoted that for many years. How does that make 8 9 it into some of the other issues that we've 10 talked about this morning which really go into 11 interoperability and systems issues in a larger 12 sense?

13Most of what I see personally is14directed towards a particular device. How are we15or what are we talking about in the larger sense,16what kind of tools? I see that as a challenge17and an opportunity for innovation really.

DR. GOLDMAN: Yes, Rick.

MR. TEVIS: One of the issues that I
see as we move forward to test beds, actually
test beds of any sort, is resources. You know,
it's a human resource. It's a financial

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resource.

2 I think Shawn and I are lucky to work 3 for organizations that have the resources to be able to do that, but the small rural hospital or 4 5 smaller hospital can't do that. You know, I have friends at Hopkins 6 7 that do a lot of their work with the applied physics lab. Well, not every hospital has an 8 9 applied physics lab to be able to do that. So, 10 you know, as we develop these test beds, we need 11 to figure out how to get it down to a level where 12 everybody can use it. 13 In our organization, to have a device 14 go on the network, whether it be wireless or 15 hardwired, we have a security review document and 16 it can be anywhere from 12 to 30 pages depending 17 on what it is. 18 And we usually give those to Phil. 19 You know, we send those to the vendors and said, 20 okay, here's what our requirements are. What can 21 you do to this? And so we go back and forth for 22 about two months usually on how that works.

1	So, you know, there needs to be
2	something that, some sort of test bed
3	certification that helps with that process.
4	MS. MCDERMOTT: If I can just jump in
5	there and say I think, you know, I'm in violent
6	agreement with that and that's actually some of
7	what we've talked about here has been a call to
8	action of why we established the Center for
9	Medical Interoperability.
10	So this is a place that is led by the
11	hospital and health system CEOs for the explicit
12	purpose of addressing their shared technical
13	challenges and we are building a physical lab, an
14	actual location, to take these things on and it's
15	all about again, you know, I think our
16	preparation.
17	You know, Shawn made a great point
18	that everything he's put in place to sustain
19	things at Kaiser, it's not feasible, practical
20	and warranted to replicate that in every other
21	system. So what can we do to have more of a
22	centralized, shared resources, again to address

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our shared challenges?

2 DR. GOLDMAN: So we have -- Wow, we're just getting showered with questions now, 3 wonderful. Why don't we start with local and 4 5 then we'll go to Twitter and then email. Great, thank you. 6 MS. MLINARSKY: Fanny Mlinarsky from octoScope. 7 Coexistence has been mentioned a number of times and I was 8 9 wondering whether coexistence, is it accurate to 10 assume these issues come up mostly in unlicensed 11 bands since licensed bands are already regulated 12 well? And if that's the case, how are they 13 tested for today before devices are deployed and 14 how do you deal with them? Thank you. 15 DR. GOLDMAN: Thank you. Volunteers? 16 So we'll all point this way and we'll see what 17 happens. 18 MR. BERGER: Let me say the dominant 19 interest seems to be in the unlicensed bands. 20 I'm not sure there are fewer problems in the 21 licensed bands, but there are more capable 22 network operators who have those licenses in the
spectrum and are incented to run excellent 1 2 networks. It's obviously more diverse than the unlicensed bands. 3 4 One of the things that I see a lot and 5 a great test case is just up the road here at National Airport pretty much morning, noon and 6 evening at each of the major rushes. 7 You can see everyone crowding in and 8 9 something like 75 percent of the traffic on one 10 or two channels of the 25 or 30 WiFi channels 11 available. 12 So group behaviors are real 13 interesting. That kind of thing is worth a lot 14 of study and I would speculate we're seeing the 15 same sort of thing. I know Shawn's smiling so, 16 let you take it. 17 MR. JACKMAN: Yes, coexistence is a 18 good topic and it means a lot of different things 19 to different people. 20 For me, I'm looking, I would agree 21 with Steve, it's an unlicensed spectrum 22 coexistence test. So I'll look at, let's say,

the 2.4 gig ISM band coexistence with ZigBee,
 Bluetooth and which version of Bluetooth, right,
 WiFi, even as we're looking going from, let's
 say, an 802.11, in this case n, to 802.11ac, two
 different, use the same spectrum but different
 protocols.

Really what's the, I'll be looking
more at performance, you know, for that type of a
code system. So maybe I'll look at it for
different purposes. Even 900 meg, there's still
some systems, less and less systems that are
using that space.

So I'll look at, let's say that there's an incumbent system in a facility. In this case there's temperature monitoring at 900 meg. I have to understand and characterize how that system works. It means is it continuously transmitting? Is it spurious?

Depending on how many, let's say,
temperature sensors are out there, how frequently
from a time delay perspective is that system
operating?

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Well, can I put another system in 1 2 There are some legacy phone systems that, there? probably all gone now, but, you know, at 900 3 4 megahertz. Well, how do I then take that 5 spectrum and carve that up? And unfortunately it's different, it may have been configured 6 7 differently for every facility. So we have to 8 look at spectrum awareness. 9 DR. GOLDMAN: Can I ask you to 10 clarify? You mentioned temperature monitoring. 11 MR. JACKMAN: Yes. 12 DR. GOLDMAN: So you're not talking 13 about patient temperature monitoring, right? 14 MR. JACKMAN: No, facility. There's 15 refrigeration units throughout hospitals. Good 16 question. So we have to make sure those 17 refrigeration units are within temperature 18 ranges, and there are some medications in there, 19 if they go outside that range, they'll lose their 20 effectiveness, so we have to constantly make sure 21 that the unit is operated within the right range. 22 So just using that as an example to

talk about, I would argue I'm pretty far down the 1 2 stream, not looking at a device itself and saying how does this device work with this other 3 4 spectrum. 5 Steve, we were talking this morning around, with LTE and how does that impact maybe a 6 7 device that does, that looks, cardiology rate? The way that that pulses if the electrical 8 9 engineering wasn't done right, it could actually 10 pick up something erroneous. 11 I expect the manufacturers to deal 12 with that. So maybe that's the wrong expectation 13 but that's absolutely my expectation, is the 14 manufacturers have to ensure that and they're 15 looking at coexistence with other wireless 16 systems and technology. 17 Look at the old, the "don't use your 18 cell phone here", right, and the signs that were 19 all up, and I had never, I had a Nextel phone 20 with a speaker system on my computer. 21 Every time I got a phone call it would 22 go tsh, tsh. You'd get up close and there's a,

so you think about that and you go there's an 1 2 interaction there, right? That interaction is something I could 3 4 hear. How many times do I not hear it and then 5 it maybe affects the data that comes out of that That was just the feedback for me. 6 system? But so the coexistence topic here of 7 a device may not function right and depending on 8 what kind of device that is I could have a much 9 10 greater level of concern than others in the 11 coexistence topic, so hopefully that answered the 12 question. 13 DR. GOLDMAN: Hence, the focus on risk 14 management. 15 MR. JACKMAN: Indeed. 16 DR. GOLDMAN: So there are, there's 17 another, two other questions here. Very easy 18 question. "Is there a standard, unified 19 definition of a wireless medical test bed and, if 20 not, who is responsible for defining it so that 21 we have a standard working definition?" 22 (Off mic comments)

Excellent question. 1 MR. BERGER: But 2 as I said in the introduction, I think there's a family of problems to be solved. I personally 3 4 don't think there's a single test bed. I think 5 there's a family of test beds to address different parts of the complex issue. 6 7 DR. GOLDMAN: It sounds like we're, maybe the word test bed is part of the challenge 8 9 in terms of we're talking about different 10 functions and capabilities for testing but --11 Let me make a further MR. BERGER: 12 When we started the Dynamic Spectrum comment. 13 Access group in the IEEE, to my surprise the 14 first thing those most insightful said we had to 15 do was come up with a common vocabulary. 16 They said otherwise we'll have no end 17 of discussion to where we're talking past each 18 other using the same words with different 19 definitions. 20 I see that in this topic. We've got 21 too many disciplines. Too many words mean 22 different things in different arenas and those

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arenas are cooperating, and certainly when we 1 2 talk about test beds, we're going to have to invent some new vocabulary and make sure we all 3 4 understand it if we want to save ourselves a lot 5 of time. Phil. 6 DR. GOLDMAN: 7 MR. RAYMOND: I would add to that and I feel obligated to mention WiFi certification. 8 9 You know, we talk about unlicensed and 10 coexistence and interoperability. As chair of 11 the WiFi Alliance health care segment task group, 12 I need to bring that up. 13 And that's a challenge we see, that 14 the enterprise, and specifically health care, 15 doesn't understand the value, but if you want to 16 talk about a test bed, that's really what they're 17 all about, is testing for interoperability on the 18 different capabilities and functions and within 19 802.11 or WiFi and providing certifications and a 20 level of assurance. 21 So to me, that's a beginning or a 22 foundation of moving forward and leveraging and

maybe working with that group and with their experience and their ties to IEEE in terms of building test beds is certainly something to 4 consider moving forward.

5 Great, thank you. DR. GOLDMAN: It has been proposed and there will be, I know later 6 7 today there will be discussions about the need for use cases to clarify some of the things that 8 9 we're talking about.

10 So, Stephen, to get to your point 11 about the need for definitions, for those out 12 there in video land who couldn't see the room, 13 there was violent agreement with a lot of head 14 nodding that an agreement on terminology and 15 definitions is vitally important to ensure that 16 we all work on the same problem in the same way 17 and maybe we'll talk a bit after about those use 18 cases as a next topic after the questions.

19 So we're going to take questions in 20 the room and then we're going to go to an email 21 question.

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DR. BAKER: Mr. Raymond, how are you?

So this is Steve Baker from Welch Allyn. 1 2 MALE PARTICIPANT: Rotate your mic 3 towards you. There you go. 4 DR. BAKER: And I have a leading 5 question for Mr. Raymond. So would you say that WiFi certification guarantees that WiFi devices 6 in a hospital interoperate without issue? 7 8 MR. RAYMOND: No. 9 DR. BAKER: Good. All right, so back 10 to Steve Berger's comment, a layered test 11 approach or family of testing where WiFi 12 certification or Bluetooth SIG certification is a 13 first step and then we move on to more and more 14 complex and more integrated testing. 15 MR. RAYMOND: Yes, complementary 16 testing. 17 MR. BERGER: And I wanted to make a 18 comment. We're in the area of conformity 19 assessment and that's a process that those 20 heavily involved in laboratories understand. 21 But essentially there's a certain 22 performance we want to see in the deployed

environment and we're looking at a number of 1 2 processes hopefully that will deploy that. Let me ask one question and, again, 3 4 I'll go back to the example at National Airport 5 If you go out at the right time of day here. when a lot of planes are coming and leaving and, 6 7 therefore, a lot of people are there and you watch the packet error rate, it'll go up to I've 8 9 seen it as high as over 20 percent of packets not 10 How common is it in our networks that surviving. 11 they warn of problems? Because it's clearly 12 technically possible to do that. 13 MR. RAYMOND: Warning of the problems

14 is very important. I would tell you that, you 15 know, it depends. You know, tying that to use 16 case and to Shawn's comment earlier about 17 telemetry where you're talking about real-time 18 streaming data, 20 percent error rate is pretty 19 much going to be universally unacceptable. So 20 yes, that poses a significant challenge in 21 hospitals, so I'll pass it.

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MR. JACKMAN: Yes, you know, the use

cases are incredibly important and we're going
 to, we need different types of labs to measure
 different types of data.

We may be looking at interoperability between two different systems of, maybe two different protocols of Bluetooth and a WiFi in the same 2.4 channel.

8 We could be dealing with ultra-9 wideband. How is that going to interfere with 5 10 gig? There are many test beds that will be 11 needed to measure different things.

12 And in those test beds, there'll be 13 different requirements. If we're testing an LTE 14 system, you may put that in, you'd have to put 15 that in a Faraday cage, right, unless you want 16 somebody knocking on the door from one of the 17 carriers. Hey, I bought that spectrum. Don't 18 turn that on, yes.

19DR. GOLDMAN: All right, let's go to20a question submitted through Twitter. "Can we21set aside better spectrum for wireless devices22than the current 802.11 ranges which used to be

called junk spectrum?" I'm just reading. 1 I'm 2 just reading. "Can we set aside better spectrum for wireless devices other than the 802.11?" 3 4 MR. JACKMAN: Spectrum management, 5 that's a topic that I know is in this room. We've had many conversations around this. 6 I've made pretty darn good use of what some people 7 would refer to that as junk spectrum. 8 9 Worked really hard to clean it up and 10 you have to get rid of devices. You have to 11 sunset some systems. It takes time to do that. 12 There's obviously cost involved in it. 13 Even the 2.4 gig ISM band which 14 largely most people say, oh, why are you using 15 that? Well, look at what I'm getting out of it. 16 And sometimes you get a device, I can't control 17 whether this does 2.4 or does 5 gig or not. 18 Sometimes it's like, Shawn, the device 19 I'm too far downstream. is made. You know, I 20 wasn't in the requirements process when they were 21 developing the product. 22 So I have to make use of that spectrum but spectrum management as a whole is incumbent
 on anybody operating a wireless network and
 supporting that.

DR. GOLDMAN: Don and Kerry and Phil, whoever wants to jump in first. I saw you each have comments.

7 MR. WITTERS: Go ahead, Kerry. Thanks. 8 MS. MCDERMOTT: No, actually 9 I had sort of almost a follow-on question for you 10 related to that if I may, and that is as we think 11 about not just how you're managing the spectrum 12 but there are a lot of new technology options to 13 look at how you manage what's inside your walls 14 so, for example, the use of small cells for 15 health care, you know, and is that something that 16 you've been able to take a look at or is that 17 something where we would actually need a test bed 18 to help us sort out first? You had a comment. 19 MR. JACKMAN: Well, you've actually

20 touched on a topic that, one that, gosh it almost 21 seems like it was staged, right, because it --22 MS. MCDERMOTT: I swear that wasn't.

1 MR. JACKMAN: Yes. I'm heavily 2 involved in small cell. Small cell is, from my definition, is a replacement technology to a 3 4 traditional distributed antenna system commonly 5 referred to as DAS. So for, let's say, the big wireless 6 carriers to plug into an antenna system in a 7 building, it's a pretty, I would argue, archaic 8 9 way of retransmitting those signals. 10 The technology is changing to where, 11 like WiFi access points, where you put up a 12 single radio and it's got a network connection in 13 the back so fully instrumented radio head. 14 That's how the indoor cellular market is moving 15 and so now, so that's a different spectrum and so 16 I have to put a separate overlay network for 17 that. 18 And there could actually be more than 19 one carrier supported on one small cell. I have 20 seen every equipment vendor that's making product 21 in that space, there is absolutely no consistency 22 to how they're developing their products. Some

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of them, you know, will single radio, totally, 1 2 totally different designs. There's not only wireless components 3 4 to that, there's also wired components. How do 5 we share maybe the same Ethernet backbone, right? And that's a test and something that actually we 6 just did. 7 We're part of a FOA for one of the big 8 9 carriers for indoor small cell now and we just 10 actually went through all of this testing, 11 transmit power levels, how it may affect 12 different devices, coexistence. 13 So it's a big, resounding yes and 14 that's just one. We just picked up, there's a 15 whole list of other technologies that also we're 16 looking at trying to --17 DR. GOLDMAN: Don and then Phil. 18 MR. WITTERS: Well, I just wanted to 19 remind the panel and the audience that what we're 20 talking about is an industrial, scientific and 21 medical band that's been set aside both 22 nationally and internationally and it's been

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utilized widely in other industries.

calling it, Julian, but there are other
frequencies that have secondary use for medical
devices and only one that's really primary, the
wireless medical telemetries service down at,
well, it starts at 608 to 614 then goes up to
1,300/1,400. There's the medical implant
communication service under, that's now under
MedRadio at 402 to 406.
But you have to back away from this
and think about what we're dealing with. Most of
the systems now are not only utilizing one form
of wireless but they have two, three, sometimes
four.
Part of that is getting from a sensor
on the body perhaps out to something like a
platform that's like a cellular phone and then
wirelessly out on a cellular network.
Some are utilizing two or three
technologies that are doing different functions
at the same time or in a sequence of things that

are dealing with these wireless issues as well. 1 2 And one other point, if we come back 3 to what we think coexistence is, coexistence and 4 electromagnetic compatibility have overlap but 5 they're not the same. When you talked about your noise on 6 7 your speaker, that's electromagnetic interference. Coexistence can be much more 8 9 complex, especially if you're dealing with 10 technologies operating in the same frequency 11 band. 12 And some of the wireless, popular 13 wireless operate in the same frequency band under 14 completely different rules, completely different 15 allocations of channels. 16 Some have ways they can deal with 17 somebody who's on a channel very quickly. Others 18 are not so resilient in that respect but are 19 still dynamic. 20 Some of the newer issues that FCC has 21 been inquiring and issuing some rules about 22 include listen before talk so that you are able

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to get a clear spectrum when you, at least at 1 2 that point in time but you may have to wait for at some point in time. 3 There's lots of issues here. 4 It's not 5 a ubiquitous, unique type of environment. It's very dynamic, very different and we need to 6 7 understand that. When I see perhaps submissions from 8 9 medical device manufacturers that have utilized 10 for whatever reason or function, sometimes 11 they're not clearly aware, and that's one of the 12 reasons that the guidance was developed, what 13 these issues are and how you need to address 14 them. 15 If you have a wireless function in a 16 device, there's a standard electromagnetic 17 compatibility test that's been, oh, 20/30 years 18 evolved. 19 But if you don't have the wireless 20 technology performing its function while you're 21 doing that test, then you've missed perhaps a 22 piece of that that you need to include.

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1	That's not the same as doing a
2	coexistence test where you're now putting it into
3	an environment where you do have these other
4	interferes operating perhaps on the same
5	frequency range that you're operating on.
6	And I did think just one example
7	real quick of the remote control. Wireless foot
8	switches are used in controlling various things,
9	dental apparatus, surgical tables, things
10	typically that are in front of the person and not
11	usually at great distances but those can be
12	utilized. They are in medical devices these
13	days.
14	DR. GOLDMAN: And OR tables height and
15	tilt and
16	MR. WITTERS: Exactly, exactly.
17	DR. GOLDMAN: A few months ago in our
18	lab we worked on remote control of ventilators
19	and infusion pumps to work on a research response
20	to Ebola so that with remote control they could
21	avoid entering the patient's room to adjust the
22	infusion rate or to adjust ventilator settings.

1	You know, it's too early for a
2	clinical deployment. We're still trying to
3	understand the risk management of remote control
4	for safety-critical devices like that.
5	But one of the questions that came up
6	obviously is how would we evaluate that type of
7	system to ensure that it would be safe prior to
8	deployment and during deployment?
9	So I think of that in the scope of the
10	innovation aspect. It's not only innovation
11	around the radios and innovation around the
12	communication aspects but innovating clinical
13	care pathways to meet modern challenges. How do
14	we ensure that we can deploy those safely?
15	So, Phil, you're in the queue to
16	respond and then we have a question within the
17	audience here and then we have one by email.
18	MR. RAYMOND: Yes, and I'll just kind
19	of summarize. Don gave some great examples and I
20	say this not because I'm sitting in the FCC
21	building but I think there's, you know, good
22	precedence and good best practices around freeing

up spectrum and band being another one. 1 2 And as a subject matter expert, one of the things we talk about in terms of best 3 4 practices, absolutely use the spectrum available 5 to you. Don't put, you know, talk about risk management, don't put everything in 2.4 6 7 gigahertz. 8 DR. GOLDMAN: Thank you. 9 MR. RAYMOND: So, you know, 10 unlicensed, licensed, protected spectrum, taking 11 advantage of all of that is risk control measures 12 or risk mitigation. 13 So to answer the original Twitter 14 question, absolutely, and I think the FCC has 15 shown continued due diligence around making 16 spectrum available, both unlicensed, protected 17 and whatnot. 18 DR. GOLDMAN: Thank you. There was 19 someone standing at the mic before who sat down. 20 Please. 21 MR. HOGLUND: Dave Hoglund. Address 22 both Phil and Shawn. I've seen in my experience,

affects you, Shawn, as the device companies 1 2 assume, this more is about wireless LAN, they assume that all the wireless LAN development that 3 4 they're doing on the embedded adapters, it's all 5 the same. And I think there's a real precedent 6 7 that they have to test, validate and verify beyond WiFi certification such as roaming 8 9 algorithms, such as passing all the security 10 supplicants. 11 And then conversely, on the hospital side before they go to deploy, I think there's a 12 13 need for doing ecosystem testing to scale the 14 architecture and number of devices, both voice, 15 video, real-time monitoring infusion pumps. 16 Doing that conversely will allow the systems as a 17 whole to work better. 18 MR. RAYMOND: I would just say in 19 agreement. 20 MR. JACKMAN: Yes, violent agreement. 21 The WiFi certification from the WiFi Alliance is 22 pretty paper thin, and from my perspective, I

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have not seen any real evidence that they're 1 2 addressing the roaming and security issues. And those are the two biggest issues I run into with 3 4 every new device that comes in. 5 Just by the way, if you have a different radio there versus the one that you 6 7 connected here and as you walk away your signal gets weaker and you have to roam at the right 8 9 time, that's a client decision for WiFi. I can't 10 That's a client decision. fix that. That's the 11 way the protocol is written. 12 Cellular networks are different so now 13 I have to test that device to make sure it does 14 it and it has to do it in a secure way using 15 802.1X and, you know, WPA2. 16 Well, which security protocols does it 17 do? Did it actually implement them right? I see 18 system after system where they don't implement it 19 right. 20 And we have to go back to the manufacturer to say so, you know, we found 21 22 something. How can we help you resolve this

because we're not putting it in, right, until
 these issues do get resolved.

MR. CONLEY: Yes, this is to Shawn.
WiFi test, you know, just the device primarily,
WiFi certification and fail, I spent three years
running engineering at WiFi Alliance so I know
how these systems are put together.

8 But I will tell you wireless broadband 9 is getting ready to do interoperability testing. 10 They haven't typically done that and they'll do 11 their roaming test. So the whole ecosystem is 12 starting to embrace interoperability.

DR. GOLDMAN: So, Mick, while you're at the mic, and we'll also have the team answer this, one of the questions that came in by email is, "Someone mentioned about the test bed certification program. Is this something already in the market or is it going to happen in the future?"

20 You just alluded to what's happening 21 in the industry and I saw a few folks ready to 22 comment on the mic. So maybe responding to

Mick's comments as well as to the email, does anyone want to take that?

MR. JACKMAN: I'd like to know the 3 4 details of the test, right? It goes back to what 5 we talked about earlier. I would say, initially at least, I could be wrong, but my perception was 6 the WiFi Alliance, well, we have a test program. 7 What are you testing? Can you give me the test 8 9 Well, no. You have to be a member to get plan? 10 that. 11 Okay, so you're telling me the thing 12 is certified and all I know is I'm having 13 problems with it when I try to hook it up. So, 14 wait, what are you testing again? 15 So I'd love to know the detail and if 16 that work is being done, is it a bunch of 17 manufacturers and chipset vendors coming together 18 or you have some real, you know, end users, 19 people operating real networks with real 20 problems? Are we informing those test cases? 21 I'd love to help contribute to that. 22 MR. CONLEY: Yes, and I'll comment on

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1 the next panel. I'm on the next panel so I'm 2 going to give it a little stick around for that 3 one.

DR. GOLDMAN: All right. Well, I think the break is probably after that, Mick, so you're probably safe but I'm not sure actually. Don, you have a comment.

8 MR. WITTERS: Well, I just wanted to 9 make sure that we got in at least the piece of 10 information that this is not new. This has been 11 evolving over many years.

12 Several standards groups, like the 13 International Standards Organization, has a 14 document for essentially risk management across a 15 system, the 80001, which does have a specific 16 document that one of the next panelists, Rick 17 Hampton, helped write on wireless technology. 18 That wasn't the first and I'm hoping that won't 19 be the last document in this area.

There are several documents that have been evolving over many years and there's a wealth of information that could be and should be

looked at in the area of wireless medical 1 2 devices, systems, health care. There's a lot of people who put a lot 3 of time and effort into these documents and I 4 5 would encourage anybody here, anybody in the audience, anybody listening to find out about 6 7 these. And, in fact, if you really want to 8 9 help make the change, participate in them. 10 That's where we get the changes. That's where we 11 need to hear the new voices, the new 12 understanding. 13 Several organizations have stepped forward and have been formulated in the last few 14 15 years, Kerry's organization and a few others that 16 are related to that. 17 Some of the manufacturers that have 18 seen this and the need for it and have made tremendous strides in putting together 19 20 organizations that do, in fact some of them have their own certifications and several of these are 21 22 really making strides to help understand this, to

help formulate those basic definitions that Steve 1 2 was mentioning and formulate some basic frameworks by which this can move forward. 3 4 DR. GOLDMAN: Thank you, Don. Steve 5 is going to make some comments and wrap up and then I'll conclude and that'll be the end of the 6 7 session and, yes, there is a break between 8 sessions by the way. Okay. 9 MR. BERGER: Very good. Well, 10 excellent discussion, very, very interesting. 11 Let me just throw out a few things that stuck in 12 my mind. 13 It seems to me one is that there's not 14 a single problem but a family of problems to be 15 addressed and the issues are multidisciplinary 16 and interrelated in complex ways. We've got some 17 ontological systems to be understood if we're 18 going to solve these problems. 19 I think it's clear that wireless is 20 not just adding a new function but it's extending 21 systems, certainly geographically. We've heard 22 it talking about health care moving more into the

home, but in other ways as well and creating new 1 2 relationships between disciplines that perhaps didn't relate so much in the past. 3 4 And finally, as Don said, we have 5 international conformity assessment processes. The challenge is how to apply that most 6 appropriately to a distributed health care 7 delivery system. 8 9 DR. GOLDMAN: Thank you, Steve. First 10 of all, thank you to all the panelists and to the 11 audience and all those out in video land that 12 submitted their questions. It's good to get. 13 Without that, we can tend to get stuck in our own 14 thinking so it's important to be challenged. 15 And I think that the award for the 16 best phrase of the morning goes to the challenge 17 of managing systems is like continuously painting 18 the bridge so that's, I think, I got some 19 messages about that and it's painful, isn't it, 20 but that is the nature of life. 21 Also another key message this morning 22 is the notion that the test bed is a tool or

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maybe a family of tools for risk management and I think Don emphasized that point, as did everyone else.

We also should keep in mind that this 4 5 is an activity that is intended to facilitate innovation in health care. So it's not just 6 7 about solving yesterday's problems. Test beds have to be something that help us pave the way 8 9 for the future for greater adoption of wireless 10 to facilitate clinical work flow and equipment 11 management and all that's needed both in the home 12 and in the hospital.

13 And finally it was mentioned, but not 14 often enough, that in the end we have to think 15 about patient safety. Ultimately we're trying to 16 deliver health care wherever we're trying to 17 deliver that or empower people to take care of 18 their own health if we're not delivering it 19 through a health care delivery organization and 20 so ultimately it's the safety of the people in the process that matters most. 21

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So I think that's a wrap. Thank you.

1	There's a break now with FCC, what did you,
2	think snacks, doughnuts, none of the above?
3	MS. ONYEIJE: Thank you so much. We
4	really appreciate this one.
5	(Applause)
6	MS. ONYEIJE: So we are going to take
7	a short break. I'm going to try to make up time
8	like a pilot who was dealing with headwinds and
9	let's come back right at 11:00 if we can.
10	The programs are available at
11	registration so if you can pick one up on your
12	way out and we'll see you back in about 12
13	minutes. Thank you.
14	(Whereupon, the above-entitled matter
15	went off the record at 10:49 a.m. and resumed at
16	11:01 a.m.)
17	MS. ONYEIJE: So we're going to ask
18	the moderators and discussants for Session Two to
19	take their places.
20	Thanks so much everyone. If you can
21	take your seats. After this session there will
22	actually be a 1-hour break so you'll have an

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opportunity to continue chatting.

2 I just want to be respectful of these folks and give them their full time. So we are 3 going to be transitioning now into a discussion 4 5 that we've labeled Overview of Current Public and Private Wireless Medical Device Test Bed Programs 6 7 and Initiatives. The workshop builds on itself, you 8 9 The first session we talked a bit about know. 10 what in an ideal world we would have available. 11 This session is designed to figure out against 12 that yard stick where we are. 13 And I am going to just invite our moderators to sort of take the lead. We have two 14 15 illustrious moderators to lead this discussion. 16 Dr. Wendy Nilson is bi-agency, I 17 guess, as she is the Health Science Administrator 18 at the National Institutes of Health as well as the Program Director at the National Science 19 20 Foundation. Welcome, Wendy. 21 And then Seth Seidman is her co-22 Seth is the Senior Electrical moderator.

Engineer at the Center for Devices and 1 2 Radiological Health at the FDA. So the time is yours, Wendy and Seth. 3 4 Thank you. 5 Okay, that's on. MR. SEIDMAN: **All** right, well, yes, thank you. For those that a 6 chance to review the agenda over the break you 7 probably saw each session had sort of a list of 8 9 questions to answer and one of the ones from the 10 previous session was are test beds needed? 11 Many people probably assume this was 12 a rhetorical question, considering we have an 13 entire workshop dedicated to it. I can assure 14 you it is not a rhetorical question. Why? 15 Well, first, it was one of my 16 questions. Second, because all too often I 17 review wireless medical devices that don't 18 address the risks that are associated with 19 wireless technology, and this is a shameless plug 20 here. You can find those risks in the RF 21 22 Wireless Technology and Medical Device Guidance

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Document that FDA published.

2	So I think we heard also that test
3	beds are a tool last session and there are one
4	way to address some of these risks, and as they
5	discussed the question, were test beds needed, I
6	heard a couple of really good ideas of what they
7	could be used for and what tools that they could
8	be used for.
9	Mainly I think we heard coexistence
10	was one of them. We heard also interoperability,
11	and I think we also touched on security, amongst
12	some other things.
13	Of course, had I just answered no to
14	this question we could all be headed to one
15	seriously early happy hour, so, you know, you
16	know who to thank for that.
17	In all seriousness I wanted to get to
18	some of the test bed programs that we have here.
19	I think before sort of that definition that it's
20	a tool for risk management, I wasn't sure if we
21	really had test bed programs here, but I think we
22	do now, so I think that's really good.

I think I'd like to start by 1 2 introducing Dr. Hazem Refai. Dr. Hazem Refai is the Williams Professor for Telecommunications and 3 Networking at the OU School of Electrical and 4 5 Computer Engineering Telecommunications Program in Tulsa, Oklahoma. 6 He is the founder and director of the 7 Wireless Electromagnetic Compliance and Design 8 9 Center at OU Tulsa, better known as WECAD. 10 WECAD's mission is to conduct basic and applied 11 research examining medical device coexistence 12 with various RF wireless systems and 13 technologies, as well as validating electronic 14 and electronic compatibility. 15 He has published more than 160 16 referred papers for national and international 17 conferences and journal articles. His field of 18 interest includes the development of physical and 19 medium access control areas to enhance wireless 20 coexistence, the characterization of hospital RF 21 equipment for medical electronics, and cognitive 22 radios and networks.

1 He is a past IEEE ComSoc Tulsa Chapter 2 President and served as the organizations North American distinguished lecturer tour coordinator. 3 He has developed a test bed there at Oklahoma 4 5 that addresses one of these tools, which is, or issues, which is wireless coexistence and so I 6 7 was hoping he could give a brief overview of the 8 program there.

9 DR. REFAI: Thanks, Seth. I had a 10 slide, but that's okay, we don't need it. The 11 question we looked at when we started looking at 12 a coexistence, a wireless coexistence, so you 13 have a medical device company that comes in that 14 is not really interested in wireless that used to 15 perform a medical therapy and then you have 16 wireless standards that come in that says okay, 17 we have radios that operate in the wireless and 18 then the medical device companies started looking 19 into integrating wireless interfaces into their 20 devices.

So it's not their, you know, design.
They took a wireless interface and integrated it
1	into a medical device. When they took this
2	wireless interface and integrated those usually,
3	the wireless interfaces are designed according to
4	a standard.
5	Now if you look at 802.11(b), (g), and
6	(a), , and all the standards, they are not
7	exactly a specific design. They don't lead to a
8	specific design. They allow you to design, but
9	there is some sort of a flexibility in there.
10	So this is one degree of challenge
11	that is a specific, you know, more or less
12	designed specific to a vendor in lieu of a
13	standard.
14	So the standard would pass and I have
15	my device, can conform to the standard, and I
16	have it, but there are variations of these
17	devices that exist out there.
18	So now you have a wireless interface
19	that has a physical layer, the hardware, the
20	components, on the top of it is software layers,
21	you know, the medium access control, the IP, and
22	so on.

You take those two and you take the 1 2 medical device and interface it, so now you have a complex system, it came to be a medical device 3 plus a wireless interface. 4 Then when the interface is interfaced 5 with a medical device the medical device usually 6 7 go and implement some software on the top of the software that comes onto the interface and with 8 9 that they introduce other things into the 10 picture, you know. 11 Not necessarily to improve the 12 coexistence of the device itself, just more or 13 less to make it operate more, save energy, and do 14 certain things. 15 Now with that integration, and so you 16 have an integration process, then you have a 17 modification process, and then you have a 18 standard that's really offering that and as a 19 result it becomes more of a medical device with 20 an interface, wireless interface. 21 So the complexity of now, looking at 22 it from how would this device coexist with other,

it elevated from being a medical device to an
 interface according to standard, through
 modification to the software, and now we are
 putting a device that it says is it coexisting
 with others.

So when we looked at it, it became 6 7 more of a hardware problem and a software problem that it's a very complex, especially if you don't 8 9 know what exactly the modification of the 10 software that happened, to veer a little bit from 11 the standard, and we said okay, how would you now 12 look at this device and try to allow it to 13 coexist with other devices.

14 So we took that as a system and we 15 said okay, if we project this system how is it 16 going to behave in the frequency domain, the 17 spectrum? So can I describe the behavior of that 18 device in a frequency domain?

How is it going to perform in an environment, in a space, that's another element of it. So you have a frequency, you have a space, you have an environment.

How is it going to do with the power domain, which is power related to space a little bit, but it has its own issues, too, and then finally, if I have, if I were to ask, you know, to coexist with 2.4, then I might be co-channeled with other devices that are going to use the same channel.

How am I going to coexist now, so you 8 9 have a time domain element to. So we took a very 10 complex system and we tried to project it into 11 four domains, maybe if you look into orientation 12 or antenna designs and stuff like that you can 13 add one more domain to it, which is, you know, 14 the major loop in the antenna design, or minimal 15 when it comes out with the medical devices.

So you looked at that and now we start looking at saying okay, this is a complex system, if I go unprojected into these I might be able to go and test for coexistence and able to quantify issues that come back to coexistence in lieu of looking at it as a system with all these multiple layers of hardware and software on the top of it

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that is being implemented.

2	And this is how really we looked at,
3	is how to do we set up a lab that is going to be
4	capable of first characterizing the behavior in
5	these domains and then plus integrating it in an
6	environment that could be a test bed environment
7	to validate that it's going to coexist with
8	others or not.
9	DR. NILSEN: Great. And we're going
10	to move on and talk about some more test beds,
11	and next will be Mick Conley. He's the
12	Development Manager Industry Programs for
13	Underwriter's Laboratory, and he gave you a
14	little sneak before.
15	Mick Conley is an industry expert on
16	certification in interoperability testing
17	programs for wireless technologies and he is a
18	member, leader of many of the many groups,
19	including the WiFi Alliance led group, NFC Farm,
20	and many, many others. So, thanks. Mick.
21	MR. CONLEY: Thanks, Wendy. You know,
22	we had quite a bit of discussion in the previous

panel on test beds and as we've just heard, you 1 2 know, we have, you know, isolated test beds that are being created doing real good work in their 3 4 own entity, but I think the industry needs a 5 common place to go. WiFi Alliance was used in an example, 6 7 and I got up and was kind of ribbing Shawn a little bit there, but the reality is WiFi went 8 9 through 15 years of determining how to prescribe 10 a recipe for a test bed that would handle 11 critical mission, everyday functionality, and so 12 critical mission with security and performance in 13 different qualities of service. 14 have the same thing in the medical We 15 industry and we have a lot of, you know, very 16 bright test beds in individual areas that are 17 costing individuals a lot of money. 18 I think there needs to be a key 19 sponsor, possibly FDA getting a collection of 20 member, consensus-driven people that start 21 prescribing used cases, Phil mentioned gaps in

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one of his first talks on the last panel.

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Gaps

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to me are defining used cases.

2 You know, as we just heard you can have a system developed to complete compliance of 3 to the specification, but I can develop one, you 4 5 can develop one, they may not operate because I have optional features, I have different timing, 6 7 but I am completely within spec. So we have to have, I think, 8 9 interoperability and I hope coming out of this 10 workshop that there is some momentum by the 11 centers of influence that have the ability to 12 drive something here to put an industry program 13 together that has the respect of the using 14 community and of the manufacturing community for 15 medical equipment, because I think there is huge 16 savings and I think there's certainly a safety 17 component to it. So, thank you. Thanks. 18 MR. SEIDMAN: And then I 19 think the last test bed program, or he'll correct 20 me and say test bed method, is from Dr. William 21 Young. 22 Dr. William Young's 15 years of

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experience in wireless communication systems 1 2 includes diversity antenna design, R propagation measurements, MIMO system applications, 3 electromagnetic interference testing in wireless 4 5 network security analysis. He has developed RF laboratory 6 7 measurement techniques adopted in the 2013 revision of the National Fire Protection 8 9 Association Standard. 10 He is currently involved with the ANSI 11 C63.27 project, which is focused on wireless 12 coexistence test methodologies. Dr. Young holds 13 an M.S. from Washington State University and a 14 Ph.D. from the University of Colorado, both in 15 electrical engineering. 16 From 1998 to 2010 he was with Sandia 17 National Laboratories and joined the NIST 18 technical staff in 2010. He has authored over 35 19 technical reports, conference papers, and journal 20 articles covering aspects of wireless systems, 21 electromagnetic propagation, and MIMO technology. 22 His recent efforts are focused on

spectrum sharing in the NIST communications 1 2 laboratory. So, Bill, if you can sort of explain the methods that you guys are doing over at NIST. 3 4 DR. YOUNG: Okay, thanks. I think 5 the, you know, the speaker before just mentioned a recipe, and we view that as a method. I mean 6 7 it's just a different term, but it's the same idea. 8 9 What's the process you go through to 10 test, and from in this perspective is, is that 11 test repeatable? What are the metrics that you 12 are interested in capturing? How do those 13 metrics relate to actual performance in the 14 field? 15 These are all questions that we look 16 into. The notion of a test bed is a good notion, 17 but I would say that it's more about the testing 18 method. 19 The test bed is put together to 20 support the method, so you need to know what 21 questions you are trying to answer and the 22 approach that you're going to take to answer them

before you go ahead and construct a test bed. 1 2 A singular location to say that this is where we bring the devices and we test them, 3 4 yes, that's where you may want to get to in the 5 end, but the first steps have to be taken in identifying what are the questions you are trying 6 7 to answer and what are the metrics that you're going to use to evaluate the products, and then 8 9 what is the repeatability of that testing. 10 These are all things that we have dealt with. As was mentioned we have developed 11 12 standards for the National Fire Protection 13 Association in interference-type testing, which 14 very closely related to this, they are also using 15 the ISM bands. 16 The interesting thing here, it's been

brought up numerous times, that these protocols
that are being used are not, while they may seem
to be standard there are slight differences.

20 Well I can assure you in emergency 21 response they are radically different. The wave 22 forms don't look like WiFi signals, they don't

look like Bluetooth signals, they look like something. FCC legal, but a very different wave form.

So while it may be nice to assume that it's predominantly WiFi signals or Bluetooth signals that you are dealing with, there are other signals out there in that band that need to be taken into consideration.

9 DR. NILSEN: Thank you. So we've 10 talked, we've had our test bed people talking, 11 now we'd like to have some of our other experts 12 talk who are using this, and I'd like to 13 introduce Greg Bowden.

He's the Senior Reliability Engineer
at Medtronic, and Greg Bowden has been employed
in the medical device industry for 20 years and
is currently a Senior Reliability Engineer at
Medtronic's Diabetes in Northridge, California.

His primary duties includes planning
and executing product validation and verification
testing, root cause analysis, and corrective
action implementation, cross functional team

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1 member for risk management and EMC testing. 2 Greg. 3 MR. BOWDEN: Thank you. So in the 4 world of test beds I'm the guy hunkered down in 5 the lab doing the grunt work. So, yes, I care about predictive 6 assessment based on these test results and a 7 unified methodology for running the test, so 8 9 that's my first thing. So there were a couple 10 good points brought up during the first 11 presentation about that. 12 Some excellent points about the 13 changing landscape of a technology as you are 14 trying to develop a medical device on a platform 15 on which you're going to have to hang your hat 16 for many years and your product life cycle and 17 being able to provide the proper methodologies 18 that are going to sustain that product over the 19 life cycle. 20 There was some good assertment about 21 risk management. ISO 14971, it's going to 22 require that you, on the minimum at a yearly

basis, assess your risk management process and
 take a look at your devices.

3 So as this feedback comes in you're 4 going to have to formulate new strategies to 5 address these issues. So Don made a good point 6 about having your platform and your life cycle be 7 able to withstand that breadth of time.

8 You know, that's a long time. You're 9 not going to change like Apple changes iPhones. 10 You design a medical product you're going to have 11 to sit on that for a while.

You're not going to make some change, everything you do is going to require a submission. Everything you do is going to require a test. Everything you do is going to require you to go back and start over again.

17 So when you have that unified 18 methodology that will be these test beds we're 19 going to have to sit on that for a while and 20 we're going to have to have many test beds to 21 address many of the implementations and 22 situations for our medical devices.

For me, not all of my devices I work 1 2 with tap into a larger infrastructure, so I'm not talking for my devices WiFi radios. 3 You know, 4 I'm talking Bluetooth, I'm talking some of the 5 900 MHZ that was brought up, even I work with some seriously legacy devices that operate in the 6 7 400 MHZ region. So, yes, there's probably, if I get a 8 9 half dozen test beds just out of that alone, and 10 I'm also talking about ad hoc connectivity. So 11 not all of these devices, particularly medical 12 devices, tap into that larger wireless 13 infrastructure. 14 So these are ad hoc connections that 15 provide intermittent packet transmission of 16 information and everything that goes with that in 17 terms of the interference. 18 So, yes, to Steve's point in the 19 previous presentation, that's a lot. That's a 20 I am hoping that we can go into a deep dive lot. 21 and discuss some of those details as we progress 22 through the day.

1	There's a lot of firepower in the
2	room, so, you know, let's hit the ground running.
3	MR. SEIDMAN: Greg, you mentioned, you
4	know, many different test beds and my thought was
5	that each test bed would be addressing a
6	different problem, you might be addressing
7	coexistence in one test bed, you might be
8	addressing interoperability in another test bed,
9	or security or something.
10	But you also brought up an interesting
11	point that maybe even in the layer of coexistence
12	you might have a different test bed for each
13	different frequency you're looking at.
14	MR. BOWDEN: Yes.
15	MR. SEIDMAN: Can you explain some of
16	the current test beds or, you know, procedures
17	that you are using right now and explain what
18	those look like?
19	MR. BOWDEN: A lot of what prompted
20	the testing we're doing now is implementations of
21	radios that operate in the 24 GHz ISM band. You
22	know, that's the fast lane in the 21st Century

right now and where we started was basically 1 2 getting everything we can get that operates in that band and provide a characterization of the 3 exclusion band. 4 When you look at, shameless plug for 5 you, the FDA RF Guidance Document one of the, 6 7 what really prompted that was that, you know, you want to close the gap presented by the exclusion 8 9 band, get out of jail free card for your 10 consensus standard testing. 11 And what we're really doing is

12 characterizing the exclusion band. We want to 13 know what the devices are doing in the exclusion 14 band against competing wireless technologies, and 15 so that's what we're providing there.

16 So if I am doing a ZigBee radio, I 17 want throw other ZigBee at it, I want to throw 18 WiFi at it, every flavor of WiFi I can get my 19 hands on, and every flavor of Bluetooth I can get 20 my hands on at every bandwidth I can dial up, at 21 every power level I am capable of throwing at it. 22 MR. SEIDMAN: Okay, great. And sort

of the same question to Michelle, too. Michelle 1 2 Jump has worked in various aspects of the regulatory industry for over 15 years. 3 She holds a Master of Science in 4 5 Regulatory Science from the University of Southern California and a Master of Science in 6 7 Biotechnology from California State University. She is also RAC certified. 8 Her 9 current role is in regulatory affairs at Stryker 10 Corporation specializing in software and 11 connected devices. 12 She participates in a variety of 13 standards development work, including such topics 14 as interoperability, software, wireless, cyber 15 security, and software quality. 16 As a member of the AAMI Software 17 Working Group 6 she has been actively involved in 18 the development of a new technical information 19 report on wireless coexistence. 20 At Stryker she chairs corporate 21 working groups in both interoperability and software as well as consults with teams on a 22

regulatory strategy for software and emerging technology.

So thanks for joining us and I'm 3 4 wondering a similar question, you know, what test 5 beds or procedures are you currently using right now to address some of these issues? 6 7 MS. JUMP: Thanks, Seth. So as you had just heard I do not share the same level of 8 9 technical background as some of my friends here, 10 but I do have perhaps a wider view dealing with 11 many different divisions at Stryker. 12 And what I would say is that one of 13 the advantages is that with the larger 14 corporations where the products are built on a 15 framework requiring wireless those divisions are 16 able to create their own mini wireless test bed 17 that has your basic products that are based on 18 the intended use, the intended use environment, 19 and the risk assessment of that product so that 20 the design engineers can start to test that 21 product within their environment right there in 22 house so that you get that immediate feedback.

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But when you are starting to look at 1 2 more complex systems and also a variety of different compositions you might see in a 3 4 hospital then we're starting to look outside for 5 third-party testing, test beds I guess you'd say. But for certification processes in 6 7 those because the complexity is just too great and that's one of the things that's I think a big 8 9 challenge for every company is the complexity and 10 the different devices that you could meet out 11 there in any single customer's hospital 12 environment is a challenge to try to anticipate 13 the best way to create a representative test 14 environment. 15 That's why I am very interested to see 16 where this conversation goes, because I think 17 there's a lot of interest on the manufacturer's 18 side to say, you know, what is a nice set of 19 representative environments depending on the use 20 environment of your device, the intended use of 21 your device. 22 I think the other thing is that for

larger companies I think it's easier to set up these mini test environments, but for smaller companies, and I think it's a lot harder to add wireless to those products, so when we think about, we've talked about innovation today a little bit today.

7 One thing I would like to add to the 8 conversation here is efficiency. Because when 9 you think about wireless there is a lot of 10 potential for adding efficiency to devices that 11 don't necessarily have to communicate wireless, 12 but if they were able to do so it would be 13 beneficial.

14 And if you are looking at corporations 15 that may not need to use wireless for their own 16 use I think that there is the potential of being 17 able to leverage these test beds to encourage 18 companies to add wireless functionality to their 19 devices to increase the efficiency of the 20 hospital process and collecting that data that 21 they may not otherwise want to invest in 22 something like their own customized test bed if

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that product's functionality base does not
 require it.

3 So that's one other thing that I 4 thought was an advantage of looking at the idea 5 of a test bed would be the efficiency for 6 companies that maybe don't want to invest in that 7 much infrastructure but could definitely increase 8 the efficiency of a hospital.

9 MR. SEIDMAN: Okay. I would also be 10 interested in making Bill's thoughts and others, 11 you know, of Greg's earlier comments that there 12 will probably be a, you know, there's not going 13 to be a one-size solution for test beds.

14 There's not going to be one test bed 15 to solve all these problems. So I'm curious to 16 your thoughts on what you see in the future, or 17 how you see a test bed and how that will be 18 addressed.

DR. YOUNG: Well I think that, all right so you think of a test bed as a static entity that's not going to work well here. A test bed, any type of test bed, will actually

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have to support all that type of testing. 1 2 So I would argue that in a rigorous test bed you would have the ability to perform a 3 4 range of tests and, obviously, as Michelle just 5 pointed out that can be very expensive for the small operators and the large operators maybe can 6 7 afford it but even for them it's a significant 8 cost. 9 So if we're going to go down the test 10 bed path I think it's that if we can develop a 11 test bed with the flexibility to perform a range 12 of tests and as long as we know what those tests 13 are and what's required of them I think you can 14 construct a test bed that will actually support 15 that. 16 MR. CONLEY: Yes, let me walk through 17 the one test bed example that I liked is WiFi, 18 not necessarily because I'm overly bias because 19 I've been there, but they came about putting the 20 test bed, and much to what Bill was talking 21 about, you have different needs for test beds, 22 different functionalities.

So what the WiFi Alliance has done is 1 2 they make sure that they have a minimum of three unique silicon vendors in there and so you think 3 4 you cover 80 or 90 percent of the marketplace 5 with them. You have some X number of a certain 6 class of a device against a Y number of another 7 class of device, depending on what program you're 8 9 testing for, whether it's security, whether it's 10 video, whether it's, you know, there's going to 11 be automotive. 12 You know, they have a number of 13 programs and I think that is a model that should 14 be looked at in any new test bed that's being 15 created. 16 How do you cover the marketplace with, 17 you know, the people who have a vested interest 18 to sell into that marketplace, and it usually 19 starts at the silicon now. 20 I know in the last panel, you know, 21 Shawn mentioned you don't know what they're 22 testing for unless you have a copy of that test

plan and, you know, you have to be a member to be 1 2 and that costs money to get that test plan. But it is those members in the WiFi 3 4 case, 600-plus strong that have come together on 5 Now there is some specifications consensus. through FCC and FDA here that have already been 6 7 created that are pretty rich in what's needed. And then if those could then be viewed 8 9 and looked for gaps or used cases and then there 10 could be a consensus organization within the 11 community, the medical community, it could be 12 Medtronic's, it could be a number of people, that 13 come together to create that test plan. 14 You know, I think the patient care 15 would be a little more confident. I think the 16 manufacturers would be more confident that their 17 product is really interoperable with, you know, a 18 competitor's product. 19 So the model that WiFi put together I 20 think is something that we in the medical 21 industry we should look at. They took 15 years 22 to put it together.

It may not be perfect for the medical 1 2 environment, but it may be at least a starting point to where you get one efficient test bed 3 that can be modified fairly efficiently and then 4 5 kind of franchised out into different third-party testing environments. 6 Thank you. 7 MR. SEIDMAN: Yes. I'm glad we have a little bit of disagreement here at least, 8 9 whether it be multiple test beds or a single test 10 bed. 11 And I want to look to Hazem here, he's 12 got a coexistent test bed. I mean is this 13 expandable to other areas? 14 DR. REFAI: So here is the question. 15 Let's, if we look -- This is a very good question 16 by the way. 17 If we would look at EMC testing, EMC 18 testing here are ten steps, you do them. One, 19 two, three, four, five, six, seven, eight, and 20 then once you do these steps you are EMC 21 compliant. You're done. 22 Now how do you go and transform, it's

some sort of a 10-step scenario for coexistence. 1 2 Knowing that coexistence had hardware and software that more or less implement to allow to 3 4 share the spectrum. So if you think of that, and we 5 thought about that in the University of Oklahoma, 6 7 we looked at it and said okay, it's a very complex issue if you look at it from that 8 9 perspective. 10 But I can, as I said, can I do it in 11 projection on different domains to be able to go 12 and test it in these domains. Yes, you can, and 13 if that's something that could be done then maybe 14 at one point instead of what all the labs, the 15 hospital said, oh, we build so much into our 16 system to test the device for coexistence. 17 So we go and buy System A, buy System 18 B, buy System C and put it in the lab and then 19 take the medical device and expose it to those, 20 all systems, and if it coexists with these 21 systems oh, I'm done. I'm coexisting now with 22 other systems so I'm fine.

Is that an actual comprehensive coexistence test? It's not, because all of these elements that come in from Company A, B, C, they have interaction with each other so they could coexist.

6 So if we wanted to go out for a one-7 way solution whereas that solution is a 10-step 8 is really where you have to engage testing 9 equipment, you have to engage scripts that you 10 develop to be able to go and simply the complex 11 system into domains and then test for that.

And when you test for that then you will be guaranteed that even if I go and put my system into an environment where it has multiple of these systems in the same environment it's going to coexist.

I guarantee it to you after I test it in the lab according to a 10-step solution, which we're not there yet, that it's going to be coexisting if you take it on the real system, real environment.

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DR. NILSEN: Great. I think we're

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3	questions.
4	Those of you that aren't in the room
5	submit questions by email to livequestions, one
6	word, at FCC.gov, or don't forget us on Twitter.
7	It's hashtag testbeds, so please, those of you
8	who are not in the room or even if you are in the
9	room and you want to use technology go for it.
10	I do want to, we do have a question
11	from Twitter, or sorry, from email, and it said,
12	and I'll throw this out to the panel, "What sort
13	of test bed features would help people in the
14	deployment for security of wireless devices in
15	the networks?"
16	So the security of medical device,
17	what would we need in test beds?
18	MR. CONLEY: Well security I think in
19	the medical world may actually be two things.
20	There is the protection of the commissioning of
21	devices and data itself through encryption, but
22	there's also another, you know, issue that's

getting a feel for the complexity here. I just want to remind people that they could submit 2

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starting to surface and that's privacy.

2 So I think when we talk about security I think we all have to start considering privacy 3 4 as well because much of this data goes beyond, 5 you know, the hospital bed or the care center, you know, it goes, you know, somewhere to get 6 7 analyzed and privacy becomes kind of a concern. Particularly, you know, when there is 8 9 age in place or home care or something like that 10 where there is maybe less protection in the 11 neighborhood than there is the hospital walls. 12 But security, the encryption of that, 13 that's being looked at by other organizations, 14 depending on what technology you are talking 15 about. 16 DR. REFAI: I will add a little bit on 17 this. Security has really two aspects of it. 18 One is the hacking, which is the privacy of the 19 patient information, but the other one is the 20 spoofing, you know, which is pretending you are 21 somebody, part of that patient network that you 22 enact on specific things that really might

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endanger the safety of the patient.

2 So these are two different things. Now I am aware that NIST has, I mean I don't do 3 4 any security testing, but NIST has a protocol for 5 encryption in terms of security, improving the security of the devices. 6

7 MR. BOWDEN: Yes, there is an entire InfoSec test suite performed by medical device 8 9 companies that address the issue of spoofing and 10 hacking in medical devices there.

11 So along with that, complimentary to 12 that, is the requirement for the encryption as 13 well. So that has been broadly implemented 14 across medical devices, you know, in the wake of 15 a lot of the hacking incidences that have taken 16 place in the medical device industry on devices. 17 DR. NILSEN: Okay. 18 MR. SEIDMAN: All right. We also have 19 a question from the audience. 20 MS. MLINARSKY: Yes, hi. Fanny 21 Mlinarsky, octoScope. One question I had in

particular having Mick formerly of the WiFi

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Alliance on the panel is to get all the panelists 1 2 opinion on this question. WiFi Alliance has been certifying IEEE 3 4 802.11 technologies. 802.11 is a huge, you know, 5 number of standards. WiFi Alliance selects portions of the 802.11 standard and test 6 interoperability and it ends up being the 7 regulator of what actually ships out into the 8 9 market. 10 So whatever is tested by the WiFi 11 Alliance has a stamp tends to be deployed whereas 12 the rest of the technical standards don't ever 13 make it out to the market. 14 Is it possible or desirable that if 15 there is eventually a medical test bed or a 16 serious of test beds, a family of test beds, that 17 the same kind of thing will happen in the market? 18 In other words, test beds will be the 19 gatekeepers of what gets deployed into the 20 hospitals. 21 MR. SEIDMAN: Anybody? Rob, okay. 22 MR. HAVASY: We hope, that's what

we're driving for. But let me just point out the 1 2 test bed in a coexistence for specifically medical devices, you're looking at a test bed 3 4 that does a performance, right, just is it 5 conforming to a standard, the WiFi Alliance. But then if you look at just the 6 7 performance of this the test bed really in the coexistence we don't look for just a performance. 8 9 We look for one, is it safe, is it going to 10 coexist with others? So that's one. 11 Number two, the test bed is going to 12 guarantee that the medical device once it's 13 deployed on an actual network is not going to 14 degrade the performance of the network, so it's a 15 two-element thing. 16 I'm coexisting and testing the medical 17 device that can coexist, but at the same time, 18 not that I'm coexisting with others, but then 19 when I coexist I'm going to shut down everybody 20 and say oh, okay, I'm operating, because, you 21 know, you could just like take some of the packets and label it as voice and ask your 22

network to go and send it as a voice not a as a
 medical packet and get access to all the
 bandwidth you could get.

Well that's cheating the system, and if you do it the coexistence should tell you that no, you have degraded the performance of that device.

8 The guidance that's put by FDA says 9 when you try to go and do coexistence testing you 10 have to really validate the functionality of the 11 device but at the same time that functionality is 12 not going to inhibit other functionalities from 13 being shared on the spectrum.

So you have those two elements in the coexistence. Now when you go to WiFi Alliance well there is a test bed, they've been doing it for years, since the standard is out in there and so they can validate the WiFi.

But they don't, here is how much throughput you put in the system and this is how much is going, you're going to be able to share the network.

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But this particular test bed is really 1 2 targeting more of a medical device that is being able to coexist, function safely, and allow 3 others to function and share the spectrum and the 4 5 time and the frequency and so on. I see Mick wants to 6 MR. SEIDMAN: Just to add something to this, I know 7 chime in. we're talking about certifications and test beds 8 9 and don't forget we are talking about standards 10 as well. 11 So if somebody wants to comment, maybe 12 Bill or Mick about the pros and cons of each of 13 these. 14 (Off mic comments) 15 Michelle, start us off. DR. NILSEN: 16 MR. SEIDMAN: Ladies first. 17 MS. JUMP: So I just wanted to make a 18 quick point on the way we are thinking of test 19 beds as an entity versus a methodology, and I 20 think I'm going to point to Bill right back there 21 because if we think of, to use your term, a 22 gateway, right, into another, into being able to

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be put on to market.

We think of that from the 510(k) perspective, right, and so there are some companies that have their own tests beds that they should be able to use.

If these test beds are available as a 6 resource to apply the appropriate methodology and 7 standards that would be, I think, preferable to 8 9 the industry to allow the appropriate flexibility 10 based on the type of product you have, the risk 11 profile of that product, the risk profile of the 12 communication being used over that wireless 13 connection.

14 So I see it more as what are we 15 expected to be able to meet based on the type of 16 our device versus having to go through a test bed 17 of a particular type that should be flexible 18 based on the methodology that's driven from the 19 used case, intended use environment, and the risk 20 level of the device.

21 DR. YOUNG: I want to make a comment 22 on testing to a standard. This is something that

comes up in the work that I do with the NFPA. It's one thing to test to a standard and makes sure it meets the performance requirements of that standard, but then most of the vendors will add features. And the features is where you get in trouble because the features, at least for the NFPA, have to cause no harm and that's something

We talked for the testing for the basic functionality, but it's those additional features that get included that often cause the problem. They make the marketing difference for the manufactures but potentially aren't covered in some of the testing.

I think is missing in a lot of standards.

So I just point that out that a lot of problems you may be seeing may be due to stuff that really isn't governed by anything and really doesn't have to be tested, so that needs to be taken into consideration.

21 MR. CONLEY: Yes, you know, I've 22 spoken quite a bit on WiFi. WiFi does not test

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for performance, so to the point about 1 2 coexistence or co-interference they do very little testing. I think in the medical industry 3 we need to pay attention to that. 4 In the Department of Transportation, 5 particularly in toll booths and bridges, they 6 have something written into their specifications, 7 or requirements now heading towards 8 9 specifications, that another technology or 10 another even same technology, same device, on a 11 common frequency cannot disrupt the performance 12 by 60 percent. 13 So the last panel talked about being 14 in a hostile environment, even differing 15 frequencies, LTE Channels 40 and 41 interfere 16 with the 2.4 ISM band, so you can even have a 17 tower some distance away or you can have a handset that's running LTE that can disrupt your 18 19 WiFi. 20 And WiFi, you know, their receive 21 filters aren't that sophisticated so they still, 22 you know, receive bleed from, you know, the other 1

channels.

2	So these are areas I think in critical
3	care safety that as our standards evolve and if
4	we start pushing them into testing programs we're
5	going to have to call for a performance testing.
6	MS. JUMP: And just to add one more
7	thing, I'm going to keep talking about risk here,
8	is to your point, Bill, of you can't just look to
9	standards to be able to meet the appropriate
10	requirements for your device.
11	That's why every standard that you are
12	complying to also has to be built on appropriate
13	risk management, thorough and appropriate risk
14	management, and that will bring in those features
15	to understand how those features may create risk
16	to the patient, and that's going to be crucial.
17	We can't just make a cookie-cutter
18	testing environment, it really has to be based on
19	the risk assessment of that device and what it's
20	going to be doing in the hospital environment and
21	with the patient.
22	MR. SEIDMAN: Steve. We have a

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question from the audience.

2	MR. BAKER: Thank you. Steve Baker,
3	Welch Allyn. Dr. Young mentioned something about
4	these additional features which made me think
5	about one of the earlier comments that, you know,
6	we can test in a lab and guarantee device
7	performance and that kind of frightens me, this
8	concept that lab testing can guarantee
9	performance in the real world.
10	The second comment that was made that
11	I want to clarify is I thought I heard one of the
12	panelists say that the guidance from the FDA says
13	when you do coexistence testing we're making, I'm
14	testing my medical device, that's the DUT, and I
15	put other devices around it for coexistence
16	testing.
17	My understanding is I am testing my
18	device's performance. I am not testing if those
19	other devices are working correctly. They're not
20	my devices.
21	I might have bought a Philips patient
22	monitor that also runs in my patient, and I don't

I

1	know what their test protocol is, I don't know
2	what their performance levels are.
3	So I'm going bump on Don
4	MR. SEIDMAN: I think you have someone
5	behind you that would like to answer that.
6	MR. SILBERBERG: Jeff Silberberg, FDA.
7	If we asked you to do wireless coexistence
8	testing and you test the effect on your device
9	and don't test the effect on the other devices
10	we'll ask you to redo the testing and check the
11	effect on the other devices. Just FYI.
12	MALE PARTICIPANT: And now I get to
13	follow up with Jeff
14	MR. SEIDMAN: So he's saying it's two-
15	way, yes.
16	DR. NILSEN: Oh. Here we go, now we
17	have the audience answering, okay.
18	MR. HAMPTON: So testing devices is
19	great
20	DR. NILSEN: Can you say your name,
21	please?
22	MR. HAMPTON: I'm sorry. I'm Rick

Hampton with Partners. I'm on the third panel in 1 2 no time. It's fine to test devices, but I don't use devices, I use systems. And that's one of 3 4 the problems that we have with this whole, you 5 know, wireless test bed medical grade wireless technology stuff. 6 We're looking at this as though all we 7 have to do is test approve a small device and 8 9 that's all we have to do, but if that device 10 doesn't fit in the system and the system fails 11 the patient is harmed. So my question is, it's great to test 12 13 devices, it's great to certify devices, but that 14 doesn't explain why I've got 500 new computers 15 back at my hospital that don't connect to our 16 network even though they had been through, you 17 know, WiFi Alliance testing and all this other 18 stuff. 19 It's the system that needs to be 20 tested as well. 21 MR. SEIDMAN: Thanks. I think we have 22 a lot of different ideas here of what, you know,

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certification does, what standards do, what test 1 2 beds do, and everybody has great ideas on this. And I guess the question is, you know, 3 4 is there like a central repository that, you 5 know, everybody can share, that people can access so that we can share this knowledge and 6 7 information amongst each other to create, you know, a test bed that's useable for all? 8 9 (Off mic comments) 10 MR. SEIDMAN: I mean --11 DR. NILSEN: Greg looked like he was 12 really interested in the answer. 13 MR. SEIDMAN: Yes. 14 In my response to that I MR. BOWDEN: 15 had mentioned that a lot of my testing is done 16 per protocols that become the proprietary 17 information. 18 I personally would love to see a 19 single repository of all this information. I'm 20 guessing all the meaningful outcomes from this 21 testing are rolled into that gunnysack of 22 proprietary information held by private

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companies.

2	A lot of the background research
3	information and great stuff is coming out of the
4	academic institutions and so that was the basis
5	for my initial test construct, but in terms of
6	outcomes and results and procedural content, you
7	know, I haven't seen a lot of meaningful
8	information made publicly available.
9	DR. NILSEN: All right.
10	MR. SEIDMAN: Yes, and how do we get
11	around this problem? Do we solutions over there
12	at NIST?
13	DR. YOUNG: We got no solutions for
14	you, sorry.
15	MR. SEIDMAN: Okay.
16	DR. NILSEN: What about the questions
17	of systems?
18	DR. YOUNG: Well, yes, so I was going
19	to take on the question of systems. That's an
20	excellent point, and we seem to be focused on a
21	singular device and if the singular device passes
22	everything is great, and obviously that's not

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true.

2 Again, this is why we're stressing the idea of methods. Ideally, you would have methods 3 that you could employ in a test bed and you would 4 5 learn from those methods how you could create in situ methods so that people could use those in 6 7 diagnostics in their own system. The reality is you're not going to be 8 9 able to replicate everybody's different 10 configuration. You'd like to have consistent 11 ways of checking within that system how well it's 12 working. 13 Hopefully you can learn that by using 14 a test bed and test methods and get them out to 15 the user community in general. That's about as 16 far as we're going in our thinking on that at 17 this point. 18 DR. NILSEN: Others? 19 MR. AHLUWALIA: Yes. 20 MR. SEIDMAN: We have some more 21 questions from the audience. 22 MR. AHLUWALIA: Hi. My name is Surjit

Ahluwalia. I am with Cisco Systems and I'm on I
 guess the fourth panel.

I have a question. So, you know, 3 we're talking about test beds and I think we are 4 5 all agreeing, I am validating with you that there is, you know, there is no way to guarantee, 6 7 right, a device works in a healthcare organization. I think everybody agrees. 8 9 So the question I have is how do you 10 know you've reached the right level of testing? 11 So, for example, you know, are you trying to get 12 five nines, you know, are you trying to reach a 13 certain level of, you know, maturity, and how do 14 you define such a level because what if, you 15 know, something happens in that remainder 0.1 16 percent or whatever that is and causes a patient safety issue or some other worse situations. 17 18 How do you define where you draw that 19 line?

20 MR. SEIDMAN: I'm going to point to 21 our risk management person over there because I 22 think that's the answer. Do you want to take

this one, Michelle? 1 2 MR. BOWDEN: Yes, I'd like to take it, 3 too. 4 MR. SEIDMAN: Or, Greg. Greg, start 5 us off. Go ahead, Greg. 6 MS. JUMP: 7 MR. BOWDEN: When I'm executing my testing I'm looking for probabilities. 8 Now 9 you're talking reliability and confidence level, 10 so when I do my testing I throw everything at it 11 I know I have access to and I do it for as long 12 as I can to establish a high level of confidence. 13 Life does not give you 100 percent 14 confidence, so to your point I'm relying on field 15 data to provide that last little bit of 16 confidence. 17 So in terms of radio performance we 18 have a pretty good handle on that one. I haven't 19 seen any, in my devices any adverse effects other 20 than hacking where we've realized any of the high 21 level risk through radio performance. 22 There's always been some other

mechanism in the device. But, to your point, I 1 2 basically do as much testing as I can to establish those margins. 3 4 MR. AHLUWALIA: I guess you see my 5 I mean so are you suggesting that if a question. device passes your lab test then it reaches that 6 7 level of maturity that everybody can use? Do you see what I'm saying? 8 9 MR. BOWDEN: Yes. 10 MR. AHLUWALIA: How do you define 11 where that line is and how do you say if you go 12 through these sets of tests you are now good to 13 go and this reduces the probability of a patient 14 safety risk, that's what I'm trying to ask? 15 How do you define that line, because 16 if you cannot --17 Then it's best case testing you MR. BOWDEN: 18 are doing. It's best case testing. 19 MR. AHLUWALIA: Okay. 20 MR. BOWDEN: So you do everything you 21 can throw at it with what you have available to 22 you, absolutely. Good question.

DR. REFAI: So I'll add -- Michelle, 1 2 do you want to --MS. JUMP: Go ahead. Go ahead. 3 4 DR. REFAI: No, no, go ahead. I can 5 go after, that's okay. MS. JUMP: You guys are all so 6 7 gentlemanly. And I think I also wanted to point out again, because I am going to speak about 8 9 risk, it also depends on the criticality of the 10 transmission, right. Because if I fail to transmit on the 11 12 first round but the data is not of a time 13 critical nature then you may have a lower bar for 14 what you consider passing as long as you have the 15 functionality built into the device to retry, as 16 long as it's possible. 17 So, again, it goes back to how 18 critical is that transmission that's going across 19 that wireless network. 20 MR. SEIDMAN: Yes. I mean I want to 21 echo that, too. I mean that's the answer I was 22 expecting is it's a risk management process, a

2 I mean if you have something that is 3 life critical that has to get through 100 percent 4 of the time don't use the 2.4 band, probably 5 don't use wireless. I mean it depends on, you know, the 6 7 function that you need to work on on that wireless technology. 8 9 MR. BOWDEN: You know, and that 10 absolutely shouldn't happen through a 11 retrospective analysis because if you, the minute 12 you hang that medical device moniker on something 13 now you're asserting design control. 14 So you're going through your design 15 development phases, early on you kick in your 16 risk management process for your design 17 development, you should already know that. 18 You shouldn't be shooting from the hip 19 late in the cycle trying to decide what it is

20 your radio is going to do. The minute you
21 decided that this was a medical device that

22 should already have kicked in.

So there shouldn't be that many, if 1 2 any, surprises when you start to get to your product qualification and verification testing. 3 MR. SEIDMAN: Yes. And that test plan 4 5 procedure that you do beforehand is mentioned in the guidance document as well that we were 6 7 referencing. 8 MR. BOWDEN: Absolutely, yes. Yes, 9 absolutely. You should already know 90 percent 10 of all this before you get to that point. 11 MR. CONLEY: And I think, you know, 12 the answer, this is technically, you know, how 13 you find out if your equipment's really behaving, 14 but strategically how do you define what you want 15 to look for. I think it's in the specifications. 16 You have to get subject matter experts 17 together in the industry, whether they are 18 doctors or administrators or liability 19 individuals that deal with liability, and they 20 define what the level of risk is acceptable and 21 what's not acceptable you make sure that the 22 equipment is tested to behave above that level.

MR. SEIDMAN: Yes, that's absolutely 1 2 I mean a wireless expert and I review correct. the wireless technology, but, you know, we lean 3 4 our clinicians, we lean on other people that, you 5 know, understand that for each specific application. 6 7 MALE PARTICIPANT: Yes, just one --8 DR. NILSEN: We've got one more quick 9 question real quick. 10 MALE PARTICIPANT: Okay. 11 DR. NILSEN: Let's have our last 12 question, please introduce yourself. 13 MR. HOGLUND: This is David Hoglund 14 So I agree with the testing is very good again. 15 for the devices companies, specifically say wire 16 line, isolate that. 17 When you deploy that into an 18 enterprise environment, at least my experience 19 has been, and the challenge is the enterprise is 20 constantly changing. 21 So the last speaker here was from 22 Cisco, so he may validate and verify how the

device needs to work for roaming, security, the 1 requirements for the pass V&V. 2

3	However, if there is changes within
4	the systems of systems, like Rickey said, in
5	terms of firmware or software on the enterprise
6	side, I think there needs to be a communications
7	link between those companies and enterprise
8	manufacturers to continually ensure validation
9	verification for the application use.
10	DR. NILSEN: Great. Hazem, or
11	DR. REFAI: So you added more
12	complexity to the already complex issue, which is
13	the enterprise network.
14	MR. BOWDEN: Well and the thing about
15	that, too, is that when you have a medical device
16	you're doing a lot of testing. So we're talking
17	about a depth of testing for a specific
18	functionality in the devices, but with a medical
19	device you already have a suite of tests that's
20	going to get you a 500-page test report at the
21	end of the day.
22	(Off mic comments)

(Off mic comments)

Yes. 1 MR. BOWDEN: So opportunities 2 for snuggling up to, you know, your industrial partners are few and far between, and that's a 3 4 hurdle, you know, that's a speed bump. 5 I would love to know what everybody else is doing and what they've got going on and 6 7 have an information exchange like that. You know, I'm having in 2015 that's just making that 8 9 virtually impossible. 10 You know, I'm sure, if you're here in 11 this room you are probably one of the busier 12 people in your organizations. If you are here 13 talking about test beds you're swamped, you know, 14 just like I am. 15 I think we have one last MR. SEIDMAN: 16 question and then we're going to wrap up. 17 DR. NILSEN: Okay. Quick question, 18 please. 19 MR. SILBERBERG: Hi, great. Jeff 20 Silberberg, FDA. Yes, I just want to, a quick 21 tutorial on ISO 1497, you don't have to be 22 perfect when you go out the door.

1	I mean risk management says three ways
2	of dealing with risk, one is inherent safety,
3	safety by design, and labeling is the third one,
4	it's allowed, although it's not preferred.
5	MALE PARTICIPANT: And in that order,
6	too.
7	MR. SILBERBERG: And once it goes over
8	the And the risk management process includes
9	monitoring what goes in the field, feeding that
10	back into the design process and management
11	process.
12	MR. SEIDMAN: Yes. I think that was
13	a great way to
14	DR. NILSEN: So I think this has been
15	a great panel, and thanks to our panelists. I
16	think we've come up with, we were building on the
17	idea of the family of tools and the fact that
18	there isn't just one thing as a test bed, I think
19	that came out pretty clearly.
20	We also talked a little bit about
21	efficiency and I think that came out again and
22	again in helping sometimes. The bigger companies

it sounds like have test beds, but given the 1 2 complexities of these topics there might be real efficiencies in having test beds in this area. 3 4 We had some really kind of stimulating 5 conversations though on what level, what's the right level, how do we define this. 6 We know 7 there is standards, 149171, I mean we've heard about it again and again. 8 9 But it seems like, well the question 10 is how do you define what's right, what's good to 11 But we also, I think the idea of that qo? 12 there's a feedback group in this and that any 13 test bed we create won't send things out the door 14 perfectly, that they're going to have to have 15 feedback on the end. 16 So, Seth, do you want to make any --17 MR. SEIDMAN: Yes, great. No, I think 18 that was great. Thanks. 19 DR. NILSEN: So we're working really 20 hard to get you to lunch on time, so we thank you 21 for the panel and --22 MS. ONYEIJE: Thank you so much. We

greatly appreciate it. So I am glad I didn't 1 2 have to be the task master today, we're selfregulating and we love that here at the FCC. 3 4 I wanted to do two very quick 5 housekeeping things. I think if you came in on this side you got a sheet that gives you some 6 7 good options for nearby restaurants and cafes and the like. 8 9 There are two things I want to just 10 The FCC does have a cafeteria, a flag for you. 11 café downstairs. It is within our secured area 12 so if you are interested in doing that if you 13 could just meet out here on my right toward the 14 exit door and we will have someone escort you 15 downstairs. 16 I also know that recently there have 17 been a bevy of food trucks right outside the main 18 entrance if you are interested in the D.C. food 19 truck scene that's a good place to go. 20 We just ask that you be back by 1:00 21 if you possibly can. So our first two panels 22 have really set the stage and we want to make

sure, and I think somebody on the first panel 1 2 said it, that we are not only solving the problems for today but future proofing as much as 3 4 we can toward the challenges of tomorrow. 5 And Dr. Greenspun is going to try to bring us that kind of picture. So as we go into 6 7 the nuts and bolts of this afternoon that we have that picture in mind. 8 9 So see you back at one o'clock. Thank 10 you. 11 (Whereupon, the above-entitled matter 12 went off the record at 12:01 p.m. and resumed at 13 1:01 p.m.) 14 Okay, so we are going to MS. ONYEIJE: 15 ask folks to start taking their seats. A11 16 right, so just let me take a few minutes and talk 17 a little bit about what we're going to do this 18 afternoon. 19 By now you've probably had a chance to 20 look at your program. And you know that the 21 afternoon is divided into three sessions. The 22 first one is a 30 minute spotlight session. We

are going to take a bit of a break from the panel
 format.

The hope, again, is to ground the 3 discussion to come in the afternoon and kind of 4 5 what's coming. I think there was one panel as to use the term freight train, that there's a 6 7 freight train potentially coming at us and we should better understand what that broader 8 9 context is. 10 And then we're going to have two 11 panels in the afternoon with, again, wonderful 12 groups of experts talking about how do we get 13 from where we are now to where we want to be? 14 So I'm going to invite Dr. Chris 15 Gibbons of the Connect2Health Task Force forward 16 to introduce Dr. Harry Greenspun. Chris? 17 Thank you, Karen. DR. GIBBONS: It's my pleasure to introduce our next speaker, Dr. 18 19 Harry Greenspun who as you may have noticed in 20 the program is the Director of the Deloitte 21 Center for Health Solutions. Before he was at 22 Deloitte, he was the Chief Medical Officer at

Dell, and before that Northrop Grumman. 1 2 And he's also co-author of a work called Reengineering Healthcare, A Manifesto For 3 4 Radically Rethinking Healthcare Delivery. And 5 there's much more. I'll let you read it on your 6 own. But the most important thing that I 7 actually just learned about Harry is Harry 8 9 trained at Johns Hopkins, as his bio said, in 10 anesthesia and critical care. I also trained at 11 Hopkins in surgery and in preventative medicine. 12 And it turns out that we were at 13 Hopkins at the same time. So we probably had 14 surgical cases together where he was the 15 anesthesiologist and I was with the surgical 16 team, and we didn't know each other until today. 17 So it's a small world. But at this time, welcome 18 with me Harry Greenspun. Thank you. 19 DR. GREENSPUN: I wouldn't recognize 20 Chris unless he had his, like, his face covered. 21 That I would recognize. So it's great to be 22 here, and it's so great to actually see so many

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familiar faces.

2	You know, Julie was here and Bakul has
3	been here, and always great to have Kerry
4	McDermott back at the FCC, so particularly proud
5	of that fact.
6	So as Chris mentioned and I guess was
7	said, I've been trying to sort of move from some
8	of the technical discussions and talk about some
9	of the broader ecosystems things that are
10	impacting how healthcare is moving, what's
11	happening with innovation, and why this is
12	driving so many changes in behavior.
13	And fundamentally, the changes going
14	on in healthcare is we're now moving from our
15	typical fee for service environment to value.
16	Everyone's talking about value and outcomes based
17	reimbursement.
18	And what's different about that is
19	that it changes what healthcare does. But more
20	importantly, it makes us do things that we're not
21	very good at, and its four key things.
22	It's causing us to share information,

we never really have done that before. 1 It's 2 asking us to coordinate care. We need to actually engage consumers in a way that we 3 4 haven't done before. And the last thing is really harness 5 And so I want to talk about each of these 6 data. 7 things and how they're changing what we do and how that's driving a lot of innovation and some 8 9 of the barriers to each one of these things. 10 So the first one is about sharing 11 information. And what's been interesting is 12 when, you know, Chris and I were residents, the 13 only ones who really cared about what was going 14 on with the patient were us, right? 15 And we didn't actually have to move 16 information around very much. We didn't actually 17 get it outside of the organization. And when you 18 dealt with most physicians in private practice, 19 there was actually a disincentive to share 20 information with other doctors because as a small 21 business operator, you actually want to keep your 22 patients.

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1 The reason people went to a doctor is 2 because the doctor knew a lot about them. But as we get into sort of value and outcome, suddenly, 3 4 you know, having the right information with the 5 right person at the right time becomes critically important when it's freely available at the right 6 time. 7 But is anyone worried about that, all 8 9 this information flowing around? Anyone scared 10 of that? What are you scared of? 11 (Off mic comment) 12 DR. GREENSPUN: So sort of privacy and 13 security. And another quick poll question. So 14 who's afraid of having their identity stolen and 15 having their bank accounts drained? Okay. 16 So who's afraid of having your 17 identity stolen and somebody getting a 18 colonoscopy in your name? Right? So this guy in 19 front, I appreciate your honesty there. 20 So one of the things that we need to 21 think about is that healthcare information being 22 moved around is different from the types of

information that's being moved around in other 1 2 areas. And you know, when we survey 3 4 consumers, and our Center For Health Solutions 5 does this regularly, we surveyed consumers globally, they were very willing to share 6 7 information, aggregate information available to 8 research. 9 But what they're afraid of is not the 10 wholesale loss of their data. What they're 11 really concerned about is single pieces of 12 information in their medical record. 13 You know, it's that rash they got in 14 Vegas or some other thing where they got care --15 (Laughter) 16 DR. GREENSPUN: Took a little while. 17 Where there's data that they don't want to share 18 that for whatever reason is important to them. 19 And to have the ability to granularly control the 20 permissions of who has access to what is going to 21 be very, very challenging in healthcare. 22 And as we've seen, there have been a

series of recent, very high profile, large number of breaches in healthcare. And we found that, of course, the value of healthcare data on the black market is actually much higher than financial data.

6 It tends to be much more persistent, 7 it tends to be much more accurate. And the 8 repercussions for individuals if they lost their 9 data can be much greater because suddenly if 10 there's misinformation in your medical record, 11 that can have profound and long lasting results. 12 And we are generally protected, as we

13 are in financial services, from those sorts of 14 things. So the sharing of information is going 15 to be, you know, a critical issue.

And the information that we carry on our phones and the information we have in other sorts of accounts, moving freely is on one hand very encouraging but also very concerning to a lot of individuals.

21 The second area is around care 22 coordination. And again, in the past, sort of in

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the fee for service world, we didn't really care
 what happened to someone after they left our
 institution.

So you cared a lot about the person who is in front of you. Didn't really care what happened then. And like, whose doctor cares about them? Just I mean, not a trick question. Does your doctor care about you? Sure.

9 Is your doctor thinking about you
10 right now? Probably not, right, because the
11 doctors don't really think about what's happened.
12 But again, in a value based world, the transition
13 from a doctor's office to a hospital to a rehab
14 facility back to home, all those transitions
15 actually become very, very important.

And we've seen repeatedly that in these transitions of care, bad things happen. Right? Medications get missed, procedures get repeated, people die. All right, really bad stuff happens during these transitions. And so if the outcome, and ultimately

reimbursement of providers is dependent upon

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things going well, they suddenly get very concerned about what goes on there. So again, we're seeing a lot of opportunity and a lot of convergence in the marketplace related around building up these kind of resources.

6 But the other struggle is when you 7 think about data flowing around is that we really 8 don't have good tools to make this happen. So 9 you think about most electronic health records 10 are really designed for an individual physician 11 taking care of an individual patient in front of 12 them at that time.

They don't build in the work flows and all the other issues related to make sure care happens smoothly. When I was doing my oncology rotation at Hopkins, Chris probably had a similar experience; the attending said to someone, you know, you got cancer.

19 If you don't have a daughter, you
20 should get one because someone's got to keep
21 track of all this stuff. Right? And
22 unfortunately that's the way healthcare has gone

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for so long is trying to understand who's 1 2 actually responsible for this. We've thrown it on patients and 3 4 families. Now we're going to be responsible for 5 having the tools and techniques to make sure all the things happen at the right place at the right 6 7 time. Okay, does that make sense? Okay. I want to talk a little bit more in 8 9 depth about consumers because consumerism is 10 going to be a huge thing for a number of reasons. 11 Again, another poll question. Who's got a good 12 There you go. How do you know? doctor? 13 I interviewed him. MALE PARTICIPANT: 14 DR. GREENSPUN: You interviewed him, 15 that's interesting. You don't see that very 16 often. Like, you know, you audition your doctor. 17 That's impressive. What makes your doctor good? 18 MALE PARTICIPANT: We have a lot of 19 commonalities. We share a background. 20 DR. GREENSPUN: Shared interests, golf 21 buddies, all that kind of good stuff. Yes, yes. 22 So it's interesting. So again, we surveyed

1	consumers and we asked them about quality, we
2	asked them about how good is their physician.
3	And what you get is what it's like to
4	go to the doctor, or what your doctor is like.
5	Right? So it's the service experience. The
6	doctor listens to me, you know, she answers all
7	my questions, I can get an appointment when I
8	need it.
9	Its service experience. No one says
10	that based upon my family history and my age, I
11	have all the necessary preventative care that I
12	should get. No one says that, you know, I had
13	the same operation as RG3 and I was back I was
14	back to running three months later.
15	So you're laughing about RG3. This is
16	the problem about living in Washington, right; we
17	have no one we can really hold up there. This is
18	being live broadcast? Okay. My mother in law
19	may be watching so I can't make any jokes about
20	her. Not that I would.
21	So no one talks about that. And so
22	often when we're trying to talk about quality and

outcomes, when we're talking to consumers, often
 their measure of quality is not what healthcare
 has typically measured.

And so Chris, for example, would be judged by the quality of the scar left behind after an all day operation, right? And so when Chris and I were both interns, it was probably left to him to close up the patient, the last little bit. The surgeon is already off dictating something.

So that surgeon's work is actually
judged by Chris' work. Did you do a good job?
DR. GIBBONS: Of course.

DR. GREENSPUN: Of course you did. There you go. Which is why you're not at Hopkins right now. So in any event, sorry about that, Chris. So I'm not there either, so that says something.

So one of the issues, when we surveyed consumers globally, unless you come from a country that is known for excellent chocolate or awesome beer, you are typically very dissatisfied

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with your healthcare system.

2	And that's usually based upon not
3	understanding how your healthcare systems work.
4	It's really based upon the last time you got
5	care. And so we think about, you know, as we
6	bring in lots of information from consumers about
7	making decisions, we wind up actually getting
8	data that is about service, not about quality as
9	the most important thing.
10	So you think about the types of things
11	that you could look up. You could look on
12	Angie's List, you could look on Health Grades,
13	you could look at U.S. News and World Report.
14	A recent study, actually, if anyone
15	saw this recently that the major rankings of
16	hospitals done by lots of different sources, how
17	many hundred top hospitals do you think there are
18	in the United States? How many do you think?
19	Give me a number.
20	MALE PARTICIPANT: Five hundred.
21	DR. GREENSPUN: Five hundred?
22	Anybody, we'll do like Price is Right.

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(Off mic comment) 1 2 DR. GREENSPUN: So the list of top hospitals, there are actually over 700 top 100 3 4 hospitals in the United States. And what is 5 worse is that best, which often these lists are which consumers also read the data they have 6 7 available to them, the best hospital is judged by criteria that often are pretty opaque to the 8 9 average consumer. 10 So what they can get is this is the best hospital, but it's best because you're 11 12 talking about safety, or it's best because you're 13 talking about some kind of service. And in a 14 recent study in Health Affairs, they showed that 15 only about ten percent of hospitals that were 16 listed as best by one of these rankings were listed as best by another. 17 18 And many were best on one list and in 19 fact worst on another list, right, because they 20 have different criteria. So consumers trying to 21 get information about how they should get care, 22 where they should go, what's good for them is

very hard for them to pull that information
 together because again, they have very limited
 quality information, very little cost
 information, and only sort of the social media
 aspect of how they can get data about what it's
 like to go to one of these places.

So this has to change because again,
we're putting a lot more financial burden on
individuals to make better decisions hoping
they'll do good stuff. But also as outcomes
become more necessary, or judging by outcomes,
you need to go to better places.

And anyone from New York? Any New
Yorkers here? Okay, we got one in the back here,
excellent. Hiding, pretty good. So New York has
an interesting thing that very other few states
have done.

18 They have a registry of cardiology and 19 cardiac surgery. It's risk adjusted. For those 20 of you who don't understand risk adjustment, I'll 21 explain that if you're Chris, right, and you're 22 an awesome surgeon, very few of your patients
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die.

2	But if you treat really complex
3	patients, some of those patients die. So if
4	Chris has a mortality rate of five percent, which
5	is a pretty high mortality for almost any
6	specialty, I want to know is Chris seeing really
7	sick people and therefore five percent is
8	amazing, or is he seeing really healthy people
9	and therefore five percent is terrible?
10	So it's risk adjustment. So you can
11	look at individual physicians, you can look at
12	individual hospitals to find out what their risk
13	adjusted mortality is.
14	So do you remember when Bill Clinton
15	needed heart surgery in 2002-ish? Where did he
16	go? Anyone remember? No? It was in New York.
17	He went to Presby, he went to New York Presby.
18	Right? Good hospital? Stunned silence at this
19	point. So I've been there.
20	Seems like a great place. But at the
21	time, their risk adjusted mortality was actually
22	quite high. Now Hillary may have known that at

the time. I should never say that in a
 government building.

So one of the factors is that this 3 4 data has been around for a long time. And people 5 who kind of, should have known about quality and outcomes, you know, may or may not have based 6 7 their decision upon where to go on that. And what we found is there was a 8 9 study, I mean, this data's been around for a long 10 time, that the average consumer actually ignores health data and outcomes data and is said is 11 12 operating on other sorts of things.

13 And so again with our survey of 14 consumers, we talked about trust. Like, who do 15 you trust for health information? So who do 16 people like for health information? Who do you 17 want to go to?

(Off mic comment)

DR. GREENSPUN: Yes, everyone loves
their doctor, right? Got to love doctors, right?
They like doctors, they like academic medical
centers, they like organizations that are

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dedicated to their particular disease.

2 Then you start getting some of the middle area, they actually love the FDA and NIH. 3 4 So as unpopular as the Government may be at 5 different times, people still love the FDA and NIH, right, and they really value the information 6 7 they get from there. Then you get sort of a little bit 8 9 You start getting into the sort of the loose. 10 web search stuff, like, I'm just going to look 11 something up. And there's always this myth of 12 consumers going to doctors with a big stack of 13 papers saying, like, I searched this and I 14 believe I have hairy cell leukemia. Right? 15 Doesn't really happen. What they do 16 is they say I have this, you know, I have this 17 condition or I got this diagnosis. And so I got 18 this information and does this apply to me? Help 19 me understand it. 20 So they take it to someone they trust. 21 So who do you think lives at the bottom of the 22 barrel of healthcare information trust? So we

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got insurance companies, right? Bottom of the 1 2 barrel. Who's living down there with them? Anyone? People pleading the fifth 3 4 back here, right? So we got insurance companies. 5 Who else doesn't really care about you but just wants you to be healthy enough to keep working? 6 7 (Off mic comment) DR. GREENSPUN: Your employer, right? 8 9 I actually said that to an employer one time, 10 like, they don't really care about you, and they 11 got very upset. 12 And I said well, you know, from the 13 point of view someone just hired you, do you 14 think the person really thinks you care so much 15 to them or they just want to make sure you're 16 working hard and if you're sick you stay home so 17 you don't get other people sick. 18 So insurance companies, your employer, 19 and who else do we not trust? Who's trying to 20 sell you stuff all the time? 21 (Off mic comment) 22 DR. GREENSPUN: Pharma, right? So

employers, insurance companies, and pharma, least trusted among consumers for health information. The irony of this is that these three parties are the ones that are most commonly giving people health information.

Just think about people pushing out 6 7 health information to you, that's where it's coming from. So it's a very sort of, it's an odd 8 9 kind of thing. And innovation world, and we 10 think about where a lot of these organizations 11 are going to, they're trying to provide more 12 services, trying to get more engaging with 13 consumers.

But at the same time, consumers just don't trust them. So it's a big gap for us to move along there. The other thing interesting about consumers is that what I always find very interesting is that, you know, healthcare has always lagged behind other industries.

20 But we've always felt, you know, 21 pretty good about ourselves. And I was at a 22 hospital in Houston. And they said they wanted

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to be the leader in consumer engagement tools and
 IT. They wanted people to really recognize how
 advanced they were. I said fantastic.
 Can people make an appointment online?
 No. Can they access their records? No. Do you

6 have a map of the hospital? No. And I'm looking
7 around sort of scratching my head. And there's a
8 Chipotle in the lobby. And you know, not a
9 shareholder in Chipotle. But anyone have the
10 Chipotle app on their phone?

11 This guy right here, right? So with 12 your app, you can find the nearest Chipotle based 13 upon your GPS coordinates and order a custom made 14 burrito that's waiting and ready for you, paid 15 for at the exact moment you want it, yes?

Yes. So what I was saying to these guys at the hospital, I said there are people, you haven't had too many, I can tell, you're still pretty healthy, that there are people wandering around your hospital lost and are waiting for an MRI, waiting for some sort of form to get faxed back and forth and they're ordering

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1	burritos from the Chipotle in the lobby.
2	Who do you think they believe is the
3	more advanced technological institution? And so
4	we have this big gap where sort of people live in
5	this Jetsons world, yet you go to the doctor and
6	it's like an episode of the Flintstones.
7	And it's not like in every other
8	aspect of our lives, we understand. Like, if you
9	go to a doctor, doctor says, you know, we're
10	going to draw, we're going to do a blood test on
11	you and if it's abnormal we'll call you in a week
12	or two.
13	And, like, I got a text message the
14	instant a package gets delivered to me. I know
15	this technology exists. And so one of the
16	interesting thing about consumers is that
17	although people's needs haven't changed, their
18	expectations have risen dramatically.
19	Think about your banking app right
20	now. Like, five years ago your banking app on
21	your phone would tell you where the nearest ATM
22	was, right? And then maybe three years ago you

could use your phone to deposit checks, right? 1 2 Now your phone is money. So again, our needs haven't changed but our expectations 3 have risen dramatically. And when you couple 4 5 those rising expectations with the consumer's view of quality being related to service, 6 7 suddenly healthcare starts getting pretty scary 8 for the average consumer. 9 Like, God they can't do these basic 10 things that I would expect them to do. One of the ironies of health information exchange, 11 12 remember the whole debate years ago of launching 13 these HIEs was that in consumer's views, this was 14 already happening. 15 Of course, my records are electronic; 16 of course my records are winding up, you know, 17 where I'm getting care. They didn't realize that 18 no, they're sitting in a big paper chart in a 19 closet somewhere. So again, these expectations 20 have risen dramatically. 21 The other thing that's interesting is 22 we have so many consumers now who are tracking

Who's got, like, a bio sensing, who's got 1 stuff. 2 a wearable on right now? Jarrin what do you got? MR. JARRIN: Fitbit. 3 4 DR. GREENSPUN: You got, okay. Who 5 else got something? What do you got? (Off mic comment) 6 7 DR. GREENSPUN: Okay, so I got everything. I got the activity monitor, I got 8 9 the heart rate monitor, I got the rectal probe, 10 everything cooking. Right? I want to be very 11 thorough here. 12 And what's interesting is I look 13 around the room and all the people that raised 14 their hand look super healthy. Right? So we 15 have this idea that we're going to take these devices that, like, Jarrin, you do triathlons, 16 17 right? 18 MR. JARRIN: Marathons. 19 DR. GREENSPUN: Marathons, oh excuse 20 me mister athlete. There we go, yes. You know, 21 that constantly all of a sudden we have this 22 great tool for healthcare in our hands. We got

to appreciate these are not designed for that. 1 2 And the FDA a while ago came back reminding these wearable folks that you know 3 4 what, your device is not just for the gym. 5 Right, it's got to work when the power goes out, it's got to work when you travel. 6 It's got to work for my dad. And you 7 know, they weren't designed that way. And we 8 9 also, if you imagine, I'll use my first visual 10 since I didn't make any slides, that if you have 11 sort of the healthiest people, bell shaped curve 12 to the sickest, we have these very healthy people 13 who are monitoring all sorts of stuff about them. 14 And a couple questions arise of A, you 15 know, do they even need that because they're very 16 healthy but B, are they actually monitoring 17 things that are actually valid. Right? You say, you know, I've seen devices 18 19 that monitor stress and monitor all sorts of 20 other things but does it really, is it really 21 doing what you say it's doing? Would you say 22 it's really accurate? Is it only sort of just

modifying your behavior for some reason? 1 2 For example, I mean, I have this activity monitor. My dog has one as well. 3 It's 4 actually at the end of the day; my wife will 5 compare how much activity we've each had and figure out who's going to sleep on the floor. 6 7 But, you know, so many of these devices in the fitness and wellness world are 8 9 avoiding moving into the healthcare space because 10 afraid of regulation, we have to talk to Bakul 11 about that as well. And being very silo'd. So 12 the information moving from these devices to 13 devices is actually very hard to do. 14 And you can't get a full picture of 15 what's going on with someone. So as we think 16 about, you know, employing these devices to 17 monitor people remotely to make sure what's going 18 on and get a real accurate sense of what's 19 important, you have to make sure does it really 20 matter. 21 I mean, just because I have a fitness 22 app on my phone, right, doesn't make me an

12 of begs the question of all of this is, you know, 13 what are we doing about data that actually is 14 going to advance healthcare. And you know, 15 obviously big data analytics, very important. 16 I spoke at NIST I think a year or so 17 Me of all the PhDs, and I sort of made a ago. 18 comment, I guess I'm the only one with a medical 19 doctorate here. That did not go over well. 20 But you know, we think about all the 21 data that's being generated and all from devices 22 and from all of electronic records, one of the

athlete. And just because I have a diabetes app on my phone, it doesn't make my hemoglobin A1c go down.

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We have to actually tie these things to real outcomes; real evidence to make sure it works. So we think about pulling this information together, making them inter-operable. You know, that's the way we're actually going to drive value out of a lot of these devices and a lot of these systems.

And sort of the final thing which sort

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1 things we have to think about is that most of us,
2 we don't live in the doctor's office, we don't
3 live in the hospital.

We have all this other data that 4 5 actually is probably much more predictive. Ι mean, you got three diabetics discharged from the 6 7 hospital. What do you think is one of the most predictive things of who's going to get 8 9 readmitted? It's their credit score. It's the 10 guy with bad credit is the guy who's going back 11 to the hospital.

12 They're going to have trouble taking 13 their meds, they're going to have trouble getting 14 a ride to the hospital, all sorts of things. 15 They got other issues going on. Right? They got 16 more stress in their lives.

And one of the most fascinating sort
of examples of this is you remember when Target
was trying to figure out who was pregnant? This
was fascinating.

So rather than, you know, doing a
 pregnancy test on people which is kind of awkward

in a large, big box store. The struggle that 1 2 retailers have is that, you know, when you've had a baby, it becomes a matter of public record and 3 4 people buy that. 5 And then you get inundated with So they said by the time the baby's 6 coupons. 7 born, like, kind of a cat's out of the bag at that point. Bad cliché. But what we want to do 8 9 is we want to find out so we can get them the 10 right stuff along the way. 11 When they're going to buy their 12 furniture, when they're going to buy some 13 additional clothes. And so what they realized 14 was that when they looked through, they started 15 with people who in their baby registry first, 16 they looked at, say, well these women were all on 17 vitamins which is pretty common, but they started 18 buying more vitamins. 19 And then they started buying fragrance 20 free lotion. And then all of a sudden at some 21 point right before they delivered, they bought a whole lot of cotton balls and fragrance free 22

laundry detergent because if you're buying that
 stuff, you're having a baby.
 Right? I mean, it makes sense.
 Similarly, you know that if you join a health

club for the first time and then book a hotel room in your city, you are --

(Off mic comment)

Having an affair. 8 DR. GREENSPUN: Α 9 little fast on that one. So there's a lot of 10 data that we can get about people. So we can 11 think about I was on a panel with a genomics 12 company. How many of you actually have had your 13 genome sequenced? Anybody out there? Anyone 14 who's had their genome? There we go, over there.

So it was interesting. I think it's fascinating. I think it's going to be an incredible volume of data we'll get and a great way we can do a lot of research. But I bet I could predict more accurately your risk of heart disease based upon your credit card bill than your genome.

And same thing with risk of sudden

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death or all sorts of things. And so we'll see 1 2 that this kind of data that we have available, the interoperability issues and the aggregation 3 4 of issues that we're going to have to deal with 5 to move this information around smoothly is not just going to be in the hospital. 6 7 It's not just going to be in the home. It's not just going to be these wearable devices. 8 9 It's going to be pulling in all sorts of data 10 from lots of other areas. 11 So I'm just about out of time and I'm 12 sure they want to get me out of here. But any 13 questions that sort of arise from this because 14 it's sort of going to be a big shift in how we do 15 things. Over there. 16 MR. AHLUWALIA: So you talked about 17 the healthcare system being really lagging and 18 bad. 19 DR. GREENSPUN: I didn't say bad, I 20 said lagging. But go on. 21 MR. AHLUWALIA: Who's responsible? 22 DR. GREENSPUN: So it's interesting.

The question was for those who did not hear from 1 2 the microphone is that I said a lot of terrible things about healthcare, to paraphrase. 3 4 Who's responsible for fixing it? And 5 so for a long time, there was no, no one was really responsible for fixing anything but their 6 7 part. And what's interesting now is as we start moving to these alternative methods of payment, 8 9 suddenly there's an alignment of incentive. 10 It's important for me to do my job 11 well. It's also important for me to make sure 12 that wherever a patient goes, that group does 13 their job well. So it's important for me to 14 establish a network and a relationship with 15 people who do a good job. 16 And it's also important for me to

17 incentivize my patients to do the right thing.
18 And what's interesting is that we've often heard
19 doctors going well, you know, I can't do anything
20 once they leave my office.

21 But if you think about it, like, all 22 of us, you know, I travel a lot. I almost always

fly the same airline. I almost always stay in 1 2 the same hotel chain. I almost always shop at 3 the same grocery store. Lots of other industries have figured 4 5 out how to get people to do stuff. Like, Jarrin, back to you for a second. So you know, you do 6 7 all this marathon running. You post your runs on Facebook or Strava? What do you do? You share 8 9 that stuff. 10 MR. JARRIN: I don't. 11 DR. GREENSPUN: You don't? 12 MR. JARRIN: No. 13 DR. GREENSPUN: No, who does? Someone 14 must share their exercise. You do? Do you like 15 exercising? 16 FEMALE PARTICIPANT: Yes. 17 DR. GREENSPUN: No you don't. Right? 18 No one really likes to exercise. What I bet you 19 like is sort of the moral superiority you feel of 20 your friends as you're on --21 (Laughter) 22 Am I right? DR. GREENSPUN: I mean,

it's the same feeling I get when I beat my dog, I 1 2 mean, like on the leaderboard thing. I don't hit the dog at all. Right? 3 4 And so again, lots of other industries 5 figured out there are other aspects that allow us So you know, there are ways that 6 to motivate. other industries have been very effective at 7 motivating people to make better choices. 8 9 And you know, we can have doctors make 10 better choices, we can have pharma make better 11 choices, we can have technology companies make 12 better choices all because they're aligned, and 13 the patients can be brought along at the same 14 time. 15 One last question, if there's a 16 question. Fantastic. Well anyway, thank you 17 very much. I really appreciate the time. 18 MS. ONYEIJE: Thank you so much, 19 We really appreciate that. You know, I'm Harry. 20 intrigued by this notion that what we're really 21 talking about today is transitioning to a trust 22 model.

And so I'm going to invite the third 1 2 session up to the dais here. And you know, we had a title, Identifying and Prioritizing Key 3 Features, Functions, and Gaps in Wireless Medical 4 5 Device Test Beds. But I'm so intrigued by the Flintstone 6 7 metaphor that Harry used. I'm thinking I'm going to retitle it Yabba Dabba Do Time. Seriously, we 8 9 have two folks here who are going to be 10 moderating this panel for us. 11 I just want to take a second to tell 12 you a little bit about them. Ed Cantwell is the 13 Chief Operating Officer of the Center for Medical 14 Interoperability and he's taken on this challenge 15 of moving us from where we are now to where we 16 want to be, what the steps should be, what the 17 features and end should be, where are the gaps. 18 We've been talking about that a little 19 bit already today, but we're going to flesh that 20 And he is joined as a co-moderator by Ira out. 21 Keltz who is the Deputy Chief of the Office of 22 Engineering and Technology here at the FCC.

So Ed and Ira, the time is yours. 1 2 Thank you. Thanks, Karen. Well, good 3 MR. KELTZ: 4 And it's tough to follow the last afternoon. 5 act, but we will try to entertain you over the next hour and a quarter. 6 7 So I'm Ira Keltz with the Office of Engineering and Technology. And here to hold 8 9 what I hope will be a very interesting discussion 10 looking at the identifying, prioritizing the key 11 features and gaps in medical device test beds. 12 So I think recapping and trying to key 13 off of what we heard this morning, I think, you 14 know, there were a couple key messages that we 15 heard. One is its very complex and people using 16 lots of devices. 17 And can you put up the first slide? 18 Is there a clicker to do that? So this is kind 19 of, you know, everybody wants to use their own 20 device all the time kind of like this guy here, 21 and it causes you all kinds of problems. 22 So great, thank you. You know, so we

kind of heard that. This might be slightly
 different context, but that's kind of what I was
 hearing this morning.

And then the second thing is we've got devices that want to be all things to all people, and you want them to work all the time. And it becomes very complex.

8 So you know, with that in mind, what 9 I'm hoping that we can do here is take what we 10 heard this morning and these problems and the 11 complexity of it and try to boil that down to 12 some actual action items, some things that we can 13 actually do, and how do we get started on solving 14 the issue of breaking down the complexity?

And, you know, what that actually is I'm not sure if it's that we actually have a national test bed. Do we end up with a bunch of test procedures so we could take a bunch of different devices and know how to test them against what to ensure compatibility and coexistence and so on and so forth.

So that's kind of what I'm going to

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throw out to the panel here as we go through. 1 2 Let's see if we can actually get to making some recommendations and coming up with some ideas to 3 move this forward out of the realm of just 4 5 discussion of this is really difficult to, how do we get there. 6 7 With that, I'm going to turn it over to my co-moderator, Ed Cantwell who is the Chief 8 9 Operating Officer of the Center for Medical 10 Interoperability. 11 MR. CANTWELL: Well, it's a pleasure 12 to be here. I think our intent with this panel 13 is to start to transition to talking about 14 solutions versus the problems. 15 So we're really fortunate to have such 16 a great panel that represents hospitals, IT 17 vendors, medical device vendors, and technology 18 companies. So with that, let me let the panel 19 introduce themselves. And if you'll bring up the 20 slides. 21 DR. BAKER: Hi, I'm Steve Baker from 22 Welch Allyn.

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MR. WYATT: I'm Ed Wyatt with Ruckus 1 2 Wireless. 3 MR. HAMPTON: I'm Rick Hampton. I'm 4 from Partners Healthcare. 5 MS. MLINARSKY: Fanny Mlinarsky, 6 octoScope. MR. RIHA: Chris Riha from Carilion 7 Clinic. 8 9 MR. CANTWELL: All right, thanks. And 10 Rick, can you start us off. 11 MR. HAMPTON: Yes. So if you can bring the slides back up again? Sorry about 12 13 that. So basically I work in a hospital. This 14 is the typical header information; you don't need 15 to worry about that. 16 This is a slide that I showed to some 17 folks at FCC actually; I think, Julie was amongst 18 the first to see this about ten, fifteen years ago. Even though, you know, a lot of the 19 20 discussion so far has been around WiFi and that 21 type of stuff, this is a list of all the FCC 22 services that hospitals use. This is certainly

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in mine.

2 And you'll notice there's everything there except broadcast. We don't have an AM 3 4 radio station, FM radio station or TV. But we 5 pretty much got everything else that we use in our hospitals. 6 7 And you know, since it's used to take care of our, run our operations, it is used 8 9 somehow in patient care. So these are all the 10 different types of wireless systems. Just so you know, wireless systems 11 12 really aren't wireless. There's a lot of 13 infrastructure in the back. So when I brought up 14 the issue earlier about, you know, how do we deal 15 with the systems. 16 We've talked a lot about coexistence 17 and interference, but a lot of my problems are 18 in the back end. And so when people think about 19 their smartphones and their Fitbits and that 20 stuff, that's great. I have to worry about 21 making all this stuff in the background work. 22 You know, the bottom line for me when

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you talk about wireless test beds is the number
 one for creating these test beds is to ensure the
 safety and health of the patient.

You know, anyone can create an app. Anyone can sell an app on an iPhone. But making it safe is what really requires the testing and the insurance of these test beds.

8 And so my first challenge to the folks 9 from the FCC and the FDA is, you know, you talk 10 about these medical grade systems, I need someone 11 to define for us what it means to have a wireless 12 medical grade infrastructure system or whatever.

13 Once we know what we're trying to do, 14 you know, what is the scope or what is the reason 15 for this, then I think we can get to the test 16 beds.

A couple of other things that I put down here, I think these slides will be available later. But here are some other hot points. The only one I'm going to touch on now is I'm going to kind of poke Ira and the folks from the FCC because back in 2012 when they started all this,

one of the things that I heard was going to go 1 2 with the wireless test beds was an expedited system for experimental licensing. 3 4 That's going to be important for 5 future systems. And I got to be honest with you, I've worked with some researchers lately where 6 7 not being able to get experimental licensing stuff cleared through the FCC has been a real 8 hindrance to some of the new stuff. 9 So with 10 that, let's go on to whoever. 11 (Off mic comment) 12 MS. MLINARSKY: Hi, thank you. So I 13 was going to have some slides as well, but maybe 14 I can get started. Essentially we have a mission

16 are more mission critical than others.

And we really have an analogy, a very
large intersection with a lot of traffic without
a traffic light. We have, especially in the
unlicensed bands a lot of technologies trying to
operate and there's no regulation of how they
access the airwaves.

critical application. Some of the wireless apps

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So the question that I think we should 1 2 ask is, like a lot of speakers before me have asked is A, what is critical? What is the 3 4 framework, what is the back end, what is the end 5 mission of the application, and then define the test bed that's appropriate to qualify either a 6 device or a system of devices to that standard. 7 So I know the font is very low and 8 9 everybody's just had lunch, so I'm not going to 10 put anybody to sleep here and I'm not going to 11 read any of this stuff. 12 Basically, this table gives you some 13 of the test standards in the industry just as 14 examples. By far, the most testing is done in 15 the cellular industry and that's because mobile 16 operators own the headache of support. 17 They have to support people with the 18 phones who will not pay their bills unless their 19 phone works. So there's a long pile of 20 standards, there's automation, there's a lot of 21 testing being done before that phone makes it to 22 the airwaves, before the carrier allows it on

their network. And that's by far the most 1 2 structured industry as far as testing goes. WiFi is far behind that. Even though 3 4 there is WiFi alliance, essentially, WiFi 5 Alliance is run by vendors who want to get a The stamp means they interoperate with 6 stamp. other vendors. 7 A lot of folks here said well, okay, 8 9 you passed the WiFi Alliance test, my devices 10 still don't interoperate. And that's the nature 11 of the beast. So the question is, we have to ask 12 the right questions and what's the purpose and 13 how do we design the standard? 14 The WiFi Alliance has had a huge 15 influence in making WiFi a success. It basically 16 picks probably maybe a tenth of what the IEEE 17 802.11 produces and makes it real, makes it into 18 a product because they create a certification 19 standard and they select, each of the technology 20 gets certified and gets out to the market. 21 And recently they have even started 22 defining standards that have not been defined by

the IEEE such as direct WiFi. Another standard that's worth mentioning is the IEEE standard for performance, testing performance of wireless devices, a committee that I started and was active in for a while.

6 We have a number of medically focused 7 standards which deal with both access, wireless 8 access, wired access, interoperability, and how 9 the devices communicate with one another, how did 10 they come out of the box and play together.

11 So these are just some examples. You 12 can use these slides for reference. Obviously 13 there's a lot of information here. The main 14 point is all of these protocols and applications 15 and operation, they rely on the physical air.

16They have to work over wireless. And17yes, some critical monitors will be hooked up via18Ethernet. But the nature of sensors, you know,19if I want to check my child's glucose, it's20mobile, it's wireless.

21 Glucose usually gets checked once a 22 day, not critical. I can use it like a text

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message, its okay. Some other sensors are more 1 2 critical to get through. So there's a lot we need to sort through and define what's important, 3 How do we certify these devices? 4 what's not. Already we've mentioned most of the 5 trouble is in the unlicensed bands. This is just 6 a slide that shows unlicensed bands. 7 There are many issues with the unlicensed bands because of 8 9 what I mentioned earlier. 10 There's no traffic light, essentially. 11 WiFi is a very friendly system in that it's 12 listen before talk. So it's sort of like an 13 orderly speaker in the room where they will yield 14 to others when they're speaking and there's an 15 orderly protocol called contention based access 16 to get on the airwaves. 17 But other devices don't behave that 18 way. They will jump in and transmit, and they 19 don't listen to anybody else. And so how do you, 20 you know, without a traffic light, manage that? 21 No matter how much you're going to test it, you 22 have a problem at the protocol level, not in the

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test bed.

2	And so there have been some efforts.
3	This is one example of GE initiating some of the
4	licensed bands just below the 2.4 ISM unlicensed
5	band where maybe chip sets could operate. I'm
6	not sure whether any chip set actually do that,
7	but today we don't have a licensed band.
8	So to finish off is basically yes, we
9	need the test beds, yes we have a lot of
10	questions before we build the test beds. My
11	company happens to build wireless test beds that
12	are controlled environment test beds. And so we
13	hope to be able to contribute. Thank you very
14	much.
15	MR. CANTWELL: All right, thanks.
16	Chris?
17	MR. RIHA: Hi. I've got a list of
18	slides that are out in the hand out. I'm not
19	going to bore you guys with them. But the bottom
20	line is I've got a similar responsibility to
21	Shawn at Kaiser, Rick at Geisinger, and then Rick
22	at Partners in the maintenance and the support of

the medical systems and the medical devices. 1 2 The only difference is we're a little bit more drought resistant than our friends in 3 4 California, a little bit more snow depleted than 5 our friends in the northeast. And what I bring to the table is the 6 rural hospital facility. We've got two critical 7 access hospitals. Same challenges, I'm going to 8 9 say limited resources as we all have. 10 But one of the things that I want to 11 talk about right now is we've heard a number of the earlier panels, and as Fanny just mentioned, 12 13 I think we're all proponents of the wireless test 14 system, test bed system. 15 One of the things that we all need to 16 be aware of and I think we are acutely aware of, 17 particularly after the last panel right before 18 lunch is that the test beds will provide us the 19 opportunity, provide the vendors the opportunity, 20 and the consumers that if I put this system in my 21 system of systems, it shouldn't break anything. 22 It may not work within my system, but

it shouldn't break anything. That amount of 1 2 assurance is very valuable to us as consumers, but we still have the onus within our 3 4 organizations to see how it's going to operate in 5 our environment. There's not a silver bullet, it's not 6 7 going to be a plug and play. It's going to be a hopefully plug and don't break. So I want to 8 9 just preface my comments with that. 10 MR. CANTWELL: Okay, thanks. Steve? 11 DR. BAKER: Hi, Steve Baker. So my 12 thought on the test beds is going back to what 13 Steve Berger said, is it a protocol or is it a 14 lab? Well, both. 15 So you start with what Rick said, what 16 do we need to test, develop the protocol, and 17 then we can develop a test bed that's tested. 18 Otherwise, you know, what Fanny's doing, great 19 testing, what's being done at the University of 20 Oklahoma, great testing, but it's all disparate 21 testing. 22 UNH interoperability lab does some

sort of WiFi like testing, maybe a little more,
 maybe a little less. But it's all separate; we
 don't have, like, a protocol.

And what I propose is that you have the kind of a layered protocol. You do, just like integration testing, you do single unit testing, one device one access point, many devices one access point, many devices many access points.

10 Start adding noise. Oh, you now start 11 adding non WiFi devices in the same band. Right, 12 so you build this up. And hospitals could then 13 point and say well, I want something for a life 14 critical application, it's got to pass at level 15 seven before I'm even going to consider it.

Well now all of a sudden there's an incentive to the medical device manufacturer to start doing that because right now, honestly, my marketing people say I don't hear a request from hospitals that they're going to preferentially buy our equipment, or conversely they're not going to buy our equipment if we don't do this

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testing.

2	The robust testing we do is invisible.
3	So basically, until there's a pull from the
4	customer, the hospitals that my marketing and
5	sales guys hear, it's hard for me to convince the
6	company that we should do more robust testing to
7	beware of the freight train that's coming.
8	Another thing that I like to see, and
9	this goes back to some of the stuff that Julian
10	has harped on for years and years is data. So if
11	there's an event that's not a life event but just
12	a mistake with maybe a configuration at Partner's
13	Hospital, but there was no adverse patient event,
14	is it reportable? No.
15	And we don't know what the performance
16	of the Welch Allyn devices at Partners compared
17	to the Phillips devices compared to the GE
18	devices. I know for Welch Allyn hospitals which
19	hospitals have the best performance and which
20	ones don't. But that's not public knowledge,
21	right?
22	For Hazem to have a really cool
system, wouldn't it be nice if he could do his simulations and then go test that in the hospital and bring the data back and look at the results and then compare it to a whole bunch of hospitals?

So we have a full closed loop system, 6 and that's a long way out. But if we don't 7 provide a way that medical device manufacturers 8 9 and hospitals are allowed to provide data in a 10 way that won't result in law suits, then it's 11 going to be hard for us to be able to confirm 12 that the test beds are doing what we want. 13 Thanks. 14 MR. CANTWELL: Ed?

MR. WYATT: As a AP manufacturer, we do tests like it's been said before, we test a great deal. But we found a couple years ago that the way we test and how we test may not be realistic.

The Tom's Hardware did a test several years ago that, what they did the first kind of test of capacity. And it was not done with

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simulators, it was done with actual hardware 1 2 meaning laptops and tablets and things like that. And some very unique things occurred 3 4 during one of the tests when they had 50 laptops, 5 they introduced ten iPads. When they did that, all the traffic from one vendor went to the iPads 6 7 and starved the laptops. Now you would never see that if you're 8 9 doing the traditional one to one tests, and you 10 would never see that if you're using a simulator. 11 So the testing that we do is done with real 12 devices, is done with different types of devices, 13 tablets, phones, laptops, things like that to do 14 it just to see how the devices are going to 15 behave because every manufacturer is going to put 16 their own spin on their dryers. 17 So that also needs to be thought of 18 when you're talking about this. 19 MR. CANTWELL: Well thank you. For 20 the record, does the U.S. have a national test 21 bed for wireless health? Anybody that thinks

22 that, raise your hand. Okay.

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1	So let's start with that as the
2	premise. Whose responsibility is it to build it?
3	Government's, industry's, vendor's? So think
4	about that question as we have the dialogue.
5	To start on the questions, and there
6	were some excellent questions provided to the
7	panel, and I'll start with the first one. What
8	does the test bed look like?
9	And when I say look like, not
10	theoretically. How big does the building need to
11	be, how many people need to be employed? We'll
12	start with Chris. Chris, if you have an
13	expectation from Carilion that you're looking at
14	a new device, and what do you envision that this
15	test bed looks like?
16	MR. RIHA: I'm looking for a seal of
17	approval that will handle all of the approved
18	protocols as far as, like, physical. It's almost
19	like a CE stamp of approval so that I know that
20	if I'm buying this device or my organization's
21	purchasing this device, theoretically, and I use
22	the word theoretically in quotes, it should work

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in a healthcare environment.

2	To give you a real life case study, I
3	get a lot of requests, our department gets a lot
4	of requests for oh, I got this new cool device
5	and it connects wirelessly. First question I
6	ask, does it support WPA2 Enterprise.
7	You would be surprised at the number
8	of vendors that give me a deer in the headlights
9	look. I would assume that any type of testing
10	environment would support the security and
11	privacy as well as the connectivity.
12	MR. CANTWELL: Rickey Hampton who
13	rightfully points out that wireless, capital W
14	means all form of wireless not just WiFi, do you
15	expect this certification that Chris mentions is
16	that a platform certification, is it a system
17	level certification, is it a device level
18	certification?
19	MR. HAMPTON: When I look at it, I
20	look at a systems level. I mean, the first thing
21	I look at with any new wireless system that
22	proposes to be part of a medical system is I look

at patient safety, the device efficacy, and the
 security.

If the wireless piece is crucial to the functioning of that medical device and it doesn't, if it doesn't ensure those three things, we don't put it on our wireless network. In some cases, we don't purchase it at all.

8 You know, and we keep focusing on WiFi 9 systems in hospitals, but Rob Havasy is here 10 someplace. Rob used to work for us. But you 11 know, we've got a group of people who are looking 12 at connected health applications outside the 13 hospital, and I get involved in that too.

So we have to, you know, when I look at this stuff, I have to look at not only patient safety, device efficacy, and security in the hospital, I have to look at what it might be like out in the patient's home where we don't have a standard enterprise WiFi network, where they may not have a WiFi network at all.

We may have to use the cellular system. You know, find any one of those wireless

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companies that's going to put their stamp of
 approval and say we'll be responsible if our
 network goes down and the data doesn't go
 through. Doesn't happen.

5 So when I look at a test bed, I look 6 at something that's going to ensure those three, 7 you know, key properties if you will that a bunch 8 of us on this panel and the others put together 9 as part of the risk management program when we 10 start connecting these medical devices together 11 over networks.

12 You need to ensure those three key 13 properties remain, patient safety, device 14 efficacy, and security. That's what I'm looking 15 So I'm looking for it at the systems level. for. 16 MR. KELTZ: So when looking at that, 17 you know, Steve put out the notion of kind of a 18 layered protocol of testing of what seems to be a 19 kind of very logical process of starting with the 20 simple case and working to a much more difficult 21 case, more devices and much more difficult 22 interference environment.

1	You know, Fanny put out an analogy of
2	the cell phone companies would never let a device
3	on their network that's going to cause a problem
4	because customers aren't going to pay.
5	Yet it seems like I keep hearing we
6	get devices in hospitals and healthcare
7	facilities that do just that which kind of seems
8	a little, the priorities may be a little out of
9	whack.
10	So taking the notion of testing to
11	make sure things are going to work the way we
12	intend and trying to come up with a logical way
13	to do this testing, so how do we get there?
14	Who's responsible, what do we put together?
15	Do we need to form a standards
16	committee, a body to lay out the process? Or is
17	each healthcare facility responsible because each
18	environment is different? Or can we characterize
19	a couple of different environments to test
20	against based on everybody's, you know, on a few
21	cases, representative cases?
22	So how do we get there? How do we get

to the place that we need to be to make this work?

3 MR. HAMPTON: This is like the 4 proverbial, you know, the proverbial story about 5 the blind man trying to describe the elephant. 6 You know, we all come at this from our own 7 perspective and so we look at one individual 8 piece.

You know, so what I'm trying to do
here is take the 60,000 purview because that's
kind of what Partners pays me to do, I'm lucky in
that respect. But first off, you know, I'm going
to go back to what I said earlier. I think
someone needs to define what it is that we mean
by a medical grade wireless network.

Everyone dodges that issue. Once we have an idea of what we're supposed to create with this wireless medical grade, or medical grade wireless system, then we can start putting standards together to define it.

Once we have the standards, we can
start building out the test beds. But so far, no

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one's really defined it. We've done a great, 1 2 please don't take this wrong, the FCC's done a great job about talking about how wonderful it is 3 4 that they've created all this spectrum that's 5 generated billions of dollars in revenue in new technologies, but they've never really helped 6 7 anyone direct how we're going to be using it. So now the medical stuff comes up, and 8 9 that's a critical issue if you're going to be 10 diagnosing patients or treating them remotely. 11 So now we've got to step in, we've got to start 12 help defining what it is we mean when we say we 13 expect people to create health systems with it 14 because health systems are not regulated, medical 15 systems are. You know, that's the old issue what is 16 17 a health app. So we've got to get better 18 granularity in what government expects us to do 19 with this stuff and what they're willing to help 20 us with. 21 DR. BAKER: No. I mean, well, 22 different question. But following up on what

Rick said, so I think it is probably the FDA or 1 2 maybe the FDA together with the FCC comes up with 3 that definition. Of course the difficulty is, well, 4 5 medical grade wireless network; the definition of it is generically a network that supports the 6 medical devices for their intended use. 7 I have an infusion pump; I 8 Great. 9 have a life critical patient monitor that's 10 sending alarms. You know, it's a different 11 definition. And coming to grips with that and 12 saying, that's why I had this idea of the layered 13 approach. 14 Well, for the one device you might 15 only need to pass at level three and the other 16 you might need to pass at level five or six 17 because it's more robust testing. And basically 18 what that's coming down to is what Michelle had 19 talked about and what Donald Witters talked 20 about, it's a risk based definition. So I don't think we have a hard 21 22 definition, right, because that one I gave is a

great definition but it still doesn't tell us
 what we have to test to.

3 MR. KELTZ: Okay, so what I would
4 respond back is, you know, one for Rick, I mean,
5 you've got the stage. Tell us what a wireless
6 grade medical network is to you then.

7 And then my second question which may 8 be more to the panel and to Steve's point is so 9 who, you know, if you define this layered 10 approach and different levels of risk, so who 11 should be defining that?

12 Is that something you want the FDA and 13 the FCC to do, or is that something industry 14 should get together and define for different 15 types of devices what the risk level is and then 16 try to define what the performance requirements 17 should be?

18 And you know, I'll kind of throw those19 out generally to the whole panel.

20 MR. HAMPTON: So when it comes to, if 21 I buy a telemetry system from Steve, we did buy a 22 telemetry system from Steve that runs on 802.11a,

I've not installed that on my IT network wired or wireless.

I build out a completely separate wireless system for his stuff. The FDA requires him to define what those systems have to meet in order to support the intended function of his devices.

8 So when I build out a system from a 9 device manufacturer on an infrastructure designed 10 and provided by that manufacturer, I know what 11 constitutes a medical grade system for that 12 particular medical system. Steve has defined it 13 for me; Phil has defined it for me. The folks 14 from GE have defined that for me.

15 So as long as I put it on the network 16 that they prescribe for me, I know what 17 requirements I have to meet. And if anything 18 goes wrong, they're held liable for producing a 19 system that doesn't perform its intended 20 function.

21 When we get to the notion that now 22 we're going to converge all of these systems onto

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our IT network, the question I've asked for 1 2 years, and it's funny watching my friends scurry out the door when I ask this, but the question is 3 4 if I take that, if I take Steve's system off of 5 his dedicated wireless network and I put it on my IT network, what does that make my IT network 6 7 because when he provides it it's a registered or a regulated medical device. 8 9 But if I take it off that system and 10 put it on mine, does that make my IT network a 11 regulated medical device? No it doesn't. What's 12 that make it? Well, it makes me potentially 13 adulterating a medical device because I've taken 14 something and modified it to do something it was 15 never intended to do. 16 In other words, I've just taken all 17 the legal responsibility for creating a medical 18 system I can't guarantee will work, which is why we don't have critical medical systems on our IT 19 20 network. 21 So I guess the question is if you 22 really want the answer to the question, if I take

a wireless system off of a regulated device that 1 2 Steve and Phil and the folks from GE or whoever provide to me and I put it on my network provided 3 4 by any of the IT, you know, networking companies, 5 who is responsible for making sure that works? You know, what does that make that 6 7 network become? It used to be regulated and now it's not. 8 9 Ira, maybe we should MR. CANTWELL: 10 look outside healthcare for best practices. So 11 what industry do you think is most like 12 healthcare in terms of the IT challenge and more 13 and more the wireless challenge? 14 Which industry has the responsibility 15 to touch almost all of the population and provide 16 content? It's the cable industry. And if you 17 look at the way that they've solved this problem 18 is they didn't ask the FDA and they didn't ask 19 the Government or the FCC to solve it. 20 They created their own organization 21 led by the people that procure the devices and 22 the infrastructure. And they defined the

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architecture and they defined their equivalent of medical grade in the cable industry.

It's a 30 year plus proven record. 4 It's taken their industry through extraordinary growth, and it's probably the backbone of most of the content that we as consumers have.

7 So the question is do you think healthcare is ready, and the partners and the 8 9 Carilions and the Kaisers, do you think they're 10 ready to come together and claim wireless as an 11 asset for their industry and as such start to 12 define what it is, because I would be hard 13 pressed to ask Ed White why don't you design the 14 medical grade network to include in the body, 15 around the body, around the bed, in the room 16 wireless networks. So do you think we're ready?

17 MR. RIHA: Let's use a parallel 18 example in the healthcare world of standards 19 driven principal that works, DICOM. It was an 20 industry driven standard. And guess what, it 21 works.

Every vendor has their own little

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nuances; they can do their own little special 1 2 things, their market advantage. But it has interoperability and it works. 3 4 MR. HAMPTON: It was regulated under 5 All those pack systems are regulated. the FDA. The DICOM standard is not 6 MR. RIHA: 7 though. 8 MR. HAMPTON: It's not. 9 MR. RIHA: Right. 10 MR. CANTWELL: But Chris is right, 11 it's an excellent example of the users coming 12 together and agreeing on something so the vendors 13 know what to build to. What Rickey points out is it's a seven dimension chess game. 14 15 It's RF, it's digital, it's security, 16 it's human behavior. So it's very unfair to ask 17 Welch Allyn or Ruckus to come in and warrant 18 their performance when they have no control over 19 how many devices, what protocols, what beacon 20 rates are set. 21 So the question is can we rise up and 22 is it time for U.S. Healthcare to have a point of

view on what wireless really means in a hospital? 1 2 They've defined building automation, they've defined electricity, they've defined every other 3 4 base building utility. But wireless still is like this 5 orchestra where there is no testing whether or 6 7 not all the instruments play together. MR. HAMPTON: Let me add one more 8 9 You know, I don't want to make it thing, Ed. 10 sound like every potential application, healthcare, medical, however you want to split 11 12 that difference, not everything requires the 13 highest degree of reliability. 14 You know, if someone is using their 15 Fitbit and they're feeding that stuff into some 16 application that they're sharing with their 17 doctor, no one's going to die if your performance 18 during a run is three minutes slower than your 19 last performance. 20 But I'm also hearing people talk about remote control of medical devices for treatment 21 22 therapy. That's pretty critical, folks. That's

not something you just want to ignore. So there needs to be some definitions to help define which of these applications really don't require the reliability and which do.

And the ones that require the highest, 5 you know, reliability, those somehow need to be 6 defined and protected so that the consumers when 7 they go out and buy this wonderful device that 8 9 they're going to take home and they're going to 10 use it, I mean, one that I've heard numerous 11 times is it's going to monitor my heart rate so 12 that if I have a potentially fatal dysrhythmia 13 it's going to automatically diagnose that, send 14 my ECG to my cardiologist, call 911 and let the 15 ER know to prep for my arrival.

I look at other things, and FCC has gone to fairly great lengths to ensure that, you know, we have e-911 capability so that if I pick up my smartphone and I hit 911, the 911 dispatcher knows where I'm at within a couple of meters.

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They've taken that kind of lead

1 already on some of these things where the
2 expectation of the public is if I need help I'm
3 going to get it no matter what. And I think we
4 need that same kind of leadership on some of
5 these wireless health sets used to help show that
6 we expect that reliability to be there. Did that
7 shackle you enough?

8 MR. KELTZ: Pretty much. So on that 9 point, I mean, do you really think, and as an 10 industry, do you really want us to sit and try to 11 define your networks? I mean, I don't think 12 that's really what you want.

MR. HAMPTON: Okay, so do me a favor. Go out and open up your favorite web browser on your favorite device, okay. Google wireless or medical grade wireless networks and tell me how many companies have white papers and position statements on how if you buy their product you could build this.

20 And then go down and read the fine 21 print that says your mileage may vary. I don't 22 think industry can possibly do this.

MR. KELTZ: Well, but, you know, using 1 2 Ed's example of CableLabs, I mean, could the industry get together, could the big players, the 3 4 little players get together and define this 5 because it would help the industry as a whole. I mean, I would think it would help 6 7 both from your sales point of view if you could go out and you could make that assurance that 8 9 based on coming together as an industry, you 10 develop certain standards and the levels of 11 performance for various devices and then say 12 look, these meet these industry defined levels, 13 standards, and protocols and that gives you a 14 very high assurance that it is going to work 15 whether it's on your IT network or what you call 16 your medical network or whatnot. 17 So I'm wondering, again I'm still torn 18 between is this the Government's role to define 19 or is it better for the industry to come together

19 or is it better for the industry to come together 20 and come to a meeting of the minds on how they 21 think this is going to work and should work 22 within their facilities.

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MR. HAMPTON: I would invite you to do 1 2 what I did and call AT&T, Comcast, Cox Cable, Verizon, and all of them. We've had them, we 3 4 actually had representatives from a lot of those 5 different companies at some of the AAMI conferences that we've had in the past on 6 7 wireless systems reliability. And I've asked them point blank, and 8 9 we've had a lot of those companies come in and 10 talk with us about, you know, providing 11 connectivity for connected health. 12 And I've asked them point blank what 13 kind of reliability guarantees can you give us 14 for critical stuff? Oh, we will never do that. 15 No, we can't do that. Just keep that off our 16 networks. 17 They're looking for guidance, too. Ι 18 mean, no one knows what medical grade wireless 19 is, so someone needs to do that. Sorry. I would 20 like to give you an out, I just don't see it. 21 MR. CANTWELL: Why don't we, let's 22 poll the panelists there because, you know,

Rickey's pretty clear. He thinks the FCC should 1 2 do it. Let's poll. Chris, how about you? I don't agree with Rick. 3 MR. RIHA: 4 And I'm one of his friends and I'm scurrying for 5 the door. I think it should be an industrydriven, but I'm philosophically opposed to more 6 7 Government regulation. To that point let me add 8 MR. HAMPTON: 9 I am not in favor of Government one thing. 10 regulation. But sometimes I think you have to 11 have it. My dad was a cop and, you know, one of 12 the things he said is we wouldn't need speed 13 limits if everyone drove at the right speed. 14 But when people don't do or won't do 15 what they're supposed to do, that's when 16 Government has to step in. So if you can 17 convince all these people to do it --18 (Simultaneous speaking) 19 MR. RIHA: -- getting gray hair by the 20 second. 21 MR. CANTWELL: Fanny? 22 MR. RIHA: One more thought, though

that I want to share is it really depends on the 1 2 organization and how they're implementing technology. We talked about medical grade 3 4 wireless technology and we think about medical 5 telemetry, life safety. Well, you got these things, you build 6 7 in work flows that say all right, code blue alerts are going to go over the cellular network 8 9 now because we're going to do a quiet hospital. 10 Have you created a medical device? No. Is it a 11 life safety issue? Yes. 12 MR. HAMPTON: And to that point, I can 13 honestly say I've heard from at least four 14 hospitals who have had serious, life threatening 15 incidents. One has told me that a patient 16 expired. 17 And I got to be honest with you, I was 18 visiting someone close to me a while back, and 19 that alarm system didn't work. And if I hadn't 20 intervened, I think the patient would have had 21 much more serious outcomes. 22 And it's one reason why we don't have

1	those things in the hospitals where I work. I
2	can't trust the systems.
3	MR. CANTWELL: Fanny?
4	MS. MLINARSKY: So I would go back to
5	Ed's point about what has worked, and you brought
6	up cable industry, CableLabs has done a great
7	job. I brought up 3GPP, the cellular operators
8	industry.
9	So it needs to be in this case, I
10	think the analog is the hospital administrator.
11	Who has the headache? Whose headache is it?
12	Those people will want to solve it. And the more
13	they can come together as a forum to solve it,
14	the more interoperable devices the vendors will
15	design through the standards that they create.
16	And I think the hospital
17	administrators and IT folks have the power to
18	allow or disallow and define policies in the
19	hospital just like an AT&T or Verizon has the
20	power to define the policies on their network.
21	MR. CANTWELL: Ed?
22	MR. WYATT: Yes, I kind of read the

idea for us as a manufacturer; we work with our 1 2 customers all the time. We can make any adaptation to anything that we need as long as we 3 4 have a plan. And from our perspective, it would 5 probably be the same as somebody give us some road map of what we need to do. 6 7 (Off mic comment) 8 MR. WYATT: Yes. 9 MR. CANTWELL: Steve? 10 DR. BAKER: Well, somewhere between Rick and Chris. So I think we all agree we need 11 12 a plan, right? So far, the industry hasn't come 13 together to create a plan. Right? And we have 14 all kinds of new companies coming in. 15 They have a USB port, they put a USB 16 WiFi dongle on it and they say hey, we got a 17 wireless medical device. Anybody have one of 18 those fail in their hospital? Yes. So while I prefer that the industry 19 20 would do it, maybe there needs to be some Government incentive to do it. Certainly the FCC 21 22 and/or FDA shouldn't just go in a closet and say

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hmm, well this looks good, right?

2 If you guys do come up with a definition it's, based on your track record, 3 4 you're going to call in Rick and Shawn Jackman 5 and maybe Phil. Touché. But, you know, how long are we going to wait for industry, whether it's 6 7 medical device manufacturers, the infrastructure manufacturers or the hospitals to do this. 8 9 There's a pretty big significant 10 difference, right? We've got, in cellular, a few big players, in cable a few big players. 11 How 12 many thousand bed hospitals are there? 13 How many hospital chains are there 14 that have more than five hospitals and how many 15 hundreds and hundreds of 100 and 200 bed 16 community hospitals are there out there. So it's 17 a lot bigger herd of, it's herding 1,000 cats 18 instead of 50 horses. 19 MR. WYATT: There's also, there's a 20 big difference between when you're comparing cellular to this is a cellular company does have 21 control of the client device. 22 They can look into

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the device, they can see what's happening with 1 2 the device, they can turn the power on, they can turn the power up or down or whatever. 3 4 In WiFi based on the way the 5 standard's written, you have no control of the client, and that's the big issue. 6 Talking to 7 Shawn earlier, I can't tell you how many times I've seen on our own internal lists power save. 8 9 An iPhone goes to sleep every 90 10 seconds and wakes up and goes to sleep. It does 11 this constantly to save its battery. But if you 12 look at a laptop or any of the medical devices, 13 I'm sure they all go to sleep too. 14 And if the access point's not set for 15 the same power save number, the device data that 16 the device is trying to send is going to get 17 lost. It's not going to be buffered properly, 18 it's going to be transmitted when it's not 19 supposed to be, something's going to happen and 20 this is part of the stuff that needs to be 21 discussed with these testing and how they're 22 going to interact together. And that's not part

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of the WiFi Alliance standard.

2 MR. CANTWELL: So at least you think you're going to get off. Do you think for the 3 FCC intended for WiFi to be the backbone of a 4 5 healthcare wireless network? MR. KELTZ: That's why they call it 6 7 ISM. MR. CANTWELL: And do you think we 8 9 should, as an industry, hospitals and health 10 systems, petition for protected spectrum more 11 that the whopping WMTS spectrum? 12 (Off mic comment) 13 MR. CANTWELL: So, I mean, maybe 14 that's a path where it may not be dedicated but 15 it may be prioritized, the use of small cell 16 architecture. But who has the most to win or 17 lose at this game from a time? Since time is the enemy because the problem is growing every day 18 19 exponentially. 20 Do we have the time even if Rickey 21 could waive his magic wand and have the FCC do 22 it? So how do we create this sense of urgency,

and is procurement power perhaps an asset to bear in buying the type of architectures that they want out of their vendors because I would think 4 hospitals, Shawn has more control, I know not absolute control, but he has more control over the devices that enter his hospital if it's 7 procured.

What walks into the hospital, you 8 9 know, you just have to manage. So I think it is 10 time, and I think it's almost an inevitable 11 outcome if it's going to be fixed, it has to be 12 fixed by the people that buy the systems.

13 Now Steve's exactly right, how do you 14 herd 5,500 hospitals? But they're really in the 15 hands of only about 30 companies. So the problem 16 may not be as complex as we think.

17 MR. HAMPTON: I'll disagree about the 18 complexity. But, you know, going back to 19 hospitals buying the appropriate components. 20 Okay, how many people out there make components 21 that you sell to hospitals? How many of you know 22 what a medical, you know, a wireless grade

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medical system is?

2	How many of you know what to build it
3	to? Okay, no hands. How many of you make stuff
4	that you sell to hospitals? Okay, there's enough
5	back there. So there's people back there that
6	sell stuff to hospitals and they don't even know
7	what they're building it for.
8	So we've got an apple, we're putting
9	the cart before the horse in some cases. If we
10	don't know what standards to build it to, if we
11	don't know what the expectations are or the
12	requirements are, you know, it's nice to talk
13	about test beds, but what are you going to test?
14	You know, and let me go back and touch
15	on the spectrum piece. I've been a licensed HAM
16	operator and commercial radio operator for way
17	too long. So I've worked with the FCC a lot in
18	some way, shape, or form. And it's always kind
19	of a love/hate relationship.
20	No matter how much spectrum you have,
21	you always want more, and everyone's that way.
22	I've not always agreed with how the FCC has

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divvied out the spectrum.

2	But be that as it may, I got to be
3	honest with you, the recent goings on between the
4	auctioning or the analog to digital TV
5	conversions, the required auction to take place
6	of that has created a position I think has really
7	put the FCC between a rock and a hard place.
8	They created the wireless medical
9	telemetry service, and now they're having to look
10	at sharing it. You know, before it was protected
11	spectrum. It was basically us and radio
12	astronomy in the 608 band, channel 37, TV channel
13	37.
14	And now because, you know, Congress
15	required them to auction off all of the spectrum
16	that originally they had planned to allow TV
17	white spaces stuff, there's no space for TV white
18	spaces except, ta da, TV Channel 37.
19	So now they're looking at, you know,
20	the protected spectrum that we used to have,
21	we're now going to have to share it. So what
22	does it really mean to create "protected

spectrum" when the FCC, the body that's required 1 2 to do the protecting cannot protect it either. I got to be honest with you; I've got 3 4 grave reservations about our wireless systems 5 that are in that band. I'm still waiting to figure out what I'm going to do with them, where 6 I'm going to put them. 7 So the point of it is the FCC can 8 9 giveth and Congress can take away. Did that get 10 you off the hook, Ira? Do you have any job 11 openings at the FCC? 12 MR. CANTWELL: Rickey might. Α 13 question from the audience, from Twitter and 14 email, and this is a pretty good one, will the 15 internet of things and device data analytics 16 radically change medical device test beds and R 17 and D? 18 DR. BAKER: Yes. What I think that's 19 really maybe getting at is if we, let's say we 20 knew the definition of a medical grade wireless 21 network and we had the test protocols, right, 22 well wireless is a pretty fast changing

technology.

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2 So you build the test bed, you invest all this money, and in six months it's obsolete 3 4 because the new latest greatest thing or standard 5 or protocol has come out. So that's one of the things that is a challenge is it's a moving 6 7 target. And as Shawn pointed out, it's a 8 9 moving target that's still anchored ten years ago 10 because I've got stuff in my hospital that's that 11 old. Anyone else? 12 MR. CANTWELL: Should it be a hospital 13 only problem? How about care in the home? 14 Should healthcare as a vertical market have a 15 point of view of the wireless environment inside 16 the home? 17 I think that's the, you MR. HAMPTON: 18 know, the problem for the future. You know, like 19 I said, I'm already looking at stuff that we're 20 trying to use in the home. 21 And the nice thing about, you know, 22 modern technology is our smartphones and whatever

else, other devices we might have, it has enough 1 2 computing power to do a lot of things that used to require mainframes and stuff that only resided 3 4 at hospitals. 5 So with the right sensors, I think a lot of this stuff can move out to the home. 6 And 7 that again is, you know, begs the question at what point does a simple sensor and an 8 9 application stop being a fitness device? 10 I mean, Polar's been making heart rate 11 monitors for a long time but I never really 12 thought that I would use a Polar heart rate 13 monitor in a hospital to keep track of a cardiac patient. 14 Right? 15 You know, so at what point does the 16 Polar group or any of these other manufacturers 17 that make fitness monitors, at what point in time 18 do those become medical devices? And that's the 19 question that I think the FDA and the FCC really 20 need to look at because it's really going to 21 upend how we do regulation of these things. 22 And frankly, you know, when it comes

1	to medical devices, we've got these things called
2	liability. You know, who absorbs that?
3	MR. CANTWELL: Let's open it up for
4	questions. Shawn?
5	MR. JACKMAN: Shawn Jackman, Kaiser
6	Permanente. We talk about WiFi a lot up here.
7	With small cell, the cellular indoor, they're
8	doing cellular indoors now. To what extent
9	should we be looking at medical grade wireless to
10	also include LTE and perhaps, you know, some
11	variant of 3G?
12	MR. CANTWELL: My personal opinion,
13	medical grade wireless as used by Rickey means
14	every wireless frequency that is intended to
15	support a medical cause. It's like a, you know,
16	the analogy is in most hospitals you have a
17	critical electrical network, right, a failsafe
18	electrical network. So I think it has to be all
19	encompassing.
20	MS. MLINARSKY: If I could jump in on
21	LTE, that's actually a good question because LTE
22	at least has, if you deploy IMS which is IP

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Multimedia Subsystem, you have priorities. 1 2 Something that can be managed by an operator to 3 assign higher priorities to more critical medical 4 services. 5 MR. WYATT: But then you run into the problem of spectrum because every operator is 6 running LTE on different band. 7 MS. MLINARSKY: Including a licensed 8 9 now. 10 MR. WYATT: Yes, so they have LTE-U 11 which opens up a whole other issue. 12 MR. HAMPTON: Licensed assisted access 13 stuff, yes. 14 MALE PARTICIPANT: Qualcomm just 15 changed it yesterday to LWA. 16 MR. HAMPTON: Whatever they call it. 17 A rose by another name. 18 MALE PARTICIPANT: But it's collision 19 avoidance now, so that's what they're talking 20 about. 21 MR. RIHA: We still have 900 MHZ 22 phones for another year.
1	MR. CANTWELL: Next question?
2	DR. REFAI: Yes, Hazem Refai,
3	University of Oklahoma. So the densification of
4	5G which is the Femtocells and the small cells
5	and so on, a lot of capability is coming in the
6	systems, the new systems as self-organized
7	networks.
8	And so self-organized networks are
9	going to be adapting power, adapting maybe
10	sensitivity, adapting their packet length,
11	adapting their polling windows, and adapting all
12	of those based on an environment, given
13	environment deployed at.
14	So is that going to help coexistence
15	or is it going to hinder coexistence, and how do
16	you do a test bed to go and accommodate and test
17	for these type of activities?
18	MR. WYATT: The problem with something
19	like that is going to be backlog. You might be
20	able to do all what you just said within small
21	cell itself, but how is it being backlogged to
22	where, with what?

So to give our vendor an opportunity 1 2 to come into your hospital to deploy, you're going to give every cellular vendor the same 3 4 access, and how many cables are you going to run 5 through the building to do all those small cells is another thing that we're running into an issue 6 with just, I'm running into an issue talking to 7 cellular operators about that. 8

9 DR. BAKER: One of the other issues 10 with small cell is you have hundreds or thousands 11 of different medical devices and medical device 12 types. So just like in, now suppose, in theory 13 if it's cellular the only way you get on the AT&T 14 network is if you validated that cellular module 15 with AT&T.

So a lot of that may be mitigated. But if you have a whole bunch of different manufacturers producing devices that are running on these and each one tweaks them a little bit, then we return to this same problem of well which driver is it. And you could have a lot of changes then.

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So in the world where if that comes to 1 2 fruition where we're using small cells, cellular to send data in hospitals, I would love to just 3 have, there's three radios, there's the Sprint 4 5 radio, there's the AT&T radio, and there's the Nextel radio or whatever, right? And we all buy 6 7 the same radio. Before we get to Mark, let 8 MR. KELTZ: 9 me just throw something else out or make a 10 comment. So you know, Rick, you had mentioned 11 what's going on in the TV bands, specifically 608 12 to 614 and changes that may be happening because 13 of the incentive auction and as we're responding 14 to an act of Congress. 15 So one of the things, you know, that 16 occurs to me, well first of all, as Julie opened 17 up this morning and said one of the most 18 rewarding things that we do is things that really 19 have a real effect on people and help them, and 20 often that's working on the medical devices and 21 some of the things we're able to enable. 22 And I completely agree with that

You know, I personally find it one of 1 notion. 2 the most rewarding things that we do. So the last thing that we want to do is have an adverse 3 4 effect on medical devices, medical networks. And as we proceed, that's our goal in 5 moving forward with any changes that may be 6 7 happening. That said, and Mark, maybe this plays in a little bit what you might be going to ask or 8 9 comment on, but so part of enabling us to make 10 whatever changes and do no harm is a certain 11 amount of testing. 12 And I know Mark has been involved in 13 some testing on Channel 37 of devices against 14 medical telemetry. But it's largely kind of 15 user-defined by the folks doing the test. So is 16 this a place where folks can maybe get together 17 and agree maybe in a limited case, you know, is 18 there some standardized way that we should be 19 testing these and defining an environment and 20 characteristics to inform the commission on how 21 best to move forward rather than it just being 22 completely haphazard, everything's sent to the

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record.

2	We take a look at it and then, you
3	know, we make some judgments based on the
4	results. And then there's typically a lot of
5	disagreement over different parties with
6	different positions on how the tests were run and
7	what they mean.
8	And it would be much better if, again,
9	there was an industry consensus that could come
10	together and say here's how we think it should
11	be, here's what we think the thresholds are, and
12	as a unified position.
13	I mean, maybe that's kind of too much
14	to ask. But is there a way to get to that?
15	MR. HAMPTON: I think there is, but
16	first you have to find what it is you're trying
17	to get to. So let me really set Mark up for a
18	comment because, you know, at one point in time I
19	asked okay, so if we're going to have this
20	contention problem between WMTS and TV white
21	spaces, and one of the things that TV white space
22	has proposed to do is to create some kind of

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connectivity for medical devices.

2	Why don't we look at just wholesale
3	swapping from WMTS to TV white spaces? I'm not
4	opposed to that as long as I know that the
5	systems will work. And I got to be honest with
6	you; it's more than just about RF coexistence if
7	you look at how TV white spaces is set up.
8	So for those not familiar with it, the
9	FCC's looking at creating exclusion zones around
10	hospital to prevent the interference. And the
11	size of the exclusion zone is pretty much the
12	argument point right now.
13	You know, the question is so the TV
14	white space device is supposed to determine its
15	ability to use those areas based upon some
16	database. I know some pretty smart hackers, but
17	I don't see a whole lot of investigation into how
18	secure those systems can be made.
19	There's been GPS spoofing, so is it
20	possible? And I don't know. This is a Hollywood
21	scenario that the hackers out there will just
22	love to get their hands on.

You know, there's been people who have 1 2 been able to spoof GPS. So if they go and spoof GPS readings around a hospital, can they cause TV 3 4 white space stuff to interfere with telemetry in 5 WMTS? Is that hypothetical? 6 It's possible; I don't know how probable it is. But you know, 7 that's all of the stuff I have to look at. It's 8 9 not just the coexistent stuff. So do you want to 10 give Mark a shot? 11 MR. CANTWELL: Did he ask and answer 12 your question? 13 (Simultaneous speaking) 14 MARK: Well, I started to come up here 15 to applaud Rick on his comment about WMTS. You 16 know, we've been working in this area probably as 17 much as anybody. And as Ira said, we did some recent testing that got filed by GE and the WMTS 18 19 Coalition. 20 And I'm not going to get into the 21 noise about that. Rick makes a very strong point 22 about some of the ironies involved around WMTS.

And if you go back and look at the original rule 1 2 making for TV white space, there were a lot of comments on the record that said, you know, let's 3 4 keep Channel 37 sacrosanct for patient care and 5 radio astronomy. I was actually going to ask a 6 7 question, and I'm happy to talk in the break about what we did in the measurements. 8 We did 9 show in the measurements that we could configure 10 a situation where we could cause interference. 11 And we're going to go back out and do 12 it again so we can have the repeatable. Ι 13 thought the gentleman from NIST this morning 14 described a very good method for producible test 15 results, and so we're going to try to do that. 16 But what I actually wanted to do is to 17 make a question, maybe it's rhetorical, I don't 18 know, about the point Ed made about should there 19 be more spectrum available for healthcare. 20 The FCC last year, I think it was June 21 last year, finalized the rulemaking for M bands 22 where they were allocated 40 MHZ to medical body

area networks. And since then, you know, they've
 been working on the frequency coordinator part
 which they just finished.

But Ira, correct me if I'm wrong,
there's no manufacturers banging down your door
for equipment certification.

7 MR. KELTZ: I've heard rumors that 8 there's equipment in the pipeline ready to go.

9 MARK: I've heard rumors, too, and 10 that's been three years out. So you know, the 11 point to be made on it is that if you make it, 12 will they come.

13 Or are you making it because they've 14 asked for it because the issue is, and maybe this 15 is more of a soapbox, is that when the 16 manufacturers came to you, and it was GE and 17 Phillips, to the commission for allocation of the 18 rules and whatnot, they were pretty hot to trot. 19 And the rulemaking process took a lot 20 longer than they had expected, and that's just 21 because they probably didn't have a lot of

familiarity with the way the commission works.

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And the commission did their proper, you know,
 vetting. And I know you're going to make a
 comment, Ira.

4 And it's not a comment about the 5 rulemaking process. It's more the setting expectations. And so since this is a workshop on 6 7 test beds, let me shift to the test bed question and that is, you know, can we conceive test beds 8 9 to test coexistence of medical body area network 10 systems with aeronautical mobile telemetry, which 11 that's the sharing paradigm there.

12 And to Rickey's point again, can we do 13 that to also test WMTS which never really had to 14 do it, coexisting with unlicensed devices which 15 now can include any number of things, and I won't 16 comment about the NAB thing.

MR. KELTZ: All right, let me be a little more specific on the M BANS. And as you know, once we enable rules, it takes time for the manufacturing process to develop and production lines and develop the test protocols and so on and so forth.

And, you know, we just finished as far 1 2 as finalizing rules and the designated coordinator and so forth. So again, so I know 3 4 our lab has been working with some folks on 5 finalizing the test procedures from Mark's perspective. 6 7 And that is, my understanding is very close to being finalized. And now that a 8 9 coordinator is in place, that there are folks who 10 are very close and ready to submit equipment for 11 approval and they've just been waiting for the 12 lab to finish up its work. 13 And I think that's been moving at a 14 pretty good pace given, you know, how the 15 regulatory process has moved. So I do think we 16 are going to see things happening in that band 17 relatively soon. 18 And I think that will be a good thing 19 and it will open up, you know, spectrum that is 20 right now would share with aeronautical 21 telemetry. It should be fairly compatible, you 22 know, the way we've worked through the

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proceeding.

2 And I think people are looking forward to it, and hopefully it will provide an avenue 3 for folks to use devices without maybe some of 4 5 the issues that we've heard today. Getting to your second point of 6 testing of these various things, I'll throw that 7 out to the panel to answer of, you know, again, 8 9 what would be the best way to do this, to set 10 something up and to work through those issues? 11 Is it the Government's responsibility to be doing this, is it the industry? 12 I mean, I 13 know I keep harping on this but I don't think 14 we've really converged on, you know, there's 15 differences of opinion but where do we want this 16 to go and how are we going to get it done? 17 MR. CANTWELL: Dr. Goldman, why don't 18 you ask the last question, and then we'll try to 19 wrap up. We've got about five minutes. 20 DR. GOLDMAN: Well thank you. Thank 21 you, Julian Goldman from Partners Healthcare and 22 Mass General Hospital. I was instructed we

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1	should all introduce ourselves. Right? Okay.
2	Thank you. So I've been listening to
3	a lot of really good ideas, good debate.
4	Achieving consensus may or may not be possible.
5	But I was also reminded of one of the goals for
6	the session of identifying and prioritizing key
7	features, functions and so forth.
8	And that's the title of this session,
9	but I think throughout the day we've been coming
10	up with a lot of wonderful ideas, and I wonder
11	how we'll end up defining the next steps.
12	So if out of that range of things that
13	have been brought up, for example which are the
14	most important devices or which are the most
15	important physical or clinical domains, which are
16	the most important functions, which are the most
17	important frequency bands or technologies.
18	At some point today, and I'm not
19	trying to put this on you in this panel but I was
20	listening to this and it's a very rich
21	discussion. It's so rich that I wonder if we'll,
22	you know, when we will be able to prioritize it

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or start to decide what to work on next.

2 So I thought I would kind of gently ask because I'm eager to see what the priorities 3 4 are based upon the panel's discussion what you 5 think might be the first or top few things to work on, if that's an appropriate way to look at 6 7 it. MR. CANTWELL: Well, I think it's an 8 9 excellent question because it's otherwise for the 10 panel it's a so what. You know, it's a great 11 discussion. I can tell you at the Center for 12 Medical Interoperability we did an interesting

13 exercise.

We took ten health systems and asked them to prioritize by modality and by device and by frequency what is most mission and life critical as it relates to the use of wireless as defined by health system level platform.

And it is fascinating because it not
only produces a prioritization, it produces the
list of vendors that are expected to participate.
So we'll share that with you. Is Chris Gibbons,

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does -- yes? You need to just step right up to
 the mic.

How did you even know? 3 DR. GIBBONS: 4 I just actually sort of follow up on something 5 Julian said. You know, we're physicians so forgive us if it's a little bit naive, but the 6 7 conversation that I've been hearing and have learned quite a bit, it sounds like we're almost 8 9 using a notion of healthcare system that's 10 becoming antiquated.

And I go back a little bit to what Harry was saying a little while ago, and I think Rick has brought up some of this. But you know, medical care happens outside of hospitals, but we've mostly been talking about hospital environments.

17 And I would encourage the panel to 18 think about is that thinking adequate when we 19 talk about, you know, the future where more and 20 more of what used to happen or today happens in 21 hospitals isn't happening in hospitals anymore. 22 And just to point out it's not just

the future. When Harry and I were interns at 1 2 Hopkins almost 25 years ago and both in the cardiac units, there were patients that we 3 4 operated on for cardiac surgery and they got this 5 device, a left ventricular assist device. These are extremely sick patients and 6 7 I stayed awake all night many nights because they could change on a dime and die, and you have to 8 9 take care of them. Now, today, less than 25 10 years later, patients are going home with those 11 devices. 12 That was the cardiac ICU. We couldn't 13 envision patients going home with those devices. 14 And so this is not just the future. This is now. 15 And so if we're thinking about only the hospital 16 environment as the place medical care happens and 17 only devices that are used in the four walls of 18 those hospitals, we might be designing systems 19 for the past instead of the future. 20 MR. CANTWELL: Last questions, and 21 we'll summarize. 22 MR. SILBERBERG: Hi, Jeff Silberberg,

Three quick points if I can remember all of 1 FDA. 2 First of all, I hope I speak for my them. colleagues when I say that we're not particularly 3 comfortable with the term medical grade wireless. 4 I know that. 5 MR. TEVIS: Well, maybe not 6 MR. SILBERBERG: 7 everybody knows, Rick. Second of all, what is a medical device is hopefully clearly defined. 8 The 9 FDA and our regulations, it's used to diagnose or 10 And there's also guidances as far as, you treat. 11 know, what is and is not -- maybe it might be a 12 device but we don't regulate it like mobile apps 13 and things like that, that we have guidances on 14 that. 15 And we also have a process that if 16 you're not sure if something is a medical device, 17 you could ask us and there's somebody, and expert 18 that looks at it and says yes or no. 19 And the final point I would like to 20 make, I heard so who's going to do this? Is 21 industry, is Government? Some of the groups that 22 we've already mentioned have been working on this

for a while, and everybody. So C63 is, you know, 1 2 Government, industry, healthcare. Everybody's involved. 3 The AAMI 4 organization that, the committee that's working 5 on that. So you know, it's not going as fast as we would like. Get involved, you know, 6 participate and maybe we can come up with 7 something good. Thank you. 8 9 So let me try to bring MR. CANTWELL: 10 it to a close, although I had to chuckle at an 11 email question, how do we protect our mission 12 critical WiFi medical devices, which I think just 13 so summarizes the problem we're all frustrated 14 with. 15 Right, you're putting mission life 16 critical things over an unprotected band. But 17 here's my conclusion, there is no national 18 wireless test bed and there needs to be. Whether 19 it's industry led or FCC led, I think it's a 20 hybrid. 21 But unless the people that pay money 22 change behavior, the Steve's and the Ed's

companies won't change, period, because the free
 market's going to continue and they have to
 protect their businesses.

4 But we must define it at a complex 5 enough platform level that you don't stumble right out of the blocks. 6 It's not a component 7 issue; it's not a device issue. It is perhaps the most, healthcare and wireless are the two, 8 9 when you combine the two it's the most complex 10 use of wireless on the planet.

All right, so we have to step up to make almost make the environment what our children expect because they've grown up with it in their hands. And to Dr. Goldman's point, you got to start with something real.

So, you know, let's build something real, let's put real products in it, and let's get our hands dirty on it, but let's be inclusive. All right, it's not a standards body action as much as it is let's come together, figure out the reference architecture for what is medical grade, and start to work on it. So those

are my key takeaways from the panel. 1 So 2 anything? All right, thank you very much. So we're going to take 3 MS. ONYEIJE: 4 a short break and reconvene at 3 o'clock for our 5 final panel of the day which is going to wrap this all together, answer all those burning 6 7 questions you have. We'll see you in 15 minutes, thanks. 8 9 (Whereupon, the above-entitled matter 10 went off the record at 2:47 p.m. and resumed at 11 3:03 p.m.) 12 MS. ONYEIJE: All right. If folks can 13 begin taking their seats, we're going to 14 reconvene for the last panel of the day. 15 So our last panel of the day is titled 16 Driving Innovation and Safe Coexistence of 17 Wireless Medical Devices. And that is a 18 balancing act, if I've heard every one. So no 19 pressure on this group at all. They are more 20 than up to the challenge. 21 Our panel is going to be moderated by 22 Dale Hatfield who is a senior fellow at the

University of Colorado, Boulder, and the former 1 2 chief of Engineering and Technology for the FCC. And also we have Robert Havasy, who is 3 vice president of the Personal Connected Health 4 5 Alliance and executive director of Continua. We are delighted to have all of you and looking 6 7 forward very much to the discussion. So, Dale and Robert, take it away. 8 9 MR. HAVASY: Thank you. 10 MR. HATFIELD: Thank you very much, Karen. It's great to be back at the Commission. 11 12 I never got to sit up here very often. So 13 anyway, it is a pleasure to be back. I wear 14 several hats and, as Karen mentioned, I am today 15 wearing the hat of the University of Colorado. 16 I've been to, over the last 50 years, 17 been to a lot of wireless related meetings. But 18 I don't think I've ever been to one that showed 19 so dramatically what some of the opportunities we 20 have for us in this space, but it's so balanced 21 by then what tremendous challenges that we face. 22 So I'm really looking forward to our part of the

discussion and trying to wrap things up here in a
 good way.

3	Chairman Wheeler, when he was running
4	the Technical Advisory Committee, raised
5	challenges at every meeting to come up with
6	actionable recommendations. What should the FCC
7	or the FDA should be doing next? And I think
8	that's a pretty good focus for us this afternoon.
9	I'm not going to say very much more.
10	I will introduce the panelists and then turn it
11	over to my co-moderator here. As Karen
12	mentioned, the co-moderator is Rob Havasy, and
13	we'll turn it over to him just in a moment.
14	We have been working the way down.
15	Surjit Ahluwalia I could say that earlier, I
16	can't say it now who is director of Advanced
17	Services at Cisco. On the phone we have Dipu
18	Ganguly who is chief executive officer of AkibaH,
19	Inc.
20	We have Scott Gresbach who is program
21	leader at GE Healthcare Global Services. We have
22	Robert Jarrin. He's senior director of

1	Government Affairs at Qualcomm. And then
2	finally, at the very end, we have Jeff Tri,
3	section head, Information Technology at the Mayo
4	Foundation for Education in Research.
5	The full biographies are in the
6	program. And I would urge you to take a look at
7	them if you haven't done so before now. So with
8	that, I'll turn it over to Rob.
9	MR. HAVASY: Thank you very much,
10	Dale. And thank you to our hosts for giving me
11	the invitation here. I have the very distinct
12	pleasure of looking out at the audience, those of
13	you who have stuck around for the day.
14	As Dale mentioned, we have Dipu
15	Ganguly on the phone. And he has the distinct
16	displeasure of being on the computer right here
17	in front of me and therefore staring at my face
18	about two feet away. So I have both the best
19	seat and he has the worst seat in the house,
20	unfortunately.
21	But what we have here is basically a
22	live demo of the problem that we kind of just

realized, right? We have a MacBook and we have some telemedicine type tools, some consumer tools happening here that we have, on the fly in the last few minutes, tried to hook up. So we're going to find out how well interoperability really works in live, you know, in real time here.

8 I think we've had some discussions 9 over the day, and being the last panel we also 10 have the distinct pleasure of being able to build 11 upon all of the things that happened before us.

So I feel both terrible for the people who went first and had to come into a cold room. But by the same time, we've also really been developing some of these thoughts throughout the day. And I hope you'll bear with us as we riff on some of these things.

I think where we want to go first really points to the comment that Chris Gibbons made. And I had seen it on Twitter and was going to bring it up even if the question hadn't come forward. And that is this. Are we really

thinking about healthcare the right way? 1 2 And if we were worried in the last panel about defining what a medical grade system 3 is, how do we really define what medicine is and 4 5 will be in the coming years? And I think one of the first things we want to get to is let the 6 7 panel have a chance to comment on that. From my own perspective, having been 8 9 in a large healthcare system for close to ten 10 years with my colleagues who you heard from 11 today, Julian Goldman and Rickey Hampton from Partners HealthCare, I've seen the changes 12 13 happening first hand as value based care, new 14 payment models, as population health and 15 demographic trends. 16 And all these things are coming to put 17 pressure on the U.S. healthcare system and on 18 healthcare systems around the globe. We're really finding, we're seeing new problems that 19 20 need creative solutions. 21 And it's creating a climate for

innovation, right? And that innovation is really

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dependent, it seems lately, on mobility and 1 2 ubiquitous wireless communication, both inside the hospital and outside the hospital. 3 4 And part of that is really following 5 what other people earlier talked about as a changing locus of care, right, which in effect is 6 7 really coming full circle. Healthcare in the United States began 8 9 in the home, right? Only sick people who were 10 too poor to have a doctor come visit them went to 11 a hospital. But over time that changed. And 12 care began to focus around the general hospital. 13 And then care began to diffuse its way 14 out through primary care, and ambulatory care, 15 and other things and is now coming again back to 16 the home. We're talking about making house calls 17 like Marcus Welby used to do when I was on 18 television. 19 And my daughter can't believe it 20 actually happened, that the same doctor who, you 21 know, gave you your inoculations was also the one 22 who delivered the baby and showed up at the

hospital when you were sick. And that's really 1 2 what we're talking about with this kind of ubiguitous connectivity, right, that healthcare 3 4 can be omnipresent in our lives. 5 So this morning we heard about, and this afternoon, we heard about all of the 6 problems that are happening. And I think today 7 we really want to focus on how we foster the 8 9 innovation that we can help to solve those 10 problems while making sure we keep an eye on the fact that this is medicine. And some of this 11 12 may, in fact, be more critical and different than 13 other general wireless types of innovation that 14 are happening. 15 And so, I think, maybe we'll open it 16 up just there if the panel would comment in 17 whatever order you want. We can start with 18 Surjit, or we can actually start with Dipu if you 19 want. 20 What do you think we're talking about 21 when we talk about healthcare now? What does 22 healthcare look like to you, and where do we

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think it's going to go as this locus of care 1 2 changes over the coming years? Do we want to let 3 4 MR. AHLUWALIA: Okay, I can start. 5 MR. HAVASY: We'll let Surjit start. MR. AHLUWALIA: So if you look at, you 6 7 know, really like the comments I think Harry made earlier around, and I think Chris as well, where 8 9 you look at healthcare, it's really going beyond 10 just the hospital network today, right? You're 11 really starting to go and look at doing care at 12 home. 13 You've got, you know, the advent of 14 smart devices, your phones and your tablets, you 15 know, your wearables, all of these things are 16 starting to play a big role in healthcare. 17 And, you know, as you look at the 18 question of innovation and, you know, that's part 19 of the theme of what we're going to talk a little 20 bit, there is a lot of innovation that's 21 happening, right? 22 I mean, I work at Cisco and I, you

know, support healthcare. And I just compare it with so many other industries, right? And, you know, healthcare has really been the biggest 4 culprit in terms of being, you know, in terms of adopting technology and leveraging it, right? We heard so many examples today.

And it's also a problem. 7 Because, you know, that's one of the reasons why the cost has 8 9 gone up significantly. You know, they haven't 10 really leveraged all the technology that they 11 could have to actually make care better.

12 You know, as I talk to healthcare 13 customers I hear, and this is actually maybe even 14 a global comment we actually have a sick care 15 system, not really a healthcare system.

16 I mean, how do you really, you know, 17 how do you get to a healthcare system? How do 18 you focus on care before a person falls sick? 19 How can you look at wellness, and what are some 20 of the things that one can do before and then 21 even after?

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So, you know, innovation is big, care

1 is everywhere. You can only control so many 2 things today. One of the focuses that Cisco is 3 really getting into, and we obviously are one of 4 the vendors that sell and provide technologies 5 into healthcare, is how do we help our customers 6 really, you know, achieve the outcomes that 7 they're trying to get to?

And we actually ran into some of our partners, specifically GE Healthcare, and Scott here will talk a little bit more about what we're doing together with medical devices, but what we're really trying to do is to figure out how to make the system work.

How do you leverage all of the various technologies, capabilities, wearables, smart devices, and make it work in an environment where you are having innovation at just a completely different pace than what healthcare has really been used to a little bit?

20 So let me just stop here, and then 21 maybe I can answer more comments a little bit 22 later. We can go to you, Scott?

1 MR. GRESBACH: Sure, yes. So, you 2 know, from a GE Healthcare perspective we continue to see the proliferation of many, many 3 wireless devices continuing to get on the 4 5 enterprise IT networks. Certainly we've talked about, you 6 7 know, the other bands becoming available and so forth, but, you know, today that doesn't help the 8 9 WiFi networks in themselves. 10 One of the challenges that we have is, 11 you know, as Surjit said, the constant, rapid 12 change of technology and devices on iPhones, and 13 tablets and apps all coming out in the consumer 14 market kind of driving those technologies at a 15 very fast pace. 16 Those type of technologies and 17 innovations we're seeing more and more on a 18 shared infrastructure on the IT network. But at 19 the same time, we also see older technology that 20 hospitals have made investments on. 21 And they have devices that, you know, 22 may have some older protocols that are still on

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1	their network. They had made an investment.
2	It's maybe five, ten year old technology or
3	devices that are on their network. They've made
4	that investment.
5	So I think the challenge is how do we
6	move forward and continue to, you know, coexist
7	on the network with all these devices, but yet
8	allow all devices to work to their specification.
9	So one of the things that you know, that's a
10	reality, a lot of devices moving, you know,
11	getting on the network.
12	So one of the things that we are doing
13	in addition, from a manufacturer's standpoint,
14	all the innovations that are going on with the
15	different bands and so forth, what we're doing
16	also to kind of compliment the rigorous testing
17	that's going on at the manufacturer level, at the
18	design level, is kind of on the back end when the
19	device goes into the hospital.
20	GE is partnering with Cisco to
21	actually go into hospitals to help our customers,
22	whether they're GE devices or not, agnostic, and

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actually to help them get those devices on the 1 2 network, do the risk assessments, collect the requirements for the medical devices so that 3 4 those devices will be able to operate on the 5 network to specification. So that requires requirements 6 7 gathering of the specific devices, feeding that back into the design cycle, continuous 8 9 monitoring. And that can all be done as one 10 option using the IFC 80001 framework to be able 11 to do that. And so we're looking to do that. 12 Thanks, Rob. So thanks MR. JARRIN: 13 to the FCC and the Connect2Health Task Force 14 which helped to put together today's workshop. 15 When I think of what healthcare will 16 look like in the future, I actually have to just 17 look at today. We have a number of devices that 18 are out in the marketplace currently which are 19 medical devices that have been cleared by the 20 FDA. 21 For example, a two-lead ECG jacket 22 that can strap onto the back of an iPhone, asthma

sensors that get put on top of an inhaler that gives you near real time environmental scans, you know, supply chain management behind it, et cetera.

5 You know, obviously the home use medical device stuff like medical grade weight 6 scales, when you use that term, only because they 7 go through quality systems, blood pressure cuff 8 9 monitors, thermometers, et cetera, all of these 10 which are now smart technologies because, at least in one way, shape or form, they can offload 11 12 their information into the Web, or into a 13 platform or get it somewhere else where it can be 14 utilized.

15 And then I think of, you know, 16 aspirational real future stuff. I think of 17 things like the Tricorder Qualcomm X Prize where 18 we're helping to fund the creation of a device 19 that can appropriately diagnose, I believe, 12 or 20 more conditions within a number of days and can 21 do it in a better way or equal to a panel of board certified docs, you know. And that's 22

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1	supposed to be delivered by, I believe, next
2	year. So that's what I think of healthcare.
3	And one of the things that was put to
4	this panel in some of the questions initially
5	was, how do we future proof these technologies?
6	But I think that folks immediately think of
7	technological ways, you know, obviously make
8	things backwards compatible, et cetera.
9	I think that's important but, you
10	know, this has to go hand in hand with
11	regulation and with sensible policies. And part
12	of that is the genesis of this discussion of
13	wireless test beds.
14	This is something that came up in the
15	2012 mHealth Task Force. It then became a
16	recommendation that myself and Dr. Goldman worked
17	on with the Consumer Advisory Committee which got
18	the full approval of the committee. And here we
19	are, you know, years later and still discussing
20	this issue.
21	But it goes beyond the FCC, I mean,
22	there are other things. For years, we've been

advocating as an industry that health IT is
 really the broader meaning of not just electronic
 health records.

I think that the Office of the 4 5 National Coordinator took a huge step forward just a couple of weeks ago when they announced 6 7 through Meaningful Use Stage 3 that they're finally going to allow uploading of patient 8 9 generated health data into an electronic health 10 record. At least that's one of the proposals in 11 the current proposed rule. That's a big deal.

You know, those are the kinds of things that really get us to that next level of what healthcare should look like. But going back to the conversation of the wireless test beds, we need to discuss, not only as an industry but also all of the stakeholders.

When we first started talking about this, it was academia. It was non-governmental bodies, including non-profits that work in the area. It was people from industry and really the garage entrepreneur, all of which were talking

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about, hey, how do we really find a safe place 1 2 that we can discuss these issues? We can come up with tools, we can share tools, we can share best 3 4 practices and come up with conformity and 5 harmonization to better develop products jointly. And that's really the conversation. 6 7 It may be for some members of the industry, it may not be. It may be for some 8 9 members of the public, it may not be. But at 10 least there's enough of an interest that 11 something should be done. 12 And I think that one of the things 13 that we should work on as a panel is maybe trying 14 to put together what that next step forward 15 should be after today. Thank you. 16 MR. TRI: So I have to thank the FCC 17 and FDA for this work group. So our leadership 18 at Mayo has set a goal for us that by the year 19 2020 we would reach out and touch, in a 20 meaningful way, 200 million patients. 21 So if you think of that number, you 22 can't really scale brick and mortars to that

So I think it's about how do you do 1 size. 2 connected care and in what ways can you serve connected care? 3 4 So we believe that, you know, most 5 healthcare interactions will be carried out in the future over connected mobile tools as an 6 extension of established patient providers' 7 relationships so that healthcare will be a 8 9 continuum, not just a point in time as you're in 10 the hospital. 11 Dipu, do you have some MR. HAVASY: 12 comments about the future of healthcare? 13 Do we have audio? 14 Yes. Can you hear me? MR. GANGULY: 15 MR. HAVASY: Yes, we can. 16 MR. GANGULY: Okay. The future to me 17 looks very much like this. We have, I think 18 there is a two-pronged approach to the future. 19 What we have today is a proliferation of wireless 20 devices across the board, hospital, clinics and 21 homes. 22 And as Surjit mentioned, what we have

is a sick care system. What we need to have is a
 healthy care system, healthcare system. But
 that, to me, we have a reactive system, and we
 need to go to a proactive system.

5 One specific opportunity for innovation is to create an infrastructure and an 6 7 ecosystem, especially on the data front so all of these devices can produce data that can be 8 9 aggregated in a meaningful way and fed to EMR 10 systems. We know that EMR systems are not quite 11 unified yet. I think there is work that needs to 12 be done there.

13 And then, of course, some of the 14 things other folks have been talking about, 15 making sure that devices that come to this 16 environment operate correctly, evidence what 17 happened today with our system here. It didn't 18 quite work right.

So I think there has to be test beds
that are geared towards the indication specific
use that these devices are going to play in. So
that's kind of where I look at the immediate

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future --

2	(Telephonic interference)
3	MR. GANGULY: integration and
4	intercommunication between various devices.
5	As far as the future is concerned, to
6	me it's in the home. Connected home is here to
7	stay, and it's going to pervade the medical
8	device sector as well. Different kinds of things
9	will emerge there, and the test beds have to
10	evolve with that.
11	And again, I think one needs to take
12	a top down view of all of that. What are the
13	indication-specific aspects of all of that? What
14	specific test beds need to be created to address
15	these educations? That's how I see this
16	evolving. So that's what I have to say right
17	now.
18	MR. HAVASY: So there's a question
19	that's been on my mind. And I think I'll start
20	it off this way and let everybody talk about it.
21	Earlier in the day, there was a
22	mention that the lack of wireless test beds might

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be an impediment to innovation. Then later on we 1 2 heard Harry Greenspun tell us that, well, too much regulation and difficult to interpret 3 4 regulations around medical devices are keeping 5 people away from the medical device space. So that might be an impediment to innovation. 6 7 And so I think the most basic question is, given all that we've heard today, all of the 8 9 problems and how this is such a multi-dimensional 10 problem, can we design systems that allow 11 innovators to innovate, while still solving some of the problems that Rickey and other people are 12 13 actually having in the real world today? MR. AHLUWALIA: So I have a little bit 14 15 of input on this, on this question. So, you 16 know, if you really think about it, you know, we 17 talked about why healthcare has not really been 18 leading but more lagging, if you will. 19 We know that healthcare today is going 20 through a transformation. I mean, we can see it. 21 We've seen so many different industries, you 22 know, really adopt technology, and leverage it

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and get more efficient.

2	We heard about the banking and the
3	finance industry. We know how retailers, you
4	know, doctors, absorb technology, you know, how
5	you book flights and how you travel today.
6	Even today, you go to a hospital and
7	you're starting to write I'm so and so and, you
8	know, here's my details. And if I have an MRI
9	done somewhere else I've got to carry the little
10	disc for the image with me.
11	So the opinion part of this equation
12	is I don't think any one company or any one
13	organization can really address the
14	transformation. The transformation is very big,
15	and it's very broad.
16	And it's happening, you know, there's
17	continued innovation that's happening, of course,
18	in the medical space, right, you know, the way
19	we're treating patients, the amount of care we
20	can provide, the amount of, you know, people that
21	we can cure if they have cancer I'm sure has gone
22	up, right, over the years.

1	Medical devices have continued to
2	innovate. But the pace of innovation that's
3	happening in the IT space, I think, is way beyond
4	where it has been specifically in healthcare.
5	If I have the numbers right, you know,
6	just a few years ago there were less than 20
7	percent healthcare organizations were reporting
8	in EMR, you know, as they have some kind of an
9	EMR deployed.
10	Today I believe it's more like 80
11	percent. And this has happened in the last two
12	or three years, right? And so that level of
13	adoption of technology is just significant.
14	And I believe that this is a shared
15	problem we all have to work together to address.
16	We can't just put it on the regulators, and FCC
17	and FDA. Because, frankly, if you over regulate
18	it, you'll have companies stay away from it. You
19	will stifle and stop the innovation that's
20	happening.
21	And if you leave it, you know, too
22	open, you've got all these other problems you're

dealing with. And, you know, if it's your son or 1 2 daughter on the table going through surgery you really want some level of control. 3 So I think the answer is somewhere in 4 5 the middle. It's hopefully like the partnerships that we're trying to do between Cisco and GE. 6 7 And, you know, we need to do that across the board with many of us really playing 8 9 our own -- you know, taking steps, taking 10 ownership of our areas, if you will, of what we

have to offer in the system and really playing as
one team to continue to provide this balance.
That's an opinion I share.

MR. HAVASY: So Jarrin used a phrase earlier; we need to get all of the stakeholders involved. And so I want to throw one in that I haven't heard yet today. How do we get a patient voice in here? And how do we get a consumer yoice in here?

And is it possible, can that voice be adequately represented by other stakeholders that are already at this table, whether that's

industry, because you're selling to consumers, 1 2 whether that's clinicians and physicians? Can you represent the patient voice? 3 Or is there a need for a different way 4 5 to bring patients into this room, into this conversation, and to make sure they have a voice 6 in whatever the system is. 7 And I'll add a little color to that. 8 9 We talked about -- and I'm very passionate about 10 this idea -- that if this locus of care changes 11 we move these devices into very much uncontrolled 12 space, right? 13 We've heard how difficult it is to 14 control a hospital where you're procuring the 15 devices, and you have to take what walks through 16 the door. But when we get into a home, or into 17 people's pockets or they buy what they're going 18 to buy, that is even more difficult. 19 So any ideas? And, Dale, you too 20 please, and Dipu. How do we get patients to be 21 part of this conversation, and could we set up 22 test beds that adequately represent their

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interests and needs?

2	MR. TRI: I can take that one. You
3	know, I think it all depends on the abilities.
4	So if you have somebody like Rick Hampton or
5	Shawn, they're probably okay, you know, winging
6	it and figuring it out. But if you take my Mom
7	and Dad, they just want to plug it in and work
8	like a telephone.
9	So I think it's that continuum of
10	expertise and ability. And maybe the
11	infrastructure needs to figure out all the
12	nuances to make it work appropriately and not the
13	end consumer.
14	MR. HATFIELD: I would, it depends a
15	little bit on what the organization looks like.
16	For example, I was early involved in a group
17	called the Broadband Internet Technical Advisory
18	Group which was associated with net neutrality
19	issues. And I don't want to go there, but
20	(Laughter)
21	MR. HATFIELD: But as part of that,
22	the funding mechanism where people contributed,

part of the money was set aside to fund what we 1 2 called community representatives. In other words, typically the problem is people can't 3 4 afford to come to meetings and so forth. So we 5 provided a mechanism to allow people to participate from the community. 6 7 And I think, generally speaking, that 8 worked pretty well. But that presupposes there's 9 a group of some sort that's agreed to get 10 together and move some of these issues forward. 11 MR. AHLUWALIA: I'll share a point on 12 To me it sounds like if you start thinking that. 13 about the patient, I mean, at some level we're 14 all patients. And we all fall sick, and we 15 represent our interests, right? And you can 16 think about it from, you know, as part of your 17 parents or your children. And you try to 18 represent them. 19 But to me it's very different, right? 20 The needs are very different. So if you're, you 21 know, an elderly person, chronically ill, versus

if you're healthy, kind of that bell curve we

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heard about a little earlier, different people
 along that spectrum will have very different
 needs.

4 And maybe one way to really look at 5 that is, and this is where maybe FCC or FDA can help us look at doing some surveys, collecting 6 7 some feedback, getting their voice into, you know, what matters, what doesn't matter. 8 Are 9 patients okay with letting their data live on a 10 cloud? As long as, you know, if they can see 11 benefits in doing it, are they concerned about 12 privacy, are they concerned about other things? 13 That may be one way to look at it.

14 Does anyone think we're MR. HAVASY: 15 at a point where maybe patients don't know what 16 to ask for yet, right? This is the sort of Steve 17 Jobs philosophy, right? People didn't know they 18 needed a music streaming service in an iPod until 19 he told them they needed an iPod and a streaming 20 service. Can we do that in a way to really get 21 meaningful advice back about what patients need? 22 My experience, right, having deployed

lots of devices in patient homes, is I want to
 plug it in and it works. And that's important
 feedback, right?

Because none of these connected health systems, healthcare doesn't work unless patients engage. And unless we make it easy for them and we give them tools that allow that, we're really, I think, failing the ultimate consumers of this. So is there a way to gather that feedback in a meaningful way? And what does that look like?

Any other ideas on what that organization looks like? Do we literally -- and Dale makes an excellent point, right, there's a difference between offering access and enabling access to get patient voices into this conversation.

17 So do we literally pay for some trips 18 to bring people into this room and talk? Do we 19 let industry form an organization, make it 20 outright through the Consumer Electronics 21 Association, somebody, to go out and engage them? 22 Do we make it part of a regulatory scheme to say,

well, somebody in this regulatory chain needs to engage patients?

And I'm not going to leave here today 3 4 unless I get to use one of my favorite quotes 5 I've ever heard. Many years ago at one of the first connected health and wireless health 6 conferences I went to, a doctor up on stage 7 pointed out that patients are unencumbered by the 8 9 regulatory process, right? They're going to do 10 what they want to do. And if we want to have 11 successful healthcare, we have to figure out how 12 to engage them.

But we can't make them do anything. We can't make them embrace standards, we can't make them configure their own networks the way we'd like. So how do we reconcile that, right? How do we reconcile that conundrum?

18 MR. GRESBACH: I think one comment 19 that I have regarded from the patient point of 20 view, you know, whether you're talking the home 21 environment or a healthcare environment that has 22 all this infrastructure and an army of people to

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kind of manage the network and so forth, or in 1 2 some cases very few people to do that. I think from a patient centric point 3 of view, you know, I think the expectations are 4 5 still there from the patient standpoint whether it's a home environment or it's a brick and 6 mortar building. 7 I think the patient wants a safe and 8 9 effective product. They want the product to do 10 what it's intended to do. They want privacy and 11 they want their protected health information to 12 be protected. They want a secure environment. 13 So all that, some of the same entities 14 that you talk about from a patient standpoint, 15 when you're in a hospital environment from a 16 patient standpoint, those expectations really 17 don't change, I think, in the home environment. 18 I think those pillars are still there. 19 And in some ways, it could be and may be more 20 challenging in some respects, because you're now 21 in a, like you said, an uncontrolled environment. 22 Dipu, I want to make sure MR. HAVASY:

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you have a chance to weigh in. 1 2 MR. AHLUWALIA: Assuming that technology works. 3 4 MR. HAVASY: Well, yes. This is 5 telemedicine in a nutshell right here. It doesn't look 6 MR. AHLUWALIA: Okay. 7 like it. 8 MR. HAVASY: Sorry? Okay. Well, I 9 just wanted to make sure you had a chance to 10 weigh in on this. 11 MR. AHLUWALIA: Let me just add one --12 MR. GANGULY: Yes. Can you hear me? 13 MR. HAVASY: Yes. We can. Go ahead, 14 please. 15 So what I wanted MR. GANGULY: Okay. 16 to say is what we're doing at AkibaH, we are 17 focusing on the technology we are trying to bring 18 to market first. And we're looking at what 19 aspects of what's available today --20 (Telephonic interference) 21 MR. GANGULY: -- the users, we're 22 treating our patients, these are chronic care

patients. We're treating them like consumers. 1 2 We are trying to ask the question what about what you have available to you today don't 3 4 you like, and parse that into more specifics and 5 create an overall user experience that would make them comply with the various regimens of care 6 7 that are required for them. And I think we look at the various 8 9 indications that we are trying to target with 10 these technologies and find out what about what's 11 available for those do the patients like and what 12 they don't like and parse it into capabilities, 13 usability requirements. 14 And I think the test beds can evolve 15 into specific ways of testing those usabilities 16 as well. So that's kind of where we are heading 17 with our company in terms of doing those kinds of 18 focused approaches. 19 So what I heard from that MR. HAVASY: 20 is usability needs to be a part of this. 21 Usability needs to be an important part of this. 22 And I know from my own work that is absolutely

the driver of health technology adoption among
 patients and consumers.

So whatever that structure is, and I 3 don't necessarily want to revisit what we had in 4 5 the last panel and debating whether this is a government role, or an industry role or whatever. 6 7 But it does seem like some form of usability needs to be part of it. And some other voices 8 9 would be nice to make sure are included. Fair? 10 Jarrin, do you have something? 11 MR. JARRIN: Yes. I mean, you know, 12 from Qualcomm's perspective obviously everyone is 13 a patient, everyone is a consumer. And 14 hopefully, everyone is carrying around a 15 smartphone or a device and really, hopefully, 16 they're utilizing our chip or our technology. 17 So, you know, mobile broad band to us, 18 you know, take that to the furthest extreme which 19 is we believe that 95 percent of the country, 20 like the FCC has said, is covered by at least one 21 mobile broad band operator and that most people, 22 you know, if not everyone, has access to some

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form of a device.

2	So then break that down to healthcare
3	segment, the biggest issue that we've seen in
4	healthcare is the adoption. So what comes first,
5	adoption by healthcare systems, by large
6	institutions, by small scale clinics, by doctors
7	themselves, or adoption by the consumer?
8	And in a way, it's almost like a
9	symbiotic approach, right? Some consumers are
10	adopting early, some are not. Some doctors are
11	adopting early, some are not. But the important
12	thing here is that it's changing. And it's
13	changing really rapidly.
14	Six years ago, seven years ago, when
15	I spoke about mHealth, people would look at me
16	and say what are you talking about, you know?
17	And now, I mean, look at so much of that happened
18	to really profile how patients, you know, now
19	have access to digital medicine. And it's really
20	personalized.
21	So, you know, I think some of the
22	things that have been left behind, unfortunately,

we all talk about healthcare as if it's this big thing out there that's just kind of -- you know, and I think you said it perfectly, everyone's a patient.

5 Everyone has a patient that's important to them, whether it be a loved one, a 6 7 child, a friend, whatever. We're all sick at some point and have to deal with the massive 8 9 problems of the healthcare system. And that's 10 the one thing that we all have, right, that we 11 have access to is the problems within the 12 healthcare system, whether personally or not.

13 The institutional approach towards 14 episodic care has got to change. There is no 15 going back. So, you know, how we get there goes, 16 I think we're all part of that. And every little 17 thing counts. Every agency counts, everything 18 that's done in this room, you know, for 19 healthcare, really does count.

And usability is a big aspect of that. It's interesting; I'm on the usability work group for the ONC. And, you know, some of the people

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that have come into talk about usability from the 1 2 perspective of things like health IT and EHRs, you know, a color coding system could mean 3 4 something completely different from one nurse to 5 another, you know, from one doctor to another. And things that people assume when 6 7 they're producing these things automatically, you know, are not things that should be assumed. 8 9 Those things get left out. 10 So yes, human factors testing, 11 harmonization of that stuff, all of that is part 12 of this big puzzle. And I'm not sure that we can 13 just point at one thing and say that's going to 14 be the one, that's going to be the driver. 15 MR. HAVASY: Maybe we can shift this 16 a little bit. And if there are questions, 17 please, I know everybody's tired, but the 18 microphone is available and please tweet them or send them by email. 19 20 Earlier in the day something was said, 21 a question was asked. And someone said, you 22 know, did the FCC think that WiFi was going to

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become the backbone of all of these healthcare systems, right?

And if I put my informatics hat on I 3 4 say oh, God, no, jeez. But if I put a different 5 innovative hat on and say, well, of course, right, because it was an unlicensed spectrum, 6 7 unencumbered by a lot of hard regulations to understand. And it fostered the development of 8 9 very inexpensive components that meant lots of 10 new people could try lots of new things with new 11 technology. 12 And we were toying with this idea at

13 lunch. And I'll set it up with a short story.
14 And I see there's a question. So if you want to
15 sit or stand, that's up -- and it goes something
16 like this.

17 One of my favorite stories talks about 18 innovation, and there was a gentleman named Paul 19 MacCready. And back in the 1950s a guy in 20 England named Henry Kremer set up a prize for 21 aviation, right? It was XPRIZE of its day. 22 He said I'm going to give some money

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to the first person who invents a human powered airplane that can fly around a soccer pitch, and then I'll give even more money to someone who invents a human powered airplane that can fly across the English Channel.

And the jet age of the 1950s could 6 7 knock this out in a couple of years, and everything will be great. And that prize went 8 9 uncollected for over 25 years until Paul 10 MacCready came up. And he, in 18 months, 11 collected both of them with the Gossamer Condor 12 and the Gossamer Albatross, two human powered 13 airplanes. And the story went viral a few years 14 ago in Silicon Valley. And you can Google it and 15 find it on blogs all over the place.

And what Paul MacCready said was his advantage was that he tried to solve a different problem rather than building a better airfoil or a lighter airplane, he simply came up with a way to build lots of airplanes really fast and crash them a lot in ways that didn't kill the pilot. And he said at one point he was

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basically, he literally went to the hardware 1 2 store, right? Instead of getting a room full of quys -- because in the 60s it was all quys with 3 4 slide rules -- and trying to design the next 5 great airfoil for five years and then flying it and hoping for the best, he built it out of 6 7 plastic, and duct tape, and a bicycle chain and flew it, you know, three times a day. 8 9 And he was able to then iterate so 10 fast he got there. And that's where the story

11 sort of ended, right, that rapid iteration is the 12 solution to this.

13 About 20 years later, Paul MacCready 14 gave a speech at the Lemelson Center at the 15 Smithsonian Institution. And these words are 16 burned in my head. And you can find the 17 transcript online. He said, "Perhaps my naiveté 18 was the exact thing needed at this pioneering 19 stage of flight. But thank God the wings of 20 airliners on which I spend so much time are 21 designed by professional structural engineers and 22 not by me."

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(Laughter)

MR. HAVASY: Right? So here we have the sort of Godfather of innovation and rapid innovation saying there comes a time for technologies to grow up.

And we were toying with this idea at lunch. And I'd really like to bounce this around a little bit. Maybe WiFi was not the end-all, be-all, right? Maybe the unlicensed portions of the spectrum aren't really what we need once we figure out how these systems should work and we start deploying them at scale in hospitals.

But it might very well be the very thing we need to allow the innovation. So how do we balance that? How do we balance that, and how do we set up test beds to handle both sides of that so that at least the first tries are good enough that they don't kill people?

But we get to what Rickey and his colleagues so desire, right, systems that are truly robust, and bullet proof and good for a healthcare network.

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MR. AHLUWALIA: All right. I'll take 1 2 stab at this. So maybe I'm going to come back to wireless test beds. But I want to shed a little 3 4 perspective on, you know, at least how we are 5 seeing a little bit of innovation occur in healthcare and how we're seeing some of this 6 7 transformation occur. There was a question earlier in the 8 9 day or somebody, I guess, through Twitter or 10 something came and they started talking about 11 Internet of Things and Internet of Everything, if 12 you will.

13Actually, that's how we're seeing, you14know, that's how at Cisco we're kind of getting15more and more organized as to try to look at what16innovative Everything can really help and, you17know, enable transformations, not just in18healthcare but many verticals.

Now, if you look at it from a
healthcare perspective, you know, we define
Internet of Everything as people, process, data
and things, right?

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1 The people in healthcare are, you 2 know, your patients. We spoke about that. We talked about, you know, physicians, of course, 3 4 nurses, other care providers. The processes are 5 more about, you know, the flows in healthcare, right, how you flow through an emergency 6 7 department or, you know, different types of flows that everybody is familiar with. 8 9 And there's a lot of innovation 10 occurring. How do you improve the patient 11 experience when you're thinking about the 12 patient? How do you make the doctor, or the 13 nurse or primary care physician better and more 14 productive, right? 15 How do you get, you know, there was a 16 healthcare facility that told us or told me they 17 get 100,000, you know, reports or calls in their 18 emergency department. And only 20,000 of those 19 are actually real. And if they can reduce it in 20 some way, then, you know, obviously there's a lot 21 of incentives in so many different ways, right? 22 So there's a lot of that innovation occurring.

1	Data is all about, you know, big data
2	probably has the biggest promise in healthcare.
3	But, you know, at least personally having grown
4	up in the high tech space, I almost look at it as
5	artificial intelligence in the 1990s.
6	It was going to change everything,
7	right? But it hasn't really changed it yet. So
8	I think big data, you know, even though there's a
9	lot of promise, it hasn't really proven itself
10	completely. And there needs to be more
11	innovation, right?
12	And then the things are medical
13	devices, your smartphones and, you know, all
14	these different wearables, et cetera, that all
15	need to interconnect.
16	So if you look at all these areas and
17	you look at all the innovation that's happening,
18	all of this requires some level of connectivity.
19	It requires some level of an easy way where you
20	want to be able to innovate, you want to be able
21	to try different things, you know.
22	I guess you brought the question do

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patients even know what they want? And by definition, innovation is something you're discovering, something new. If you knew about it, you know, it wouldn't be innovation to begin with.

6 So what we need is to create a system, 7 create a platform with the capability -- actually 8 this is more than just wireless, right, because 9 you also have so many different things that I 10 just talked about that just leverage networking 11 in general.

But mobility, make no mistake, is one of the big transformations that's happening in healthcare. We need to have a system that is easy, that is cheap, that is quick, agile, where you can innovate without necessarily killing people.

18 And then, you know, at some point, you 19 graduate and you mature, like you're saying, and 20 you deploy it for use cases that are more, you 21 know, I guess, clinically relevant, if you will, 22 and really touch the lives of people.

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1	So, you know, I look at customers that
2	we work with in healthcare and, frankly, many of
3	them or at least some of them have wireless
4	infrastructures that they've deployed when many
5	of these technologies didn't even exist, right?
6	These wireless infrastructures have
7	been around for five, ten years. And smartphones
8	just came to being in the last five years. So
9	there's a lot that we need to do in terms of
10	really making this transformation happen.
11	And the reason why WiFi or whatever
12	technology is being used at large is because it's
13	easy. It's already there. It's already being
14	used on the enterprise side. And people want to
15	leverage, and try different things and innovate,
16	right?
17	So our job is to figure out how to
18	make that happen in a way that actually reduces
19	cost, makes it easy to play, at the same time
20	doesn't kill people. Just a little perspective.
21	MR. GRESBACH: Yes. I think, you
22	know, just to trump on that, the consumer market

does obviously tend to drive industry, whether
 you're talking probably healthcare or in many
 other fields. It just does.

The challenge is just to be able to work out those issues with the stakeholders, you know, the manufacturers and the responsible organizations, the hospital and some of that.

8 And, you know, there's been a lot of 9 talk today about 80001. And I think, given the 10 state of where we're at right now with the 11 proliferation of wireless devices on the network, 12 I think 80001 will continue to have a big play 13 until, you know, a new spectrum is opened up. It 14 just will.

15 It's a tool that we can use to kind of 16 help manage, you know, integration of medical 17 devices on the network, gathering of the 18 requirements for those different devices, feeding 19 that back so that when you deploy those devices 20 onto that shared infrastructure that they will be 21 safe, effective, secure.

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And it doesn't stop there with 80001.

It also, not only getting the devices onto the network, but there's a continual change management process with 80001 event management network I don't think we've talked about too much, just about appliance, wireless LAN network monitoring as well. A lot can be done with that as well too.

You could say it could be a little bit 8 9 reactive in some cases, but it depends on the way 10 you look at it. It could be very proactive, 11 actually, because if you're going to acknowledge 12 that, okay, this is where we're at, this is where 13 the innovation and the market is going, and we 14 have a lot of devices on the network, let's be 15 proactive about it.

Let's do change management, event management. Let's proactively trend events that happen on the network, and let's try to mitigate those events through risk, application of risk on the network.

21 MR. JARRIN: You know, I think that 22 each band of spectrum, and obviously each type of

interface has its own unique property and qualities.

Unlicensed spectrum is easy to access. 3 4 Obviously it's cheaper. You know, and the 5 technologies that are in unlicensed, I would say, are quite sophisticated and, you know, important. 6 7 So whether or not unlicensed spectrum and WiFi, you know, should be the backbone or not, that's 8 9 really, I think, a market dynamic. 10 I think one of the important things is 11 that, you know, the FCC approaches it in a very 12 technology neutral way in the way they institute 13 there are rules and policy. I think that it's 14 important for the FCC to help those that are 15 coming into the space to understand those rules. 16 Again, going back to the 17 recommendation from the 2012 mHealth Task Force, 18 you know, make that understanding easily to 19 approach from the developer perspective. I'll 20 leave it at that. 21 MR. HAVASY: There's a question from 22 the audience, and then we have one Twitter

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question queued up as well. 1 So, sir? 2 MR. SAYRAFIAN: Thanks for all the interesting discussion. It's end of the day, so 3 4 I hope my question is not -- name, oh. I'm 5 Kamran Sayrafian from NIST. The title of this workshop is Role of 6 7 Wireless Medical Test Beds. I wish we had all the panelists here. So my question is actually 8 9 addressed to each one of you individually and the 10 other panelists that are not there. So I would 11 appreciate it if they could come here and answer. 12 So if you are in charge of building a 13 wireless medical test bed, in your personal 14 opinion or your organization's opinion, and in 15 one short sentence, what is the primary objective 16 of a wireless medical test bed? So each one of 17 you, one sentence. I really appreciate that. 18 Thank you. 19 MR. HAVASY: So maybe we'll do this, 20 right? Because that is, it's easy to pontificate 21 and answer that question with 30 sentences, it's 22 really hard to pare that down to one.

So why don't I give people a couple of seconds to think about it. In the meantime, and then we can also have some other people from the audience come up and answer that. Let me hit this Twitter question first. And then I think that'll give us a chance to really answer that question with the answer it deserves.

So this question came in. Is there an 8 9 opportunity to create an interoperability and 10 coexistence standard using test beds? And are there different -- I think the answer is are 11 12 there different certification levels that would 13 go along with that? So can we really do the 14 technical coexistence and the interoperability in 15 a kind of one single system?

MR. AHLUWALIA: I guess my view is, and I think we've discussed this all throughout the day, right, there's no one test bed that can solve everything, right? You know, we will need, you know, a system of test beds, if you will. My personal opinion is I think, you know, the different stakeholders that are

involved, right, like the wireless device
 manufacturers, you know, Cisco being one example,
 the medical device manufacturers and then
 healthcare organizations, everybody has to, you
 know, have their fair share of doing validation
 and testing.

7 And if we can really develop the right specifications on, you know, what are the 8 9 expectations for the various stakeholders as they 10 develop, and validate and develop their test beds 11 to deliver technology into a healthcare organization, if everybody does their part well 12 13 and then we leverage like Shawn does in Kaiser, 14 you know, the final test is make sure that, you 15 know, things are actually working in the 16 organization where they're intended before you 17 actually put it on the network, right?

I think that's probably the answer that, maybe not the most ideal answer but, you know, at least better than where we are today, let's put it that way.

MR. GRESBACH: So I think from a test

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1 bed perspective, yes, you've got to be safe, got 2 to be effective and, you know, that platform has to be adaptable to technology, new devices, 3 4 emerging technology, got to be kind of a dynamic 5 type of environment so that, as technology and innovation evolves, you can continue to 6 effectively test and deploy, you know, medical 7 devices effectively. 8

9 So, you know, what would MR. JARRIN: 10 be a wireless test center? I think the creation 11 of a national center -- and I say that, and I'm 12 not stating that I would like the creation of an 13 agency or a physical center somewhere, it could 14 be housed anywhere -- but I think I'm going to 15 have to pontificate. I hate that. I'm sorry, 16 Rob.

17 If I were the guy, if I were king for 18 30 seconds, this is what I would say should be 19 the outcome of today. So Michele Ellison and 20 Karen and everyone, what I would say is, you 21 know, the takeaway from today would be like what 22 the last panel said which was there is no

national test center, okay, but there is interest in something.

So I would say the takeaway is the 3 4 creation of a public/private partnership that the 5 FCC and FDA should oversee. It would put out a request for information from the industry, from 6 7 everybody, academia, et cetera, of what are your testing tools, what are your testing problems, 8 9 what are the issues in this space, obviously 10 taking the report from today's event, then coming 11 out with a list of what are next steps. 12 And the next steps should be this 13 creation of a national center which could be 14 housed in many different places. The idea is 15 that it would have expertise, it would have 16 access to experimental licenses and tools to help 17 those that are developing medical devices that 18 are converged, converged wireless medical 19 devices. 20 MR. HAVASY: Yes. I mean, I think 21 Dale just asked an interesting question. And I

was going to ask something very similar which is

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the question was is there an opportunity to
 create such a standard.

And I would have to turn that to the 3 4 audience, right, to our healthcare partners out 5 there and say, I don't know, would you pay more for devices that carry some sort of industry 6 certification of at least baseline 7 interoperability, and then coexistence in your 8 9 network and then higher levels of maybe 10 certification above that, right? 11 Because I think there's a desire for 12 it. The question is -- is it a commercially 13 viable -- is there a commercially viable model to 14 support it? 15 We are stacking up questions here. 16 It's like Reagan Airport at noon. So please? 17 MR. CAHN: My name is Professor Edgar 18 Cahn. I'm the creator of Time Banking. 19 Fifty-five percent of the care that 20 keeps people out of nursing homes, according to 21 the Congressional Budget Office, 80 percent if 22 you listen to AARP, is informal care. It's one

thing to say how do we get the devices talking to the formal systems.

We have a system of Time Banking that 3 4 has thousands of people, and they're spread to 38 5 countries. But there is no way, given the digital divide; we've now got a mobile 6 7 application that will work on smartphones. But we're working in neighborhoods 8 9 where people don't have smartphones where we need 10 connectivity. We need to ask how do we get 11 connectivity to a person who's just got a phone 12 to call and then and to link with the smartphone 13 systems and the Internet systems. 14 So that's the problem we face on the 15 ground dealing with neighborhoods that we deal 16 with. And those are predominantly Black, 17 Hispanic, Native American. They're not middle 18 class that have the smartphones. 19 And I don't know whether that's even 20 on the, you know, on the radar screen. But I 21 wanted to put it on the radar screen. 22 MR. HAVASY: Well, I think it plays a

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1	little bit to a question. We'll build off the
2	last one, and I'll incorporate that into a
3	question, I think. And I'll put it this way.
4	It was put forth in the previous panel
5	that maybe hospitals need to solve this problem,
6	right? Hospitals should get together and put
7	forth a set of standards and a test bed here, and
8	that would be great.
9	My question to industry is what
10	happens then when we have sort of an American
11	healthcare system, and a European healthcare
12	system, and an Asian healthcare system and they
13	all decide on different standards?
14	Would industry tolerate different
15	regional approaches to this? Or would they like
16	a more harmonious one? And that plays very much
17	into that question.
18	Because what you're pointing out is
19	not a uniquely American problem, right? A large
20	swath of the world are not people who buy \$10,000
21	Apple watches, no offense to Apple, but are
22	people who are buying low cost sub-hundred dollar

handsets from manufacturers that we've never
 heard of in the United States.

And if we want to look at this, as many of the companies on this panel do, as a global healthcare problem, we have to solve many of those same problems.

So I guess I'll turn it over to you that way and say, you know, what about that? What about this idea of can we, is there a place in test beds to ensure the kind of interoperability that would drive access to this care? And is it a kind of problem that we can look outside the United States to help solve?

14 MR. CAHN: Let me add one factor, and 15 that is that the recent studies show that social 16 isolation is as deadly as smoking tobacco. And 17 so part of what we're trying to do is say how do 18 we reconnect our neighborhoods? How do we create 19 the functional equivalent of extended family? 20 It's a different frame, but it feeds into the 21 problem.

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MR. AHLUWALIA: I'll have to share a

little, but I don't know if I have the answer to 1 2 this question. But I will just share an opinion. Talking to healthcare organizations 3 4 outside the US, at least this is my personal 5 opinion; I think 80 percent of the challenges are They're global challenges we see. 6 shared. 7 You're always going to have a little bit of, you know, uniqueness. 8 9 Especially, you think about security 10 regulations in Europe, it's going to be a little 11 different than what the US has and same thing in, 12 you know, all the way if you look at Australia, 13 et cetera. 14 The problems in India and China are 15 quite different, right, because they have a lot 16 of people that probably don't get any healthcare. 17 So, you know, they need to get some kind of 18 healthcare. 19 The way I look at the question that 20 was asked is one of who pays for this? How do 21 you pay for trying to get the advanced care and, 22 you know, at some level standardized care or a

basic set of care that everybody gets, and then
 you kind of build from there.

And that's actually one of the biggest reasons why a lot of this innovation is happening to begin with, especially in the U.S. It's driven because of cost. You know, there's more than 20 percent of the U.S. GDP is actually being spent on healthcare.

You know, I asked this question for
some; at least to get a perspective on is it the
same problem that's in Europe or some other
countries? And the answer I got was, you know,
not all the time. Cost is not the only factor,
but it is a factor. There are other factors that
they consider as well.

But, you know, I think anything we do here, if we make it too complicated, we put too much regulation on it, we raise the bar, I think it will slow down the transformational process.

20 My perspective is we've got to look at 21 where we are today. People do what they want to 22 do. Patients are using devices without all this

great stuff that we're talking about. 1 I've 2 heard, you know, and no offense to physicians, but they do whatever they want to do anyway, 3 4 They find ways to go do things, right? right? 5 And, you know, so our challenge is how do you make it better? If you agree that the 6 7 current state is really, really bad, then we should try to get on a journey to improve it, as 8 9 opposed to try to find that ideal state and, you 10 know, solve for every little thing before we can 11 even, you know, dip our toes into it. And that's 12 a little perspective. 13 MR. HAVASY: So just to set the bar 14 here, we have one more question queued up and 15 live here. I have a very interesting Twitter 16 question and about seven and a half minutes left. 17 And we're going to need to do a wrap up at the 18 end of this. So Jarrin, go ahead. 19 I'll go guickly. MR. JARRIN: So, you 20 know, one thing that became obvious to us when we 21 were doing the mHealth Task Force was that 22 sometimes there's a lack of interagency

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collaboration.

2 For example, and please forgive me FCC if I'm getting this wrong, but I believe that the 3 4 TracFone program, one of the criteria or elements 5 in order to be able to participate in the program was that you have to be a Medicaid eligible 6 beneficiary or something to that effect. 7 My senses are delicate because I have 8 9 an 11 month old, and she refuses to sleep at 10 night. But I digress, you know. 11 And then it became obvious to us that 12 even though there is this eligibility criteria, 13 there wasn't much communication going on between 14 CMS, and specifically state Medicaid and 15 TracFone. And I believe that something has 16 happened since then. There has been some 17 communication, some kind of a partnership. 18 But that's the kind of thing that 19 should happen. Because much like what the 20 gentlemen was talking about, we've got, you know, 21 this entire demographic of America that may not 22 have access to a smartphone, does have access to

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another kind of government service yet the two 1 2 agencies that are principally in charge of trying to get those services to that person aren't 3 4 really even communicating cohesively. 5 So that's an issue. And there's a lot of that that happens, you know, for example, the 6 7 Department of Housing and Urban Development, you know, with the CDC, with HHS, other agencies 8 9 within HHS, et cetera. That's a whole other 10 conversation but a very important one. So I'm 11 glad that he brought it up. 12 MR. HAVASY: Please? 13 MS. SHERLING: Good evening. My name 14 is Sandra Shirley. I'm with Research Associates, 15 and I'm also a consultant with TimeBanks USA. 16 And one of the things that the 17 literature has been showing for decades is that 18 we have an explosion of an aging population who, 19 according to a court case, Olmstead, requires 20 that they be in the least restrictive 21 environment. 22 Most aged people want to age in their

own home and in the community. And I offer to 1 2 you that this is going to drive the future significantly in this area. 3 One, these people do not want to be 4 5 institutionalized, and that's a waste of healthcare money to institutionalize them and re-6 7 hospitalize constantly, as well as put them in nursing homes, because they don't have adequate 8 9 informal care at home. 10 And there's not a bridge between 11 informal care and formal care, which I also then 12 offer to you is that that is what the technology 13 can do. One of the things that the technology 14 can do is facilitate people aging in place, the 15 devices that help them to keep their prescription 16 regimen, that help them to be monitored, if at 17 all possible, for blood pressure or whatever. 18 And certainly the digital divide issue 19 can come into play when you're talking about 20 addressing health disparities. 21 But certainly the cost of 22 institutionalizing people is far, far greater

than people working together collaboratively,
 industry, regulators, technology people,
 networks, to come up with how this can operate
 and creating an infrastructure bridge between
 informal care and formal care. That is
 hospitals, communities and home.

7 And there are several ways that that's taking place now. I would like to talk more, but 8 9 know that you can't. But Dr. Cahn, the founder 10 of the Time Banks is dealing with a lot of these 11 issues in terms of respite care. And there are a 12 lot of opportunities in that regard. Thank you. 13 MR. HAVASY: Thank you. And I think 14

14 that brings us to an important point. And being 15 conscious of the time, I'm going to --

16 MR. AHLUWALIA: I just wanted to say
17 I agree with her.

18MR. HAVASY: Yes. I think you'll get19a lot of nods from everyone up here on this panel20for sure.

21 MR. HATFIELD: Especially aged 22 persons.

1 (Laughter) 2 MR. HAVASY: Don't put words in my There was a question that came up on 3 mouth. 4 Twitter. And I think it plays into something 5 that we're hearing here as well. And my own experience tells me that this is true. 6 7 And the question says this, "It appears that the discussions have focused on 8 9 lower data rate applications, PG equipment 10 settings, which is patient monitoring. Are there 11 considerations or thoughts for higher data rates 12 and limited latency for wireless imaging, video 13 streaming, use of ad hoc equipment, et cetera?" 14 And what that points to is something 15 that I have seen, I think some of the companies 16 here have seen as well, right? And that is, 17 again, as this locus of care changes, what used 18 to be the provenance of a hospital network 19 managed by a professional with enterprise grade 20 equipment is going to end up being a distributed 21 network on home grade equipment, right, managed

by people who don't manage networks.

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In my organization, Continua, it used 1 2 to be the Continua Health Alliance, I have a use case that was brought forth for an in-home 3 4 ventilator. You don't get much more critical 5 than that. And this is a piece of equipment that's more than just an idea. This is something 6 that is, they're asking for standards on how they 7 move that data around, because it's ready to go 8 9 home. 10 And that points to your point as well, 11 There was a doctor I used to work with right? 12 who said very famously, "If you ask people how 13 they would like to end their lives, they would like to end their lives at home in bed surrounded 14 15 by family." If you look and find out how they 16 actually end their lives, they end up their lives 17 in a hospital room alone hooked up to tubes. 18 And so any consideration, any system 19 we put in place, has to take into account the 20 fact that we are not just talking about the 21 hospital, right? And I'll begin a little bit of a 22

summary here. And then I absolutely want to make 1 2 sure that we've hit all the points, and we get a summary of what we think we should go forward 3 4 with here today. But what I heard are things like we 5 need to take into account not just the hospital 6 7 but other environments, because healthcare is a continuum of care. And people are within that 8 9 continuum, wherever they are at any point in 10 time. 11 We see the acuity and the frequency of 12 the data generated by different parts of the 13 system actually becoming more diffuse, right? 14 What used to be the high acuity, high frequency 15 data that was only found in an intensive care 16 unit is moving to other locations in the system 17 right now. 18 And we see innovation being more 19 diffuse as well, right? We see people using 20 unlicensed spectrum and inexpensive components to 21 go out and try new things. 22 And whatever the test bed looks like,

whether it's a public/private partnership, 1 2 however the leadership gets this together, it needs to take into account all of those pieces in 3 4 addition to solving that seven layer chess game 5 that someone said earlier, right, that is the -and then somebody else called it the hostile 6 wireless environment inside a hospital, right? 7 It's not just a hostile environment. 8 9 It's a diffuse environment; it's an environment 10 that has stakeholders that very rarely have their 11 voices heard in the design of these systems. 12 And whatever it is we come up with 13 from this work needs to take that into account. 14 So with that said, I will certainly go down the 15 road. Dale, I'm going to give you a chance as 16 well. Let's have some final thoughts here. We 17 have about a minute left. 18 MR. HATFIELD: Real quickly, what I 19 heard is that we need to create some sort of a 20 public/private partnership. One of the things 21 that Steve Berger -- is make sure we're talking a 22 common language, common terminology. Somebody

needs to establish requirements. I'm picking up 1 2 on Bill Young's sort of thing, set of requirements. 3 4 And the question is medical grade 5 requirements and then the test methods. Okay, Somebody should be then you have test methods. 6 7 working on test methods. And then, of course, that informs what 8 9 you need in terms of a test bed or test beds, 10 probably more than one to account for the fact 11 that they need to work in various environments. 12 And then I think there's probably an educational 13 component to all this as well. 14 MR. AHLUWALIA: I just have one thing, 15 I guess, or a couple of things I'll end with. 16 One is, you know, there was an ask for having 17 actionable items. 18 We do have, at Cisco we have an 19 effort, initiative, we call it a share wave, 20 which is really a test bed to help do some 21 testing, wireless testing. We didn't get an 22 opportunity to share more with you, but if you're

interested we can definitely share more. I have
 a colleague that actually is with me here that
 leads that initiative.

And we would love to get more input, partner with, you know, other stakeholders who are obviously doing this for GE. But the more we can work as one team to, you know, take if forward and try to help address and do our fair share, we'd be happy to do that.

And the only other thing is that, you know, I don't think we answered that other question of the one liners, right? So I'll just take the opportunity and say wireless networks, hopefully, can be an enabler for innovation and better patient outcome. So that's my two cents.

MR. GRESBACH: I think just in closing I think moving forward I think stakeholder input was a big one. We gathered requirements, gathering of medical devices, thorough testing, both at the deployment of the device from the medical manufacturer and then, if at all possible, post design.

And then application of risk 1 2 management as well, I think, is big in this as So we need to be able to continually 3 well. 4 monitor the risk and then, you know, apply the 5 appropriate risk measures for whatever type of device we're deploying on the network. 6 MR. HAVASY: We're over by about a 7 minute at this point. So if you want to get one 8 9 more sentence in, you can have your sentences. 10 I've said enough. MR. GRESBACH: 11 Thank you. 12 MR. TRI: So mine is really quick. 13 You know, I think the challenge is healthcare 14 organizations are really risk averse. And the 15 challenge before us is how do you innovate in a 16 risk averse environment? And I think, you know, 17 maybe there are lower levels of care where we can 18 be innovative, but at high acuity patients we 19 wouldn't want to be until the process matured. 20 MR. HAVASY: And Dipu, if you have 21 anything left to say, we'll give you the closing. 22 And, of course, now is when it freezes.

MR. GANGULY: No, I think this was a 1 2 fascinating discussion. Again, my big focus happening in life now is to design things that 3 address usability and make them easier to use in 4 5 these kinds of environments. MR. HAVASY: All right. Thank you. 6 7 Thank you all very much for sticking around for I know we have the closing left. 8 the day. 9 MS. ONYEIJE: This was fantastic. 10 (Applause) 11 MS. ONYEIJE: So for all of you with 12 staying power, we have just one final, just a few 13 thoughts here. 14 This has been beyond our wildest 15 I will tell you that it has been dreams. 16 engaging, it's been robust, it's been 17 provocative, and that really is due to all of the 18 hard work of everybody in this room. 19 And I would be remiss if I didn't just 20 offer a pretty formal thank you on behalf of the 21 FCC's Connect2Health Task Force and the Office of 22 Engineering and Technology, to all of the

moderators and discussants, to the audience, and participants and the many staffers who worked both at the FCC and FDA behind the scenes to make today what it was, and from my perspective, a wonderful success due to all of you.

I also wanted to thank the FDA Center 6 7 for Devices in Radiological Health -- that's a mouthful for me, for some reason -- just for 8 9 partnering with us. They have been wonderful 10 partners, and we are incredibly grateful for 11 their willingness to collaborate. And with that, 12 I think the last words here are going to go to 13 Julie Knapp and to Bakul Patel.

MR. PATEL: Thank you, Karen. Wow, is all I can say. This was very interesting, and challenging and some would say mind twisting at the same time.

18 If I were to sort of show here's 19 what's in the next episode of Glee, I would have 20 done that. But I don't think we're ready yet. 21 So I'm going to share a couple of things.

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And before I do that, I really want to

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repeat what Karen said. Thank you to the staff, 1 2 Heather, Seth, Debra and Ben, and Karen especially for pulling the meat of the work that 3 4 goes behind arranging this fantastic meeting. 5 Special thanks to the moderators. 6 (Applause) 7 MR. PATEL: Yes. Special thanks to the moderators and the panelists for taking time 8 9 out of their busy days, and being here and 10 discussing these important topics. Before I turn it over to Julie, I want 11 12 to reflect on a couple of things that I heard 13 today and maybe have you guys walk away with 14 those thoughts as well and sort of be part of the 15 solution that we need to put together. 16 I heard a lot of topics brought up. 17 I've heard about interoperability, I heard about 18 other industries, I heard about make a great wireless. And they seem to be all sort of 19 20 converging towards two big things in my mind. 21 And they may not be two big things; they end up 22 to be one big thing.

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What is the test environment are we thinking about? And what does that mean to the test beds that we are talking about? And when I think about test environments, I think about the configuration.

And when you look up software test 6 7 environments, you think about the PC, and the nodes and et cetera that sort of goes with it. 8 9 And the test bed seems to be more encompassing in 10 terms of, you know, in the test protocols and how 11 many radios are there, et cetera, et cetera, et 12 How many devices should be in the cetera. 13 picture or environment, et cetera?

14So those two thoughts sort of emerged15out of all the discussion. So I'm going to leave16one question, open question to all of you. The17discussion we had today, I think, needs to be18narrowed down to something that's tangible that19we can all take the next step towards.

20 And how do you frame that from, you 21 know, at least in my head, of what's an 22 environment? What's a test bed? And maybe if

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you start from there, we can actually make some 1 2 progress. I was talking somebody in the hallway 3 4 and he was, oh, wireless test beds, my company 5 could use that. I mean, that was resounding from 6 that one person. But if there's an indication of how 7 this topic is going to be very important to a lot 8 9 of people, not just the hospitals, Rickey 10 Hamptons who struggle with this day in and day 11 out -- and I'm sorry to call on you, Rickey, but 12 you are favorite. 13 (Off mic comments) MR. PATEL: And the small businesses 14 15 who struggle with, don't have the resources to do 16 this. So the question to take back is the 17 discussion we had today, again, reflect on it and 18 sort of frame it in what can we provide. What 19 can we do tangible as next steps? It would be 20 very helpful. 21 So thank you again, everybody. And 22 thank you for staying with us all day. I'll turn

it over to Julius next. 1 2 (Applause) 3 MR. KNAPP: Always dangerous to go last. Just a terrific day. I want to thank 4 5 everybody who participated and listened in to all the conversations. 6 7 A couple of things that struck me, I kept thinking about Steve Berger's comment this 8 9 morning about trying to have a common language. 10 And because what really came home to 11 me as we went through this is we're talking about 12 test beds. But I think I heard through the day, 13 well, I'm talking about reliability, I'm talking 14 about interoperability, I'm talking about EMC, et 15 cetera, et cetera. 16 So, you know, Bakul and I were 17 chatting, and we both used the same expression, 18 you can't boil the ocean. So part of the 19 exercise, I think, for us is to try to, as Bakul 20 said, narrow this down a little bit into some 21 tangible things that can be done. So we will get 22 together, and huddle and see what we can do to

1	advance this process a bit. But I want to thank
2	you again, all, for sharing your ideas. It
3	really was a terrific day.
4	(Applause)
5	(Whereupon, the above-entitled matter
6	went off the record at 4:19 p.m.)
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This is to certify that the foregoing transcript

In the matter of: Promoting Medical Technology Innovation: The Role of Wireless

Before: FCC and FDA

Date: 03-31-15

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

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