March 20, 2014 Workshop Transcript: Examining Health Care Competition

Hosted by the Federal Trade Commission

March 20, 2014

FTC Conference Center
601 New Jersey Ave NW
Washington, DC 20001

[Video 1 of 8]

Professional Regulation of Health Care Providers

[Video 2 of 8]

Innovations in Health Care Delivery

[Video 3 of 8]

Advancements in Healthcare Technology

[START OF WORKSHOP, DAY 1]

WELCOME REMARKS AND ANNOUNCEMENTS

- **Tara Isa Koslov, Deputy Director, Office of Policy Planning, Federal Trade Commission**

TARA KOSLOV: Good morning, everyone. Good morning and happy spring. Welcome to the FTC's workshop examining health care competition. My name is Tara Koslov. I'm the deputy director of the FTC's Office of Policy Planning. We're delighted to welcome you here today. On behalf of the entire workshop team, we would like to express our appreciation for the high level of interest in this workshop.

We're grateful that so many of you have joined us today in person. I'd also like to recognize that we have a live webcast, and we are making the program more accessible to a wider audience in that way. So hello to everyone who's watching the webcast as well.

Before we get started today with the substantive program, I have some administrative details that I need to review. The first would be please silence, not necessarily vibrate, silence, if at all possible, any mobile phones, BlackBerrys, or other electronic devices. If you must use them during the workshop, please be respectful of the speakers and your fellow audience members. Please be aware that, if you leave the building for any reason during the workshop, you will have to go back through security again. So please bear that in mind and plan ahead, especially if you are participating on a panel so that we can do our best to remain on schedule.

Please try to avoid having conversations in the hallway directly outside the auditorium while panels are in session. The background noise from the hallway does carry over into this room and it can sometimes disrupt the discussion. And also, the microphones that we're using for the webcast are very sensitive so some of the hallway conversations can be picked up on the webcast.

For those of you who are not familiar with this facility, the restrooms are located out in the lobby behind the elevator banks, to the left of the security desk where you came in. In the unlikely event that an emergency occurs and the building alarms go off, which we certainly hope will not happen today, please proceed calmly to the main exit in the lobby and assemble across the street on the sidewalk in front of the steps of Georgetown Law School. At that point, the security guards will let us know when it is safe to return to the building.

I'll take this opportunity to remind at least our first panel -- and we'll remind others later -- everyone should please make sure you speak clearly into the microphone so everyone can hear your remarks and also because we are creating a record of today's proceedings. A reminder to everyone that lunch is on your own today. And if you don't know the neighborhood, we do have a list out on the table of some local lunch spots in case that's useful to you.

We have provided a table outside where speakers and attendees and others have left copies of some handouts and other materials that might be of interest. To be clear, the FTC does not necessarily endorse any of those materials, but we're happy to provide the table space as a courtesy. And, finally, if anyone has any questions throughout the day, please feel free to ask any of the staff who are wearing the FTC badges or those sitting at the registration desk. And we'd be glad to help you.

I do also want to say a quick note about our use of webcasting, social media, and the Q&A process that we'll be using for the workshop. We've done our best to get all of the speaker materials loaded ahead of time so that they are available to webcast viewers. If any are not available during the webcast, for those of you who are watching the webcast, we will post them as soon as possible following the workshop. For those of you who are following us on Twitter, we will be live tweeting today's workshop at #FTCHealthCare.

We do have comment cards available here in the conference room, and audience members will be able to submit questions or comments for each panel. During each session, FTC staff will be walking around, and we will collect the cards, and the cards will be brought up to the moderators. We will also have someone monitoring Twitter. So if additional questions come in through Twitter, we'll catch them that way.

And, time permitting, the moderators will do their best to select some questions to offer the panelists. Even if we don't get to all of the questions during the workshop itself, we assure you that we will carefully review all of them and take them into account as we continue our research and inquiry on these important topics.

To open today's workshop I am delighted to introduce FTC Chairwoman Edith Ramirez. Chairwoman Ramirez was sworn in as a Commissioner of the FTC on April 5, 2010 to a term that expires on September 25, 2015. President Obama designated her to serve as Chairwoman effective March 4, 2013. I actually had the privilege of serving as her attorney adviser for the first year that she was a Commissioner, and it has been an honor and a pleasure to work with her as we have both moved on to our new roles.

Chairwoman Ramirez has embraced the agency's longstanding commitment to promote health care competition and has been a strong supporter of our efforts, over many months, to organize this workshop. Please join me in welcoming Chairwoman Ramirez.

OPENING REMARKS

- **Edith Ramirez, Chairwoman, Federal Trade Commission**

EDITH RAMIREZ: Thank you, Tara, and good morning everybody. And welcome. It really is a pleasure for me to open up this two-day workshop. And I'm really delighted by the level of interest that we've seen already. We've already received a number of comments through our public comment process, and I'm also very happy to see a full room here today. And I know that many more are watching the webcast.

So I don't have to explain to this audience why competition in the health care industry is such a high priority for the FTC. Health care accounts for over 17 percent of GDP. And study after study tells us that vigorous competition in health care markets reduces costs, improves quality, and expands access to care for consumers. The Commission has a strong record of success in promoting competition in health care markets, and our work in this industry remains one of my top priorities as Chairwoman.

And while many of our health care enforcement matters receive a great deal of attention, it's important to recognize that health care also represents a significant part of our competition policy agenda. We engage in continual study to sharpen and update our understanding of health markets and practices. That study has taken many forms, including several previous workshops, advocacy comments to federal and state regulators and lawmakers, and ongoing collaboration with our colleagues at the Department of Justice, the Department of Health and Human Services, and other federal agencies. We've also engaged in retrospective studies of prior enforcement actions, such as those that paved the way for our successful second-generation challenges to anti-competitive hospital industry consolidation.

Although I have recognized the value of retrospective study in the past, today's event is about equally important prospective study. I believe that looking back on our previous enforcement activities can help to better inform our current and future priorities, but, in an industry such as health care, which is undergoing significant and rapid evolution, we must also invest our resources to understand and anticipate change. Workshops like this one help us to maintain our cutting-edge knowledge of the industry, and they also educate us about important developments that may impact the competitiveness of health care markets in the near and long term. Given the importance of these markets to our economy and to American consumers, it's essential that we understand not just today's markets but tomorrow's as well.

Over the next two days, we'll study certain activities and trends that may affect competition in the health care industry. We've assembled an impressive group of health care policymakers, scholars, and professionals, and I want to thank them all for agreeing to join us and sharing their expertise.

And what I'd like to do is just spend a couple of minutes explaining how we arrived at today's agenda and what we hope to accomplish over the course of the next couple of days. As you all know, the health care industry has evolved significantly in recent years. Some of these changes have been spurred by legislation. For example, the Affordable Care Act authorized HHS to develop and test innovative health care delivery models in an effort to identify ways to improve health care quality and make services more affordable. FTC staff worked closely with the Department of Justice and staff from HHS and the Centers for Medicare and Medicaid Services to publish the 2011 "Antitrust Enforcement Policy Statement Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program."

Some aspects of today's workshop reflect our continued efforts to understand the competitive implications of emerging health care delivery models, such as retail health clinics and telehealth initiatives. But many of the developments and changes we've observed in the industry and that we'll explore today reflect general and longstanding concerns about the key drivers of virtually all health care choices: the so-called triple aim of reducing cost, increasing quality, and expanding access. And I would add to that a fourth dimension -- promoting coordination of care -- which has gained even more attention in recent years, and which has the potential to support and foster all of the other goals when done efficiently and procompetitively.

For example, although the ACA and the American Recovery and Reinvestment Act require the widespread adoption of electronic health records, the movement toward broader adoption of EHRs was already a growing trend well before these

legislative reforms were enacted. And health information technology certainly would have continued to proliferate even without reforms and funding. Along these lines, the workshop will examine the competitive implications of advancements in health care technology, including electronic health records and the extent to which they may be used to reduce health care costs while promoting quality, access, and care coordination.

Another key example is health care quality, which has been a significant focus of the health care industry for many years. For over two decades, the Agency for Healthcare Research and Quality and many other industry stakeholders have looked for ways to improve health care quality, affordability, efficiency, and accessibility. Following their lead, a major goal of this workshop is to help the FTC better understand the most recent developments in health care quality measurement and assessment and how this information may affect competition for health care services.

A third example is professional regulation, which has long been of great interest to the FTC and the entire health care community. Just two weeks ago, FTC staff released a new policy paper, "Competition and the Regulation of Advanced Practice Nurses," which focuses on various physician supervision requirements imposed on APRNs in many states. The policy paper builds on a series of FTC staff advocacy comments on APRN scope of practice issues. And today's panel will go back to basics, exploring the historical, legal, and economic underpinnings of professional regulation in health care. But the panel will also look ahead, highlighting some cutting edge aspects of the relationship between professional regulation, cost, quality, access, and care coordination.

With respect to these and other topics in the workshop agenda, our ultimate goal is to enhance the Commission's expertise and knowledge base regarding competitive dynamics in this critical sector of the economy. Workshops like this one are what enable us to meaningfully capture a moment in time in an enormous, rapidly

evolving industry that touches the lives of all Americans. We fully recognize the value of our unique study authority, embodied in Section 6 of the FTC Act, which specifically authorizes us to gather, compile, and disseminate information to serve the public interest. And, as many of you know, this year marks the FTC's centennial. And as we reflect on our past strengths as well as our future opportunities, we view this study authority as an essential element of our mission.

In assembling today's panels, staff's aim was to bring in speakers who could really help us explore new concepts and not just from an academic perspective but also from a practical, real-world perspective. One of the first things we learn as competition lawyers is that competition is a highly fact-specific discipline. Those who have the greatest command of the facts are best positioned to understand markets and serve as effective advocates.

The FTC embraces its role as an advocate for sound competition policy, and we know that our credibility depends heavily on our understanding of the industries where we do so much of our work. That's why we're here today. We expect that, over time, our learning will support all of the Commission's efforts in health care -- advocacy, enforcement, and consumer education. The more we learn, the better we can do our job of protecting competition and promoting the interests of American consumers.

The specific workshop topics have been selected and organized not only to explore the details of each subject but also to highlight the relationships between topics. For example, this morning's discussion of professional regulation will serve as a predicate for this afternoon's discussion of innovation in health care delivery models. Advancements in health care technology, addressed in today's final panel, are highly relevant to, and often enable, the emergence of new health care delivery approaches.

Tomorrow's sessions include not only separate panels on health care quality and price transparency, but also a session devoted to the important connection between

these two issues. We plan to explore the extent to which both quality and price information enable meaningful choices by consumers, physicians, and other health care decision makers.

But before we move on to the substantive program, I'd like to take this opportunity to thank the many FTC staff members responsible for organizing this workshop. The Office of Policy Planning took the lead, but the effort was truly agency-wide, benefiting from participation by the Bureau of Competition, Bureau of Consumer Protection, Bureau of Economics, the Office of General Counsel, and several of our regional offices. Their collective goal was to identify core health care competition policy issues that are in need of further development. And staff also engaged with many outside stakeholders, including our colleagues elsewhere in the federal government, to ensure we were focusing on the issues most likely to affect future health care competition. And let me also thank again all of our distinguished panelists for their participation in the workshop. They bring a wide range of experiences and perspectives to the table, and we certainly couldn't hold a successful workshop without them.

In closing, I want to emphasize that these two workshop days represent the beginning of our inquiry, not the end. We will accept public comments on all of these topics through April 30, and we encourage interested parties to submit information that would further our understanding of any of these issues. And with your assistance, we plan to build a record that will help all of us continue a fruitful discussion about the value of maintaining competitive markets for health care services.

Thank you very much. Now let me turn the floor back to Tara.

TARA KOSLOV: We're going to go ahead and get set up for our first panel so if you will just indulge us for a minute. We need to move some people up here and make sure that we have our remote panelist who is participating from the West Coast via

video conference. There she is. So just give us a few minutes to get settled, and then we'll get started. Thank you.

PANEL DISCUSSION: PROFESSIONAL REGULATION OF HEALTH CARE PROVIDERS

Moderators:

- **Tara Isa Koslov, Deputy Director, Office of Policy Planning, Federal Trade Commission**
- **Patricia Schultheiss, Attorney Advisor, Office of Policy Planning, Federal Trade Commission**

Panelists:

- **Gail Finley, Vice President of Rural Health and Hospitals, Colorado Hospital Association**
- **Morris Kleiner, PhD Economist & Professor, Humphrey School of Public Affairs, University of Minnesota, Twin-Cities**
- **Lisa A. Robin, MLA, Chief Advocacy Officer, Federation of State Medical Boards**
- **Barbara J. Safriet, JD, LLM, Visiting Professor of Health Law, Lewis & Clark Law School, formerly, Dean for Academic Affairs & Lecturer in Law, Yale Law School**
- **Joanne Spetz, PhD, Professor at the Philip R. Lee Institute for Health Policy Studies & Associate Director of Research Strategy at the Center for the Health Professions, University of California, San Francisco**

TARA KOSLOV: We're going to go ahead and get started. So you've heard from me already -- Tara Koslov from the Office of Policy Planning. This is my co-moderator for the panel, Patricia Schultheiss, also from the Office of Policy Planning. You heard a little bit from Chairwoman Ramirez about our goals for the first panel. We're really trying to explore some new areas relating to the regulation of health care professionals and, in particular, focus on some of the implications for competition.

Professional regulation issues are something that the FTC has been engaged in for quite a long time, but what we really wanted to do, our guiding principle in putting together this panel, was trying to figure out what were some new areas that we could go into beyond the ones that we have covered in many of the competition advocacy comments that we've done in recent years, which have covered, for example, APRNs, CRNAs, Certified Registered Nurse Anesthetists.

We've had several recent comments relating to dental hygienists and dental therapists, a comment relating to dental service organizations. So those are some of the issues that we have covered. If you're not familiar with those, you can look on the FTC's website and you can find a list of all the prior advocacies that we've done.

We also were not intending to use this panel to rehash issues that we covered fully in the policy paper that Chairwoman Ramirez just mentioned that we put out a couple of weeks ago, which looks like this. It is on our website in case anybody wants to see it. Policy Perspectives: Competition and the Regulation of Advanced Practice Registered Nurses. So, as I said, trying to explore some new issues.

In thinking about how to structure the workshops, what we hope to do today is, in the morning, using this panel, we're going to discuss the regulatory framework that governs health care professionals. Some of those regulations raise interesting competition issues in and of themselves. And I think that's some of what we're hoping to explore with today's panel, but, in addition, as Chairwoman Ramirez indicated, what we hope this panel will do is also set up some of the predicate and some of the background for the afternoon panel on innovations in health care delivery, including telehealth and retail clinics, because there are implications from the professional regulation sphere. I'm going to turn it over to Pat to briefly introduce our panelists.

PATRICIA SCHULTHEISS: Good morning. Thank you for all being here. We're not going to go into a detailed bio of any of the panelists -- there is a bio packet. I don't know if they're out there, but we also have them online so please refer to those. But I will introduce them in the order in which they're going to speak.

The first speaker is going to be Barbara Safriet. She is a JD and a visiting Lewis and Clark Professor of Health Law and Policy. And she is also a former Associate Dean for Academic Affairs and a Lecturer in Law at Yale Law School. Barbara is joining us remotely from Portland, Oregon this morning. So, she's up very early to participate. Our

second -- and Barbara -- hi, Barbara. And Barbara's going to provide a legal overview of the history of professional regulation.

Our second speaker will be Morris Kleiner, a PhD economist. He's a professor at the Humphrey School of Public Affairs, University of Minnesota, Twin-Cities. And Morris has been working for decades, doing work in occupational and professional regulations, looking at it from an economist's perspective. And he will be our second speaker, providing the overview from the economist's perspective.

Our third speaker will be Joanne Spetz, also a PhD in economics and a professor, the Philip R. Lee Institute for Health Policy Studies and associate director of research strategy, Center for the Health Professions, University of California in San Francisco. And Joanne is going to provide a specific example within the nursing profession.

Our fourth speaker will be Gail Finley, the vice president of rural health and hospitals, Colorado Hospital Association, and, again, Gail's going to provide a specific example, a real world example of some issues related to professional regulation that have affected hospitals in Colorado and in which she has been involved.

And our final speaker will be Lisa A. Robin. She's the chief advocacy officer for the Federation of State Medical Boards. And Lisa is going to provide us with an overview of some of the work that the Federation of State Medical Boards is doing with respect to facilitating an interstate compact to facilitate physician licensure across state lines. And they are also working on standards for telehealth. So, Lisa will be providing a presentation on what they're doing. I think with that --

TARA KOSLOV: We'll turn it to Barbara.

PATRICIA SCHULTHEISS: We will turn it over to Barbara in Portland. Let's see how this works.

BARBARA SAFRIET: Thank you and good morning. I'm glad to be able to join this conversation on competition in health care delivery. I'm not quite sure what the status of competition here is in Portland on health care delivery but I can say that in the competition for personal health so far I'm losing. I'm in my fourth week of the flu, and the flu seems to be an incredibly strong opponent. So, I apologize for my raspy voice. And I will also probably apologize for stopping to eat yet another cough drop or whatever.

I've been asked to talk briefly about the history of licensure and regulation in the health care arena and then talk about the current regulatory framework. So first history -- and this will be brief -- and then the current status of things, which in so many ways are essential to competitive opportunities for a variety of health care providers in our delivery system. So, first the history.

In the beginning -- we won't go back quite that far -- but in the early 1800s, there were some licensure statutes, principally for medicine. First barbers and surgeons but then medicine. And we had some state licensing requirements. However, during the Jacksonian era -- 1830s through 1850s -- many if not all of these laws were repealed.

This was consistent with kind of the ideological debate that was going on then of favoring the common man over experts, promoting laissez-faire economics, and especially opposing what was then deemed to be a very strong coalition of especially privileged, economically elites controlling policy making in this country. So the few laws that did exist were repealed.

However, then, during the late 1800s and early 1900s, we had a dramatic turn from populism to progressivism. We also had, fortunately for all of us, the development of truly scientific methods like germ theory and the rest. There was a movement then to get away from laissez-faire, anything goes, yes, the common man has good sense and

can make choices, but we do now acknowledge -- they then did acknowledge -- the rise of experts and expert bodies of knowledge.

And, we had a proliferation of reenactment of practice acts, principally medical practice acts for physicians. Let me just note that, in all of this, ideology played an enormous role, as it does, perhaps, in all regulation. But in this licensure of physicians for example, versus unlicensing physicians, political ideology, economic ideology, social ideology, even religious beliefs and ideology played a hand in the movement toward re-instituting licensure.

The purpose of licensure, ostensibly, is to counterbalance what are called market failures. There's an informational asymmetry. The ordinary patient does not know, cannot know, the full breadth of knowledge of scientific information and the rest. And the provider, ostensibly, who has that, has much more information. The second kind of basis is, even if the consumer or patient had such knowledge, they don't have the expert ability to be able to accurately assess quality and those sorts of issues.

As a result, we have instituted licensure, which is surely anti-competitive in that it states who can enter into a market and provide services. We restrict the authority for practice to those who have met certain educational requirements and now have passed certain licensure examinations.

So we've used licensure repeatedly, the power of government, to say who can legally do x, y, or z, and who can't. We have used licensure to control entry into the market. But, we have largely relied on the private professions and their associations themselves to define the contours of that regulation. There has always been and continues to be a strong role for professional private associations interacting with regulation.

For example, early on in the 1900s, no one could be appointed to a state medical licensing board, governmental authority, who was not a member of the local and state

medical society. Similarly, this time with professional associations, and the governmental authority reached into the judicial arena because one could not maintain, in many states, professional membership in the state and local medical society if one testified as an expert witness in a malpractice case without prior approval of the medical society.

I'm not saying this is necessarily good or bad. Some of you who know me might know what my views would be on that, but I raise the example only to highlight -- there has always been government regulation but intrinsically dependent upon an enormously active and influential role for private, professional associations. That reliance continues today because the licensure examinations, the accreditation standards for professional education, both of our proxies -- if we want -- for competence, as preconditions for licensure, you must have graduated from a professionally accredited education program plus passed a professionally developed licensure examination, both proxies for competence.

They're all developed -- those accreditation standards and the examination itself -- all developed and administered by private entity, not the government. Now, the government has accepted these standards, but the standards themselves and the content of them are determined by private entities. The reliance on the private-public partnership, so to speak, in the health care arena continues through professional certification examinations, which are now increasingly being rolled into continuation of licensure or maintenance of competence requirements, which are being instituted by more licensing boards.

Certification and credentialing by private hospitals, private health care providers, malpractice insurers, and others depends upon establishing certification. Certification which is rendered and approved by whom? Private associations. So my main point is there has been a tradition of government regulation, which is anti-competitive -- only

you can do this. If you're not approved or licensed, you can't do this. And the underpinnings of the content of our regulations, in the main, have been and still are developed by private professional associations.

I'm not saying that's a bad thing, but I am saying, when one looks at competition and regulation, one needs to keep that history in mind and to guard against potential biases or human nature, which we all in some ways are self-interested. On the governmental side of health care regulation, we have a scheme in place where we have in each and every state a practice act, a law, which says, you can practice nursing or medicine or occupational therapy or dentistry or whatever else only if you're licensed and meet the prerequisites established by the state.

The unique thing about this is that the licensure scheme is state-based. So we have 51, including DC plus the territories, different practice Acts for each and every health care provider. And the number of health care providers continues to proliferate. So although we have national educational accreditation standards, national licensing standards in the main, and national certification standards, we still have state-based licensure.

And it varies by state. In some states, particular providers are licensed where in other states, they aren't. We tend to talk about licensure as our main focus of competition and the rest, but we also have to acknowledge that an enormous amount of health care is delivered each and every day in a variety of venues by people who are not licensed. And I think often in the regulatory arena, there is a pejorative notion about care being provided by unlicensed people.

So when we're talking about competition, we need to look not only at licensed individuals but unlicensed as well. For example, profusionists, the ones who keep you alive while you're having open-heart surgery and the rest, are not licensed in each and every state. This does not mean they're incompetent or not good, but it means that, so

far, they've not joined nursing and physicians and the rest in being uniformly licensed across the board. In addition to this licensure scheme in all the states and the district, state-based licensure, every health care profession, licensed profession, other than physicians, faces kind of a third level of regulatory control. And that's scope of practice.

Physicians were the first to be licensed, and in their licensing scheme, they secured what is now called GUMP, General Undifferentiated Medical Practice. And the breadth of this definition of the medical practice act is essential to understand the current competitive environment because the definition of the practice of medicine includes almost anything that one could imagine would ever be relevant to the diagnosis, treatment, of any condition, real or imaginary, physical or mental. I could read you a definition, but we don't have a lot of time.

But by virtue of having gotten there first and having established, in law, this general, undifferentiated universal scope of practice, physicians now, as their knowledge domain expands, never have to go back to the legislature to seek any modification of their authorized practice. Whereas every other health care provider that is licensed, as they sought legal recognition of their professional role, they had to go to the legislature to seek legislative authorization, and they encountered a totally occupied field, the definition of medicine.

So what we have now are licensing acts with scope of practice provisions embedded in them, which are carve-outs from this universal definition of medicine, which are allowed under certain circumstances for other kinds of health care providers. The importance of this cannot be overstated. Because what we have are scope of practice provisions embedded in each state law which basically say what an advanced practice nurse, an optometrist, a physical therapist, an occupational therapist, a clinical psychologist can do.

And it's all carved out of this universal practice of medicine. Scope of practice is an extraordinarily complicated and contentious area because basically -- why is it contentious? It says, what legal authority do you have to use your abilities? And it varies state to state for each of our health care providers.

In a nutshell, scope of practice, although complicated and contentious, basically turns on three different concepts. One is ability, or, what can you do? What are you able to do based on your education and training? Second. What is your authority? That's the legal part. What may you do based on your own license? And then the third concept is pay.

Because, to make the regulatory regime even more complicated, many of the payment systems that we have are tied to your state license and scope of practice statement, which, for all health providers other than physicians, varies across the states. So eligibility to be paid for your services under Medicare, Medicaid, private insurance, the rest, often is tied directly to your legally authorized scope of practice.

This has resulted in enormous consequences for competition because, just as the knowledge domain of physicians and all others has expanded enormously and physicians then, through their medical practice act, can accommodate and utilize those new skills and abilities because they have universal authority, each and every health care provider other than physicians must almost always reckon with a more restrictive scope of practice embedded in their state law, which says you can only do this, this, or this.

The restrictions are enormous. The conflicts are enormous. But the competitive aspects are equally enormous. There are dramatic effects on access, quality, and cost.

For example, we have, in some states, scopes of practice of various health care providers tied to where they practice geographically. Are they within a particular geographic area? And even though their ability does not vary based on their geographic

location, their authority varies based on where they practice. In some states, for example, advanced practice nurses have more prescriptive authority, more independent diagnosis and treatment authority, if they are practicing in a facility which is a not-for-profit. If they walk out the door and go next door to a for-profit facility, suddenly, by law, their legal authority is diminished.

Now it's patently obvious that their ability has not changed, but the law says, based on where you're practicing and the corporate nature of that practice, your legally authorized practice is somehow diminished. So restrictions through scope of practice for all health care providers is enormously important from a competitive point of view. It affects access to care, quality of care, and surely cost of care.

But it also affects choice made by patients and consumers of care because it restricts it. We have so many different modalities now of providing service, which don't recognize the artificiality of state boundaries. So, for example, in metropolitan areas, which are on state borders, you might have a provider giving service to patients in one state and in another state. They just cross the river to get it.

Well, that provider's authority varies as well, depending upon where they are practicing. Will their prescriptive authority be recognized in another state as their patient goes back across the river and all of a sudden, for example, the nurse practitioner has no prescriptive authority in that state? There are enormous ramifications not just for patient choice, but for the recruitment, retention, and deployment of providers of all kinds, affecting dental hygienists -- one of my favorite examples to use is one of the most underserved needs we have in this area is in oral health.

And having spent a great deal of time in long-term care facilities of late, there's a dramatic need not only for children's dental services, but for the oral health of the elderly and vulnerable populations. Well, if have a dental hygienist who, by law, is

restricted to providing services only with a dentist on site or immediately available to supervise, you have immediately set up an incredible barrier to access to perfectly competent care by that dental hygienist, in long term care facilities, prisons, skilled nursing facilities, and the rest.

So the continuing effects -- universal practice authority for physicians and restricted practice authority for all others, especially embedded in scope of practice laws, which still vary state by state, has major consequences for innovative techniques in delivering care and enormous effects on cost and access. There are easier and better ways to do things, but each and every restriction that we have today needs to be individually assessed to see if it's truly justified by a public safety concern or is it justified by historical inertia or some other consideration?

I think I have now elapsed my 20 minutes and I'll be quiet and take another cough drop.

TARA KOSLOV: Barbara, thank you very much. That was wonderful. And the technology worked great. Just so you know, we were able to see and hear you really well.

BARBARA SAFRIET: Oh, good.

TARA KOSLOV: This was a bold experiment for the FTC. This is actually one of the first times, if not the first time, that we have had a panelist by video. So we were really excited to be able to do this. Professor Kleiner.

MORRIS KLEINER: Well, first of all, I want to thank you for inviting me. I want to thank the chair and the FTC for hosting this conference. Delighted how many people are interested in these issues.

And what I would like to do is to -- before I am held up for malpractice and lose my economist license -- I need to talk about issues related to some theory and data and

some history about occupational regulation. But within that context, what I'm going to be talking about is, what is the issue? And how did we get here, secondly? And what does this mean for access to services, quality, and prices? And then conclude with some potential public policy issues.

So why should you care about the issue? Perhaps, given this audience, it's sort of obvious. But if you walked out onto the street in front of this building, virtually everyone would say, aren't we glad that licensing covers doctors, lawyers, dentists. Well, let me think -- interior designers, fortune tellers, rainmakers, and frog farmers? In fact, all of those occupations are licensed in at least one state.

And the other question is, is this a small issue or one that consumers and others might suggest would influence economic growth and prosperity? And over the next 15 minutes or so, I may not convince you but hope to get you to rethink the issue, especially with a focus on health care. So, when I'm talking about a regulation, I wanted to define at least the way economists commonly view this terminology.

I'm really not talking about private regulation. For example, Microsoft has its licensed programmers. I'm really focusing on government regulation, and it really starts out along a continuum from registration, where the government provides a list of individuals -- for example, like in Angie's List -- individuals who can be on this list, certification, where the government gives a right to title -- an example would be a certified financial analyst -- that is, those are the only ones who can use that title but others are allowed to provide the service, including your brother-in-law who might want to give you advice on how to invest your money.

But, lastly, licensing is the most difficult and the most stringent, and it really says that the government says that only those who receive pay and get permission can practice that particular occupation and receive funding for that service. So occupations

as they develop are individuals and groups that provide similar tasks, have common procedures for doing a job. And, occupations don't start out as being licensed.

Occupations evolve. They organize. And, they select licensing as a method to obtain professionalism, status, as well as to limit the supply of practitioners. Occupations often tax their members through dues and engage in political activities that often lead initially, perhaps, to registration, certification, and, eventually, to licensing. The process of regulation across political jurisdictions, as was mentioned by the previous speaker, often takes years or decades in order to move from registration to full licensure.

Now, in the history of occupational regulation, I thought I would start out with one of the founders of economics, Adam Smith, and on the founding of this country he also came out with a book called The Wealth of Nations and, as part of that, mentioned occupational regulation. And “The patrimony of a poor man," he said," lies in the strength and dexterity of his hands; and to hinder him from employing his strength and dexterity in what manner he thinks proper without injury to his neighbor is a plain violation of this most sacred property. It is a manifest encroachment upon the liberty both of the workman, and of those who might be disposed to employ him."

This was a sort of the founding of economics -- had issues dealing with economics. Also in a counter view to the work of Smith, there have also been lawyers who viewed occupational licensing in a very discreet manner and saying that certainly law has a lot to say about the regulation of occupations.

And this is Robert Jackson, who was a former US Supreme Court Justice and also was the chief counsel at the trials at Nuremberg and in a case, Thomas v. Collins, noted a number of things -- those of you who are movie buffs, Spencer Tracy played him in a famous movie called Judgment at Nuremberg. He was really modeled after Justice Jackson. But in this case, Thomas v. Collins, he noted that the modern state owes and

attempts to perform a duty to protect the public from those who seek, for one purpose or another, to obtain money. When one does that through the practice of a calling, the state may have an interest in shielding the public against the untrustworthy, the incompetent, or the irresponsible.

So, there's a very clear rationale, at least in the legal system, for providing protection to the public regarding this issue. And certainly if you walk a few blocks to the Federal Trade Commission, there's a statue in front of it looking at the animal spirits versus regulation and the balance between those two issues.

In contrast, sort of the general view of many economists -- and most notably Milton Friedman, who won a Nobel Prize, in fact wrote his dissertation on occupational regulation along -- and it became a book along with Simon Kuznets who also went on to win a Nobel Prize -- but Friedman throughout his career dabbled in issues of occupational licensing. And perhaps his most famous quote was in Capitalism and Freedom, where he noted that the overthrow of the medieval guild system was an indispensable early step in the rise of freedom in the Western world.

It's a sign of the triumph of liberal ideas and widely recognized as such. By the mid-19th century in Britain, the United States, and, to a lesser extent, the continent, men could pursue whatever trade or occupation they wished without the bye or leave of any governmental or quasi-governmental authority. In more recent decades, there's been a retrogression, he argued, an increasing tendency for particular occupations to be restricted to individuals licensed to practice them by the state.

So this was the sort of the to and the fro, starting with Adam Smith, Justice Jackson, and then Milton Friedman suggesting what's the role of government. Well, certainly the role of government has, over time, been to license occupations. And this gives sort of a question of, who is licensed? And I would like to give you a brief

background on what's been happening. What are sort of the general trends in the economy? And then focus on some health care issues.

Well, this gives sort of the trends. The red line shows the growth in occupational licensing in the 1950s, about five percent of the workforce was licensed. And, in fact, some of the work I'll be presenting is some joint work with Alan Krueger, who was most recently President Obama's chief of the Council of Economic Advisers who was interested in these issues. And this shows the sort of growth of occupational regulation to about 30 percent in 2008.

And this also reflects that there are about 800 occupations that are licensed in at least one state, and when you add, remember, certification, that brings up to about 1,100 occupations are licensed in at least one state. With the general growth rates being very dramatic and positive.

So in this graph about 29 percent of workers who were surveyed in both a Westat and a Gallup poll that was done between 2006 and 2008. Another six percent said that they were certified. Remember these are individuals who have a right to title. And another three percent said they either had to be licensed or certified in order to keep their job, and, in terms of individuals who work or must have permission from the government or eventually must have permission, that gets you up to about 12 percent.

In contrast, and perhaps some changes in institutions, the green line shows the decline of unions from the 1950s to the current level of around -- at least to keep it comparable -- about 12.4 percent. And at least in the context of Milton Friedman, they were viewed very similarly. That is, groups that might restrict supply but also may have positive benefits in terms of voice. But some very different trends with respect to one group versus another.

As the US has moved from a manufacturing-oriented economy to one focused to a much greater extent on services, the focus has changed from unions that provided a

web of rules for collective bargaining agreements, to occupational regulation where the government, with the assistance of professional associations, monitors entry and continued maintenance in the occupation. So, in the 1950s, the thought experiment might be the steel worker and that worker in 2010 might be a personal trainer who might now need to be licensed.

Why is this important? So that when one looks at -- when the economist looks at this -- and a lot of analysis has been done on this -- is when you control for human capital factors, a licensing raises the earnings on an annual basis. And certainly if one looks at this over the course of a career, that's a lot of money, between ten percent to 18 percent, depending on the time period and methodology. And, this is very similar to the effect of unions on earnings.

In terms of health care's specific issues, there's an increasing number of occupations that are becoming licensed in health care, so that, when one looks at excluding doctors, about 74 percent of non-physician health care services are licensed. And, obviously, physicians are universally licensed, and there's an issue that comes up in terms of coverage. That is, is there a law covering an occupation versus occupational attainment?

Certainly, for physicians, everyone has to attain a license. In other occupations, they're covered, but not everyone attains that license. So, I thought I would say, how did we get here, providing a bit of the history. And I thought I would also use the case of physicians.

In the case of physicians, as was pointed out, licensing laws in the late 1800s were first passed by states in order to stem what physicians viewed as the uncontrolled access to the market. By 1881, about half the states had physician licensure. However enforcement became much more serious around the 1890s, and unlicensed medical practice was to be punished by fine and/or imprisonment.

Now the real growth of a lot of licensing or the control of the market was a report called the Flexner Report in 1910. And, that was sponsored by the American Medical Association and led to the eventual control of medical education and the regulation of physicians and auxiliary workers. The main consequence was the rise of physician licensing -- and the physicians are required to pass a test and do additional residency in order to become licensed.

The number of physicians relative to the population declined by about 15 percent over a 30-year period. And Friedman and his colleague Simon Kuznets noted that led to about a 17 percent increase in earnings relative to other occupations in health care, specifically dentists. Now, nurses really followed the sort of trend that I talked about earlier, that is, the movement from certification to licensing.

By 1923, all 48 states had certification, but after World War II it really moved to licensing. Subsequent to this sort of growth there's been a bit of a backlash. In cases largely which involved the FTC it was viewed that occupations couldn't set standards for minimum wages or minimum prices and that occupations were no longer viewed as public entities looking after the public welfare but were viewed much more as businesses.

Now, what has been happening in terms of regulation or barriers to licensing? One big issue comes with respect to physicians -- and this is in work with one of my students, Jason Hicks and some of the work that he's done -- noting issues of immigrant doctors. And, you'll notice that in 2000 there were more slots open for residencies than there were people applying.

So, what had happened was that there were a lot more US-born International medical graduates, and they increased from 1991 by about 500 percent. Also, there was a dramatic increase in the number of international doctors in the US who came here from other countries in large part because of the relatively higher pay in the US relative

to virtually any other country for physicians; whereas the number of domestic physicians, which is the bottom line, grew by only about one percent.

The number of residencies has remained stagnant during this 16-year period. Now, what has happened in terms of applying to become a resident -- you need to do a residency in order to become licensed -- is that US doctors, domestic content has remained constant, and they are almost always matched to a hospital or other facility to do a residency. But the squiggly line up there shows what happens to people who are able to get residencies who are from other countries or have studied medicine in other nations. And, certainly one can think of low quality ones but also high quality ones such as the University of London or other places.

So, there's been sort of huge variations from about 25 percent being placed to a high of about 69 percent being placed. One of the other barriers to foreign doctors has been the issue of what happens when they become a resident, and the next slide shows state residency requirements. And, for foreign-trained doctors, there are some really significant barriers.

The time to licensure for a physician who receives a license before they become board certified -- and that's important because they can moonlight before they become board certified and that results in an increase in their earnings between 40 percent and 50 percent. If you're a foreign-trained doctor, it's very difficult to do that after a year. It's very difficult to get your license as a physician.

If you're a domestically-trained doctor, you can do a lot of it in one year and virtually all of it within two years, whereas foreign-trained doctors -- very few, only a couple -- can receive their licensure as a physician in a year and in fact, most of them, it takes two or three years. This dramatically increases the costs and reduces the number of physicians in those states that make that more difficult for them to enter.

I want to briefly cover some of the issues of access versus quality. One commentator noted some of the issues of, first of all, access. And there is really what is developed what I call the battles among universally licensed occupations. And one commenter tweeted in whether or not a dental hygiene clinic can be a successful model in the state of California.

The free market can determine that, but dentists are notoriously, they argue, poor business people so that dental hygienists should be allowed to practice. Another issue deals with when there's an overlap. This is an issue that particularly comes to play with respect to occupational therapists and physical therapists. This is sort of the Venn diagram. They carved out specialties among themselves, but OT and PT overlap and who wins the battle in the state legislature determines who can practice.

In terms of other issues with respect to quality, there are a number of particular issues with respect to what happens in medicine. Do tougher regulations result in higher quality? Well, work among economists suggests that's not the case. With respect to nurse practitioners versus doctors and treatment of, for example, well-baby visits. There are very few of those cases where there are many differences measured by malpractice lawsuits or infant mortality.

Differences between domestic and foreign doctors show very little difference in terms of patient outcomes. In terms of all of these measures, what might matter for policy? George Shultz, who was around Washington for a long time, suggested that politicians want immediate solutions but policy takes a long time, and that's a problem with occupational licensing.

I'd like to conclude by noting a couple of recent policy issues. One is that in the 2012-2013 legislative session, a couple of governors have really turned some of the tide. In Iowa, Governor Terry Branstad vetoed the licensing of addictive disorder counselors and Governor Michael Pence in Indiana vetoed the licensing of diabetes counselors and

anesthesiologist assistants and dieticians. This is a bit of man bites dog. Very unusual to have governors vetoing licensing legislation, especially when they come from the same party as the governor. And both issues they used as their justification much of the work that economists have done, including some of those at the FTC.

Finally, I want to note from a 1952 publication by the Council of State Governments a licensing fable. And this was a story of a governor of a Midwestern state was approached by the representatives of a particular trade anxious to enlist the governor's support in securing passage of legislation to license their trade.

Governor, they said, passage of this licensing act will ensure that only qualified people will practice this occupation. It will eliminate charlatans, incompetents, and frauds, and it will thereby protect the people of this state. The governor from long experience was somewhat skeptical. My distinguished guests, he asked, are you concerned with advancing the health, safety, and welfare of the people under the police powers of the state or primarily interested in creating a monopoly situation and eliminate competition and raise prices? The spokesman for the occupational group smiled and said, governor we're interested in a little of each.

And hopefully, that will serve as the basis of some discussion later on.

TARA KOSLOV: Now that our first two speakers have given us that framework, what we've done is we've invited our other three speakers to share some specific examples of how some of these issues are manifesting themselves in health care markets today. So professor Spetz, Dr. Spetz, you can come on up.

JOANNE SPETZ: Thank you. Let's see. There we go. Great. So we have the next slides are up. Technology is saving us so far without occupational licensing there. I'm going to talk a little bit about some work that we have done or that we did several years ago under a contract with the HRSA, Health Resources and Services Administration, to look at the national licensed practical nurse workforce.

We specifically were interested in how the regulation surrounding this workforce affected their utilization. So let's start by spending a moment talking about who are licensed practical nurses. We're all very familiar with the big occupations, medicine, nursing, dentistry, pharmacy. Licensed practical nurses also are a very large population of the workforce. In California and Texas, we call them licensed vocational nurses because we're all a little strange in California and Texas.

But these are nurses who typically have one to two years of education, and that education can come from a variety of different venues. Many are educated in community college programs, some in vocational schools. There are some adult schools and even high schools that offer LVN training as a vocational occupation. Military Medical Corps. Many people can complete their military service and are authorized to take the examination, the licensing examination, in their state immediately upon separation from the military. So this is also a very common point of entry into the civilian workforce for veterans.

Licensure was mandated in all states by 1965, and I have not studied the history of this profession in the same level of depth that other speakers have studied licensing histories, but I would imagine that they probably started with some kind of a registration before they moved into the licensing and certification in most states. The scope of practice varies, of course, across states.

One interesting nuance that we identified when we were doing this study is that, in some states, there is a joint board of nursing. And that board of nursing will regulate all nursing, registered nurses, licensed practical nurses, the whole set.

In other states, there are separate boards for registered nurses versus licensed practical nurses. There are about, I think, six or eight when we did the study and the numbers were dropping, but there are still a few that have these separate boards.

These boards don't always coordinate their regulations, which resulted in some amusing case studies. We had one case study where we were doing a focus group with licensed practical nurses. We read to them as part of the focus group their practice act. And their universal response was, well, we're not allowed to do that. Who said we're allowed to do that?

And, we were like, well, it's in your practice act right here. So we were wondering what was going on. Turned out that the registered nursing board prohibited registered nurses from delegating those tasks to licensed practical nurses. So, although the LPN board authorized it, the RN board disallowed their authorization from a supervisory responsibility. So, there are some very bizarre things that happen or things that seem very uncoordinated depending on different states.

LPNs are employed across all sectors of our health economy. The most common settings are hospitals and nursing homes. Many are employed also in physician offices and other settings. And so, we really do see them across our health sector, including many sections of the health sector that are anticipated to grow rapidly over the next 15 to 20 years.

This includes knowing that we have growing long term care needs and that there is going to be increasing need for LPNs to help provide those needs. A rising need for registered nurses in higher level roles, which may create a gap in terms of who's going to provide more of the basic care needs. If registered nurses are moving into care coordination, education, high acuity patients, there's still a lot of basic nursing care that needs to happen.

And there's a whole literature about impending nursing shortages as the baby boomer generation retires. LPNs are in a position where they could potentially help to fill some of those care gaps. They also have a broadening role in outpatient care. Growing numbers of physicians' offices are employing licensed practical nurses for a

variety of different purposes. In most states they're allowed to, for example, administer medications, and do vaccinations and such, which makes them good providers in physicians' offices.

And then the medical home model would potentially leverage their skills. And some people focus on this workforce in the context of building career ladders. If you allow, say, a recently separated military member to become a licensed practical nurse and start working that could provide the starting point for them to continue on to pursue a registered nurse license and move on it through a career ladder.

As I mentioned, there's a lot of variation in the LPN scope of practice. Most of the information isn't published regulations, but some states also have published position statements or other semi-regulatory guidance. Some states only offer decision trees, which are kind of interesting. I'll show you an example of one of those.

Some states have very explicit lists of what's permitted or not permitted. Whereas other states are very general and their regulations almost read like, if you are competent to perform brain surgery, under the letter of the law you'd be allowed to do that. But we know that you probably wouldn't be competent for that and nobody's going to let you do it.

There's a whole range in this. So, to look at a scope of practice decision tree -- this was one that we obtained from Maine a years ago. So, step one -- this is for a licensed practical nurse to decide if they should do the task. So, first describe what's going to be performed and review the scope of practice. So, you have to go find those documents in theory and read them and see if you are allowed to do it.

Here's the summary of their scope of practice -- contributing to data collection, which would mean collecting vital signs and so on, participate in developing a plan of care and such, and then the next step would be, well, is what you're thinking of doing or what your employer is asking you to do explicitly permitted or prohibited? And, if you're

not sure, then you get to go to some other step in the decision tree. And, if you think it's within the scope, then you just do it. And, if it's prohibited, stop. So, this is the process that they recommend for thinking about what's within the scope of practice.

So what can they do? I just want to quickly go through this to provide some context. Assessment of patients and the development of the care plan for patients is a really core aspect of nursing care. You have a patient in the hospital and you have to figure out what they need or a patient in a nursing home. You're trying to determine what they need for all of their care over a 24/7 type of period.

In some states, the LPN cannot do any assessment. Precisely what "assessment" means is looking at the data and determining how to interpret them. I suspect most LPNs with 20 years of experience probably can assess the data but they are legally not permitted to make an assessment. In some states, they are allowed to do an initial assessment. In some states, the RN has to sign off on it. Some states not.

Drawing blood is another place of variation. Can they do it at all? Do they have to have additional certification? In some states they have to obtain additional phlebotomy certification. In other states not. You've also got other things. The area of intravenous administration is where there's the most variation across states.

Can they start IVs? Can they regulate the IV? Can they hang new solution bags once the IVs already in place? What about a medicated pre-mix solution? Can they hang that if it's already pre-mixed from the factory? Some states, yes. Some states, no.

OK, what about what nurses call IV push where they're injecting medication directly into the IV line? Some states, yes. Some states, no. Some states are vague. Blood products, chemotherapy products, all of these things may involve additional certification. They might not. So it's all over the map.

With the assumption, as has been noted, of course, that, if an LPN crosses a state line, does their ability change? Probably not. So, we in our study took the practice

documents from every state and we rated their scopes of practice. We looked at their published regulations, their position statements. We telephone surveyed nursing boards to obtain clarity where it didn't exist.

We rated them in two scales. First, we looked at just how restrictive their scope of practice was. And that would be the bottom bar here, where the leftmost color is the least restrictive, and then the rightmost colors are the most restrictive. And then we also looked at how specific their regulations were. Some states had specific lists of what you could and could not do and others had more general guidance.

And, as you can see, it was a pretty broad distribution of whether it was very specific or whether it was very generalized in terms of their regulatory documents. Then we looked at whether these regulations affected demand for LPNs. And, we did these economist types of things of multi-variant regressions, which I won't go into the technical detail of.

But we focused on American Hospital Association data and nursing home data from the Center for Medicare and Medicaid Services. And, what we found was that in the hospital sector restrictive scope of practice reduced demand -- about 13 percent in FTEs per point on that four point scale we developed. And, more specific scope of practice reduced demand as well.

For nursing homes, similar results. But not as large. The reduced scope of practice or restricted scope of practice reduced demand, but only by two or two and a half percentage points. And the more specific scope of practice also reduced demand, but only about three percentage points.

So our general recommendations would be to recognize that scope of practice does affect demand and that the regulations -- we could not find any evidence or research that had linked these regulations to quality differences. Some research has found that LPNs can improve productivity in hospitals and in outpatient care, although

the evidence is very limited. And, it could be that these regulations will impede new models of care that we need to develop in order to achieve the triple aim of improved care, quality, and lower costs. Thank you.

PATRICIA SCHULTHEISS: Thank you very much, Joanne. As Joanne was just explaining, the regulation of LVNs is, among other things -- can become a hospital or long term care facility staffing issue. And our next speaker, Gail Finley, will talk about a different type of hospital staffing situation that was directly impacted by regulatory choices in the state of Colorado. Gail?

GAIL FINLEY: Great, thank you. I beat you up here, sorry. I'm used to legislative testimony. You're on. You're on. You're up here. Thank you all for being here today and allowing me to come and speak to you. I've been asked to speak to a very specific set of circumstances that happened in Colorado. Around the use of CRNAs and the use of the federal opt out for the CRNAs.

And I am the vice president of Rural Health and Hospitals and I tend to focus on rural health, not just hospitals, but rural health. And, the CRNA opt out is a really good example of the issues we face in rural areas. So I don't want to assume. I'm not very good at making assumptions. So I wanted to make sure I provide you some baseline concept of what a CRNA is.

I don't want to read that for you but, in essence, it's a licensed advance practice nurse. And then I wanted to make sure that you had the appropriate reference to the Medicare conditions of participation that a hospital has to follow in the utilization of a CRNA in providing anesthesia. And then the language that's in the conditions of participation for an opt out.

So it allows for a state exemption. And I think the operative word for me here is "a hospital." Colorado is the only state of those that have opted out that has only opted out for rural hospitals. Every other state has opted out for all of their providers. So all

hospitals, all ambulatory surgery centers, et cetera. But we took advantage of this language in Colorado where it says "a hospital" and we specifically listed the hospitals that we wanted to opt out.

The interesting thing about that letter -- it just says you have to write a letter. But, in essence, this letter has to very specifically cover some very specific things with very specific language. Those of you that are attorneys know all of that. I'm not an attorney. I'm not a clinician. I'm a policy wonk.

But I had to make sure that, as we worked on this letter, worked on this process, that every single one of these things was tested to and was dealt with somewhere along the line. So what started this for us was our state survey agency went out to some of our critical access hospitals that they hadn't been to in 12 plus years and they did a survey. And they found deficient practice in two of them around the utilization of the CRNAs and the supervision that they had.

In one of them, the supervision was being provided by a local surgeon who agreed to be the supervisor of record, but he wasn't on site. He wasn't immediately available, which are actually requirements in the condition of participation.

In the other one, a group of anesthesiologists was providing the supervision for the CRNAs, but they actually lived and practiced in a community that was over an hour away. So they came down like once a month and looked at records and signed off on them. So that was the type of supervision.

Not actually saying whether any of those was good or bad. The issue was that is what the staff and the community felt like was needed in the way of supervision if they were going to do it. Fairly informal, but inconsistent with the condition of participation. So one of the things that I do at the hospital association, of course, is to look at what I need to do so that our members can meet the needs of their community.

So I started looking for what could I do. Please know that we also are in the unenviable position of always trying to deal with scope of practice amongst everyone that works in our facility. So we've got nurses, and doctors, and phlebotomists, and physical therapists, and everyone's got a scope. And everybody's got an issue. And everybody overlaps.

Usually we try to stay out of these things. We let you fight amongst yourselves, and then we try to figure out how to use you and let our teams locally decide how to best use folks. Unfortunately, this meant we couldn't provide services. And the outcome in this case was significant impact on the community.

Both of them responded by modifying their policies because they had to. In order to retain their certification as a Medicare provider and a Medicaid provider, they had to modify their policies and their practices. And, in essence, some of the outcomes as I put here -- some of the surgical specialists, orthopedics, in one community said, whoa, I don't want to have to supervise a CRNA so I really am not interested. And unless you hire an anesthesiologist, I can't come anymore. And I won't be providing services to your community.

In the other one, they were actually able to identify the funds -- and as you can see it wasn't a cheap thing to do -- to come up with around $350,000 a year to pay to have an anesthesiologist come to supervise the CRNAs. Now, what that meant -- let's see.

So, in essence, some of the work I had to do -- because needless to say -- again, this was not for nurses, and this wasn't against anesthesiologists. This was about access to care and access to services, safe. So, I had to work, really reviewing to make sure I didn't have anything hidden out there that I wasn't aware of. As a non-clinician, I don't know. I'm not staying up to date on all of that.

We were fortunate that we had, in 2008, an advisory committee report that had actually done the literature review and actually had spent a lot of time reviewing everything that was out there from a scientific standpoint about inequality or problems that we had in scope of care. They didn't just look at CRNAs. They looked at APNs in general. They looked at dental hygienists, physician assistants, et cetera. So we did have that work that basically demonstrated they could not find anything in the literature that said that there was a difference in the outcomes.

And then I actually personally had to go into every hospital in the state -- we have 100 of them -- and go online and open up every single complaint that had been filed over a three-year period about any hospital in the state and review each one of them to see if there was anything around anesthesia. I also looked at our sentinel event reporting for the same time period, opened up every single occurrence report that was filed to make sure that none of them had anything to do with anesthesia.

In that three-year period, I was able to identify one anesthetic event and it had to do with an anesthesiologist so I was able to ignore that information. I also went to the board of nursing, asked them to do a historical review for me. They also surveyed the rest of their peers across the country, specifically asking them if they had problems with the advanced practice nurse or the CRNA once they had opted out or prior to or at any point in time just to get that information so that I was aware of what was going on.

Patient safety being the biggest issue for me. I was not going to carry something forward and ask the governor to write a letter if I didn't know that we had -- I mean, if I knew we had a problem, I wasn't going to go there. Know that along the way we were also having a conversation with the anesthesiologists in the state medical society on this.

There's nothing that we need to do. We don't like to create enemies in any way amongst any of our practitioners. So there was really nothing that was being done

behind anybody's back. We're very visible, very much having ongoing meetings and conversations with the anesthesiologists in the state about how they could perhaps help with this issue. And their solution was having the practicing surgeon who was in the room provide the oversight. And, in essence, we had a lot of resistance to that by the surgeons from around the state, particularly in our rural areas.

So I had to start building the stories and so for the one community that had the deficient practice, the closest available “like care,” as I say, was approximately 97 miles away. In winter weather it meant traveling on a two lane road that was often icy and had an ice river next to it if you went off the road. And, in essence, the community was having concerns that consumers would forgo care rather than actually drive to the next community to get the care.

And then the other place actually was concerned about patient safety in that the anesthesiologist that they had hired to come in would come in if they called them and needed to do surgery but there was the potential of an hour commute before they got there, if we had an emergency surgical case. Did a map of the state, identified who worked where. I mean, for policy makers, they need a lot of visual. I think it makes it pretty easy to do.

So I created a map. I think one of the things I wanted to say -- see Alamosa County down in the south central part of the state? I looked up a little bit of information last night while I was sitting here. They have one hospital. It's a 45 bed hospital in that county. The county covers 722 square miles.

For those of you who are not familiar with DC, you guys have 68 square miles. They have a population in Alamosa County of 21.4 persons per square miles, whereas DC has 9,856 people per square mile. So I think I just want to emphasize what it means to be rural in Colorado in this area. So when you're on vacation, keep it in mind.

So when I drove around the state, I know where the surgeons are. I know where the blood is. I know what the EMS is like. I know how long it takes to get places. I have lawn chairs and umbrellas and first aid kits as I drive around. I had to create tables of information because everybody wanted to know about what was happening in their community. So I created a table for the non-CAH rural facilities, as well as one for the critical access hospitals, so we had an idea of what they were doing in 2008 when the Collaborative Scopes of Care study was done and then what was happening in 2010, at the time we had this deficient practice.

I collected testimonials and statements from some of the people who are invested in rural health care, such as the rural health center, one of the CEOs that had the deficiency. And then actually, probably one of the most significant statements we got was from Dr. Michael Barkett, who used to be the State Board of Health chair. He was there when we changed the hospital licensing rules and dropped the supervision requirement for the CRNAs and the hospital licensing regulations and practiced in one of these hospitals that had been given a deficiency around supervision.

So, what I'm going to tell you -- professional regulation, I think, is important to all of us. I won't deny it. It's something that we know we need to deal with. It helps set a minimum standard, provides some comfort to people. Needless to say, for any of you that have been reading the news lately, hospitals don't have the best PR right now. And we are very cognizant of that. And the minimum standards that get established are something that we rely on in setting a baseline of expectations for our staff and our community.

Let's see. I think I really -- probably our lawsuit may be of interest. I need to tell you that I can't tell you all the details of everything that's going on, but the rulings to date have been that we have actually survived and succeeded in defense of the lawsuit

on behalf of the governor and the Nursing Association. And we are set to go before the state Supreme Court for our hearing in early June.

The basis of the lawsuits have been around patient safety, around financial harm to the anesthesiologists, the foundation of the nurse practice act and what it reads, captain of the ship doctrine that we've got in Colorado, as well as an argument that the provision of anesthesia is a delegated medical function and not a nurse function, an independent nurse function. Anyway, that's, I think, the status of our case and thank you.

PATRICIA SCHULTHEISS: Thank you, Gail. And now our next speaker, Lisa Robin, is going to discuss licensure portability, which is an issue that affects all of the health care professionals. It has repercussions for the development of new health care delivery models as well. And, the Federation of State Medical Boards is attempting to tackle this problem head on with respect to physician licensure, and Lisa's going to give us an explanation of how they're doing that.

LISA ROBIN: OK. Well, thank you. And it's great to be the last speaker. I'm sure you're all pleased. So thank you, Tara and Pat and fellow panelists for your very informative presentations. I'm very pleased to be here today to share a brief description of the important activities underway by the Federation of State Medical Boards to accommodate these ever evolving health care delivery models.

First, I'd like to give you a brief overview of the Federation of State Medical Boards. As the nonprofit organization representing 70 state medical and osteopathic boards in the United States, territories, and the District of Columbia, these boards are responsible for the oversight of more than 878,000 practicing physicians, 80 percent of the country's physician assistants, and a variety of other licensed health care professionals. The primary mission and statutory mandate for these boards is to protect the public through the regulation of medical practice.

They achieve their mission through licensing to assure that the individuals are qualified through an evaluation of their education, training, examination, character, and professional history, and discipline, to receive and investigate consumer complaints and other adverse information and take action where appropriate against an individual's license, which can range from a revocation of the privilege to practice, restrictions, remediation, or reprimand.

I was asked to focus my remarks today on our current initiatives that we believe achieve a balance of expanded access to care, optimal use of telemedicine technologies, and, most importantly, patient safety.

Both the interstate medical licensure compact and the work group, the state medical board's appropriate regulation of telemedicine, or our SMART work group, were initiated in 2013. And they've been working aggressively to develop new policies that meet the evolving needs of telemedicine.

As so clearly articulated by my fellow panelists, health care has changed and is rapidly evolving. There have been incredible advancements in the area of telemedicine and technologies, which we will learn and talk about later today. Health care systems are expanding with locations around the country and even internationally and are developing new models of coordinated care. Implementation of the Affordable Care Act will bring millions of insureds into the health care systems, individuals who may never have accessed the health care system before.

We're facing workforce shortages and continue to seek ways to encourage providers into underserved and rural areas. The state medical boards recognize that the licensure system must evolve within the context of these changes in order to ensure consumers have access to high quality health care while making sure that we don't compromise patient safety.

The FSMB has long recognized the potential of telemedicine in improving care and access. In fact, as early as 1998, the FSMB developed and promulgated an alternate licensure pathway for physicians providing medical care across state lines using telemedicine. This special telemedicine license is currently being used in at least 10 states today, and it's worked well as an incremental step toward achieving greater portability.

With support from the US Health Resources and Services Administration, the FSMB has explored additional policy options, including the expedited licensure by endorsement process, as well as tools to support greater efficiencies in the licensure process. The uniform medical licensure application was developed in 2009, and it's being used by 22 state boards today.

And enhancements to the federation credentials verification service allows the application to be pre-populated with primary source verified information before being submitted to the medical board. All of this tremendously help streamline the licensure process. We see the interstate medical licensure compact and telemedicine standards as the natural next step in this body of work.

So, what is an interstate compact? A compact is a mechanism that allows states to collectively work together to address a national or regional priority. Compacts are not new. They are enshrined in the Compact Clause of the Constitution. And there are more than 200 interstate compacts in effect today.

Basically, a compact is a contract among states and is a standalone statute that must be adopted by each participating state. It is an attractive mechanism for expedited licensing in that the state board will retain its authority and jurisdiction over individuals practicing in their state. Changes to medical practice acts will be minimal, and issues such as the sharing of confidential information among participating states will be authorized under separate legislation that would supersede existing state laws that

would prohibit such information sharing among the boards. And, finally, governance. The rule-making and enforcement of the compact would be the shared responsibility of each participating state.

In pursuing the compact project, the FSMB has supported state boards in a three step process. It is important to recognize the contribution of the Council of State Governments in providing subject matter expertise and sharing of their extensive experience with interstate compacts throughout this process. First, the advisory stage brought representatives from state boards together to define the content areas and the process by which the compact might be administered and governed.

A smaller drafting team was then assembled to begin drafting the actual model compact legislation. The work began in November and will continue until all comments have been evaluated and consensus achieved on a final document. The last stage will be promulgating to the states and advocating enactment as state boards indicate their desire to participate as a compact state.

We are making steady progress in this effort. From the time the medical boards adopted the directive to explore the feasibility of an interstate compact to facilitate multistate practice, including telemedicine, we have engaged our boards in an aggressive and comprehensive study as evidenced by the draft that is currently being circulated. The drafting team met as recently as yesterday to have the second iteration of the model legislation ready for further and broader review.

Not every physician will be eligible for licensure via the compact. We see the compact path as an adjunct, not a replacement, for the traditional licensure application process. In order for widespread adoption, it was necessary to ensure that only qualified physicians could take advantage of the new system and that the eligibility requirements would meet or exceed current licensing requirements in all jurisdictions.

With that being said, the majority of physicians in this country currently have these qualifications and, therefore, are eligible for licensure via the compact. The eligibility requirements are a full and unrestricted license in a compact state, successful completion of a graduate medical education program, specialty board certification, a clean disciplinary record, and no discipline from any agency related to controlled substances, and that the physician is not currently being investigated by any agency or law enforcement.

So, how will it really work? First, the physician must have a license in one of the compact states, which I will refer to as the primary license. She will then apply for expedited licensure in additional compact states. The board in which the physician holds the primary license will attest to the physician's eligibility and forward the information to the compact administrator or commission. The physician will transmit all applicable fees to the commission. As far as licensing fees go, we expect the fees to be no more, and most likely less, than current licensing fees.

It's important for states that the compact be virtually budget neutral. For state boards to maintain their regulatory and oversight function, boards are experiencing very limited resources. And the costs associated with the intake and investigation and adjudication of complaints is significant. Fees and physician specific information will be distributed to the additional state boards by the commission. The receiving boards will then issue the physician a license to practice in that state with all the rights and privileges of a full and unrestricted license.

We expect this process to be very expeditious as the technical infrastructure will be in place for the commission to support a rapid transmittal and maintenance of information. To clarify, the commission does not supplant the role of state boards, rather the commission will be responsible for administrating the compact, acting as a

clearinghouse of sorts, and will be made up of appointed representatives from each compact state.

Each state will continue to exert all of its existing authority in terms of regulating the physicians who practice within its borders. This governance model is a tested and effective tool and will provide the forum for the exchange of best practices and focus state efforts and resources in furtherance of the objectives of the compact. So where do we go from here?

The next iteration will be completed by the drafting team and will be distributed to an even wider audience for comment and feedback. We've already reached out to the National Governors Association, provider professional organizations, policymakers, industry and advocacy groups to introduce the concept and solicit their feedback. To date, the overall response has been extremely positive.

We recently received a bipartisan letter, signed by 16 US senators, congratulating the work of the state boards in this endeavor. Also, we were encouraged by the comments from FTC Commissioner Maureen Ohlhausen recognizing the efforts to streamline the licensing process for physicians wishing to practice in multiple states. She noted that the compact, and I quote, "would appear to greatly facilitate the use of telemedicine while still allowing states to regulate medicine within their borders."

Now I would like to spend a very brief few minutes on our evolving telemedicine standards. This policy development effort will better define and articulate medical boards' expectations as to the appropriate use of telemedicine technologies in the delivery of health care. It was apparent that as telemedicine practice expands across jurisdictions, it was important not only to address the need to improve the licensure process, but also to better define and clarify the standards when providing services directly to consumers using telemedicine.

The work product of the FSMB SMART work group, the Model Policy for the Appropriate Use of Telemedicine Technologies in Medical Practice, is currently a draft policy that will be considered by the FSMB's member boards next month. This model policy is the result of a work group comprised of representatives from state medical boards, subject matter experts, providers, and payers of telemedicine services. It has been distributed to medical boards and a wide range of stakeholders. Comments were collected and carefully evaluated before a final draft was completed earlier this year.

We expect this policy document to serve as a framework for boards and the state legislatures to use in developing rules and laws governing the use of telemedicine technologies as they deliver care directly to consumers. The policy goes into specifics as to the standards of care the board will expect licensees to adhere to when choosing to use telemedicine as an adjunct to or in lieu of face to face encounters. The policy is written primarily for physicians; however, it would apply to other health care professionals.

The major takeaway I would like to leave with you is the same standards of care apply whether the encounter is in person or virtual. This would include authentication, informed consent, documentation, privacy, et cetera. Licensees would be held accountable for the decision as to whether the condition being diagnosed and/or treated is appropriate for a telemedicine encounter and the practice is deemed to occur where the patient, not the provider, is located.

With that, I want to thank the FTC for sponsoring this important workshop. We look forward to continuing to work with all stakeholders on these important initiatives. Thank you.

TARA KOSLOV: Thank you, Lisa. And, I believe we will now be getting Barbara back on the screen. There she is. So the first thing I would like to do to open up our discussion among the panelists is to offer any of the panelists an opportunity to

comment on anything that they heard from another speaker or pose a follow-up question yourselves to any of the speakers. Does anyone have anything they want to chime in?

GAIL FINLEY: This is Gail. And I guess I was having a conversation just before this talking about how the scope of care and provider types have been developed and siloed. And I think we've heard that actually from other speakers as well today. And so we've actually created the environment we have today by having nurses talk about nursing, doctors talk about nursing -- I mean, talk about doctors. Well, they talk about nursing too. Hospitals talk about hospitals. And home care talking about home care. And we've created all these silos both in professions and provider types.

And I think what we've got is a platform of conflict set up for us in all areas. And it's an opportunity as well, from my point of view, for all of us to just recognize that's where we are and we have to figure out how to work from there, and, in essence, that consumers are reliant on us to do that. So I think our challenge is to figure out how to do that more together than apart, as we have in the past, and that we really have to start having conversations about scope amongst ourselves.

So that's kind of a gut feel. I mean, we can put all the time like we did into the CRNA opt out. We spent hundreds of thousands of dollars and all it takes is a different governor coming in and signing a different letter and sending it in saying we don't want it anymore. That's all it would take and it would all be gone. So we've got kind of a regulatory scheme that's funky after you've done all your work. And we've got an opportunity, but we've got to take it. We've got to take it, I think, as a group.

TARA KOSLOV: Barbara, did you have anything you wanted to add?

BARBARA SAFRIET: Oh, as always, I have so much I want to say. But the group that's traditionally not represented in any of this -- the people who matter the most,

which is the public and the patients. And almost all these regulatory issues are dealt with in silos where we still silo our education for example.

And surely in the legislative process. And let's be real. It's all politics. The public, first, doesn't know what's going on, secondly, they're never consulted. So Gail your notion of saying let's de-silo things and look what really counts, which is providing good care to people where they need it, when they need it, provided by very competent providers is essential.

I don't want to pick on Lisa, because I have enormous respect for Lisa and have worked with Lisa in a cooperative way when we drafted up a little monograph on legislative considerations for scope of practice. One or two of the principles there, I think, have been very influential in affecting scope of practice decisions across legislatures.

But that is, one, to get away from the notion that everything is medicine and any effort to expand the authority so it will be consistent with and congruent with expanded ability for other providers is not viewed as an incursion into medicine. That's what many of the National Medical Associations say. They are advocacy groups, by definition, for their profession so that's OK.

But when you see quasi-regulatory groups -- and surely even governmental groups -- being so patently unwilling to acknowledge that things have changed and the patient should be put first, then we have enormous regulatory problems. And they are endemic to scope of practice. And it's so heavily weighted to this history, which I described, of universal scope of practice for medicine and then everyone else later is coming along and having to carve out from that.

So just, for example -- I'm not picking on Lisa -- but it shouldn't be styled telemedicine. It should be styled telehealth. And I applaud the Federation of State Medical Boards for having this project on telemedicine standards. And I was paying very

close attention to say that this new policy will come up and be used by the legislature. And although it was designed principally for physicians, it will apply to other health care providers and professionals.

Well, if so, it should not be called telemedicine, because nursing or physical therapy or optometry or all the rest are not medicine. They have their own professional nomenclature and stature. But, secondly, I really honestly wonder if any other professions, regulatory boards, or associations were centrally involved in the development of this telemedicine new practice policy.

Because it should not be presented to the legislature as a model and a format for the regulation of telemedicine if it is going to apply to other health care providers.

TARA KOSLOV: So I think our afternoon panel will probably explore some of the issues that are specific to telehealth. So Barbara I'm going to move us on from that topic. If it's okay with you.

BARBARA SAFRIET: Sure.

TARA KOSLOV: I've been trying to figure out a way to synthesize the historical arc that we heard, sort of the narrative of the story of how we created the system that we have for professional regulation and where we are today. So I wanted to pose this to our panelists and see if you agree or disagree with the way I want to frame it for competition purposes and kind of react to this.

So on the one hand, we've seen, over time, a situation where new occupations emerge, and they affirmatively seek to be licensed as a way to remove barriers to entry, to increase competition, to facilitate their access into the marketplace, to gain credibility as providers because they can say we come with this official endorsement from the government. There's a disciplinary mechanism. There are standards built in to ensure safety so that that conveys meaningful information to consumers. So all of those kinds of pro-competitive benefits of occupational regulation.

But then, on the other hand, we sometimes see a situation where, once a group does achieve the status of being a licensed group, they then turn around and use that to erect barriers to entry to the next group that is coming up. And so then it becomes a barrier to competition and decreases competition.

Am I getting that right? And, if so -- well, if not, definitely tell us where we've got it wrong -- but if we are, how can we as a competition authority kind of synthesize that and figure out where we're going in the future and where maybe we can try to break that cycle and keeping things moving in a pro-competitive direction?

MORRIS KLEINER: Well, can I just add, since I spoke to some of these issues, sort of the overarching issue is that certainly occupations get together, they tax their members and lobby the legislature -- and I worked in several legislatures both in testifying and providing advice -- and certainly it's very rare that there's a public member and some of those, as an economist would say, the incentive structure are -- the occupations may gain both by increased demand for their services. It's a good housekeeping seal. As a result, there's some uncertainty about the quality of the service that's being provided.

And that's a plus, but in the long run, as many others who have written about public policy, it's certainly easy to pass legislation to allow occupations to become licensed. But the long term effects tend to be those additional qualifications, additional education, and restricting supply. And the longer an occupation is licensed, the more restrictive entry barriers. They become much more restrictive.

Perhaps an example are physical therapists. Where a few years ago, it was fairly easy to become a physical therapist with a junior college education. And in the future, one must be a doctor of physical therapy in order to practice. So there's a sort of ratcheting up of qualifications in order to provide services. And there are these battles also, these turf battles, that occur among occupations, occupational therapy, physical

therapy, doctors, advanced practice nurses, dentists, and dental hygienists, just to name a few in the health area.

So those are issues that groups such as the FTC -- there are private sector groups like the Institute for Justice -- look at these issues and try to have the right type of balance like the statue in front of the FTC building.

JOANNE SPETZ: There are some new emerging occupations that will be interesting to follow. Minnesota has new dental therapists. There are about two cohorts of graduates now of dental therapists who are supposed to be prepared to do simple fillings, simple extractions. So some irreversible dental procedures, which is usually the line between dental hygiene and dentistry.

The presence of that occupation, the development of it, is going to raise some interesting questions about who hires them, where do they work, what services they perform. Do their employers really let them practice to the level of education they're receiving? But then also, I think, from a regulatory standpoint, it has raised questions about well, why not have dental hygienists with advanced skills? And why not have used the dental hygiene mechanism that already existed as a regulatory process?

You know, it's a good question. I don't know the legislative details of that, but I think as we watch that profession evolve -- and Alaska has dental therapists that have been in practice for quite some time -- it'll be interesting to see how they bump up against or collaborate with dental hygiene as well as dentistry, which, of course, has been a big turf battle.

GAIL FINLEY: I'm going to put on my old public health hat since I worked in that arena for 20 years prior to where I am today. And one of the things that seems to be missing and would be an interesting way to look at this a bit is by what you're trying to tackle. For example, in Colorado, we have very high suicide rates. And as I watch the

policy decisions around what to do about that, we're not treating it like a typical public health emergency that it really is.

I mean, more people die from suicide in Colorado than automobile crashes in almost any given year. So we wouldn't tolerate that for other public health issues, but what we continue to do is we write a bill that says hospitals must pass out pamphlets in their emergency department in English and Spanish on suicide prevention. We look at adding suicide education to licensed clinical social workers.

But we don't have a comprehensive package about what we're doing for this public health problem. We've missed the boat. By the time someone's in a hospital emergency department, we've missed the boat. So what happened to the school nurses? What happened to the primary care physicians? What happened to the other aspects? We don't look at it from the patient that's needing care, we continue to look at it, again, by the siloed profession or the provider type.

I will get a pat on the back from my public health partners for this, but I just think that's actually one of the things we keep doing. And when we say we have consumers involved is because we put two on our panels. We got one from the east side of the state, one from the west side of the state, one female, one male, and we think we have a consumer voice.

And I don't think we do very much to make sure that those consumers are actually people who feel like they can speak out and can be knowledgeable to have a conversation with a group of physicians in the room or a group of nurses in the room. Who are they to speak up? So just a couple of the other challenges I think we have in looking at other professions, regulation.

TARA KOSLOV: Barbara, did you have any response to that question?

BARBARA SAFRIET: No, not response, just hooray for public health. Public health, public health, other public health community workers have been doing what, seemingly,

comes as revelations today that we should have coordinated, team based care, which integrates clinical skills with community support. And, this comes as new initiatives from federal, state government and all the rest.

Whereas, in point of fact, community health workers and community health nurses, especially, have been doing this all along. And because they are addressing what you so carefully through all the research -- and I regret the hours you had to spend on this, Gail, and the amount of money -- to address existing needs by competent care providers, by having to do all this. You address the patients' needs. You do it safely and the rest.

And, the regulations ought to facilitate that. The one thing I would say that addresses many of these questions is that we need a fundamental reorientation -- which is hard given all the vested interests and the law -- a fundamental reorientation that no one skill, no one ability, no one competence belongs exclusively to any one provider.

There are other systems in other countries that specifically acknowledge this, like in Canada, where, for example, I have here their scope of practice statement. Which says, the scope of practice of various providers is not protected in the sense that it does not prevent others from performing the same activities. Rather it acknowledges the overlapping scope of practice of all health professionals.

We still have embedded, instantiated in our law, these rigid notions of scope of practice, which further institutionalize siloed mentality. They provoke, in fact, they necessitate, turf battles, as between occupational therapists and physical therapists and others. And, it has more to do with history, it has more to do with preserving professional autonomy and control than it has anything to do with promoting health and safety.

If we just did one thing in guiding our regulatory regime and freeing up and promoting healthy competition in order to serve the public, it would be to acknowledge,

specifically, unabashedly, that scopes of practice, scopes of ability, overlap. And, we have very good models from experience -- it's not hypothetical -- where we have removed these unnecessary barriers and we have promoted access to care, high quality care, often at less cost.

So, there's no lack of data to drive this. Rather what's lacking is the data to demonstrate that we need to continue these sorts of restrictions. I'm not a health care provider. I am an attorney. And the one profession that has escaped this ever increasing requirements for entering and education and the rest is lawyers. I'm not saying that's the way it should be, but we have escaped that.

But, if you take the public's perspective, serving the public, we have to remove the cultural and legal notions that only I can do this; you can't do it because you're in a different profession. We have to reorient our laws, which are demonstrably anti-competitive, to promote public service.

And, the only way you can do that is by gaining more and more and more congruence between legal authority and clinical ability and quit fussing about this is mine. It therefore can't be yours. And, that is what characterizes our regulatory regime across this country for all health care providers today.

TARA KOSLOV: So, Barbara, I'm glad that you brought up the Canadian example because one other question that we wanted to raise -- and I think, Morris, you might have had a point on this -- is looking at what we can learn from other jurisdictions or from other professions that might provide some examples that would illuminate the competitive problems that we're facing here. Do you want to --

MORRIS KLEINER: I've been fortunate to look at some of these issues across different developed countries. And most other countries have one system. So it's one size. It's at the national level. So the UK or China or other countries have licensing that is

national. We, because of history and various court decisions, have 50 different jurisdictions.

To the extent that it perhaps is more difficult to capture the occupations at the national level, that may be an issue, although that's not clear. That the trend seems to be very much in many of the developed countries from less to more. So countries like the UK, about 20 percent of their workforce is licensed. Canada, about the same. But if we had the gold medal, since the Olympics recently concluded, we would be the most regulated at least in terms of percent licensed of developed nations.

PATRICIA SCHULTHEISS: Okay, we wanted to, before we run out of time, get to at least something that came to us. We did receive quite a few comments before our March 10 date to be considered at the workshop and --

TARA KOSLOV: We should note, by the way, we're in the process of getting those comments posted on the website. So they will be available to everyone. So you can be on the look-out for those over the next couple of weeks.

PATRICIA SCHULTHEISS: But they were submitted to the workshop staff so we were able to review them before the workshop. And a number of the comments have been noting -- and we got them from a variety of professions -- specific practice areas where professional regulation may affect health care competition. And some of these comments suggested that these topics would be worthy of additional FTC attention.

And we'd like to ask the panelists if you have any specific thoughts regarding regulation of these health professionals and their impact on competition. And let me just mention a few of the professions that we have seen comments from. Of course, oral health, mental health, pharmacists, nutritionists, and dietitians, childbirth, and lactation consultants.

All of these are areas where -- some of them are licensed in some states, some of them aren't. Issues of who should be licensed, who shouldn't, different certification

bodies, accreditation bodies, these are all issues that are coming up in some of these, if you want to call them, emerging professions. But we would like to elicit your thoughts on how you deal with these things, especially in light of the discussion about silos and, are we creating more silos if we go in the licensure route here? Or how do you get to reimbursement for some of these services if you don't have some kind of recognition.

TARA KOSLOV: Before we answer that, if anyone does have questions, if they want to pass up -- it's unclear whether we'll get to them -- but could I just ask a couple of the FTC folks to just go down the aisles quickly in case anyone does have comments they want to pass up? And then go ahead.

MORRIS KLEINER: I have just a quick comment on advanced practice nurses and doctors. Just recently completed a study with the National Bureau of Economic Research on state regulations and allowing advanced practice nurses to provide prescriptions and the effects on a particular medical service, and that is providing well baby visits.

And, on average, the states that would allow advance practice nurses to have a greater scope practice are able to cut prices by about ten percent. And since the average well baby visit is about $100, that's about $10 per visit by allowing greater scope of practice to advance practice nurses. The reason for this is fairly simple. Advanced practice nurses get paid about half as much per hour as doctors.

JOANNE SPETZ: One component that I think makes the regulations particularly challenging is when a single profession or what you might, as a lay person, think of as a single profession actually has its own schisms within it. We see for nurse practitioners that nurse practitioners have multiple certification boards for pediatric nurse practitioners. And for midwifery, there are three different tracks by which you will find licensure for midwives.

The American College of Nurse Midwives works with midwives who are licensed often by medical boards, and then there is the certified nurse midwife, which is kind of the nursing track into midwifery. But there also is a licensed -- I might not have the term quite precisely correct -- but it's like a licensed practical or licensed practicing midwife, which has much more lay training and you can test out of what would be considered didactic coursework for the more traditional midwifery programs.

The American College of Nurse Midwives does not include them in their membership or their advocacy work. American College of Nurse Midwives and American College of Obstetricians and Gynecologists have actually issued joint statements about aligning scope of practice to explicitly recognize that for normal childbirth the ACNM membership is very well positioned and obviously obstetricians, gynecologists are going to do the surgical births. And so you have a very clear delineation they have agreed on.

But then you have these licensed practicing midwives who are kind of left out in the cold of that agreement. In some states, they're recognized. In some states, they're not. In some states, they mostly do home birth. In other states, hospitals will let them practice there. And so that just adds a level of complexity that I think makes it extremely challenging for regulatory authorities to determine where are they guaranteeing quality.

Is the issue that there's a quality difference? Versus where are they getting themselves into these internal turf battles that might actually inhibit competition? And I don't know what the answer to that is, but it's a place where, I think, there's an increasing need for evidence. Do we have evidence that there is better or worse quality of care from these different groups?

And with the lack of that evidence, of research such as what Dr. Kleiner has done, it's very hard to then advice how to move forward.

PATRICIA SCHULTHEISS: Well, I mean, is the answer then that, unless there is really evidence that there's a true difference, that all of them should be able to practice

or maybe you don't even go the licensure route? For example, you have registered dietitians or people who have degrees in nutrition that there is really no license because there's no evidence that one is -- they may be different, but one's not better than the other.

Or with lactation consultants, it doesn't matter really which accrediting body you went to if you're actually helping people. Then why do you go to the licensure role? Is that more or less what you're saying?

JOANNE SPETZ: A lot of that, I think, comes down to the employer's decision. So, for the example of childbirth, to stick with that, that usually happens in hospitals, not always, but usually. And so hospitals can make a determination. We think these people are safe. We think these people are not safe. We're going to allow x, y, z. I certainly have heard of hospitals for reasons unclear to everybody that do not allow midwives, licensed, certified nurse midwives to perform births there.

Because that's their policy or just whatever the case may be, even though they are reimbursable under most private insurance plans. Similarly, insurance companies can decide, we're willing to reimburse a service provided by this provider but not that provider. So then you could arguably say, let the private sector decide what they believe is safe. They're the ones who are going to have the malpractice lawsuits when all is said and done.

MORRIS KLEINER: Just one issue. And this is related to this. Where I come from, there's a very famous medical clinic, Mayo Clinic, and they have a lot at stake if their reputation slips. Certainly, they are not able to charge as much as they have, and they don't have people coming from around the world to get medical care there. So they have a lot at stake to make sure that the quality and the outcomes are a lot more at stake than, for example, the state boards do.

PATRICIA SCHULTHEISS: Anyone else want to address that?

LISA ROBIN: I would just like to add that I think if you look at the welfare of the consumer -- and as I am, like you, a policy wonk, not health care professional -- but I need something to depend on when I'm looking at selecting a health care professional. And the licensure or certification, that serves as some sort of bar. So you know that the individuals have at least attained some minimum standard.

So when I am selecting who I trust to take care of my mother or my child that I know that they have adhered to certain standards of not only education and training but most likely character. So I do think that we shouldn't lose that as we talk about, perhaps -- that we are the most regulated country and I don't dispute that. But I do think that it does serve a purpose when you're talking about the welfare of the consumer.

TARA KOSLOV: Barbara, did you have any comments?

BARBARA SAFRIET: I very much support that role because we need signaling devices. And they can be more robust, more restrictive, but yes, Lisa, you're absolutely right. I can't sort through all the various opportunities or options on my own, so we all rely on these governmental signaling devices. I do think, though, in this country, we have moved rather faster toward the highest level of regulation, which is licensure and, quite frankly, overlooking notions of the value of certification, which serves a great signaling function, or registration.

So I think, as a regulatory norm, we should look at all those issues and not just immediately hop to the highest level, most restrictive level of a scheme, but I very much support the continued need for signaling, which some of these things do, signaling to consumers. Licensure is not the only way to do that. There are less restrictive ways, which still achieve the same safety and public information function.

So, I support that and I celebrate that. The one thing that follows from that, however, is -- well, probably in addition to it -- it's perhaps a mindset, but it should be,

one hopes, competition and regulation has a theory. And my view of it, especially in the health arena, given the importance of health and safety, is we should identify what the goals are and then government should do the least restrictive thing possible consistent with achieving those goals because especially -- and we should regularly review those restrictions.

There may be in medical licensure, nursing and all the rest, restrictions that are in place that made sense 85 years ago, but they make absolutely no sense now. And, we have evidence, information from other states that have experimented and demonstrated that, with far less restrictive regimes, you can not only maintain quality and often improve it, but you can surely increase access, flexibility for patients, and potentially reduce costs.

I think it's helpful to keep in mind from -- it's not a theoretical -- someone should have a notion of what you're trying to do with regulation as opposed to just restrain others -- but I think it's good to keep in mind as I remind myself probably on a daily basis, we're moving quickly toward the point where, for example, the person I or you, Lisa, for yourself or your mother would seek out to treat cancer will not be licensed at all.

It will be an expert, for example, bench scientists, a molecular biologist, whomever, who can take a cell sample and specifically pinpoint the source, etiology, all the rest, of the cancer and know which treatment modalities will be the best. I don't fear that. But right now, our regulatory regime would totally quash that opportunity.

So I think we have to look in a regulatory perspective at accommodating future modalities, which are coming, but also eliminating outdated restrictions based on outdated safety notions and free us up all by using the least restrictive techniques possible consistent with achieving our goals.

But you see what that does is force people to demonstrate and articulate, what is the goal? Is this public safety? Or is this professional protection?

TARA KOSLOV: Barbara, I'm going to jump in because we've got just a few minutes left. And there are a couple of people on this end who want to add a couple of additional remarks.

MORRIS KLEINER: One note that ties into this -- and some of the things we're talking about has reached the highest levels of government -- was there was a report issued last year by Michelle Obama and Joe Biden dealing specifically with issues of the acceptance of qualifications that are attained in the military and also the problems that regulation has in terms of mobility. Both of these issues are particularly important.

The ability to move across states. And certainly, for example, for nurses, because, in part due to occupational regulation, nurses tend to move less across states than they do within states or relative to other occupations. And a number of states have passed laws accepting, especially for EMTs -- the experience that they received in the military can then transfer to state licensing.

So these are issues -- and I would second the motion to Barbara's comments that it is really important that the least restrictive form of regulation be tried rather than moving immediately to licensure.

TARA KOSLOV: We have one minute. I'm going to throw out a final question that will, I guess, be a rhetorical question that maybe it's something we can invite additional comments from our speakers to us as we evaluate these issues. And if anyone in the audience or anyone watching on the webcast has thoughts on this question, this would be a great thing to submit by comment.

So it's kind of a two part related question. As we go forward on our inquiry relating to professional regulation, what are some of the natural experiments that

would be good for us to go out and look at out there in the world to help us figure out where professional regulation is or is not working to optimize competition?

The military may be one example. That's one we've heard repeatedly that perhaps within the military system, health care professionals are subject to fewer restrictions because of the way that it works there. And that maybe that would be a good example. There may be others that we're missing.

And, similarly, are there any other areas where more empirical work would be useful? Either work that the FTC can do or more likely work that the FTC could encourage others to do that would help to further this dialogue and help us get to the right place. We -- two seconds. We're almost out of time.

MORRIS KLEINER: Very quickly. The FTC, in the 1970s and '80s, was certainly the leader in conducting lots of experiments. And they both funded and conducted experiments at the FTC, which really served as the model for informing policymakers in terms of what works and what doesn't. It would be great if many of the economists at the FTC could continue that work on occupational regulation.

JOANNE SPETZ: I think the VA is an absolutely wonderful place to look at as an example. Within their states, they are allowed to have a licensed practical nurse from any state practice at whatever level the VA regulations allow, which are not necessarily the same regulations as within that state. That could provide a really nice natural experiment for some compare and contrast across the quality of care that they're providing to veterans versus what is allowed in the community.

PATRICIA SCHULTHEISS: OK. With that, I'd like to ask everybody to thank our panelists.

TARA KOSLOV: Especially Barbara, who got up really early for this. Thank you, Barbara.

PATRICIA SCHULTHEISS: And being sick. We hope you feel better soon. I also want to say that we think that this panel has been a very good set up for this afternoon because with talking about the regulations, this afternoon we're going to be talking about new delivery models, including telehealth and retail clinics and other issues. And, regulation obviously affects all of these new delivery models. So we look forward to that this afternoon.

We're going to reconvene at one o'clock after the lunch break. And, if you aren't familiar with the area, there are sheets outside on one of the tables that will give you some local lunch spots that you can grab a quick lunch and come back. But don't forget you have to go back through security.

TARA KOSLOV: Thank you.

PATRICIA SCHULTHEISS: Thank you very much.

[LUNCH BREAK]

PANEL DISCUSSION: INNOVATIONS IN HEALTH CARE DELIVERY

Moderators:

- **Karen A. Goldman, Attorney Advisor, Office of Policy Planning, Federal Trade Commission**
- **Robert S. Canterman, Attorney, Health Care Division, Bureau of Competition, Federal Trade Commission**

Panelists:

- **Nancy J. Gagliano, MD, Chief Medical Officer, MinuteClinic & Senior Vice President, CVS Caremark**
- **Margaret Laws, MPP, Director, Innovations for the Underserved, California HealthCare Foundation**
- **Ateev Mehrotra, MD, MPH, Associate Professor, Department of Health Care Policy, Harvard Medical School**
- **Karen S. Rheuban, MD, Professor of Pediatrics, Senior Associate Dean for Continuing Medical Education, & Director at the Center for Telehealth, University of Virginia**
- **Lisa A. Robin, MLA, Chief Advocacy Officer, Federation of State Medical Boards**
- **Lee B. Sacks, MD, Executive Vice President & Chief Medical Officer, Advocate Health Care**

KAREN GOLDMAN: Good afternoon. I'm Karen Goldman, from the FTC's Office of Policy Planning, and I would like to welcome you to this afternoon's panel on Innovations in Health Care Delivery.

Several new models for health care delivery, including retail clinics and telehealth services, have emerged in recent years. Although the topics of telehealth and retail clinics at first glance seem very different, they present many similar issues and we are fortunate that many of our panelists have expertise in both areas and will be able to explain the current status and trends in both areas.

Both retail clinics and telehealth have the potential to spur competition and expand access to care, retail clinics by providing care at convenient hours and locations, and telehealth by facilitating care from providers distant from a patient's location. These models may offer significant cost savings while maintaining, or even improving, quality

of care. Both retail clinics and telehealth services, however, have raised questions about how they compare to traditional medical services, in quality as well as price. And there have been various legal, regulatory, and policy responses to them, as well as legacy statutes and regulations that were developed before these models emerged and that pose significant barriers to their deployment. Through the panelist's presentations, we will see variations in these models and possible regulatory and policy options. For example, in the telehealth area, there is “traditional” telemedicine, typically initiated by a patient's primary care provider, at a rural, under-served location and connecting to a distant location, possibly at an academic medical center. More recently, other forms of telehealth services have emerged, including convenient web-based and patient-initiated models that don't involve a primary care provider at the patient's location and may rely on a questionnaire or telephone consultation for communication with the provider. The panelists will present a range of regulatory and policy options for these varied models.

This panel builds upon the issues that were discussed in the previous panel this morning on professional regulation. In particular, that panel discussed certain proposals related to telehealth, the Interstate Medical Licensure Compact, and the model telemedicine policy, developed by the Federation of State Medical Boards. This panel will present detailed information on the status of retail clinics and telehealth, and discuss those and other regulatory and policy proposals. With that, I would like to introduce my co-moderator, Rob Canterman, who will introduce the panelists.

ROBERT CANTERMAN: Thanks, Karen. Good afternoon, and welcome to our panelists.

Our first speaker, Ateev Mehrotra, will provide an overview of innovations in health care delivery, including both telehealth and retail clinics, based on his research in this area. Dr. Mehrotra is an associate professor in the Department of Health Care Policy at Harvard Medical School.

Next, Karen Rheuban will give an in-depth presentation on telehealth and the legal and regulatory challenges to the deployment of telehealth. Dr. Rheuban is professor of pediatrics at the University of Virginia, where she is also senior associate dean for continuing medical education and the director of the UVA Center for Telehealth.

Our next two speakers, Margaret Laws and Lee Sacks will continue to explore telehealth issues, offer their perspectives, and include some real life examples. Margaret Laws is director of the California HealthCare Foundation's Innovations for the Underserved program. Dr. Sacks is executive vice president and chief medical officer of Advocate Health Care.

Our final panelist, Nancy Gagliano, will present her insights on retail clinics, based on her experience with the largest retail clinic network. Dr. Gagliano is the chief medical officer for MinuteClinic and senior vice president of CVS Caremark.

Following these presentations, we look forward to an interactive discussion among the panelists. They will be joined by Lisa Robin, the Federation of State Medical Boards' chief advocacy officer, who participated in the panel this morning on professional regulation.

And now, please welcome our first speaker, Dr. Mehrotra.

[APPLAUSE]

ATEVE MEHROTRA: So thank you very much.

I have been asked to give an overview in terms of what we're talking about when we think about innovations in delivery and a framework for thinking about some of the policy issues that are at play when we think about these. And in contrast to, I think, the other panelists on the panel who are really implementing these innovations in delivery,

I'm more of an observer. And so I'll just try to give you my own observations on what are the key issues that we need to consider.

So, I think it's useful to start by just recognizing how different the medical landscape is today versus what it was just say a couple of decades ago. If you were a couple of decades ago, you got sick, you went to a doctor's office, you went to either a primary care physician or a specialist, you could go to the ED. And now in 2014, if we look at that landscape, how different it looks. You have a huge variety of innovations, new ways of delivering care, from care over the internet like electronic visits, retail clinics. You have nurse-managed health centers, where you don't have a physician involved, a nurse providing full primary care in an independent practice. And then you have medical kiosks and physician messaging via their personal health records, a large variety of different options.

It is useful to acknowledge that when we talk about innovations, we're talking about, again, a wide spectrum of different ways of delivering care, and they vary in a couple fundamental ways. First is, what kind of care is being provided? What are the medical conditions?

Some of my own work -- and Nancy will be talking about -- care that's provided at the lower acuity scale, things such as sinusitis. But then Lee will be talking about, really at the whole other end of the spectrum, of tele-ICU or e-ICU where you're providing care using telemedicine for the sickest of patients. Karen brought this up in her introduction. Also, you see this wide spectrum of who is providing the care and who's initiating the care.

On one end, I hadn't heard the term “traditional” telemedicine, but you have the care being provided, initiated by the primary care provider, but part of a large integrated delivery system with hospitals and specialists, often an academic medical center. But then on the other end of the spectrum, I think is really where you see some

new players in the health care landscape. Small company start-ups, that have very much a kind of internet start up kind of feel, as well as for-profit companies, such as CVS who have really entered in a much larger way into the health care landscape.

And then lastly -- and I think Margaret's going to go into this in a lot more depth in her presentation -- but very different ways of delivering care. Some of the care is face-to-face, either in person or electronically. But it's interesting, also, as you look at these new innovative ways of providing care, a lot of the care is asynchronous, almost like an email model, where the care is being provided not in real time.

So as we think about these innovations, I think it's also useful -- I've described the wide landscape -- but some key themes that unify them. And at first -- and again Karen brought this up in the introduction -- it's about convenience and access. I think all of us in the audience who have tried to seek care and recognize this issue, that often to get into one of our primary care providers, often there's a delay. And sometimes for specialists, the delay is much longer. And so in terms of -- these new innovations in delivery have obviously more convenient locations, often convenient hours. And then with telehealth, it's obviously because the care is provided over the internet, they can really break down many of the access issues that we think about.

Another key theme of these innovations is the use of technology. Obviously that's critical for telehealth, but we also see it in using the internet. But I think, in particular, some of the presenters will describe some really innovative ways of monitoring patients, diagnosing patients, all using, again, new technologies.

And lastly, another key theme of these innovations is a different way of having that provider interaction. I think a kind of underlying theme that we're seeing in the US health care system is recognition that physicians are providing too much of that care. And we need to have physicians provide more care that's consistent with their scope of practice and their training, and have some of that care offloaded to other providers,

very apropos of our conversation this morning. And you see in these innovations, often, non-physician providers. And also, the interaction is asynchronous, as I mentioned before.

So we have these innovations, a wide landscape. And we do see in some cases, at least, that they have become very popular. Patients are voting with their feet. In the case of retail clinics, as an industry, over 20 million visits to date, over the last 14 years, or so. And then in some cases, for example, Kaiser Permanente of Northern California is reporting that, just in 2013, they had over 10 million virtual visits, almost matching the number of in-person visits they had. And when they mean virtual visits, they mean visits via the telephone that are scheduled, or visits where they are done by physician messaging or email.

So we have this landscape, these new innovations. So there's a policy debate ongoing about what's their role. And I think it's clear why there's a lot of excitement about these innovations. And the key thing is this, again, access. As I mentioned before, people have trouble getting into their providers. These new innovations can improve that access. But, in particular -- and I think Karen is going to go into this in a lot more depth -- there's been a lot of focus on whether these new innovations can be particularly suited for those who are the underserved -- rural Appalachia, and Margaret's going to talk about the Central Valley of California, places where there aren't specialists, and that these new innovations can be a mechanism for people to get in for care.

There's also the hope that these innovations can improve quality of care. First, just because if a person needs care and can't access it, and now they can, that will improve their health. But I also think and will describe -- some of the panelists will describe ways -- that the idea, at least, and the hope is that these innovations can even

improve what we currently have in our face-to-face doctor's visit and actually provide better care, because there's more frequent monitoring.

And lastly, it's the hope, at least, that these innovations can decrease spending. If we think, and I think many think that the increasing health care spending is among the most significant policy and societal issues our country is facing. And in a Wall Street Journal article, my boss, the dean of the Harvard Medical School, said that many of our current policy interventions -- ACOs, payment reform -- are not the right way to go. But the real way we're going to decrease health care spending, improve value, are these innovations in delivery, because they can be lower cost than our existing providers. And, also, because they can improve health, they can deter costly complications that might occur, such as hospitalizations, re-hospitalizations.

But there's also some controversy. And I think the controversy that we see most frequently about these innovations is quality. Are patients who receive care via a nurse-managed health center, an e-visit, the tele-ICU, etc. are they going to receive inferior care and lead to poor health?

There's another debate, which is that, well, yeah these innovations are interesting, cool, but they're only going to serve a limited population of those who are highly educated, who have internet access. And there is a concern that we're already improving access for those who already have access.

A third major concern we hear about these innovations is their impact on primary care relationships. And I think many of you are aware in the audience, there is literature documenting that those patients who have a primary care provider, and a relationship with that provider, typically have higher quality care and lower costs. And one of the concerns is that these new innovations can undermine those primary care relationships. And some of it is driven by new providers, for example, MinuteClinic. And there's often a concern that retail clinics or visits over the phone or internet will

undermine that. But even in the health care system that I worked in, we heard that, because primary care providers were concerned that providing that care electronically was going to undermine that relationship. And it's also important, because those face-to-face visits -- if I see a patient for sinusitis, that's also an opportunity for me to identify missing preventive care, missing chronic illness care, and actually address the full spectrum of care for the patient.

And lastly, and I think a major concern that's often not discussed about these innovations in delivery, is the concern that their very thing that makes them so interesting and special is their convenience and access is actually their Achilles heel, that they're too convenient, and that will lead to overuse. So while teledermatology might be great for a population who doesn't have access to a dermatologist, but if teledermatology is so convenient, then a lot of rashes that otherwise people would've just ignored, they're now going to seek care. And you hear this a lot from payers, that they're fearful of improving -- you know, covering telehealth and other innovations, because again it's too convenient.

So we have this ongoing debate about access, primary care relationships, quality, and cost. What I wanted to do is now just touch upon very briefly at a high level some of the research that we've done on some of these topics. And again, the other panelists will go into more detail on some of the topics relevant to their presentations. In terms of the impact on access, we have done a number of studies there. Some of the work was done on Teladoc, which is a large for-profit corporation that's providing several hundred thousand visits nationally, mostly over the telephone, but also via internet.

And in some ways, you can argue Teladoc -- our work shows that Teladoc is improving access. Often, the visits were happening in the evenings and weekends when a doctor's office wasn't open. And often, the Teladoc users had no prior contact with the health care system. So the argument was that we're getting people plugged into the

health care system. And this is something we've seen in our work on retail clinics, where almost two-thirds of patients who visited a retail clinic reported no primary care provider. So this argument they're going to undermine primary care relationships, in this particular case, there was no relationship to undermine. On the other hand, we find that Teladoc users did not live in underserved communities. They tended to live in the urban areas, where there was more access to care. And in the case of retail clinics, we find again that most of the retail clinics are located in urban areas, and relatively few are located in underserved communities. I do want to make the point that these are the same communities that the physicians are located in.

On the quality of care side, we've done a number of studies there. This is just one example of that, where we've compared retail clinics to physician offices, urgent care centers, and emergency departments for three conditions, ear infection, sore throat, and urinary tract infections. And what we studied in terms of quality is we wanted to see what percentage of the care that was provided was consistent with evidence-based guidelines that have been published. And you can see here that across the three conditions, retail clinics had similar quality care to physician offices and urgent care centers. In the case of sore throat, they actually had superior quality of care to emergency departments.

But I also caution that we should not assume that these innovations in delivery will always provide equal or superior quality of care. We did a study where we looked at electronic visits provided by a primary care practice. And we compared same patients, same doctors, but we compared the visits that were provided electronically versus those that were provided in person. And in this case, where we looked at cases for sinusitis and women who were coming in with pain with urination or urinary tract infections, we found that the primary -- when the same doctors saw an e-visit, they were much more likely to prescribe antibiotics. And the concern is that was over-prescribing of

antibiotics. And that makes sense, that when you can't see a person face-to-face, you might have a propensity to prescribe more.

The last point I'll make on the research side is we've done some work also comparing on the cost side. And in this case, the same study where we looked at retail clinics versus the other three care sites for these three conditions, we found that retail clinics were about 20% to 30% cheaper than doctors' offices and urgent care centers and 70% to 80% cheaper than the care provided in emergency departments. So, on a per visit or per episode of care, we did find significant savings.

I'll wrap up by, hopefully, giving you this landscape of what are innovations and what is some of the policy debate that's ongoing about them. Let me just think about some challenges for these innovations. While I highlighted a couple examples where we see a lot of use of these innovations, I should note, that in many cases, there are very few patients using this. And for example, the e-visit example that I provided before, e-visits represented a teeny sliver of the visits, overall, in our health care system. The evidence on the impact on access, cost, and quality, very limited, so far.

And lastly, and now bringing it back to where we are right now with the Federal Trade Commission and the issues of regulation and competition, there are a lot of barriers to this growth. And I think each of the panelists that follow are going to go through those barriers. Some of them are technical, IT related, clinical, but many of them are regulatory, financial, and legal. So with that, I'll stop, and then turn to the next panelist.

KAREN GOLDMAN: Yes, thank you so much for that interesting presentation.

[APPLAUSE]

KAREN GOLDMAN: Dr. Rheuban, welcome.

KAREN RHEUBAN: Thank you, so, let's see. Here we go.

So, hi everyone. I'm Karen Rheuban. I'm a pediatric cardiologist at the University of Virginia, and I used to think I was an innovator, but now I realize I'm a traditionalist. So I got my start in telehealth, because I was a -- I am a driving physician. So the University of Virginia has a huge outreach program, where we send docs in cars, down Interstate 81 and up 29 North and all over the Commonwealth of Virginia. And many years ago, it became clearly apparent to me, having listened to Dr. Jay Sanders, someone who I admire greatly, talk about the program that he developed in Georgia, and it seemed only intuitive that we could do this in the Commonwealth of Virginia. But we were one hospital, one health system, facing a lot of challenges in terms of public policy and sustainability that would allow us to build our program and to expand it.

So we did begin almost 20 years ago actually, officially really 1995, where I did think I was an innovator, but hmm, now it's not. So a lot of definitions of telehealth, the one that we wrap our arms around at the University of Virginia in the traditional telemedicine program, the use of technology to enhance access to health care, to improve public health, to support health related education, using communication services, and can include, in our model -- in the traditional model -- live, interactive, video conferencing, store-and-forward technologies. And the classic example is teleradiology, which is probably the original store-and-forward application with standards. We do remote patient monitoring and health-related distance learning, for patients and for health professionals, as well.

And always we want to reiterate, and this group knows well, telehealth is not a specialty in and of itself; it's simply a tool to deliver care. So Jay shared this cover of Radio News magazine, 1924, Hugo Gernsback predicted contemporary telemedicine. And as I say, that's been around for a long time. In the United States, we've been doing telemedicine, and not just phone call, but actually video-based telemedicine, for more than 50 years.

And I'm happy my colleague, Gary Capistrant, is here from the American Telemedicine Association as well.

So for patients, huge benefits, timely access to locally unavailable services, enhances patient's choice. We spare the patient the burden and cost of transportation. And as you can imagine, that's a mighty cost for families, especially when you have a patient with significant illness and no provider in the community. For hospital systems, one of the reasons that we embraced it, we want to reduce readmission to our hospital. We want to improve triage, keep patients local, and improve our quality indicators. For health professionals, we know there are huge workforce shortages. We heard great discussion this morning about interprofessional collaborations. And that is certainly something that can be and, classically, has been facilitated through telemedicine, telehealth programs around our country, working with telepresenters who are nurses and other health professionals. It also allows for access to consultative services and continuing health professional education and patient education. And it allows us to disseminate evidence-based models of care in communities that, otherwise, did not have access to those types of models, and for public health, emergency preparedness and disease surveillance.

Our center is an integrated program across all the service lines. And it's going to be very important when we talk with Lisa later about licensure. Because we basically have anyone who is on call for any services on call for telemedicine in our health system. So 800 plus clinicians are available to be on call when they are on call for a consult that might come in from a community partner. It supports our own existing missions. Again it's not a specialty in and of itself. So clinical care teaching, research and innovation, and public service and public policy.

And we are the HRSA funded Mid-Atlantic Telehealth Resource Center, serving eight states, from North Carolina all the way up through Pennsylvania. And we have in

our new funding cycle, we hope to include New Jersey as well, an orphaned state, I understand. They don't have a resource center. And we recently became the academic partner of Specialists On Call, which is an innovative telemedicine service provider, initially got its launch in TeleStroke, but now is going to be offering other specialty services. And Specialists On Call is an incredible company, which has supported more than 40,000 teleneurology services around the country, in terms of reducing stroke.

So tremendous opportunities for us. We have focused, because of issues of licensure, primarily within the Commonwealth of Virginia. And we have now 126 sites across the Commonwealth, ranging from rural clinics to hospital systems, correctional facilities. But again we work within our state, because of a lot of the public policy and regulatory challenges that we'll be hearing about in this session.

To date -- and I guess maybe we're relatively small when we're compared to some of the amazing work that's being done by others -- more than 38,000 patients have received consultative and follow-up services through our telemedicine program. And we do international outreach, although they're not counted in our numbers. And that's in partnership with our teleradiology program, so that when a provider at the University of Virginia is seeing a patient, they also have access to the radiographic images, to the electronic medical record. And we have actually counted -- one of the metrics we track is miles of travel avoided -- now 8.8 million miles of driving avoided in the Commonwealth of Virginia. And at the Medicaid rates for transportation of over $1.00 per mile, that's a huge savings for our Medicaid program as well. We provide services in more than 40 different specialties and subspecialties of health care, again, primarily live, interactive, video-based. And that's why I guess I don't consider myself as much of an innovator as some of the things we are going to learn about today.

But it's been really an awesome opportunity to improve access to care around the Commonwealth. So we can provide emergency services. We have someone on call

24 hours a day, seven days a week, including technology support 24/7. We can do a single consult at any one of those sites or a follow-up visit for a patient. We do block scheduled clinics, wherein a dermatologist or a psychiatrist might sit down at a workstation and see patients across our state, just pushing a button and going to the next community. And we offer screenings with store-and-forward technologies. And there's an example of a digital retinal image that can be acquired. And all diabetic patients need an annual eye exam. There aren't ophthalmologists in every community. And there is certainly not necessarily the availability of affordable ophthalmologic care. We're working in partnership with the community health centers to deploy low-cost technologies to do this. And then we have launched recently a remote patient monitoring program, which I'll speak about shortly as well.

So if you look at the volume of our clinical encounters, you can see how exponentially things have changed in the last three or four years. And the reason for that is public policy. We had a mandatory reimbursement bill that was signed into law in 2010. And suddenly, we had providers at remote sites, and our docs jump on board. Well, if you can be paid to provide a service, why not? So that volume has increased.

And you will see, if I pull the data from the Commonwealth of Virginia, we have now health care systems across our state that are embracing technology because of this public policy change. Our partner sites, we started out with two sites in 1995 when we started, now we're 126. And even that incremental increase has been pretty significant, since our bill was signed into law in Virginia.

We are very careful to use HIPAA compliant, interoperable technology. So we can offer telemedicine to the desktop, telemedicine in a wall-mounted technology, mobile carts, and even laptop enabled, and iPhone enabled, and other types of technologies. So these are the clinical services that have been supported through our

telemedicine program, across virtually all the specialties. And that is because our health care system is supportive of our doing this.

So we're more than 40 different specialties and subspecialties, and then again, our international presence as well. So the clinical services that we offer, we try as hard as possible to make them evidence-based. And there is a huge amount of literature. And ATA has aggregated a lot of that literature in helping to develop practice guidelines for the clinical specialties, working with the specialty societies. So we try for evidence-based as much as possible.

And we offer a spectrum of care across the continuum, from prenatal care to end-of-life care, acute care services, chronic disease management. Again, primarily, live, interactive, video-based, but we are certainly doing a significant amount of store-and-forward as well. In general, we work with partners who ask for our services. We try not to set ourselves up as competing with existing providers in a community. Yes, telemedicine can put us at a competitive edge, but I have no desire to put a cardiologist in private practice out of business. So we tailor our services that we offer to the services that are requested by the community partner. And especially, when you're working with other health care systems, it's really important that you not -- you know, we would have the door slammed in our faces, quite frankly, if we tried to say we're here to compete, as opposed to we're here to serve. And it is aligned, the work we do, with our state's health status indicators. And, I'm so happy to see Rene Cabral-Daniels here, who heads our office of policy at Virginia Department of Health. We align a lot of what we do with the needs that have been articulated by the Commonwealth of Virginia. So thank you, Rene, for all your great work.

And just a couple of quick examples. TeleStroke is the classic example of when time is brain. And as this group probably knows well, stroke is a high morbidity, high mortality condition. And there is a treatment for ischemic or clot-related strokes called

TPA, a clot-busting medication. But, sadly, across the country fewer than only 2% or 3% of eligible stroke victims actually get TPA, because you have to get it within three hours of the onset of a stroke. Oh, only five minutes. Goodness gracious. OK. So there is primarily an urban distribution, and low utilization. We and others have deployed TeleStroke programs. And we have increased in our network utilization from 0% to 25% of stroke patients. And there's the evidence well published in circulation.

Chronic disease management, we have reduced hospital readmissions by 53%, from 23% down to 10.8%. And of course, that's important, because we know we have a public policy challenge to face, readmissions penalties to our hospitals and health care systems.

Issues for consideration in any telehealth program: reimbursement, funding of telehealth. Stark and anti-kickback prevent us from acquiring and deploying equipment in communities that would be viewed as an inducement for referrals, so a public policy challenge we face. We get informed consent. We obviously have to align with all HIPAA regulations, credentialing and privileging, both by CMS conditions of participation standards and Joint Commission standards, medical licensure.

We heard from Lisa this morning about the issue of licensure. I don't know how 800 UVA doctors would apply for a license in four or five other states. It's just cost prohibitive, quite frankly. Medical malpractice is an issue. And if we go across a state border, we need to be absolutely sure we're aware of all the malpractice caps or lack of caps in other states, another public policy issue. We're working with practice guidelines and technical standards, telecommunications venues, and cost. The Federal Communications Commission has a wonderful program to help underwrite the cost of this broadband connectivity. Integration with electronic medical records and health information exchange, another important issue. And then we have a major challenge,

which is interagency malalignment, when it comes to policies. Definitions of rural, who's eligible for reimbursement, who's not.

In 2012, the Institute of Medicine convened a workshop. I was privileged to serve as that chair, to discuss the evolution of telehealth, the evidence base, technological developments, and actions to further the use of telehealth. And I would urge you to find that document. I think that it was really well done. And it speaks, specifically, to the challenges, including in public policy. We need to improve payment mechanisms; streamline licensure and credentialing; develop a trained workforce, who can be comfortable in using technology; explore the role of telehealth in new care delivery models and collaborations amongst the professions -- we heard about that this morning; conduct more research -- Dr. Mehrotra. And then, again, align the various federal agencies that support telehealth in some way. 16 different agencies, all with different policies.

Medicare reimbursement remains low in 2011. CMS reported under $6 million in paid claims for Medicare beneficiaries. That's budget dust for Medicare, and yet, a great opportunity. The Congressional Budget Office has scored any telehealth legislation so high that it has a negative impact on some of the bills that have attempted to go through to expand telemedicine. There's currently a rural requirement for originating sites, including for accountable care organizations. That doesn't make any sense. And there's a group working to try to address that at the Secretary's level. And the non-MSA definition of rural limits sustainability models. And, more importantly, access to care for our seniors, including in urban areas. And the rural definition is poorly aligned, with specialty workforce shortages. We know that as well. Here's an urban area under Medicare, the Grand Canyon.

The states can do a great deal as well. Medicaid expansion, there are private pay mandates in 20 states, plus the District of Columbia. Some of the state boards of

medicine do not have a prior in-person requirement, but some of the state boards of medicine do. In health insurance exchanges, there are benchmark plans that can include telehealth. There are correctional opportunities and state health information exchanges. And I promise, I won't be too much longer.

So I just want to give a shout out to my own state. Thank you. Virginia has been very, very proactive. Virginia Medicaid has been paying for telemedicine since the mid '90s in a waiver, but then in 2003, broadly, for urban and rural Medicaid beneficiaries. And it was really exciting that in 2013, we negotiated a dual eligibles contract with Medicare to cover urban Medicare, Medicaid beneficiaries. And I think we're one of the first states that have so negotiated urban telemedicine for anybody under Medicare. So that's very exciting. Our Virginia Department of Health -- thank you, Rene. I didn't know you're going to be here, but I'm so glad to see you -- so they provide health status indicators. They have served as originating sites, and they provide grants. Our Virginia General Assembly, which I now lovingly call the "Generous" Assembly, supported mandatory reimbursement in 2010. The Joint Commission on Health Care in Virginia, a legislative body, did a specialty workforce analysis, which was a road map for us. And the Joint Commission looked at policy options to expand telehealth in Virginia. Our Bureau of Health Professions has been looking at it very carefully and positively. And our Tobacco Commission has funded telehealth.

Credentialing and privileging has been an issue, but is less so, because CMS actually did come to the table. And we're grateful for that. Licensure we've heard about. There are some federal bills that are percolating through Congress that will hopefully expand telemedicine. And the future is bright. And I'm grateful to Mary Wakefield, at HRSA, and Marilyn Tavenner, at CMS, because of their leadership role to try to address some of these very significant policy options that have even limited us as traditional telemedicine providers.

So with that, thank you so much for your attention, and sorry to have gone over a little bit.

[APPLAUSE]

KAREN GOLDMAN: A wonderful overview of all of the innovations going on. All right.

MARGARET LAWS: Thank you very much. Thanks for having me.

And I'm going to be able to take advantage of drafting off of Karen a little bit, because she covered some of the things that I'm going to cover. I am just going to start out with a minute about who California HealthCare Foundation is and what we do, just to set a little bit of context. We're a private, nonprofit foundation in California. We do about $32 to $33 million a year in grants and projects to improve the health of the people of California. And I head up a program at CHCF called Innovations for the Underserved. And a big, big focus of the work that I do, both in policy and in on the ground demonstrations in practice, is in trying to bring innovation into the health care safety net. So to try to improve access to care, lower cost of care, and improve patient experience of care for low-income patients, and those that are served by community health centers, public hospitals, rural providers.

So what I'm going to talk about today -- I'm not going to talk about what is telehealth, because we've covered that. I want to talk a little bit about telehealth policy, with a focus on California, and then do a few descriptive dives into some of the types of telemedicine and telehealth that we're working with in California, and then talk a little bit about issues and challenges ahead. And since I don't have to do the what is telehealth, I would love to just see a show of hands. Has anybody in this room, or how many people in this room have taken part in a telehealth encounter? So a handful. And while we have you doing polls, how many people in the room have visited a retail clinic? Oh, a lot. OK, great. So I'm going to skip over both the definitions and the message that

Karen gave us that this has been around for a long time. We've been envisioning how we would use these technologies to bring care to people in remote areas. And there are some very interesting examples from the 1920s.

So I am going to jump in now just to an overview of policy across the states. And the punch line is that really every state has a unique set of telehealth policies. Some have incorporated them into law. Others have addressed them in definition of reimbursement policies and licensure requirements, and such, in their Medicaid program guidelines. And one of the things that was referenced earlier was the Telehealth Resource Center. Karen has one of the telehealth resource centers. There are 12 regional centers across the country. They were established in 2006 by the Office of Advancement of Telehealth. There is one national policy center, Center for Connected Health Policy, which is an organization that California HealthCare Foundation sponsors, heads up now. But these resource centers around the country serve to provide expertise and experience to new telehealth programs. So really a wealth of information, and of direct support to providers that are putting telehealth programs in place.

I wanted to just pinpoint this resource. The National Telehealth Policy Resource Center did a 50 state review of policies across the country. They will talk about reimbursement policies, as well as laws. And what they have up now is an interactive map. You can actually go pick your state and drill down into 12 areas of law. It covers laws, regulation, and Medicaid provisions, and covers the things you see up on the screen, as well as things like consent, location, cross-state licensing, private payers, whether there's a site transmission fee paid. So I would encourage you, if you're interested in drilling down into any particular state category to use this resource. It's constantly updated to keep an eye on what's happening across the states.

So I want to talk a little bit now about some of the policy activity that's gone on in California. AB415 was passed in 2011, went into effect January 1, 2012. And in

California, it was really considered to be a clean-up of the Telemedicine Development Act of 1996. So the last time the state of California had actually considered, in its totality, how to regulate, think about telemedicine, had been in '96. And It seemed time to modernize it. And what AB415 did was several really important things, including removing what had been a ban on email and telephone visits being counted as medical encounters. It removed restrictions on where telehealth can take place. Prior to this, telehealth visits could only take place in licensed health care facilities, which meant that you obviously couldn't have the remote access and be a home, be a school, be a community center. It removed the California Medicaid rule that provided -- basically required that a physician document in writing that a patient consented to a service before using telehealth. And it also dramatically expanded the categories of providers who could use telehealth. So it went from being physicians, nurses, a few other categories, to include nurse practitioners, pharmacists, physician assistants, RNs, dental hygienists, a lot of the people that we think we need to have engaged in telehealth to really expand access. What it did not do, it didn't require telehealth use by public or private insurers. It didn't change any scope of practice. And it didn't change interstate licensure laws. So there's continued work going on, but a lot of progress made through that pretty significant work done on that bill.

So what's happening now, Center for Connected Health Policy has undertaken a new project, Telehealth and the Triple Aim, and basically putting together a national work group to look at how the Triple Aim -- which IHI defines as improving the patient experience, improving the health of populations, and reducing the per capita cost of care -- can be achieved, or can be dramatically aided by the use of telehealth. So what this group is doing is presenting a report to the field, which will be published in June of 2014, that's going to, we hope, really provide a meta-analysis of the research on outcomes that has been done to date, that'll provide some profiles of what we think are some of the most mature areas of telehealth, including dermatology and telemental

health. And we'll make some short and long-term recommendations nationally to accelerate adoption. We will then be drilling down in California, to look at a California follow up to this Triple Aim project, which you hope can be a model for other states. There'll be a research conference held in 2015, again to try to consolidate and bring out the evidence that's been produced to date, and then a catalog of the research, which will be classified by Triple Aim objectives. So this is all work that's going on, on the policy front, led in California, but also addressing telehealth nationally.

So now I'm going to change course and just jump into a little bit more about what we talk about when we talk about telehealth. So generally understood to be three different categories. The first, store-and-forward, often called asynchronous, where images are sent and diagnosis is made based upon image and a medical history, typically. The second, live video, self-explanatory, a video interaction between a patient and a provider, or sometimes a provider and another provider. And finally, remote patient monitoring, which means a lot of different things, and we'll be hearing about a range of them as the other panelists talk today.

And so a couple of examples, again just a little more definition on store-and-forward. It's most heavily used now in dermatology, ophthalmology, pathology and radiology for obvious reasons, very image-based specialties. But what's interesting is, particularly, now that video can be transmitted more easily, more places have enough bandwidth, and video technology has improved. Areas like psychology and orthopedics, psychiatry, where you might be a remote specialist, maybe helping to diagnose a patient based on movement or a video image are becoming more possible and are being tested. One interesting example is -- I don't know how many people are familiar with the Xbox Connect and the different ways that it's being used to, basically, chronicle changes in movement disorders, so that a physician or a practitioner on the other end can see a record of a patient over time, rather than just how they're doing the day they show up in the office. So some interesting uses of new technology there.

Real-time video consultation, fairly straightforward, often being used in the scenarios that we see here to connect one physician at a remote site with a physician and a patient at another site, or in the case of something like telemental health to connect a patient directly with a provider in another location.

And then remote patient monitoring, a very broad range of things from tele-ICU, which we'll be hearing about, to impatient monitoring for anything from blood pressure, various chronic conditions, often being used at home for monitoring patients with heart disease, and now diabetes, all sorts of chronic conditions.

So a quick, deep dive into teledermatology. I'm just going to talk a little bit about what is typically happening. We've got the patient in his or her primary care medical home. In our case, in California, we're often trying to bring patients in community health centers. The example that Ateev alluded to before, in rural, Central California, there are very few dermatologists. And the dermatologists that are there will often not see Medicaid patients. So we have a huge shortage. Wait times can be six to 12 months. So we're usually using it in the scenario to bring a patient in a medical center together with a dermatologist at a distant place. So an image is taken, often by a medical assistant. A photo is uploaded, and sent over a HIPAA compliant, secure connection to a dermatologist. The dermatologist reviews the image and patient information and sends back to the primary care provider the treatment advice.

So one company that we're working with, Direct Dermatology, really evolved and was created to serve this need in the Central Valley of California, and is now working across the state and in other states as well. And basically, the providers and patients can use off-the-shelf cameras. It's a turnkey, web-based program. So there's no installation requirement for the clinics. The software is HIPAA compliant. It's a pay-per-use pricing model. So the clinic doesn't have to pay to have a contract. At the beginning of the year they pay as they send referrals. It has been reducing patient wait times in California,

from anywhere from three to 12 months down to 48 hours. And we're seeing really dramatic cost savings as well. The average cost of a consult is $85, and that compares with between $150 to $400 for a consult, depending upon whether that was an in-network or out-of-network consultation. They're doing about 500 consults a month now in California and expanding pretty rapidly.

And just a quick case example to give you a sense of the savings here. This is a patient who had had eight primary care visits for the same problem over six months. Ten prescriptions had been given, no improvement. They saw the patient in a day. They resolved the case immediately. And what's interesting about this is not just that something could be resolved that much more simply, but that the cost of those visits and those prescriptions was somewhere in the neighborhood of a couple thousand dollars, and it could have been resolved with an $85 consult. So just one example. We see many of these, particularly in the areas where people just don't have access.

So second, we will be hearing more about some of this live video. But just one example, a very compelling example of live video in California. UC Davis has been doing pediatric clinical care, live video for many years. It's a premier center across the country. A lot of research has been done there. And basically, what they are doing is connecting with states around the site, often with either critical access, or remote hospitals, or with sometimes primary care settings. And they're offering remote clinicians access to the resources of this academic medical center. And keep in mind, for a lot of these patients in Northern California, Davis is the closest academic medical center. And it can be anywhere from a three to six hour drive when weather's bad, an impossible drive away. So one of the most important things which was alluded to by Karen is not just that you get the critical specialist knowledge, but that you're allowing that patient to be treated near his or her home and support system, and not requiring that transport.

Finally, mental and behavioral health care consults, a huge area. We've done telehealth projects in California, focused on underserved populations, for about 10 years now. And every time we funded a program from the Foundation, the providers and the patients will say, we need these 10 specialties, we need them all. The one that gets used is mental and behavioral health, the ones that seem to be, really, the compelling ones to make it happen. And what we're seeing is a whole range of companies being developed to meet this need. I've just shown a couple of them up on the screen. One's called Breakthrough. They're doing work with Blue Shield of California. HealthLinkNow, which I've also featured, got a $7.7 million CMMI grant to do telehealth in Montana and Wyoming.

So the other area, where many of you are probably familiar, a lot of telemental health has been used in the correctional system. And this is a meta-analysis that came out last year of the cost and care improvement of bringing telemental health into the correctional system.

Finally, last example, remote patient monitoring is an interesting one we've been working with. A company called Propeller Health, that has a little sensor that sits on an asthma, and now a COPD, inhaler. And time and date and location stamps, where people are using their inhaled medication, sends that information up to a server, so that actionable information can be sent to both the patient's provider, as well as to the patient him or herself, to make sure they're taking their controller meds, to make sure their physician knows if they're using their rescue medication too frequently.

Really interesting program that is now taking place across the country, but we've been working with it in the health care safety net in California. So looking ahead, I just had to throw this one in. This is a picture of the Tricorder. Those of you who are Star Trek fans will know it, and those of you who are following the XPRIZE will know that there's actually a Tricorder prize going on right now. And what this would be is a device

that would be able to diagnose 15 conditions. So the contest is around developing a scanner, a diagnosis device. And there are many teams across the country competing. So what was in Star Trek, maybe we will see come to life, and will obviously create all sorts of interesting challenges for how we think about integrating and regulating telehealth.

So I know I'm out of time. I'm just going to touch on three issues and challenges, which I know we'll talk about, both in our questions and in the further panels. The first one is a big one, EHR integration, or lack thereof, how does the EHR landscape impede or help the spread of telehealth where it can be helpful. Evolving reimbursement models -- we'll talk about that a little bit later -- how do we think about a cognitive consult between a specialist and a PCP from a reimbursement perspective, because that's a really important way that telehealth is used. And then, finally, taking advantage of mobile. By sometime this year, there'll be more mobile phones on the planet than people. There's almost 7 billion now. 90% of US adults have a cell phone, and that only goes down to about actually 87%, if it's high school or lower, and 84% for people under $30,000 income. So we really have to think about how we use mobile to deliver and enable these telehealth technologies.

Thank you.

[APPLAUSE]

KAREN GOLDMAN: That was a very insightful presentation.

ROBERT CANTERMAN: Lee Sacks is our next presenter.

LEE SACKS: Thanks. Good afternoon.

Wow. You know, I couldn't help but thinking, at the start in the overview, and I'm dating myself -- the big innovation when I started practice, and I was a primary care physician, was walk-in clinics, the so-called doc in the box, with that. So I'm going to go

deep on tele-ICU and make a few comments about other aspects of telemedicine, from the perspective of my organization, Advocate Health Care.

So to put it in perspective, Advocate Health Care is centered in Illinois. We have 10 hospitals in metro Chicago, at the tip of Lake Michigan, and two hospitals in Central Illinois. We run the gamut from a 25 bed, critical access hospital, to three major teaching hospitals.

One of the things that's kind of unwritten, unlike other multistate metro areas, Chicago is so dominant, we don't talk about Metro Chicago as a tri-state area. But people regularly commute from Wisconsin and Indiana in both directions for jobs and health care. And yet, our organization has stayed focused on Illinois, because of many of the regulatory barriers of crossing state lines and the challenges of that, although we get patients who cross the border to come to Advocate.

One of the early comments was about the quality of telehealth, and while this isn't specific, ICU care drives about 35% of inpatient hospital expense and clearly drives mortality and complications. And our organization has been repeatedly recognized as a top 15 system. And just earlier this month, Truven Analytics identified the top 100 hospitals on a list of 10 balanced scorecard measures. And we had five hospitals on that list, our five largest. So I have to conclude that our tele-ICU plays a big role in taking variation out of care and moving things forward.

We have 10 years of experience with tele-ICU. The proprietary product is eICU. I think we are the client number two after the alpha site at Sentara. And some of the things I remember, when we introduced this and started to get buy-in from our clinicians, it was a second set of eyes in ears, and the growing reality that evidence-based medicine requires following checklists. And, I forgot, can't be an answer. And that's where software and the second set of eyes and ears can really help take variation out of care.

We have a central monitoring core that's in a free-standing building, not on any of the hospital campuses. And there's two-way audio. And the first edition is one-way video. The monitoring station can see patients. I think as we upgrade, and because technology is a lot less expensive, there will be two-way video. Because it freaks patients out when a voice comes through the ceiling, and they describe what they're seeing, but you can't see the doctor on the other side, or the nurse. We monitor all of the biometrics that are monitored in the critical care unit. We have access to electronic health records. And we staff it 24/7 with board-certified critical care specialists, nurses and support staff.

Today, we have nearly 250 beds in adult ICUs across our organization. From day one, there was a lot of interest among our pediatricians to do this with NICU and Peds ICU. The reality is there isn't enough of a market for anybody to develop the software to do this. And 10 years later, to the best of my knowledge, there's no product. About a year ago, we began to do outreach, and we served 58 beds in the state of Delaware. And I'll talk about how we're planning to expand.

This is a look at the current workstation. There are eight screens—I think we started with four screens. And the physicians kept asking for more. But you can see, on the far right, those are the waveforms for an individual patient on the monitors. To the left, on the lower, is x-rays. We have access to all of the digital images. Above that, and it doesn't show very well, is kind of the blackboard in the ICU, each one of the patients. And there's color coding, red, green, and yellow, in terms of the status of the patient, and if there are any alerts that need to be addressed with that. Another screen, with access to electronic medical record, the workflow for the ICU team. And then in the upper left, that's the video picture, the bedside. And if you look carefully, you can have an image of a patient there with that.

As I said, we have real-time rules and alerts. We do daily multi-disciplinary rounds with the tele-ICU team, been able to augment our bedside care. And it gives us access to a comparative database with 38 other health systems, over 400 ICUs, and over half a million patient experiences per year, which has really driven a lot of improvement and is leading to multiple peer reviewed publications.

Our ICU outcomes have continued to improve. And we're in the top quartile now in all of these, and have seen a dramatic reduction in things like ventilator days in overall hospital and ICU mortality index.

About a year and a half ago, Christiana Care in Wilmington, Delaware reached out to us and said they were having difficulty staffing on nights and weekends and holidays. And they had been a long time user of eICU. We began to provide coverage for them last May. And, interestingly, over the last couple months, with all the bad weather events on the East Coast, on an emergent basis, we've been asked to connect, not just on nights and weekends, when they had difficulty getting critical care physicians into their units.

Where are we going? We are in the process of connecting with a rural hospital, about three hours west of Chicago, in Sterling, Illinois, who has eight beds. Just this week, we've been approached by a hospital in Macomb, Illinois, about three and a half hours south of Chicago. And then, in the metro area, Silver Cross Hospital, is going to connect with us, with 28 beds. And Christiana is going to expand to their additional beds. We're also being approached by hospitals in other states, who are recognizing that you need critical mass to make this work financially. There's no additional reimbursement. It's really an opportunity to improve care and, ultimately, to reduce costs. But it requires significant capital with that.

Some of the barriers, it took a year to go live with Christiana, because we had to license, approximately 40 critical care physicians in Delaware. And even with a lot of

cooperation, it's a lot of paperwork, hassle, and expense. And as I think about going to another state, I'm guessing we're going to push our physicians to the limits of their willingness. Just within our system, when we have 10 separate medical staffs, and day one, we had to figure out how to credential the eICU physicians. And we came up with a nice method, that if you have critical care privileges at one of our hospitals, and you want to work in the eICU, it's just a formality that they all granted reciprocity. You didn't have to pay medical staff dues. You didn't have to appear in front of the credentials committee. But 10 years ago, that took a lot of work and behind the scenes arm-twisting to get that to happen.

You've heard about most of these other telehealth opportunities. We are going to deploy telepsychiatry. As a large ACO, we have a growing need for behavioral health. And while we have a fair access to it, we really need a 24/7, in particular, in the emergency departments. And our thinking is that we're going to have 24/7 behavioral health teams, in two or three of our hubs, and provide access via telehealth to all of our other sites. It can have a huge impact in greatly unclogging our emergency departments. It's not unusual for patients to be stuck two and three days waiting for an inpatient bed or a transfer. And many times, they don't get started on their treatment, because the emergency physician isn't comfortable using anti-psychotics, where with telehealth, we will be able to do that.

In our marketplace, one of our competitors is affiliated with Mayo Clinic and advertises constantly that they offer consults with Mayo. And I've seen the exam room and the equipment. You can auscultate the heart. You can look at images. You can do all kinds of things, except for touching, with it.

So to draw to a conclusion, we've seen improved outcomes. There's better service. And one of the ways there's service at 2 o'clock in the morning, when a distraught family member of an ICU patient wants to talk to a doctor, we can do that

remotely. Because we don't have physicians on staff in the middle of the night, unless they're there to do procedures. It makes our physicians more effective. They can sleep and be rested. They only have to come in to do procedures at night. It creates efficiencies. We think it's made us a better system, which drives competition in our marketplace.

And the one thing I'm confident of, that technology is going to continue to evolve faster than any of us can imagine or the regulations will keep up, but it will support more innovation. So I look forward to Nancy's comments and the questions for the panel.

KAREN GOLDMAN: Thank you very much, Dr. Sacks.

[APPLAUSE]

Our last panelist will be Dr. Nancy Gagliano.

NANCY GAGLIANO: OK, Everybody stretch. Come on, we're getting to the home stretch here. So, hopefully -- there we go.

So I'm Nancy Gagliano. I am the chief medical officer at MinuteClinic. I've been with MinuteClinic for four years now. I'm a primary care provider by training. I spent 21 years at Massachusetts General Hospital, before I came to MinuteClinic.

It was awesome to see that so many of you have had an experience with retail health. That's great. Let me give you a little bit of the background, and a little bit of the flavor of what goes on behind the scenes to make this organization work. So we have -- our model is very, very lean, very, very cost effective. We're focused on access, low cost, and the highest quality possible. We employ over 2,500 nurse practitioners across the country, which means lots of different state regulations to follow. We've seen to date over 19 million patients, since it started. We see now about four million patients a year, walk in, seven days a week, evenings and weekends. About 83% of the patients who

come to us use their insurance. So 17% don't have insurance or are coming for a service that's not covered by their insurance.

And I can tell you, for a fact, there's a significant primary care shortage out there. Half of the patients who come to us at MinuteClinic report that they don't have a PCP. And we are very, very committed to helping them find a PCP. Anybody who comes to a MinuteClinic, reports that they don't have a PCP, automatically, gets a list of local primary care providers, within about a 10 mile radius. In Chicago, we have a number of Advocate physicians on our list that we share with our patients.

MinuteClinic, we have 825 clinics already. We're growing at an enormous rate, over 150 clinics a year. We aim to be over 1,500 clinics within about three to four years. So that's 60% percent of the United States will be within 10 miles of a MinuteClinic. That's when you can really start thinking about what an organization can do to impact population health broadly.

So we are absolutely committed to high quality access and affordability. We are a physician-led company, but all of our practitioners report to nurse practitioner managers, and nurse practitioner state managers, and a chief nurse practitioner organization. So I think we're a very good model about how the two can work together very, very effectively. Part of the core -- because our practitioners work individually, they work in isolation -- so part of the core is to really focus on high quality, safe medicine.

We don't want to be doing things that our practitioners are not skilled to, or out of scope of what's appropriate in that setting. So we define exactly what we're going to take care of. We have guidelines for the care of that, and we embed those guidelines into an electronic medical record. So if you go to New Jersey, and you have a sore throat, you will be asked exactly the same questions, be taken care of exactly in the same way, as if you go to California. And the records are available throughout, and we

share our records with primary care providers. So that if you have a PCP, your PCP is sent your record at the end of the visit.

Physician collaboration is very important to us. So I think when retail health got started, there was much more of a mentality of a niche, come in, sore throat, we're done. Now we have a very different philosophy about really partnering in the community and being part of the medical home. So we take our physician collaborations very seriously.

One of the things that we have learned over the years is to really support our nurse practitioners. So in every state we're in, I have to follow a different regulation. Some states are absurd, with they require that a physician can only collaborate with two NPs. Some, it's broad-based. Some of them, the physician has to stop by once a week, and I don't know, make sure the nurse is still standing. I don't know what they're looking for. Sometimes, the nurse has to spend -- we have one state that's 500 hours of exposure to the physician before they're allowed to practice. The state regulations are very, very varied. We have to follow them wherever, but we're committed to the highest possible quality of care. So whatever this state regulation imposes, we impose what we think really, really demonstrates and supports the highest quality care.

So number one, there's a physician who's available as back-up all the time. Number two, our physicians and our nurse practitioners get on the phone together once a month. They talk about a case. They go over clinical education. They develop a clinical rapport, as opposed to an artificial rapport that a state regulation might impose. We also have a chart review system. We actually have a double chart review system I have a team of nurse practitioners who does chart review 10% of every single record is reviewed. That allows us to look for national trends. And then those records are passed on to the collaborating physician. So that physician can then get to know the strengths and weaknesses of their own nurse practitioners. It allows us to get down to the

individual, but also look nationally. And then we work very closely with ACOs in the primary care medical home. And I'll go into that in a little bit more detail.

Patient visit. Most of you have been through one, which is great. But, in essence, the patient comes in. It's a one provider model, register in a kiosk. The nurse practitioner does the entire service. We are firmly committed to point-of-care testing. And this is something that hasn't been talked about, but there are actually certain insurance companies that don't pay for point-of-care testing. Point-of-care testing allows me to see somebody who has diabetes, do an A1C right then and there, and tell them how they're doing. Or somebody who has to go over their lipid panel, if they're on medication. So point-of-care testing allows you to do the full visit and really provide the highest quality care, while the patient is in with you. With the patient's consent, we send the record back to the PCP, and the patient receives a copy of their record, right when they leave. The notes are finished. And any of you who have been involved in clinical medicine are aware that many times notes are written a day later and are not quite as complete. We call our patients back at 48 to 72 hours, if they're very ill, to make sure that they followed up, and are doing better, and that we do have 24 hour coverage.

Here's our scope. This is it. Written on one page, lots of minor illness, acute illness. We do some preventive services, lots of vaccinations. We are not trying to interrupt the relationship with the primary care provider. We have a guideline for every one of these services. If you come in to see somebody, and you have a headache, sorry, we don't do headaches. So we're very careful about staying within our [INAUDIBLE].

I said we are growing very rapidly. The other point that's important is 50% of the patients who come to see us come to us evenings and weekends. So what is that telling you? That people just don't have access when they need it. And, you know, yeah, I support the primary care medical home completely. But if you've got a sore throat, or if you have high blood pressure, and you're an hourly employed person, and to take off

from work costs you money to get your blood pressure checked. And your doc says to you, well why don't you stop by MinuteClinic afterwards, because I know they'll send me your record. And if your blood pressure is good, you stopped. You didn't have to lose your wage. If it's not good, we'll get you to the PCP. So you can start visioning how we are trying to provide access, expand the scope of care into the community.

Ateev went over this slide, so I'm not going to, about comparing cost and quality, among a variety of different locations.

The other thing that's very unusual, how many of you have ever walked into a doctor's office and seen their price schedule?

[LAUGHTER]

Oh, there's somebody back there. Right. MinuteClinic you go in, it's on the website, it's on the board. So we have one price, that's the price you charge. For people who have high deductibles or who are not insured, knowing about what it is going to cost is really important to them. But we also take Medicaid. Medicare, any other insurance.

And once again, as I said, we follow the guidelines. It's very, very important to us. You will be astounded. Guess what our number one complaint is from our patients? I didn't get an antibiotic. What do you mean? I'm going to CVS. I'm going to MinuteClinic. They're going to give me a Z-Pak. Of course, they're going to give me a Z-Pak. We follow the guidelines. And the guidelines say, don't give antibiotics for bronchitis. The guidelines say, only give penicillin -- penicillin, the cheapest antibiotic -- for strep and only when the culture is positive, or the rapid strep is positive.

So we can provide very high quality care that's affordable. We are Joint Commission certified, fully accredited by Joint Commission. Our patient satisfaction is off the roof. If you've ever been to a MinuteClinic, the nurse typically spends 22 minutes

with each patient, which is dramatically longer than in a PCP office. And we are involved in a number of other organizations around patient satisfaction and patient care.

Now, the other thing that I started to allude to is support of the primary care medical home and supporting ACOs in the medical community. So it's really important to us to develop partnerships within each city that we're in, so that we have a partner. Often, they provide our collaborating physicians. Often, we work with them on joint clinical programs. But this is a way for us to really become integrated in the community. And we integrate our electronic medical records, so that when a patient is seen at MinuteClinic, we can look and see what patients' medications are, what allergies they have, as well as send the record of the visit right to the provider into their electronic medical record. So we have right now 32 affiliations across the country. Hello? There we go.

So let me give you a sense of how that worked. This is going on today. Patient comes in, gives permission, signs in. This is the Cleveland Clinic medical record that we can see. The provider notices the patient also has high blood pressure, is there for a sore throat, takes their blood pressure, documents them, gives them feedback on the blood pressure, as well as takes care of the sore throat. And then it goes back into the Cleveland Clinic record.

And last, but not least, I'll tell you about what we're doing in telehealth. So I'm really thrilled that we're an innovation on top of an innovation. One of the challenges is for us to open a MinuteClinic in a location, we have to have enough volume to support the cost of the nurse practitioner. That's basic common sense in any business. You have to have enough volume. And, definitely, in some of the more rural locations, there's not going to be enough volume. So what we started to think about, well, if we can deploy telemedicine to support, and to do what we call load leveling, we can go into more different locations.

So in our model, what we have -- and this is a primary care telemedicine model. Much of telemedicine today is specialty based. This is primary care, with an LPN supporting the advanced nurse practitioner. The patient comes in to a MinuteClinic, and if offered the opportunity to have their visit by telemedicine. A licensed vocational nurse will bring the patient into the exam room, do their vital signs, can do a rapid strep, can do a urine dip, can actually do a flu shot, hooks them up with the nurse practitioner, who is in the same state. And yes, we did start in California, because the regulations allowed us to. The nurse practitioner can talk to the patient, see the patient, and with the peripheral devices, can look in the ear, can look in the throat, can listen to the heart, and listen to the lungs. And what's beautiful about this -- and you can almost see it in the little corner, but not so well -- the patient gets to see their own eardrum, and their throat, and listen to their heart and lungs, the same.

So we've seen close to 2000 patients now, and we just started last fall. With that, you'll see our patient satisfaction scores. So the vast majority of the patients said this was as good. But what really thrilled me was the percentage that said it was better than a regular visit, because now they had two providers supporting them, and they got to actually see their throat and their ears. So we're very excited about this. It's really, really important to us to have the regulations broadened, so that nurse practitioners can do telemedicine, as well as we can do this across a variety of different states.

So I covered a number of the issues. The key thing that I want to point out is two of the scope issues that we haven't dug into very, very deeply. One is ratios. Across the country, there are very different ratios on collaboration between physicians and nurse practitioners. We have learned, actually, that the more nurse practitioners per physician, the better the relationship. Physicians who are only allowed to have one or two nurse practitioners, don't spend time with them, don't support them very well. It's when they're invested, and they have a number of nurse practitioners, that they do the best job. And then, there are also some restrictions around -- or requirements to go on

site. And as far as I'm concerned, going on site for an hour a week, I am not sure how that really enhances health care. Thank you very much.

[APPLAUSE]

ROBERT CANTERMAN: Thank you for the very informative presentations from our panel. And at this time, we like to invite Lisa Robin to come join the panel for our discussion.

KAREN GOLDMAN: Thank you. Before we get into specific questions, I just want to thank all of the panelists. And I would like to give the panelists a chance to respond to anything that they've heard from other panelists. Do we have anybody who would like to react to other presentations? Well, perhaps not.

ATEEV MEHROTRA: I might make a couple of quick points there. One of the things that I think is really important as we come back to competition and the goal -- the role here of the Federal Trade Commission, I think Lisa's role and the stuff that we talked about licensure is really critical. And we talked a lot about scope of practice. But I think it might be helpful just to review that when we think about what is limiting telehealth and other innovations in delivery, a lot of it goes outside of the state legislatures and is other barriers.

And so, let me give you a couple of examples that I think might be helpful just to put on the radar screen, as we talk about barriers here. One is the health plans themselves. And we talked a little bit about this before our panel today, that really serve often as de facto regulators in states. I was given the example that the nurse-managed health centers told me that the scope of practice laws really weren't their barrier. But the fact that the health plan wouldn't allow them to be listed as a provider was the real limitation and why they couldn't grow. You also see things related to that about health plans putting into regulation -- you know into the reimbursement policy, and also a problem with Medicare reimbursement policy, of having a fixed payment reduction for a

nurse practitioner, compared to a doctor's visit of 85%. And a third barrier that I think is really important that often doesn't get discussed, and I think is a preview of our conversation later today, is the electronic health record. So Nancy talked a lot about these integrations at the Cleveland Clinic and MinuteClinic. And that's great, but what I hear and see, and I'll be truthful of one of the health systems that I did, was really using the electronic health record as a mechanism to deter competition, not working with a MinuteClinic in the community or other competitors, because they don't want to open up the electronic health record, because they know keeping everything in the electronic health record is a mechanism by which they can keep patients within their own systems. And so, it's as simple as not putting the resources into trying to do interoperability. So I think those are three barriers to competition that often don't come up in a conversation about these innovations, but I think are maybe just as critical as scope of practice laws.

KAREN GOLDMAN: Well, I really appreciate those comments. That's really very important for our research and education into competition issues. Thank you.

MARGARET LAWS: And Karen, one thing that I just wanted to mention that I meant to talk about during my presentation and didn't was that you can use -- just go back to the case of direct dermatology. The scenario I gave where the patient is in with a primary care provider and they're contacting together the specialist remotely is one scenario. The other scenario, which is legal and is happening, is the patient going directly to the specialist online. And so, I think as we have our discussion today and think about regulation across the states, that is another scenario that we're seeing a lot of. And I think as we think about the ubiquity of mobile and consumerism in health care, having consumers who want to and are starting to go directly via secure web-based platforms, we hope, generally speaking, to providers, whether they be mental health providers, or dermatologists, or other specialists is going to be growing. And we want to think about and talk about that as well.

KAREN GOLDMAN: Thank you for those comments. I do appreciate that. And I think the reference to mobile is especially important, as we move forward in this area. OK. So we've heard about various issues that can create barriers and affect competition, and certainly state licensure has come up a number of times today. We heard that, in Virginia, it would simply be prohibitive to get licensure for 800 physicians in other states, and Dr. Sacks also brought up that issue in regard to the ICU system.

So this morning, as many of you probably know, there was a discussion of the FSMB's draft Interstate Medical Licensure Compact, which could provide for expedited state licensure for physicians who are licensed in one state and meet certain criteria. This is one model that has come forward as a way to address this barrier of the need for multiple licenses. But it still would require licenses in other states, although that they would be expedited, and there still would be the payment of fees for these licenses. So I'd like to ask the Innovations panelists to give their reactions to the proposed compact. Do you think that it would fully address the licensure barrier in telehealth? And perhaps consider how it might compare to other regulatory options, such as the Nurse Licensure Compact, which is a different compact model, in that once a nurse is licensed in one compact state, he or she can automatically practice in the other states and doesn't need to be relicensed.

And then there are also other models that have been proposed that would not require a license in the other states. For example, the one in HR 3077, which would allow physicians who are serving Medicare patients to practice telehealth across state lines, in service of those Medicare beneficiaries. So I wonder if any of you have any reactions and would like to consider these different models.

LEE SACKS: I'll jump in. It's a step in the right direction. But I don't think it's going to solve the problem. One, it being voluntary, not all the state regulators are going to see eye to eye. Certainly, my state tends to be very conservative on a lot of these things.

But, also, the fee. I mean, for our tele-ICU, many of these physicians work two or three shifts a month. And if suddenly you have to be licensed in five and 10 states at $800, $1,000, it's either going to add more cost, or it is just going to be a barrier that you won't overcome.

We're using technology to do multidisciplinary grand rounds across all of our campuses for oncology patients. It doesn't take much to think that we would want to do that in conjunction with M.D. Anderson, or Sloan Kettering, or somewhere else. Is that going to require a state license? Because ultimately, it could impact the care of a patient. I suspect that's going on today, and it's under the radar screen, because in many cases, the patients aren't there. But the next generation of multidisciplinary rounds are with patients and family right in the room. We need to continue to be flexible. This is a global economy. We're just talking about crossing state barriers. What about crossing international barriers?

KAREN GOLDMAN: In regard to international barriers, perhaps Dr. Rheuban would have something to say about the relative ease of providing care internationally, as compared to across state lines.

KAREN RHEUBAN: Our experience is actually that it has been simpler. Again, there are different regulations, certainly, in international health. You know, the FSMB's proposal is a step in the right direction. But it's not all that portable. It still requires a fair amount of work. And I see it remaining a significant barrier to our model of care delivery, certainly. It's just going to be prohibitive to have every on-call person licensed in every state, if we chose to have a collaboration with other providers and other states. And so that's why we have not. It's just prohibitive for us right now.

And I think the nurse -- we heard mention of that -- the nurse compact is reciprocity-based and not portability-based. And again, it is a step in the right direction -- I understand state boards of medicine need to be able to protect the public. And that's

first and foremost in their minds. And I just wonder if there is some way in this electronic age that we can do this better to try to advance at these types of applications.

KAREN GOLDMAN: Perhaps Lisa would like to respond to some of these comments.

LISA ROBIN: Well, certainly. And I appreciate and understand the comments. I think that we certainly recognize that we are facing all of these challenges. And this is what we are trying to accomplish with the compact. I think it is early in the process. As we said, there are a number of other barriers besides the licensure issue. I think as you look at different harmonization of requirements to the state and looking at best practices, and as I said, perhaps there's certainly a need for more research, as we mentioned earlier, some areas that we can look at and look at the patient outcomes. However, with that being said, the role of the medical boards is critical to the consumer.

You mentioned 3077. If you have a vulnerable population that may not have the choice, if there is an adverse outcome, what is their remedy? It is their responsibility to figure out where that person is licensed, what their qualifications are, how would they even go about filing a complaint, if it's in another jurisdiction. So I think that we have to be very thoughtful, before we make a public policy decision, without sufficient evidence to know that it's safe. And that you have a system, even though there may be a very small number of professionals that aren't doing the right thing. They can do a lot of harm.

And so what we saw that, you talked earlier about states with face to face requirements. Well, the reason those requirements are there are primarily because we had a system that allowed all of these rogue internet pharmacies to come forward. And they were providing controlled substances and all sorts of prescription drugs, just on an online questionnaire, were too --

KAREN GOLDMAN: I think we will get into some of that in a follow-up question. But I did want to follow up to this question, and I'm certainly open to other comments on the Interstate Medical Licensure Compact. To ask, I think this morning we heard that in some professions, such as physical therapy, the requirements for licensure have been changing. But I wonder in regard to physicians, is it pretty uniform throughout the states?

LISA ROBIN: I think that medicine does have a lot of commonality among licensing requirements. Physicians take the same medical licensing examinations. The medical schools for domestic and Canadian schools are accredited by a body that everyone is familiar with the standards. There are some variances that each individual state believes are important for their state. But that's why I think that one of the biggest differences is the number of years of postgraduate training. And so, under the compact, everyone would have to have three years of postgraduate training, which now almost everyone has.

We envision working with stakeholders to make this system very interoperable, using technology solutions. So that it would be a very, very expeditious process. And there would be fees. We certainly envision that those fees would not be what it would currently, the administrative cost, to go state by state to license, as well as it being almost automatic. So we believe that it has a lot of support from the states, and that unlike you mentioned with the nursing compact that is -- we are hopeful that states are really going to embrace this concept. We have had overall positive response.

KAREN GOLDMAN: And do any of the other panelists have anything more to add to the debate about the Interstate Medical Licensure Compact? OK.

Then let's move on, and I want to discuss briefly the model telemedicine policy that again Lisa presented this morning. And in regard to that, we heard about the range of types of telehealth services. And I wanted to point out that in that policy, there's a

definition that would exclude audio only telephone conversations, email, instant messaging conversation, or fax, from the definition of telemedicine. And it also specifies that treatment, including issuing a prescription, based solely on an online questionnaire, does not constitute an acceptable standard of care. Of course, these provisions could affect state and federal laws regarding reimbursement and other things. So I wondered if I could get some of the panelists' reaction to these features of the model policy. Nancy.

NANCY GAGLIANO: And so I want to applaud the work that went behind this effort, because the document has covered so many issues that had been on our minds, as well as issues that hadn't been on our minds. And I think you guys did a really terrific job. I think this is going to be a very, very tricky area.

I'm going to share my personal views, in that I very much applaud the concept that telehealth is trying to define a health care interaction that is equitable, that is pretty much the same, as if the person was there live. As a physician, I know every physician on this table has taken a call on a Saturday from a patient that we know very well, and has said, you know what, I'm going to call in an antibiotic. But that's different than having a web service, and if you answer the questions correctly, or maybe you don't answer them right the first time. But then you go back, and your temperature is a little higher, and your sputum is a little bit more green, you get your antibiotic. And I know the online systems actually have ways to prevent the same patient requesting multiple times. But I do think that it is an area that we want to be careful to make some definitions around what is quality telemedicine to support.

What we all want is to have adequate reimbursement for the work. Our telemedicine visit actually costs us more than a regular visit. So we really need to make sure that the compensation covers the cost, but we can demonstrate that the quality is really there.

ATEEV MEHROTRA: Maybe if I could just make a couple of quick points. So the concern could be that care that is provided over an online questionnaire alone, telephone-based care, messaging back and forth. I have some concerns about that, because while I can understand why that might make intuitive sense -- again, I'm a researcher -- but where's the empiric evidence that the quality of care is inferior provided by those models. Some of the work that we have done to date, I think, while I did document one case where primary care providers did have a slightly higher antibiotic rate, while many of our other quality outcomes were equal, using some of these telephone-based care, as well online, questionnaires. And then I also would highlight that if we look at this landscape of innovations and delivery, these, the ones we just highlighted are by far the most popular. So for example, online questionnaires and people receiving care with that, it is very low technology. It is very low cost. You could see really increase in popularity. And as I've documented, Kaiser, as well as a number of these companies that are just providing phone-based care. Because as Margaret documented, almost every one of us has a phone sitting in our pocket right now. It's a really low-cost technology, and people are using it, as opposed to some of the internet-based ones that, while we think many of us in this room can use, a large fraction of our population are intimidated by.

So I guess I would come back to, while I can understand the logic behind some of those limitations in defining telehealth, I think your concern is right on, that it could be anticompetitive. And I think that unless there's compelling information, or data, empirical studies, that document that these kinds of provision of health is harming patients, then I'm not sure that kind of definitional restriction has merit.

KAREN RHEUBAN: So I'll be the traditionalist in this again. And just to say, I don't want to see us dumbing down health care. And so I think, "the devil is in the details," in terms of how we define it. You know, is it an online survey to somebody that that patient has never had any experience with, that provider doesn't have access to the

patient's medical record, doesn't communicate back. So there are so many details. The system you described in Pittsburgh that you published on it was in the construct of that health care system. So access, potentially, to the patient's record was available. But in other models, that might not be the case. And I don't want, you know, I hesitate a little bit. And maybe it does, certainly it does needs to be studied to define what we're talking about, in terms of online health care.

ATEEV MEHROTRA: I don't have a problem defining it differently or calling a separate category. I think my concern would be is that without evidence that it's harming patients, then what we're doing is we're just doing the same thing old thing of creating regulatory barriers.

Nancy's describing a lot of restrictions on foolish regulations, in terms of having a doctor sitting in the car going to [INAUDIBLE] Clinic saying, hello, see you, and then going to the next one. Yet then, if we create this definitional barrier, we've just cut out a relatively popular kind of care provision. And I guess my own concern would be, again, anticompetitive. I think the logic is there. If there was compelling evidence that it is harmful, then of course it should be regulated. But I think we need that evidence first.

MARGARET LAWS: And I do think there's timely access from Kaiser, to the safety net programs in California, to the Teladoc example that Ateev has studied. I think we've demonstrated that it can dramatically improve the timeliness of access. And so I agree that it needs to be considered within the context of a system. But I do think that there's a compelling enough access imperative, given what we're trying to do in the health care system right now, that I would side with Ateev, that it shouldn't be thrown out without evidence that it is harming people.

LEE SACKS: Yeah, I'd second that. You know, look at it from the patient's perspective, and especially patients who don't have a relationship. Might not it be better to have a structured interaction with a questionnaire that might triage them or

get them early treatment, than to wait until it's a crisis, and they're in the emergency department, and they're needing resources that could've been avoided, with that. So I think Nancy eloquently illustrated the discipline that the MinuteClinics have. And it doesn't bother me at all to say that there's much less variation in care there than with our physicians on the same types of visits. And that's good for patients.

ATEEV MEHROTRA: I might make one teeny, last point on this, which is that in the system that we were studying some of these electronic visits, eVisits, where there was a structured questionnaire, there was at least a good number of physicians in the room who felt that was higher quality care than the video. And the reason was is that doctors, we do things, and unlike MinuteClinic, we rush through visits. We don't ask -- oh, shoot, I should've asked that question. And the structured questionnaires, with their branching logic, I felt provided a more systematic evaluation of the patient than a face-to-face encounter, in many cases, and in terms of making sure that we've asked the right questions. So I just wanted to add that point, that we have to think that it could actually, in some cases, be more systematic and provide higher quality care.

KAREN RHEUBAN: And in a structured environment, I fully support the concept. My fear is no relationship prior at all, no information available to the provider.

ATEEV MEHROTRA: So then that would argue that MinuteClinic, also, because often they don't have a relationship with the provider. So are we going to create an environment where that relationship is critical? And I think we have to be pretty concerned about that, because that means only patients who have a relationship with a primary care provider can also access these kind of systems. So, I mean, I hear your point. But I just wanted to at least provide the counterargument.

KAREN GOLDMAN: And, Lisa, did you want to --

ATEEV MEHROTRA: Sorry, Karen.

KAREN GOLDMAN: No, this has been a fascinating discussion. And I just wanted to ask if Lisa wanted to say anything.

LISA ROBIN: I would. I would like to just clarify. The purpose of this policy is really pretty narrow. And it is certainly not intended, and it was purposely not intended, because everyone recognizes what boards don't want to do is regulate a physician having a phone conversation with patients, and those type of activities, and that is really why. And if you notice, it says, generally, this is not telemedicine.

And you see states around the country putting in rules and trying to address what is currently happening, and to try to bring some consistency. And it also says based solely on an online questionnaire. That would mean that there's no authentication that the patient is who they say they are, that these systems are not in place. So what it is trying to do is make sure that these services, where there is no structure, that that's clearly outside the boundaries of the standard of care. And it really would be no different if you are in the same office. Would you treat a patient just by having them fill out something in your waiting room, and then never see them and write a prescription for it? I think it really is parity of standards. And that relationship could certainly be established. It doesn't need to be face-to-face. If I go into MinuteClinic, I am asking for those services, and you are agreeing to provide those services. So therefore, there is a relationship.

So I think that maybe this work group is not finished with their work. They also recognize that there's a huge area that needs to be addressed. And that is for those specialty consultations, where in looking at these, maybe it is not just direct to consumer, that there needs to be some consistency. So I think this is a work in progress.

KAREN GOLDMAN: Well, thank you. This has been a fascinating discussion. And I think it relates to this morning's idea that we should be looking for the least restrictive

regulations that promote safety, but also allow access. And with that, Rob will handle the next question.

ROBERT CANTERMAN: I wanted to follow up on some comments that were made in a number of the presentations, regarding the effect of using telehealth on health care costs. I think there was a comment that in some cases, using telehealth might increase usage of health care services, which could increase costs. We also heard that, in some instances, by using telehealth, you can greatly reduce costs, by saving unnecessary, in-person visits with physicians. Do any of the panelists have any comments on that?

KAREN RHEUBAN: Well, we've certainly tracked the transportation costs avoided, which are very significant, significant for patients, for their families, time away from work, as well as state programs that actually pay for transportation. So that's a huge cost savings, correctional or the Medicaid programs. Care at a local level tends to be less expensive than at some of the academic centers, not necessarily entirely true. But if you get to keep a patient in a community hospital setting, that tends to be lower cost care than in a larger academic medical center, where you might be transported to. So I think there are some savings. And then there are workforce issues. Because we know the challenges of -- if we keep patients local, it tends to keep the hospitals functional. It tends to keep people employed in the community. So there's a lot of different costs that need to be considered, when you consider telemedicine.

MARGARET LAWS: I think there are a couple of cost examples that I think of, and one I talked about in this case, Direct Dermatology. We had been doing telehealth consults for dermatology with the UC system, which is a wonderful place, and we do a lot of work with them. But it's not a low cost provider. And they weren't able to do it at a low cost. Organizations, or companies, or initiatives, that are developed, like MinuteClinic, like Direct Dermatology, to be affordable, to be low cost, and to be low overhead can, theoretically, I think, and in practice deliver a lower cost service.

So I think there's a piece -- it's not inherently lower cost. It's a model that doesn't require the footprint, the infrastructure, or the office overhead that an in-person model requires. And so even within the UC a lot of the programs we talk to, are trying to think about how to develop telehealth components that don't carry the same high overhead that their in-person components do.

And I guess that the second one, I would say is to give the example of Propeller Health. What we're tracking there is the use of remote monitoring, as has been tracked with heart disease, as has been tracked in many other instances of keeping people out of the emergency department and out of inpatient visits. So I think those are a couple of places where you can track the impact of using a telehealth technology on lowering costs of care in the bricks and mortar system.

KAREN GOLDMAN: Thank you for those observations. We really need to switch onto retail clinics. And I want to do one last telehealth question, before we switch to retail clinics. And I just want a couple of quick answers. And that would be on the question of should there be parity for reimbursement costs of telehealth and in-person services? Any thoughts from panelists on that?

KAREN RHEUBAN: I think, yes. The way our infrastructure and the way the Commonwealth of Virginia has structured the reimbursement process is that we never make telehealth more expensive than a face-to-face visit. So we build the professional component, not the technical component. The originating site builds the equivalent of a technical component. So it never would cost more, but it at least, in the end, results in approximately the same. For us, face-to-face telemedicine is as time consuming as a face-to-face visit in the office.

KAREN GOLDMAN: Thank you.

ATEEV MEHROTRA: I would rather the market decide what the price should be, as opposed to having some sort of fixed regulation, that the price should be there. And I

might go back to that Kaiser example, where I talked about how the number of what they've called virtual visits has skyrocketed. But the number of in-person visits hasn't dropped the same amount. And the only reason I make that point is this is not a one-to-one replacement. Often, these visits are going to be used more frequently. So we have to be careful in these technologies. And I shouldn't say this is limited to telehealth. We have this across the health care system, where you have things like cardiac catheterization, or automatic, implantable, cardiac defibrillators, where in some populations, it helps a lot. But the concern, and the reason it is driving health care spending is it's used for patient circumstances where it's unnecessary and, therefore, is driving health care spending up. And I think, it would be naive to think that telehealth is not going to have the same problem, because we're having the same problem throughout our health care system. So we need to be careful.

And then fixing a reimbursement strategy, which is exactly equivalent, I think could be very problematic. And the last point I might make is, I told you about the story of many people advocating that these innovations in delivery are going to decrease health care spending and improve value in our health care system. If we fix the reimbursement right, similar to face-to-face, it isn't going to address that problem. I'd rather they were lower cost, so that they could actually try to reduce health care spending.

LEE SACKS: You know, when you're framing that question, you're really in the old fee-for-service paradigm. And if we don't think about the global costs -- I mean the reason Kaiser invested in that is because they're responsible for a population, and they see a value proposition. So sometimes it could actually increase unit costs, but it's going to save money on a global basis. And right now, it's the unit costs that are for the barriers.

KAREN RHEUBAN: But if I might just add, even with the ACO regulations, in non-rural patients, we can't use it.

ATEEV MEHROTRA: And that's foolish.

KAREN RHEUBAN: So, thank you.

KAREN GOLDMAN: OK, now we will move on to retail clinics.

ROBERT CANTERMAN: There is one question I want to make sure we have time to ask. And this actually involves an issue that relates to retail clinics. But it involves pharmacists and retail chains and what types of services pharmacists can provide. One of the public comments we received notes that community based pharmacists, such as the ones who work at CVS, and other chains, may be able to play a significant role in increasing access to health care services. The comment, for example, notes that pharmacists in some states are authorized to provide immunizations, conduct various health and wellness screenings, and conduct smoking cessation programs. I guess this is a question first for Dr. Gagliano. Are these other areas of innovation that CVS, and other similar chains, might be interested in pursuing? And what issues do these raise?

NANCY GAGLIANO: Thank you for that question. And obviously, I'm not in the pharmacy branch of CVS, so can't answer it maybe as thoroughly as you would like. However, I think as we think about two aspects of health care, one being competition that might prevent good health care, as well as being in a country that's challenged with enormous health care spend, without being able to demonstrate that we've done a great job on population health, I think we have to look at our resources broadly. And that the pharmacist is a very highly trained individual, who is in the community. They all have their doctorates, and they are in the community.

We are aware of the fact that, at CVS, a typical patient with diabetes is in our CVS about six times a month, where the typical diabetic will see their doctor about once a quarter. So there's enormous opportunity for us to leverage new types of health care

providers in different ways, to really promote wonderful health care throughout the country.

And we haven't gotten into any of the regulations. I believe, from my CVS colleagues, that we could spend a whole day talking about regulations in the pharmaceutical industry, such as a pharmacist is not considered even a provider. But they certainly are trained and skilled enough to really enhance the health care of our communities.

LEE SACKS: We certainly are using pharmacists in roles, similar to what's been outlined in the question. And if they can do it within Advocate Health Care, why shouldn't they do it in other settings? We've had a pharmacist run an anticoagulation clinic, going back to the early '90s, with better outcomes, fewer complications than any of the physicians, pharmacists running diabetes clinics with that. My father was a community-based pharmacist. He would be smiling right now, but he objected to the fact that they added years to pharmacy school, and it was the equivalent of a doctorate. But they're well trained, and we need to use them to the top of their license.

KAREN GOLDMAN: Thank you. One question. I noticed in one of Dr. Gagliano's slides that showed the range of services, there were a number of offerings related to care of chronic conditions. And this is an area in which, I believe, retail clinics have expanded into rather recently. And we are aware that some states have posed regulations related to these, and some professional organizations have raised concern about that. I'm wondering how you have responded to that, and whether you think those regulations and policies have been a barrier to your expansion, in this area.

NANCY GAGLIANO: Thank you for the question. I certainly am concerned about the regulations. Once again, this morning, I think the group did an excellent job highlighting that we have very well-trained people, who have the intellectual training to

be able to do terrific jobs taking care of patients, and regulations are saying, no, you can't.

The issue around chronic care in the United States is that it is at an epidemic proportion. We have an epidemic of diabetes, and obesity, and hypertension. And to have an artificial concept that a nurse practitioner can take care of a sore throat, but can't talk to somebody about their blood pressure, doesn't make much sense. We noticed about three years ago that, as statistics show, 33% of all adults coming to a MinuteClinic with a sore throat have an elevated blood pressure. And this is a phenomenal chance to tell them that, the 50% of them that don't even have a PCP, they should get a PCP.

So I do think that there's no reason why retail health can't be an arm of the delivery system. It does reinforce the concept that we have, that we view ourselves as an extension of the primary care medical home. So we always want a patient to have a primary care provider. But as my case earlier, why can't a patient be started on a medicine, and then have the retail clinic close to home, after work, check their blood pressure, or check their sugar, or provide additional education on diabetes? So I think in a collaborative fashion, providing access to care that's affordable in the community, together we can only do a better job. And having artificial regulations that prohibit it just really don't make sense to me.

KAREN GOLDMAN: Thank you. Any other reactions to the provision of chronic care at retail clinics?

I'd like to ask one other question. There's the possibility, of course, that the existence of numerous retail clinics in urban areas would affect the availability of care at nearby urgent care centers or emergency departments, possibly affecting wait times or freeing up emergency department physicians for the more complex cases. I wonder if there's any data or information suggesting that that is or isn't the case.

NANCY GAGLIANO: So I don't know if Ateev has some more specific data. What we do know is that when we have asked patients who have come to a MinuteClinic, if we didn't exist, what would you do? About 20%, and it somewhat depends on whether you're a kid or an adult, a certain percentage said, well, I would wait for four or five days to see my PCP. Or I would go to an urgent care. But a good third of them said they would go to an emergency room. So we do have some very hard data that patients would have turned to an emergency room. And we also know about 15% of patients who are in emergency rooms could certainly be taken care of at a retail health location, and probably closer to 30 percent, if you add in urgent care together. So there is some good evidence that the ability in the access of these types of situations does help offload patients who probably shouldn't be using the resources of an emergency room.

ATEEV MEHROTRA: I might make just a broader point about this, is that I hear a lot of physicians' concerns about retail clinics. What I don't think I hear there is, with the passage of the Affordable Care Act, we have a huge demand for care, primary care. And we also have in many cases, a shortage of -- we are having problems with access in emergency departments, another really valuable resource, in terms of, if you think about it, as a societal resource, primary care time and ED time are very valuable resources. And yet, we argue that if we could -- and it's a question of, I don't have any empirical information that it happens. But if we shifted 10% to 20% to 30% of those visits outside to these other care providers, then we've suddenly increased their access to all these patients out there, that the doctors who are caring for their patients don't see, but are out there, need care. So we're wasting a significant valuable societal resource on care they could be provided elsewhere. And I think that's something we don't talk a lot about, at least when I talk to physicians about these new care options, retail clinics, but many of the other options we've discussed today.

KAREN GOLDMAN: Thank you. Well, unfortunately, our time is up. We have quite a few questions here from the audience that I apologize we just won't be able to get to.

But we will keep them in mind as we continue our process of educating ourselves in these areas. I want to thank the panelists very much for their very stimulating presentations and this very insightful discussion that we've had. So now we will have a 15 minute break. And then we'll be reconvene afterwards for Advancements in Health Care Technology.

[SHORT BREAK]

PRESENTATIONS: ADVANCEMENTS IN HEALTHCARE TECHNOLOGY

PRESENTATION #1: INDUSTRY OVERVIEW

- **Micky Tripathi, PhD, President & Chief Executive Officer, Massachusetts eHealth Collaborative**

DANIEL GILMAN: Let's get started so we're not too far off schedule. Glad to see still a mostly full room. We anticipated a little falloff between meaningful discussion stage one and meaningful discussion stage three. But we've got most of you here still. And I think that's maybe some testament, not just to your own fortitude, but to the excellence of the panel coming up.

So we've heard a lot in the two panels today already about health information technology. We heard about health information technology in the professional regulation panel. We heard about it, certainly, in the innovations panel where there was talk both about the role of HIT in retail clinics and their like and certainly about the role of HIT in telemedicine or telehealth applications.

So now we're going to get to the big core system or platform issues in HIT. These, I think, will be relevant tomorrow, too, where we talk about attempts to assess health care costs and make prices transparent, attempts to assess health care quality and make quality information transparent. Certainly HIT plays a role there. Now, we're going to talk about the big systems at the center of this, electronic health records, EHR, EMR systems. And we're going to talk also about health information exchange and the flow of health care information.

We've got an excellent panel coming. But first, before we do the panel discussion, I think we've got two extremely helpful presentations. And I want to just say, briefly, background things. As we introduce our panelists, we're not going to read their bios at you. Those bios are available online.

Some of you will miss Leigh Burchell. She was slated to be a panelist here and, at the very last minute, could not do it. And we're sorry about that. But we have two people from the vendor space, and their bios will be up on online for you to see. Many of you will know who they are, in any case.

We'll just introduce people by name, title, and affiliation, let you read the bios. Then, we'll have a moderated discussion by myself and by my colleague, Danica Noble. She's a competition attorney in our Northwest regional office.

I suppose I should do the disclaimer since I'm talking. Anything I say today is just me. It doesn't necessarily express the views of the Federal Trade Commission or any of its individual commissioners. Any questions I might ask today, I suppose, are my own, do not reflect the curiosity of the Federal Trade Commission or any of its individual commissioners.

But without further ado, we'll get to the people who actually know something. And the first of these is Micky Tripathi. Micky is president and CEO of the Massachusetts eHealth Collaborative. And we're very glad to have him here to do a framing presentation. Thank you.

MICKY TRIPATHI: Great, thank you. Thanks for the opportunity to speak to all of you today. I only have 15 minutes, so I don't even have time for a joke. So I'm going to just jump right in.

So what we're going to talk about is just to help frame the conversation here. And I have the arduous task of trying to describe something that was true at the time that I made the presentation. And it's so dynamic that it may not be true right now. That's how fast this space is moving.

We've heard throughout the day about health care delivery and health care models are changing. Not surprisingly, the technology is changing as well. And it's moving just as fast if not faster than the business models are.

So I'll try to develop a framework that we can use to launch the panel discussion. First, try to give some insights. Got 15 minutes, so I can't describe everything. I can't describe every aspect, but tried to boil it down to a set of insights that give you a good sort of floor and a good level set on what's going on in the health IT industry and also things that might be of particular relevance to the question of competition. The views expressed are my own and not the FTC's and all the other reservations that we had.

So I'm going to break it up into three areas. One is a brief history of HIT, market drivers of HIT and HIE, and then, finally, recent changes and trends. And I'm staring at the clock. And Dan's going to keep me honest on that as well.

So why are we in this -- and I'm going to move this over so that I can see the presentation as well. So first off, health care technology itself, it's not health insurance exchange. It's not healthcare.gov. Let's just make that clear. I'm not saying that for any reason. I just wanted to say it. But you know, while health care, especially American health care, whenever I talk to people, and certainly friends, family, and others, there's always this thing of, what do you mean health care doesn't have technology? Health care's got unbelievable technology. But up until the last, let's say, five to seven years, has been limited to diagnostic and treatment types of technologies. In the area of information technology, American health care was way, way, way behind.

So first off, let's get some definitions, at least for the purposes of this. When I refer to health information technology, and I think this is fairly common in the industry, when you refer to health information technology you're talking about electronic health records or other clinician-facing applications that help with treatment, decision support, diagnostics, documentation, order entry. And it's mostly electronic health records that people are referring to. But increasingly, there are other types of technologies.

Health information exchange refers to the technologies that allow those distinct instances to talk to each other. So just to set those definitions here. We could argue about the definitions. But just so you know, that's how I'm thinking about it.

Up until five years ago, the health care system had notably under-invested in electronic health records and health information exchange compared both to other sectors in the US economy -- and you could go to Home Depot and Walmart and do a whole bunch of stuff there that you couldn't do in your physician's office let alone the hospital, and I think everyone's had that experience -- but also compared to other industrialized countries. And there are tons of charts. Commonwealth Fund, every year, does another shaming set of statistics on how we compare to other industrialized peers. Although, as you'll see, I'm not going to show the other industrialized peers, but we've made a tremendous amount of progress based on the Meaningful Use Program over the last few years.

What was the driver of that? Why did we have that severe under-investment in these technologies that every other organization in the country was seeing that they needed to make the investment in? First, misaligned economic incentives created the classic, for those of you who remember your economics, public goods problem, where there is something that is rational from a societal perspective for individual actors to invest in but no individual actor feels it is in their interest to make that investment.

We'll talk about that in a second. But that was true around the board. Every part of the health care delivery transaction had that phenomenon. No actor saw it in their interest to invest in those technologies that all of us, collectively, would have benefited from.

The second is that those who needed to make the investment, providers and payers namely, couldn't keep enough of the return to create that positive ROI. That's a part of that public goods issue, that I could make the investment but everyone else

benefits. The other piece of this that is important, and it's related to the public goods problem, is that you have something that's unique, I think, in health care as opposed to almost every other economic sector of the economy, which is fragmentation on the supply and the demand side of the transaction.

So when I think about providers being on the supply side where they're supplying the health care, incredibly fragmented, as we know. Now, that's changing over time. As we know, there's a lot more consolidation of particular primary care, ambulatory, primary care getting gobbled up hospital systems. But it's still very, very fragmented.

I looked at it a couple of years ago, and the only part of the economy that was that more fragmented than ambulatory health care was flower delivery, was florists. And as we know, I could pull out my phone right now and order roses in San Francisco and have them delivered in two minutes. I can't do anything like that, even now, with health care.

So you've got fragmented -- but then you have fragmentation on the demand side as well as you think about, first off, patients but also payers, even health plans. There are a lot of health plans that we know are very large, Aetna, United Health. They're big nationally, small in almost every market. So you have that same phenomenon of incredible fragmentation.

So unlike other industries where you had concentration on the supply side, you think about retail department stores where -- what did Target and Walmart do for the industry? Came in, used technology as a strategic lever and reshaped the industry. And airlines, banks, you start to think about all those other places, there was either concentration on the demand side or concentration on the supply side, which allowed a market actor to come in and standardize a whole bunch of stuff. Very difficult in health care to the accomplish that. That was another impediment to moving forward.

So if we're going to do this a little bit in pictures, one of things that we saw -- and I'm going to use the pointer over on this side here. I guess I could use it here. Maybe that's a little bit easier. Not to tear this apart too much, but you have, on the demand side, patients who, obviously, are getting their health care purchased for them through a payer facilitator, in this case. And then you have providers who are actually purchasing the vendor systems, the EHR systems.

And in the past, before as short as five to seven years ago, you had the phenomenon first off, as I was describing, providers who were being expected to pay for the HR systems, but all of the benefits, or a lot of the benefits, were flowing back to payers and patients. You start to think of the things, the benefits, that an electronic health record system can provide.

Oh, it keeps you on formulary better. Does the physician benefit from that? No, that's a benefit to patients and to payers. Oh, it will reduce redundant labs. Well, again, the physician isn't making money on that. Not that the physician doesn't want to do right, but, again, everyone's got to make a living and the economic incentives weren't lining up there. So you had that phenomenon. They were expected to bear most of the cost but not getting the benefits.

They also had limited ability to recoup the benefits if they made the investment on their own. So unlike other industries, banks invest in ATMs, they're able to amortize that cost across all of their customers. Providers aren't able to do that. They're not able to just up their prices. The payers pay them what they pay them.

So, you know, they didn't have any pricing power. And quality and service weren't really a real differentiator in the market. It's not like my investing in the EHR was going to, all of a sudden, give me an influx of lots of new patients. And indeed, it could have the opposite in the short-term when you think about all of the turmoil that that creates. So that was certainly a problem.

Payers had little ability to measure quality, so they didn't want to get into it at all, and no ability to prevent the free-riding of other payers. So that's a huge phenomenon in almost every market. So what do I mean by that? If I'm Aetna, and I would actually love my provider network to have electronic health records, I could give them a subsidy to do that. But I couldn't prevent Cigna and United Healthcare, and every other one of my competitors from benefiting. I couldn't tell the provider, only use this for your Aetna patients. You're not allowed to use the EHR for the others. So obviously, that creates a real dynamic of under-investment.

And then, finally, patients were shielded from all of this. And we know that. There are lots of health economics that talks about that.

So where are we now? And it's not all fixed. I don't mean to suggest that all of this is fixed, but a lot of different dynamics.

First off, who's the biggest gorilla in town that could try to break this stalemate? Medicare and Medicaid. So CMS comes in and starts to share some of the cost of the EHR deployment with its providers. If you think about that as a supply chain phenomenon, it's not any different than what Walmart, and Toyota, and Target do every day. If they can't get their supply chain to do something, they will often say, tell you what, we'll pay you 20%. How about 30%? How about 40%? I would rather get 70% of the loaf than no loaf at all. And in the same way, Medicare and Medicaid are saying, I can't get you to do it on your own. I will actually share the cost with you.

Value-based purchasing gave providers a bigger stake in it. Now, they could benefit from it. From a quality perspective, they actually had some upside. They can get some upside revenue from the plans for making that investment.

CMS and ONC certification, now doing something directly with the vendors, set a floor on capability. So you have the payers now step in, in this case the biggest payer, stepping in and saying something about the way that they would like those vendor

systems to work. And then as we know, with coinsurance and copay and the increase in that, patients are getting much more sensitized to price as well as just googling and asking physicians questions about all sorts of things. From a physician's perspective, it's very difficult to be able to respond well without having an electronic health record system -- to question about what's the difference between the generic versus the brand name drug, for example, and all the other things that go along with that.

So a very different market dynamic now, which I would argue, has really led to health IT and HIE beginning to take off. So this is data just showing -- this is government data -- on EHR adoption, and I know it's a little bit hard to see, but over the last 10 years moving from a situation where we had -- oh, my God, five minutes remaining. And I've got about 20 minutes left and slides. We had literally single digits in EHR penetration to a point now where we're well over 50%. In the use of self-reported, we're above 75%. In terms of validated of what's a basic EHR system, we're at 50%. I don't think any other sector of the economy has gone through that kind of change. There are a lot of drivers for that, both on the demand side and the supply side. Meaningful use stage one has been an enormous success in getting that kind of penetration. Now, what you're seeing is a lot of tension in what is the appropriate role of government. In some ways it's been a victim of its own success in starting to jump start the market. And now a lot of market forces are taking over. So there's a real question about how directive should meaningful use stage two and stage three be when the market seems to be taking up a lot of this on its own.

So where are we on the EHR vendor market? I'm going to start going through a little bit more quickly here. Prior to meaningful use, EHR use was largely the domain of hospital systems and large practices. And there was little to no industry pressure to standardize or to adopt, as I've described.

ONC certification sets a floor on capabilities, where now people had some sense of what they're buying. And the EHR vendor market, actually, you started to see after meaningful use stage one. Normally, in an industry, when you impose standards you think you're going to get fewer suppliers. But, what happened was there was a huge injection of dollars and limited capacity of the existing vendors to meet all of that demand. So you had a huge uptick, actually, in the number of vendors. That's starting to rationalize now, as we look at what's happening with stage two attestations.

This just a gives you a little bit of a perspective on what are the market shares for EHR vendors through the lens of what systems are providers using to certify to attest to meaningful use. And what you can see on the inpatient side, on both sides, is roughly 50% to 60% of all attestations are accounted for by four vendors in each of those. But the tail is huge. For the 2011 edition meaningful use stage one certification, there were 370 certified systems on the inpatient side and almost 2,000 on the ambulatory side. Those are certified complete EHRs, which is a very large number. I think we'd all agree. That number is lower right now for stage two, which is partly a rationalization phenomenon, I would think. But there's also still a window where people can be attesting. But I think we're all expecting that there will be a smaller number of EHR vendors going forward, but still a pretty vibrant market, as you can see.

Let's talk about interoperability for a second. There's been much more success to date in what I would call vertical interoperability than there has been in horizontal interoperability. What I mean by vertical interoperability is within a value chain. If you think about a health care transaction, the things that need to happen, in particular, if I want to be able to have e-prescribing, lab integration, radiology system integration, connection with my Midmark system or what other office devices I have, that has been a lot of steady progress there. So for any particular EHR system, that kind of vertical interoperability is pretty much standard. Yes, there are certain things that don't talk to

other things at times. But for the most part, it's pretty standard to have a full complement of those things implemented in your system.

Horizontal interoperability has been more of a challenge, in part, because you're now talking about competitors inter-operating with each other.

In prescribing, it's actually been a runaway success, owing to the creation of what one might think of as a monopoly. I know we're in the FTC, so I'm not going to call it a monopoly. I'll put quotes around it. But it is a "monopoly." The large bricks and mortar and mail-order pharmacies got together, created a single network, and created all the benefits that that kind of standardization can give as well, which is a unified nationwide network for electronic prescribing. And electronic prescribing is almost a routine thing now.

So the lab market, not the same. The national vendors, the large commercial labs like Qwest and LabCorp are only 20% to 25% of the market. The vast majority of it happens in hospital systems. So it's still very fragmented. We've got a lot of fragmentation there.

The most difficult to achieve has been EHRs communicating with each other, I would argue, partly, because of a lack of user demand. Five years ago, I don't think there was any vendor who had a physician say to them, the first thing I want you to do is make sure my system talks with the other systems across town and that I develop good quality measures to send to all the health plans. There was no physician who ever said that. It was make sure that I can continue, basically, dictating into this system, that you can form it to my workflow, because my workflow is different than every other workflow in the country. And I need to get out the door at a reasonable time. It may take more than 30 seconds, maybe one or two minutes. You can keep flashing them.

So where are we? HIE is maturing. Interoperability is maturing from what I would call HIE 1.0, which was sort of a concept coming out of, for those of you who remember

in 2004-2005 when the national coordinator's office was first created, there were lots of great pictures of the nationwide -- it was called the National Health Information network then. And it would be sort of a rational network, state-level networks feeding up into that, maybe regional networks feeding up into that. Most of that never happened. There were some places it did happen, Rhode Island, Indiana, HealthBridge in Cincinnati, Vital in Vermont. Certain places where it happened, they were able to create a construct of a health information exchange, which is what a lot of lay-people's understanding of health information exchange is, as we call it, the noun. It's an organization. It's a repository. Everyone dump your data into a hackable database, and then we match it all up. I'm only kidding. But the idea was put it all in a database, you could normalize it. You'd then get the one patient, one record. There are a lot of benefit to that. And the idea of, send it to one place one time and then use it for multiple purposes, for care, care continuity, help with disparities, population health, public health.

I mean, from a rational perspective, it makes all the sense in the world. Unfortunately, in the market, it was pretty much an abysmal failure. So now where are we? We're sort of in the HIE 2.0 world where we focus more on the verb. Health information exchange is a verb. And it's multi-layered. It's demand driven. Lots of people wanting to do this, I would argue now, from the bottom up, which is a good thing. People actually want to do this. Much more tactically focused, led by a wide variety of organizations, some of them state-level kinds of organizations, collaboratives, but more and more of the private HIE phenomenon, which is accountable care organizations and others who are doing it to serve that immediate business need.

If we think about this as a set of discreet functions then, what we have is, in that HIE 1.0 kind of world. There are certainly organizations that are out there succeeding with this. But it's a rarefied few and they don't seem to be growing, at least in that original construct of it being a broad collaboration, perhaps statewide, perhaps regional,

bringing together a whole bunch of data and then being able to do thing in it. What we're seeing more in the HIE 2.0 world is a layering of direct messaging that was started with meaningful use stage two that has the benefit of living in the world today of the current consent paradigm. The current legal structure that, basically, it's like faxing, except one level higher technologically, so that it can be incorporated into workflows. And you don't have to create a whole new legal rubric in order to allow this kind of thing. It is provider-centric which makes it easier as well. And it was certified and approved for meaningful use stage two, which is a big phenomenon. That means the providers are required to do it at some level. And the EHR systems have to be capable of some kind of technical capability to do it.

Query and retrieve is now starting to grow as a market phenomenon not yet a part of meaningful use requirements. So there's a little bit of now where the market is getting out ahead of where meaningful use is. So we'll see where that goes. But it's certainly growing and developing. You've got the CommonWell. You've got a number of other activities that are doing that.

And then, finally, what I would think of as record aggregation and data normalization, which is being able to bring that data together in a repository type of architecture where I can do all the things that we wanted to do in HIE 1.0 as well as serve the needs of accountable care. And it's accountable care that seems to be driving a lot of that with privately HIEs.

So where we see this kind of market segmentation is you've got IDNs and private HIEs really being in the domain of this kind of aggregation across systems, across legal entities for that kind of broader business purpose. Vendor-driven networks right now, like CommonWell, like Surescripts trying to do this, like the Massachusetts Highway, the HIE in Massachusetts, the New Hampshire HIE focused on being able to do direct messaging and query and retrieve. All 2014 certified systems have to be able to do

direct. There's a market ecosystem that needs to get created around that in order to make it work.

So on the direct standard, there are just a few issues to think about here. One is that the standard is out there. It's basically secure email. The market ecosystem, we just had some listening sessions with the market as part of the information exchange work group, the market ecosystem hasn't yet developed for that. So it's not like everyone can do it and everyone's doing it out of the box. But I was talking to Dr. DeSalvo before this. I just go back to thinking about when email first came about, and we had the same sorts of issues. You have one email, people don't really realize all the things you can do with it. Now, it's mature. That's kind of where we are with direct. What we heard in the listening sessions for the FACA was that the technology seems to work. But people have to get their workflows and their heads around how they're going to do it and incorporate it.

There are organizations like DirectTrust and others that are trying to fix this problem of two networks talking to each other. So if I'm on eClinicalWorks and someone else is on Allscripts, we're on different networks. So how do I get those networks to talk to each other? There's no natural way for that to happen. DirectTrust and other organizations are collaborative efforts to try to do that. You do have this interesting competitive thing where there are some DirectTrust participants who are refusing to exchange with networks who aren't DirectTrust members. You see that as being facilitating, because it starts to converge. On the other hand, you could see it as anti-competitive depending on how you look at that. So all the regular things we see out in the market are happening here as well.

I think I just have two more slides. On the query and retrieve, we have vendor-driven networks that are starting to drive this within a single vendor, eClinicalWorks, Epic, within their own systems, can do that. They, right now, again, my personal opinion,

are the only two vendors who have high enough penetration that it's valuable to me in almost every market in the US to just be on the Epic network, let's say, or just be on eClinicalWorks network, because there are so many other providers in my neighborhood who are. There are not all the providers. It doesn't solve all my problems. But it can get me some way down the road of where I want to be.

And then you have the CommonWell, for example, is a cross vendor. Athenahealth is on that. A number of others are trying to do this across vendors. When you look at the overlap of Epic, and ECW, and CommonWell, you could think of it as Return of the Jedi and The Empire Strikes Back. So it just depends on its market phenomenon. And the market is really taking over there. Then you have some collaborative or state-led HIEs like in Massachusetts or New Hampshire where they're trying to do this as well.

So let me just jump to an illustrative example. This is my last slide. So what does this mean? If you are a provider sitting in any state, let's say you're in Massachusetts, what does this mean for Health Information Exchange? How do you think about this? What are the choices available to you? How do we think about competition, both the EHRs and HIEs?

These dots represent a smattering of -- an illustrative example of -- these are EHR systems. Lets just say they're standalone EHR systems, either a hospital or an ambulatory provider. And then you have the private HIEs that are growing and trying to draw the lines around accountable care or however that gets defined and connecting up those disparate HIEs as they exist. And each of these pipes, actually, that I drew represents a real private HIE in Massachusetts. And Massachusetts is not alone. Every state has these blossoming up. And these are a provider organization, accountable care. They're forming this because they need to solve real risk problems, because they're starting to share risk.

Well, then you have the statewide HIE, the Mass highway, that comes in and tries to say, well, we're going to set a direct floor on this so that at least each silo can talk to each other. We're not going to try to break apart the silos. We're not going to pretend to do what those silos do. But it would be great if each of the silos could at least talk to each other for a patient who goes from one to the other. No silo thinks that anyone leaks from their system. So you have that phenomenon. But this says that we'll create that floor.

Well, but then you have eClinicalWorks, if I'm eClinicalWorks, I can talk to every other eClinicalWorks user outside of any of those other networks. So those are the blues. They're all connected up. Well, if I'm on Epic, I can talk to all the other Epic users. But I can't talk to anyone else. If I'm on CommonWell, I can talk to all the CommonWell users. But right now, it's still hard to figure out how I talk to the others.

So you actually have a bewildering array of choices sometimes depending on which vendor you're on and where you are in the market, which is a very frustrating and confusing thing in a time of transition. On the other hand, it suggests that there's a lot of opportunity there for growth and that there are many, many options there available that need to mature more than anything else -- so highly, very dynamic market. My personal opinion is that interoperability is flourishing, flourishing from the bottom up. It's an industry in transition. Meaningful use is a huge driver. And there are real -- the competitive issues are more about the models for Health Information Exchange, not just the products and services alone. Thank you.

PRESENTATION #2: THE IMPORTANCE OF COMPETITION TO FEDERAL HEALTH IT PROGRAMS

- **Karen B. DeSalvo, MD, MPH, MSc, National Coordinator for Health Information Technology**

DANIEL GILMAN: Thanks, Micky. So our next presentation is from Karen DeSalvo, who is not just in the Office of the National Coordinator for Health Information

Technology, she is the National Coordinator for Health Information Technology. So I turn it over.

KAREN DESALVO: Thank you so much, Dan. It is sort of an awkward title, isn't it? It's like being called the CDC of the CDC or something.

Good afternoon, I'm going to try to give the Twitter version to get us a little caught up. Micky, thank you very much for your thoughts and comments. I wish I could stay for the entire panel. But I'm unable to.

Let me just do a little grounding and talk a little bit about how at the ONC we're seeing some of this issue about how the market is doing and what we think the needs are moving into the next decade. Don't worry, I don't have slides, so you have to look at me.

Micky said that about 10 years ago there was the desire to create a National Coordinator for the Office of Health Information Technology. A place that would set a federal strategy around health information for our country and be the interface for the community to develop a national consensus agenda around how we would move forward in a part of our economy that, as Dr. Stack says, is 1/5 of our economy, which means that we must do a better job, frankly, of managing the information for that really important part of our country. We have done an enormous amount of work, if you just mark it from the past decade. And much of that is not just through building consensus agenda and through market-driven technology and advancement, but through stimulus investment from the HITECH funds that came out about five years ago in 2009.

To date about $24 billion have been invested into the infrastructure of our country to see that we could drive adoption of electronic health records, to see that we could help providers and communities adapt practices and workflows to see if they could work across competitive lines, to improve population health, to see if they could change the way care was delivered, save lives, lower costs, and then really change the

way that we are able to address health overall through delivery experimentation. It also was an opportunity for us try ways of exchanging health information to see if, at the community level, we could think through business models and regulatory environments that would allow the free exchange of health information where patients go, all across the care continuum, and not just in that one box where they happen to show up that very day.

There are some other really important investments as part of ARRA. And they include creating an infrastructure on the ground, sometimes called the ground game by our folks in the regional extension center community, that not only helps us push out information about how to adopt and adapt to technology, but importantly brings information back into the policy arm and the thinking arm of the government so that federal actions are not happening in isolation and creates this nice feedback loop that allows us to really understand what it feels like on the ground with the decisions that we make in this regulatory environment in Washington. We also invested in developing some workforce to see that people would know how to use the technology.

That $24 billion, by the way, does not include the Medicaid investments that are going on now and will continue into 2021 and are about $16 billion dollars. So there was, to this point of the market, a lot of market influence by investment. And there was also, I think you would agree if you looked at the data, and you've seen some of it here, but if you compare us to other countries, there was a rapid uptake of electronic health records that were certified standard so that we could capture information in a way that it could not just be useful inside of that electronic health record but shared between systems as patients moved from one hospital to another or across state lines.

That success also, though, meant that we had some growing pains, as Micky said. But also, if you compare it to parts of the market that we're not incentivized in a similar way, you see that we still have some pretty important gaps in the capture of good

health information. That includes non-eligible providers we call them, so behavioral health, long-term post-acute care, just two examples.

There are many more in the care continuum where, frankly, some of the sickest of the sick of our community are receiving services. And we're not yet able to capture information in a standardized way. And I point that out here at this FTC commission conversation just to say that there are times, even in the recent memory, where it's clear that the proper incentives can help drive adoption of a technology. But we have to be thoughtful, still, that it's not going to just be a market-based solution. And I think you can see that in what's happening, for example, in post-acute care, that there is still some thinking that we need to do about how we're going to help advance the capture of standardized information for patients in nursing home, patients in rehab, patients in behavioral health systems.

The effort to expand to that notion of care just being captured properly and free it, to share it across the continuum, is something that folks have been noodling on, working on, and demonstrating that it can work. And I think Massachusetts is a great example, like many other places, Oklahoma, Indiana, Michigan, Ohio, Kentucky where we are aspirational models of not just a good capture of information but also the sharing of it. And they're putting it to good use.

So the meaningful use of that data beyond just the patient care arena, but thinking about how it informs population, health, and research and, importantly, patient engagement, are all the things that we would like to see happen in an idealized world so the information is not just being hoarded and held, if you will, for information at the point of care when the patient arrives or if it's just being pushed to the other site. But we want to, as he even describes, be able to really have a more longitudinal record and ability to look for patient information, to query for it, and also to share it in a bidirectional fashion.

So I think our challenge ahead then, as we look to the next decade, is to think about how, first, ONC is an informed regulator, that we're listening to the community, that we're understanding what's the right business and regulatory environment to continue this trajectory of better standardized capture of health information, using electronic health records, not just in the places that they are being used now but expanding that across the care continuum, make certain that there is openness to that so that we're able to freely share that information in a secure way and a private way so that it can be put to the use of the patient's care and their health at the time they need it most, whether that's to save their life or for their self-management from their very home.

So we look forward to working with the FTC and the private sector. Because this is not purely a government solution. I think we all know that. We do have a federal strategy that we engage in. And by the way, we're just launching into our new federal HIT strategic plan, which is due to be refreshed. That's the chance for the VA, and DOD, and HHS as users of health care, as deliverers of health care and purchasers of health care to think about what matters to us from the standpoint of health information technology. But also, use that as a platform to build consensus with the private sector so that we can develop a national consensus agenda about where we want to go to see that we're doing a much better job of capturing care across the continuum, freeing it in a private, secure way, and putting it to meaningful use. And with that, I will stop. Thank you all very much.

PANEL: ADVANCEMENTS IN HEALTHCARE TECHNOLOGY

Moderators:

- **Daniel J. Gilman, Attorney Advisor, Office of Policy Planning, Federal Trade Commission**
- **Danica Noble, Attorney, Northwest Regional Office, Federal Trade Commission**

Panelists:

- **Janet Campbell, Software Developer, Epic Systems**
- **Curtis L. Cole, MD, FACP, Chief Information Officer & Associate Professor of Clinical Medicine and Public Health, Weill Cornell Medical College**
- **Jodi G. Daniel, JD, MPH, Director, Office of Policy & Planning, Office of the National Coordinator for Health Information Technology**
- **Dan Haley, Vice President of Government and Regulatory Affairs, athenahealth**
- **Farzad Mostashari, MD, Visiting Fellow, Engelberg Center for Health Care Reform, The Brookings Institution**
- **Steven J. Stack, MD, Immediate Past Chair, Board of Trustees, American Medical Association**
- **Micky Tripathi, PhD, President & Chief Executive Officer, Massachusetts eHealth Collaborative**

DANICA NOBLE: All right, well, now we're to the panel section. Thanks, everyone, for coming and for staying for this panel. I'm excited.

So let me just give a brief introduction to the panelists who are going to be up here. This is going to be kind of round table. I am absolutely committed to taking a question or more from the audience. So get your comment cards ready, because we are going to do this.

But maybe you want to hear this first -- I'll introduce everyone. And then they'll give us two or three top points that they want to get across. It's going to take a few minutes. So we'll get this started.

On my left is Janet Campbell. She is the senior software architect at Epic. And beside her is Doctor Curtis Cole. He is the chief information officer and an Associate Professor of Clinical Medicine and Public Policy at Weill Cornell Medical College. Then

we have Jodi Daniel. She's the director of the office of policy and planning in the office of the National Director for Health Information Technology. And then beside her, we have Dan Haley. Dan Haley is the vice president of government and regulatory affairs at Athenahealth. And then we have Farzad Mostashari. He is a fellow at the Engelberg Center for Healthcare Reform at the Brookings Institute. He was the former National Coordinator for Health Information Technology. And then, finally, Doctor Steven Stack, and he is the immediate past chair of the American Medical Association. And he also served on the health information technology advisory group from 2007 to 2013 at the AMA.

Janet, let's start with you.

JANET CAMPBELL: Great. Actually, the very first thing I should do, because we are at the FTC, I want to correct a misperception about the 1.15 million documents that we exchange per month with systems. About one in five are with non-Epic systems, including the eClinicalWorks. It used to be one in three. But then we keep adding more Epic organizations, so it skews the numbers. Anyway, I just wanted to be sure that I mentioned that.

Thinking back on this and thinking about the history, I think -- I've only been in this business not that long, about 10 years. But it has probably been some of the most tumultuous 10 years we've seen there. And certainly the process of creating, developing, implementing an electronic health record has absolutely changed.

Back when I first started, organizations were buying EHRs, as Micky pointed out, because of an organizational commitment to change the way that they practiced medicine. They looked at the way they wanted to change and they saw that an electronic health record could support them in that. And so you had very strong organizational buy-in.

Also, as well, as we looked at futures we would create as EHR developers, that was a conversation that happened between us and our users. And certainly the emergence of more regulations in that field has definitely changed that conversation. It's changed the motivators for buying. And it's changed the market as well.

It's something certainly that concerns us. We've spoken a lot about anti-competitive things today. And we saw those 2,000 ambulatory complete EHRs out there for the first level of regulations, compliant with the 2011 criteria. I think there are probably 200 maybe now, if that. So an order of magnitude that we've dropped there.

And so that's something that's certainly concerning to us as we look forward in the market as well, making sure that the regulation is there to make sure that systems can communicate effectively to help advance care. But, that the regulations are not so onerous that it knocks good vendors out of the market, because that leaves organizations with fewer choices.

CURTIS COLE: So just a couple of points that I wanted to make sure to get across. One is that electronic health records are supposed to be about patients. They're supposed to be about care. I'm a physician. I went into this field because that's what I wanted them to be and to do. But fundamentally, electronic medical records today are still primarily revenue cycle systems. They are primarily about the capture of information in order to bill and collect for what we do. In fact, this afternoon's conversation about telehealth was largely about how we define telehealth for the purposes of reimbursement. And when regulation is viewed in that context, it's a self-sustaining thing. So often times the way that regulations are measured, your compliance is through a claims transaction. And so that just reinforces the EMR as a revenue cycle system. And I think that's a bad thing and would love to see it change. But I do think the way that American health care works, that's where we're at right now.

Another point is that, whether by intent or accident, the net aggregation of regulatory forces lead to the bigger-is-better phenomenon. We have bigger health care systems. We have bigger insurance companies. We have bigger EMR vendors. And it's not necessarily that that's bad. In fact, in many ways, I think it's good. But, I don't think it's conscious. And I think that's a problem.

There is data about all the small EMRs that still exist and things like that. And I'm not blaming this on any one particular regulation, but when you have meaningful use one, meaningful use two, ICB 10, and ACOs, then all of these things, HIPAA, one after another after another, you have to have very deep pockets to be able to respond to those. And that means it's the big providers, the big vendors, the big payers who succeed.

Conversely, speaking as a CIO, enterprise class software is kind of a dinosaur. And whether you're talking about ERPs, or whether you're talking about EMRs, the computer scientists are moving away from that model. And yet in health care, we're running towards it. And that gives me a little pause.

One of the things that did happen with meaningful use is that we essentially wiped out all the homegrown systems. So my hospital had one. My practice -- I think the EMR that I use today, MedNet, is a much better system. The one that I used 10 years ago was 100 times easier to use. And a lot of that stuff, usability stuff in particular, was lost when we lost that flexibility.

And then last, in a completely different direction, I would encourage a different kind of thinking about certification. I think certifications are often done at too big a level. And we could do a lot of good by focusing on certification at the transactional level. One of the fantasies that we all have about lowering health care costs is that we all want to lower administrative costs, because that doesn't take away from care. And we spend huge amounts of money on very, very complex transaction sets that need to

be standardized. And I'm all in favor of the standardization efforts that are happening. But we don't -- today. If we had a certification body that was just a web service where I could send a transaction and it told me it passes or it fails, and if it passes the payer has to take it, that would really be a big benefit to me as a provider. And it would be a lot cheaper for me than having to worry about certification systems and full end-to-end -- it's a true end-to-end test, because it's at the most granular level.

JODI DANIEL: Thank you. Good afternoon, everyone. I've been at ONC since the first of the four national coordinators. So I've seen a lot of the changes from a policy perspective in the health IT market. So Karen's already spoken to you. So I'm going to be brief and just underscore a couple of points.

From our perspective, the goals of market competition and health IT are mutually reinforcing. So if you have a truly interoperable health IT infrastructure, that can enhance competition by allowing data to flow more freely in the health care market. It can help competition in the health care market.

On the other side, competition is really central to our health IT goals. And we want to enable folks to be able to, if you have a competitive market for the technology itself, you're going to end up having better systems. Folks can vote with their feet and switch systems more easily. In fact, if there's better product on the market you're going to have more innovation and technological progress.

From ONC's current perspective, the key challenge we're really focused on right now is making sure the information follows the patient, focusing on interoperability, and exchange of health information. So in thinking about that, we're both looking at how can we promote innovation and competition to support the exchange of electronic health information. Things like standards and certification, making sure we're promoting trust and confidence through privacy, security, and safety, as well as things like

exploring how open standards and architectures can lower entry and switching costs and looking at governance for health information exchange.

We're also paying attention to where there may be some market failures that may inhibit the free flow of electronic health information. So looking at things like pricing structure, we've heard some folks, some stakeholders, giving us some feedback about some pricing for Health Information Exchange that maybe limiting the free flow of information, any kind of practices that may lead to lock-in of information or siloing of that information, as well as transparency with respect to the products, the usability of the products, the services, et cetera.

So we are both interested in thinking about how ONC can help promote innovation and competition as well as support a competitive market. We're looking at our own authorities. We're interested in how we can work with other federal partners and very excited that the Federal Trade Commission is actually looking at this issue to look at how other agencies' authorities might work collaboratively with ours to achieve comparable goals. And we're really looking forward to this discussion to working with the FTC, and others, as well as outside stakeholders to try to make sure we have a really good market for health IT and that health IT can help support competition in the health care market.

DAN HALEY: So I just arrived this afternoon. I'm a last minute addition to this panel. And as I walked in, a gentleman at the tail end of the prior panel made reference to the use of technology, EHRs, to create closed data networks and, essentially, trap providers and patients into proprietary networks. I almost just turned around and walked back out, got in a cab, went back to Reagan and flew back to Logan, because that was the point that I was bringing to my opening remarks here.

At Athenahealth, we call this phenomenon creating biospheres. I know Doctor Mostashari frequently refers to walled gardens. Micky talked about vertical integration,

sometimes called silos. These are all different descriptions of the same basic phenomenon that everyone acknowledges is happening, but we just sort of keep rolling the policy train along without addressing it, and that is the creation of effective data silos using information technology that is intended, supposedly, to do exactly the opposite.

As a policy guy, what bothers me most about this is the extent to which federal policy that is intended to do exactly the opposite, that is, intended to create information fluidity in health care information sharing, has the unintended consequence in too many cases of actually perpetuating this phenomenon. When the government comes with a check and subsidizes the purchase of a system that deliberately does not inter-operate, does not communicate with other vendors, the government is effectively perpetuating and supporting that phenomena. When the government comes and says, we will issue blanket antitrust scrutiny waivers for entities that create ACOs, and we will put on the blinders as those entities purchase and implement closed system technologies in an effort to make their networks "sticky" and consolidate market share, government is perpetuating this problem.

Micky referenced CommonWell, which is an effort that Athenahealth is involved with, as a small, but we think growing, and inevitably growing group of health IT vendors are actually dedicated and build their business models around inter-operation, around building a national backbone for the exchange of health information. But there are an awful lot of legacy software vendors out there whose business model is still deliberately built around creating those closed systems. And they're serving a market. They're serving a market demand. And I would never -- I'm very much a free market guy working for a free market company and would never say that the government should come in and say you cannot serve a valid market demand. I would say, if the overriding policy goal is health information exchange and information fluidity nationally, then the government shouldn't be subsidizing those systems. And if the goal is sharing

information across networks and between networks, then the government shouldn't be turning a blind eye for years to deliberate data lock and market consolidation that comes from it.

FARZAD MOSTASHARI: Thanks. So I'll point to two concerns. And I'd like to focus the conversation not on interoperability per se but on competition. Because I think that's why we're here -- and two issues, two domains.

First is, as has been alluded to a couple of times now, the domain of hospitals, in particular, provider groups more broadly speaking, limiting the ability of other smaller provider groups from referring to where they want to refer to and having their patients seek care wherever they choose to and using health IT as a way to enforce those referral relationships. And there are some -- and I'm engaged very much on the ACO issue now -- who are concerned that hospital sponsored ACOs are using not just the Stark exemption that Dan spoke about, but also the access to the claims data to identify so-called leakage and to shut off, or bring pressure on their affiliated physicians, independent physicians purportedly, to limit the amount in which they refer their high value, or high cost procedures and surgeries, and so forth to other facilities.

And we have heard that the use of an electronic health record, for example, one that is provided under the Stark anti-kickback exemptions, might be one way in which you at the hospital might bring those outpatient providers closer to it and make it hard for them to leave. This was something we discussed at great length as Jodi led the discussions. And there were, I think, the Stark and anti-kickback exemptions that were extended do contain teeth in terms of being able to take enforcement action should those facts come to light.

And I think this needs to be fact patterns, rather than concerns, fears, I've heard’s, and anecdotes. So one of the things that I really urge people to do is to, if you think there is a fact pattern that you are concerned about, it's all in the specifics, and to

submit those to this docket that's been open for this hearing and other appropriate regulatory channels to deal with it. We've got to move beyond the anecdote.

The second area in which there is concern about anti-competitive behavior is on the part of electronic health record vendors who are really, and I think I will accept this, that the meaningful use of electronic health records really increase the prominence of the electronic health record vendors within the ecosystem. There were many, many different forms of health IT. But I think once we created this incentive program for electronic health records and however that would become defined, they are now the dominant tool on the desktop of physicians and hospitals. And the anti-competitive concern here is that, through dominance of the desktop, there could be limiting of competition, not against each other per se, but against third-party applications that would do other things (that would provide health information exchange services) to tilt the playing field in favor of one side. Whether it's patient portals, whether it's now analytic software. And it's clearly convenient to have, for example, a browser that's bundled with an operating system. But if it tilts the playing field too much in advantage of your browser versus other people's products, it could be anti-competitive in that respect.

So I'm actually less concerned than some have expressed about there aren't enough EHRs to choose from, I think, compared to our friends at the FTC, compared to other industries. I do think that if I'm a provider or even a hospital today choosing the system, I have a legitimate choice. The question is, once I've chosen that system, how hard is it for me to switch? How hard is it for me to use other products that aren't bundled in with it?

Jodi mentioned pricing. And this is something that is extremely poorly dealt with through the regulatory tool we have of certification. So I would argue that with certification, we have made great progress in making it feasible for systems to exchange

information with each other at lower cost. But we cannot, I don't think, that's not the right tool for the job, say what you can charge if I connect from one system to my own system versus someone else's system. And I think this is where sometimes we get into where people say, no, our system can talk to anyone. And it just costs you more, either because it costs us more or because that's just the way we price it.

So I think an issue that is very difficult for people who are not competition experts to understand is, at what point do those pricing arrangements create a barrier and other hurdles. It's not on the top of my priority list to build you an interface to that health information exchange. It's just not. So is that anti-competitive or not? When does the fact pattern trip over into that? And what are the tools that we have for addressing that?

I think the ONC has done really a lot in trying to decrease switching costs and trying to provide transparency, to try to provide standards, to enable modular certification, to enable batch transloads, to urge the Vendor Association to come up with a code of conduct around this, to ask for requests for information on what we could do around furthering the business case around health information exchange, and so forth. But there's a limit to what you can do through standards and certification. I think that's why we're here is to ask the question: is there something more that could be done?

STEVEN STACK: Well, thank you. The three points that I, on behalf the American Medical Association, had wanted to do interject into the conversation were a concern from the individual physician position perspective or the user perspective of a EHR about data lock-in and the concerns that it is not clear on the front end would what those costs would be to transport your data if you were to switch vendors downstream, that the cost may be prohibitive, and that it may not, in fact, be technologically either

easy or facilitated to be easy even if it could potentially be made easy. So we have that concern with data lock-in.

The second is contract transparency. We do hear stories from physicians about contracts that are not clear on the front-end about what the costs will be, where you just switch from one vendor to another to get your data, and what the implications to you would be if you make a change. That certainly does not make for a competitive marketplace because it's difficult for us to change even if we would like to do that. And there is a multitude of data that shows that physicians do want to change, that as many as one-in-six were planning, I think, as recently as the past 12 months to consider changing to a new software provider.

And the third was consumer choice. In this regard, I mean the physician or end user, purchaser, consumer choice, and the market. Micky showed in his earlier presentation some of the data. And I wouldn't disagree with Farzad on that. There still is a multitude of providers as far as electronic health record vendors to choose from, however, we are seeing some consolidation. And we do see a very small number, four or five major players, in both the ambulatory and in the inpatient setting who are providing 50% to 60% of the market share. So it is consolidating.

And so this leads me now to the points that I wanted to make, because I think this has been a very thoughtful opening round here. I would suggest that a lot of times, purchasers, physicians, or hospitals select these tools from these larger vendors because there is such instability and uncertainty where the marketplace is going, where the regulations are going. And the real enterprise fear, whether you're a small position in a solo office, or a group practice, or in hospital that you will purchase something that will be irrelevant, fail to make you succeed tomorrow, a vendor that will go out of business, be subsumed. There's a real enterprise risk.

And you talk about doctors deploying substantial portions of their revenue stream to purchase and maintain these tools, hospitals doing hundreds of millions of dollars, and these are things that affect bond ratings when you start to look at the expenditure that they're going to undertake. So I would suggest that, with the siloing of information thing that I've heard, I would never sit here and say that there's not a bad actor in the marketplace.

There are always bad actors. But I would say, overwhelmingly, I think CIOs have a fear of HIPAA violations, data breaches with enormous penalties and public disclosure requirements to national media, fears about the technology not working, and glitches, and viruses, and other malicious software getting into their system. I think that there are far more real and present explanations of the software just not communicating with each other, different competitor systems not communicating.

Micky showed the multitude of different information exchange paths that are developing. I think there are far, far, far more compelling and real reasons now why data is not flowing. And not anywhere on my top-50 list does it hit that, specifically, the competitors are trying to box each other out. Now, if the technology really worked, maybe that would happen. But we're not there yet, because it's an immature thing.

And the final point I would like to make is the concern about -- an earlier panel this morning talked about -- I summarize it light touch right touch regulation. Do a little bit, not a lot and try to get the most you can without interfering too much. We are here, in part, with this discussion because of the success of the Meaningful Use Program and HITECH and ARRA. Because without that, there was not this huge push this fast.

So there's the success side. The downside is, and particularly as we look to stage two, this is a heavy touch approach and there is so much specificity and complexity. So now as we move to the next stage, we see things like certifying bodies who certified the majority of systems dropping out of certification, which raises the real spectre that the

purchasers of these systems had, the fear, I'm going to buy something for a lot of money and then the vendor's going to not be certified and I can't qualify without having a certified system. And so now there's a new exemption that if your vendor's not certified, or you don't have the technology in time to deploy for 2014, you get an exemption.

So I think that some of the real fears that the provider, the health care provider community, raised are coming to pass. And that is not to say we don't celebrate and support using this technology. And as Doctor DeSalvo mentioned, we have got to find -- she kindly referenced a comment I had made to her -- we have got to do better about sharing information for the benefit of patients in the United States, particularly when our charge is to take care of patients. And with 1/5 of our GDP, we've got to do better.

We are not there yet. And I don't think that there's an anti-competitive specter that technology is being manipulated to ends that are anti-competitive at this point. I think the technology has not yet reached the maturity to serve the health sector the way we need it to.

MICKY TRIPATHI: So I just have a couple thoughts. I know everyone's already too much from me. Just, actually, I thought it was fascinating listening to this first round here, how there is no single pristine definition of free competition outside of our economics 101 class definitions. What I heard was actually different definitions of competition, even implicit definitions from everyone here.

And it's interesting that some of the things that we're talking about, like Dan, not to pick on you -- but I can pick on Dan -- when we talk about accountable care, well, a lot of health economists, if you look at the history of this, would say, no, accountable care is the market coming back, not the market being somehow outset. There was market failures before, and this is allowing a little bit more of the market to come in.

When we talk about the Stark safe harbor, remember, wait a minute, Stark was a regulation that was imposed on hospitals' ability to invest. So now we're saying that

allowing someone safe harbor from that is free market? Well, wait a minute, it was the Stark regulation that actually imposed something on the market.

So all of us have different definitions. That's the first thing. The second is that, I think, if you look in any sector of the market, there is no free competition. And so I don't think we should hold that as the goal.

If I still can't upload anything into iTunes and get it out to anything else, even my own CDs. If I buy a CD and upload it into iTunes, it's locked in there forever. I can't get it out. I can't communicate with anything else.

I can't send a Facebook message to Twitter. I can't buy a book on Barnes and Noble and read it on my Kindle. I can't get a Google Calendar invite into my Outlook. Should I keep going on?

Keurig, the coffee cup maker, just announced -- I don't know how many of you saw this -- two weeks ago, they just announced that they are going to be digitally stamping each of their cups electronically with a proprietary electronic code so that no other cups can be used in their machines. So this happens everywhere and in markets that we think are freely flowing. So I don't think we should hold that bar too high here. It's very unclear to me what free flow of information means.

And finally, I would just point out that with accountable care, the patients come to meet what's acceptable to them as well. So we shouldn't assume that patients are going to be free flowing and going everywhere and that's the happy world that they want. People are voting with their feet.

People like me, for example, like my wife, we choose to be in networks because they are more integrated. We don't expect that Mass General and Beth Israel and Bay State Health are all going to be seamlessly connected and that should be a reasonable expectation for us. We say, you know what, I'm going to stay in the partners network that delivers fine care. They're integrated. That's good enough for me. And that's better

than having the government try to come in and regulate something that could have bad effects on the market for the next 50 years.

JODI DANIEL: Can I just make one comment? The one thing I would say to the examples that you gave is that I think, particularly from the government's perspective, we are not only concerned about competition but also consumer protection. And whether or not you can use the cup you want on your coffee maker is less important than whether or not your doctor can get the data they need to treat you and provide you good care.

So there might actually be a higher bar in the health care space, I would argue, for improving the free flow of the information. And maybe that goes beyond the competition discussion and goes into consumer protection or other discussions. But I do think that there is a difference in this market compared to some other markets that you're talking about where there isn't good free flow of data or the like.

DANIEL GILMAN: OK, thank you. So here's what we're going to do. Danica and I will cooperatively ask questions. It's not a tag team.

It's not -- but some of these will be directed primarily at one or two panelists. Some of them will be for the group. If people want to respond, we're going to try to have a dialogue between getting to you and moving things along. If you could turn your name tag up on its end, then we can try and do people in the order that we see these things and maybe do some time management stuff.

I want to ask a question. But before I ask a question -- I was asked to make a suggestion from one of those pesky law enforcement people that we have in the room. And I think it's a good one.

So Farzad mentioned that people can submit to the record. The docket's open. If there are problems, if there's anti-competitive behavior, you can submit this stuff

formally, fact patterns, that's all true. And you are welcome to submit whatever you want, that's lawful, truthful, and so forth.

But beyond that, this is part of an ongoing inquiry. We're trying to learn, a, what's out there, b, what's working, c, what's not working or not working so well, where sticking points might be, and the fact patterns might fall in there. We'd like to know about them without pre-judging the question whether many of these or any of these are antitrust violations.

We just want to know what's working and what's not working first of all, before we analyze it. And to the extent that people want to contact staff at this agency and start conversations or provide us with information, plainly, there are some limits to that, but you do have the ability to do that independent of submitting formal public comments to the docket. And you can find our contact information on the web page and in the bio. So that's the suggestion.

My question, I suppose, starts with Micky. But maybe Farzad or a couple other people have things to say about this. And it's really a question about connecting a couple of your slides.

So Micky, late in the game, you had a glass-half-full slide, or maybe it was a glass-three-quarters-full slide. We had DOTs. We had EHRs. We had increasingly sophisticated EHRs. We had information flow within cylinders. We'll call them cylinders and not silos. And then maybe we were seeing tendrils of connections across not just corporate partners or affiliated business entities but across providers according to the electronic systems they were using. There were some barriers there.

Early on, you talked about the bad old days where you suggested we had some market failure, some fundamental market failure. Providers were being asked to make substantial investments in HIT. Many of the benefits accrued not to those providers but

to patients, to payers, maybe some of them to public health not even to individual patients or payers.

And then you talked about realigning incentives. You talked about the shot in the arm. So we heard from Karen about, maybe it's $19.3 billion or $20 billion, or going on towards $40 billion worth of shots in the arm. As we say in Washington, $20 billion here, $20 billion there, pretty soon it's real money.

To what extent, I suppose, both when we're talking about the adoption of EHRs, or relatively sophisticated EHRs, where we see great progress but also pockets, and not just random pockets, but systematic pockets where we haven't seen the acceleration, and when we jump from EHR adoption to health information exchange -- and I don't know what ultimately that's supposed to look like or ideally supposed to look like -- to what extent did we fail with the shot in the arm? Or where or how have we failed with the shot in the arm to realign the incentives where we haven't seen the adoption we expected?

And more than that, to what extent have we, in moving to HIE, to what extent have we realigned the business incentives? And to what extent have we just put our thumb on the scale? In other words, where entities did not have the incentive to adopt or adopt more sophisticated systems, or cooperate with each other, or share information with each other, to what extent have the checks and the meaningful use realigning incentives, to what extent did they just bribe them to buy these things? I wonder if you could speak to that.

MICKY TRIPATHI: Sure. So could you repeat that?

[LAUGHTER]

No, I guess what I would say is just a couple comments on that. One is that, to your question of where it's failed, I would actually say I don't think it's failed anywhere,

at least looking backward. Now, certainly technology should never lead with anything. But hold on a second, I just have to respond to this text.

Technology should never lead with anything. It should always be responding to a business need. So in an ideal world, I think we would have had ACA first and then the technology. But we all know that it was a very practical consideration, that with high-tech and the economic crisis that ensued from the previous administration, that this got put into that bucket. And so it was an investment that we were able to make and we were able to take advantage of the opportunity. So from that perspective, yes, it would have been better to have had ACA come first so that you could have the technology follow where we think business is going to head. But that was just a practical political reality, I think.

I guess the second piece of that is regarding whether we've got the thumb on the scales in a particular way, I guess, I personally don't see it. It feels to me like the market is really starting to take it over for a number of reasons. One is the huge investment. The $20 billion was not wasted as we showed in the data. And we can see -- talk about the fact base -- I would challenge anyone to point to any other sector of the economy, in particular one as complicated as health care, where penetration has turned in just a blink of the eye, and use of technology, and people having that in the pipeline. And that has enabled a whole bunch of other things now to happen, where the market can sort of take it over. To the extent that there were thumbs on the scales, one might argue that the thumb on the scales was the ONC program to create statewide HIEs in each of those states, right?

And I think what we're going to start to see is that 95% of them are going to fail now the ONC funding has dried up. And so to the extent that you could say there were thumb on the scales, well, that was there and now it looks like they're going to fail. And

that's fair enough. That was an experiment. But now the market is taking over with respect to health information exchange.

So it feels to me like there wasn't really sort of a failure in that respect that we could point to. Now, the last point I would make is that going forward though, we certainly could make some mistakes in over-regulating or not being able to adapt to the fact that the market has probably moved more quickly and in more highly varied ways than we might have imagined four or five years ago when the meaningful use program started.

DANIEL GILMAN: Farzad, you had your hand up?

FARZAD MOSTASHARI: Yeah. I'd say if you want to look at the analog between -- there wasn't a business case for adoption, therefore, government had to step in and government did step in and resolve that market failure. And I wouldn't use the term bribed, Dan. They had to step in and correct the market failure.

And then the question of, well, how about on the health information exchange side? And I would say there are two ways you can go down this, right? One, you can say, let's fundamentally remake the incentives of health care so it's more profitable to share than to hoard data. And I think we should do that.

And I think some of the things that are in the ACA, for example, around something as simple as a readmission adjustment -- 1%, 2% of Medicare revenue now being tied to the readmission rate -- has really fundamentally changed how a lot of hospitals view the desire to share information about their patient when the patient gets discharged. So those small payment tweaks can have a huge effect in terms of peoples' behaviors and willingness to share information. Are we there yet? No, I don't think we have the universal incentive for people to share information rather than hoard it in our payment models yet.

The second approach you could take this is to say, you know what? Give up on it. It's not a business thing. It's a public benefit. It's a utility. It's not profitable for any one group to do it. And governments should just pay for it.

But we wouldn't need -- whatever it was -- $584 million to fund state health information exchanges in that instance. We would need another $30 billion to do that and a commitment to long-term sustainability for that. And maybe that would work. I don't know. But we certainly don't have that luxury of making that decision now.

DANIEL GILMAN: Dan, you had your card up, and then maybe Curt.

DAN HALEY: Yeah, I can't sit up here and -- I'm going to pick up back on you, Micky.

MICKY TRIPATHI: Excellent.

DAN HALEY: And countenance the observation or the claim that there have been no failures in this policy area, which is nobody's fault. It's a tremendously complex policy area. There are always going to be failures. There are always going to be unintended consequences.

I would say right now, this particular month, the most glaring failure is the fact that systems subsidized by the federal government are now being -- the use of those systems -- are being deemed a hardship by that same government, sufficient to grant exemption from meaningful use requirements going forward. And that is a failure that our industry, the health information technology industry, bears significant blame for because frankly, our industry convinced policymakers that what is routine in information technology in every other sector of the economy is somehow prohibitively impossible in health care in the second decade of the 21st century.

Micky noted in his introductory remarks that direct messaging is one step up from fax. And that's right. And policy is currently geared toward achieving that one step

in health care by 2017. Meanwhile, each one of us in this room is carrying around a supercomputer in our pockets. That's crazy. And so that's the end of my rant on that.

MICKY TRIPATHI: I'll get back at you.

CURTIS COLE: At the risk of giving a somewhat ill-formed thought, I feel like maybe one of the opportunities here for health information exchange is, again, to look at the certification, to look at the incentives at a transactional level, OK? So if I get paid $0.50 or $5 or whatever more after a visit that has a coded medication list, that has a coded problem list, that has all the characteristics that we want for interoperability, and all I have to do is bounce it off a web service that says, yes, it passes, no it fails, and I can get $0.50 for the problem list and $0.75 for the med list, or whatever, you don't have to tell me that my system is certified. You don't have to tell me which one to buy.

A lot of that overhead goes away. I get to do whatever I want. I'm judged on what I actually do, which is deliver a note at the end that can be exchanged.

DANICA: All right. Thank you. And maybe this goes to Farzad's point about making interoperability profitable. What is our current understanding? What is the picture we have of the cost of health information technology in terms of quality, cost, efficiency? Is our understanding complete for any type of institution or system? And what can be done to sharpen our understanding? Dan?

DAN HALEY: This is another area in which our conception in health care is fundamentally different from our conception in every other sector of the economy. Reference was made in Curtis's opening remarks to the continued prevalence of the enterprise software model in health care. In health care, somehow, too many doctors and too many institutions still live in a world where we can all remember opening our mailbox every day and finding a bunch of compact disks asking us to try out CompuServe or AOL or whatever. And if we like it, we could purchase a license for it.

And we could use it for a certain period of time. And then we purchase another license for it.

That is still the prevalent paradigm in health care in a world where the rest of information technology has moved on to a services oriented technology platform, a cloud platform, where you don't pay upfront costs, and you don't buy a whole bunch of infrastructure, and you're not thereby held captive to having expended those tremendous costs to the extent that you literally cannot make a change because you amortized those costs over a decade, long past the expected life of the software and hardware that you've purchased. Cloud-based models have no --

FARZAD MOSTASHARI: Can I just say Amazon Web Services is 5% of the server market. The majority of the rest is on premise. So I don't want us to --

DAN HALEY: OK, fair enough. But the consumer reality is still much different in health care than it is anywhere else. You're still looking at -- and so, one would certainly, even if you accept that observation -- I do. I believe you, even though I have no personal knowledge of it -- no one would argue that the tide is not pushing strongly towards the Amazon server model. And in health care, we are still seeing health systems invest hundreds of millions of dollars on multi-year implementations of static software that will bankrupt.

FARZAD MOSTASHARI: I guess one of the things I'm a little insistent on for us today would be that we talk about the competition issues. Because it's one thing to say, I wish those damn customers would choose something else. That's not a competition problem. That is competition.

DANICA NOBLE: But sometimes it can be an information problem. That's a little bit of what my question was trying to get at. What is our information? And what is the information for consumers or of these technologies?

FARZAD MOSTASHARI: What do you mean, the information?

DANICA NOBLE: Well, how much does it cost? How about -- Doctor Stack, you mentioned transparency in the contracts and having a good idea of what this would cost over time for a practitioner.

STEVEN STACK: All right. So I'm not going to wing the actual numbers, because I didn't bring those with me. But we have those. It is expensive to buy these things, very expensive. And the hospital numbers are staggering if you look at hospitals. But for doctors proportionally, they're similarly expensive. And the cost of ownership is enormous.

And so one of the interesting things about a thoughtful panel like this is I don't actually feel in disagreement with lots of others or the desire to even disagree. It's just that the field is so large. There are so many facets.

What I would suggest here is there was some market failure of some sort, because the industry didn't move forward in this regard. But we have created new failures in attempting to address that concern. And we got overly complex.

So the things that would help a clinician save costs would have been knowing prescribing information, laboratory data, radiology data. But there was a one big bang moment. There was a piece of legislation with a major incentive component and one opportunity to get as much as we could.

And so I think well intended individuals -- meaning, collectively, society -- I've been on a number these advisory groups -- tried to do the best they could. But we over-reached. And now when Micky comments that now the market is actually beginning to respond and you are seeing innovation and evolution, we're kind of now stuck already prematurely with this big legacy system that we can't innovate out from under.

And then the one other point I want to leave -- because, see, I've instigated others to disagree -- the one other thing I'd like to observe is the program was created, if you will, as a carrot and stick program for providers, providers who don't write

software programs, providers who don't connect information to each other, providers who just had to go out and buy what was in the market or not. And it was a market that by far and away didn't exist, because it was very immature. I mean, it existed. There were software vendors and all that. But it didn't exist like it needed to do this stuff.

And so what we have is a bunch of doctors who have gone out and bought systems. And I will tell you that the incentive does not offset the cost. So the best thing you could ever have would be to be the long-term care community or behavioral health who were overlooked in the initial phase, because --

FARZAD MOSTASHARI: They don't feel that way.

STEVEN STACK: I know they don't. But they're wrong. Because skipping the incentive and avoiding the penalty -- that's the gift that keeps on giving. It's the better approach. And all of us will have taken the pain on the front end. And hopefully, they're wrong if they don't get on the train, because we have to get on this train. But hopefully the rest of us will have taken it on the chin. And they will be able to come in and join into a system that, finally, there's not just one fax machine. Now there are millions. And now the network's actually working.

So we don't have a complete failure here. We have many successes. So I don't want to trash the program and what we've gotten. But we have a number of failures. And I think that there are legitimate reason when we're talking about competition -- I agree with you, Farzad, that's what we're here about today, is FTC and competition -- I think we have participants in a market who were compelled to do a certain thing when that certain thing wasn't ready to be done. And I think they feel buffeted.

And so I think that's why I push back on one of these issues about silo-ing information, using the technology as an anti-competitive tool. We're just trying to survive and not drown under the current tool, let alone manipulate it to our advantage.

So I don't think that those kind of things are problems. I think we have to collectively work together as a society to make it work better, because patients need this.

DANIEL GILMAN: So let's go Doctor Cole and then Jodi. And then -- sorry, Farzad -- I'd like to move on to maybe another question. And we can circle back.

CURTIS COLE: So I think one of the reasons it's very hard to characterize the cost is that many of them are not explicit. We know what it costs to buy the software. We may even be able to estimate the cost of how many hours are spent on project managers and lost productivity, et cetera.

But there are a lot of hidden costs in these technologies, one of the most important of which is the cost of complexity. And we have dramatically increased the complexity and somewhat the precariousness of our health care system with this technology. One example of this which you alluded to is in we talk about health information exchange. But in fact, what we're doing is health data exchange.

What doctors want is information, or better yet, even knowledge. And one of the things that EMRs do is they give doctors too much data, OK? The ophthalmologist does not need to know what the blood pressure was on the third day of the ICU visit. It's not relevant.

And yet, it's all there. And they get very anxious when they're presented with it all. And the technology's still not smart enough to filter the wheat from the chaff. There's a very, very expensive signal to noise ratio problem.

There's also a cost of the insecurity of not controlling your domain and your data. And this actually is something that goes up with cloud services. So you were talking about consumer protection. This is not just a competitiveness issue of whether you can move from one vendor to another.

What happens when your vendor goes belly up and they turn off their servers, OK? If you have a host, if you have your own servers, at least you can hire some expensive geek to get the data out again. If the cloud service goes out, your data is gone. And we do not have ways of dealing with that. And in fact, next Thursday, I have to go in front of the audit committee of our board of trustees to explain how we're going to deal with these cloud services because they're very freaked out about it. So there are a lot of costs that are very, very difficult to measure.

DANIEL GILMAN: I'd like to ask a question that starts with our providers, our practitioners. I know we have several MDs here in the panel. But maybe Dr. Stack and Dr. Cole -- Farzad, you're right. We want to about competition. But to know about competition, we want to know what people are finding in the market and maybe not finding in the market.

So you've both been involved in implementing HIT and in applying HIT. I gather neither one of you has any desire to go back. But both, I think, at the acquisition stage, and then maybe year three or year n, what did you find in the market that you were looking for? And what maybe have you not found? And what's missing if anything?

STEVEN STACK: Why don't you start, Curtis?

CURTIS COLE: I'm sorry.

STEVEN STACK: Do you want to start? Go ahead.

CURTIS COLE: Well, we started a long time ago. So we were, I guess, what would be called at this stage early adopters. And we've been through the systems that have gone bankrupt and done the data conversions over and over again.

So one thing that we did not find in the market was stability. I think we do have that now, at least for the short-term. I would say our biggest problem on the clinical side

is our ability to interrelate with our own hospital, because they're on a different vendor, and we can't do that data exchange.

We can exchange data with our competitors who are on the same vendor as us. And I have to tell you, it's fantastic. It's wonderful. It's a beautiful thing. The patient goes to the emergency room. I get the CT. It's a push of a button. It works beautifully. And I cannot get that data from my own hospital. So the walled garden is very green.

But the biggest thing that we're facing in the medical school is the lack of support for research. So electronic medical record systems are very much the promises, the data. The challenge in medicine today we talk about is bench to bedside. How are we going to connect phenotype -- what we do as clinicians -- with genotype, which is what they're doing in the lab? And that is still an impossible dream with today's technology, but we're very excited to try to solve that problem.

STEVEN STACK: So I think Micky's slide showed that I can't really give you that five-year data, because for the multitude of docs, this journey is less than five years. So I can say AMA commissioned a large RAND study last year, and it found a number of things. One, you should all feel reassured. The thing that makes doctors most professionally fulfilled is at the end of the day if they feel they did a good job for their patients and if they were supported in that. So that's good. The Hippocratic Oath still means a great deal to us.

The second finding was they all hate their electronic health records. But when you ask them further, four to five out of them have no desire to go back to paper. They just want the tools to be better.

So I'm an end user. But my journey started July 7, 2013. That's a date that I'll remember just like the birth of my daughter. And I have no animosity that I really can feel towards my specific vendor. I really don't. But I have a lot of frustrations with the tool.

You have to learn with each one of these ones, because there's not standardization within it across different vendors. It's not like everything is Windows or everything is iOS if you're on Mac devices and stuff. It is different for each one.

And so you have to spend some time learning the conventions and the structure of it. And how do you find things? And how do you get things done? There are some things we still struggle with. And it's very frustrating. You have a sick patient. I don't know how to do this. It used to be very easy. I asked a nurse. And the pharmacy did it. And it was done.

So there's that learning curve. We'll get through that. But it's painful. It really drops the efficiency of the clinician. We are all less efficient than we used to be. Now you recapture a good chunk of that with practice. So it's not the end of the world. But we lost a lot. We fell 25% in efficiency for the first two months. And that's all revenue we lost. That's another -- how do you factor that in, all the revenue we'll never get back that we lost for that?

And then you have the problems of -- I'm an emergency physician. I used to go help out at a competitor health system because my group staffs multiple hospitals and they're in different systems. It's something I won't do anymore, because I can't -- I'm not going to learn multiple EHRs with different usernames and passwords and conventions. And I used to be able to show up and use paper and pencil and do one shift every three months to help out when they were in a bind.

And again, this is not -- don't use EHRs. We've got to figure ways to address this stuff. But that that's a real implication because it creates a different kind of scarcity that hopefully, we'll find ways around, because the physicians are not as portable as they once were. It's my choice. No one forced me to do that. But it's a choice I have to make, I think, because I can't perform at the level I feel I need to by just walking into an unfamiliar environment now.

So that's not quite the question you asked. And I still want to say I agree with Farzad. I'd like to be as much on the competition parts as we can. But there are real implications. And it is such a fast-moving environment that I think 10 years from now, many of these things we won't be griping about. We will have figured it out. And we'll be better.

But right now, it's moving so quickly and there are such enormous implications to the provider community, particularly when you overlay all the other things, the ICD-10 and quality reporting and all that stuff. And everyone seems to think we'll just take another nick off the fee schedule for Medicare. And every time we take another 2% away, they'll just do it. But it's starving the system. At the same time, we're craving all this innovation of the bandwidth, emotional, mental, economic, to do the innovation. So I think there are real challenges if we put too much on the plate at one time.

DANIEL GILMAN: Maybe Janet and then Micky, and then we'll have another question.

JANET CAMPBELL: Sure. I think this is one of the hardest things that I've heard. And it's something that we've heard in other places too, that the priorities of organizations are being subsumed under the requirements of what they need to do to meet meaningful use. So, as much as Curt wants to focus on research, he can't do it.

We can't focus on usability if we're trying to make sure that we're matching to the letter of a certification because ultimately, it's certification at the end of the day that allows doctors to get paid. And we can't leave them in a spot where they don't have that. I think as I look forward to the future of EHRs, I am concerned because the time that we have to focus is a very limited and precious resource, and it is not something that is in as much control of the hands of the doctors as perhaps it was at one point.

STEVEN STACK: Let me just -- if I can inject real quickly -- I promised Lee I would do this, and she couldn't be here with us. The AMA and the American College of

Physicians, the EHR Vendors Association, we have always dialogued, but we have begun to dialogue in more earnest.

And it's not that the vendors aren't making an effort. They do. They have a code of conduct that they have 21 or more vendors who have signed on to, that does ask the vendors to voluntarily agree to make an effort to address these concerns.

And so I think that there is -- one of the biggest successes of all this attention from HITECH and ARRA and Meaningful Use was it just got people to dialogue with each other and get together and collaborate. And this is a continued new stop on that journey. And so I do hope that -- I think the private sector is responding though. I think we are beginning to find ways to work together to address some of these concerns.

JANET CAMPBELL: High five.

MICKY TRIPATHI: I guess, I agree actually, with what Janet had just said and Steve's comment about the complexity. And that's why I'm concerned, like Janet, about what we do going forward. The certification for phase one -- the reason I was saying that going backward, I don't think we made that many mistakes, where it was appropriately focused on getting people to use systems. And I think of it as a supply chain investment. But others can think of it differently. There was Medicare and Medicaid investing in their supply chain to get people to do what they wouldn't otherwise do on their own because of the economics of it.

But going forward, I think that we are in danger, now that the market has taking over, of having certification be too strong and get in the way of people's being able to innovate. And I know that there's a near-term frustration that I think both Cole and Steve have expressed about current systems. But I guess it just seems to me that none of this stuff gets better without people using it, that there is no software lab where you're going to have someone designing the perfect software. It only gets better through use.

And I just reflect on the founding of my company as a non-profit. In 2004, we started with a $50 million financial investment from Blue Cross Blue Shield to run three pilot projects in Massachusetts. We had five different EHR vendors and wanted to create three stand-alone health information exchanges. And in a three-year period it was very, very difficult.

The only one that actually got stood up and is still live, was one that eClinicalWorks created connecting all their own systems. So it's a stand-alone, everyone in the community on the same EHR. That one's still alive, and it was a huge struggle over that time period. We couldn't get anything out of those systems at that time.

Fast forward to where we are today. There are many, many private HIEs in Massachusetts that I'm very familiar with, that in a year get themselves stood up, have a repository, have four or five EHRs contributing data. And it's not perfect, but it's actually contributing to care and contributing value. We have a data warehouse that my business runs. Seven years ago we couldn't get anything out of these systems. Now we have nine different EHR systems that contribute something like 350,000 records a month that we're able to run analytics on and provide that back to customers. So it takes time, but it only gets better through use.

FARZAD MOSTASHARI: I just want to quickly add something that I hope is relevant to the competition discussion, which is, this points to, I think, the power, but also the limits of certification as a tool. And what people overwhelmingly want is, the government should just set standards so that the data would move. Will you just set the damn standards so the data would move, right? Overwhelmingly, you ask people, what do you want the government to do, right? At HIMSS there was a poll. It was like 98% of people thought government needs to set the standard so the data will move. And yet --

MICKY TRIPATHI: Where's Karen?

FARZAD MOSTASHARI: And people talk about why stage two is so much harder and people can't keep up, and the specificity, why there's so much specificity to that, right? Because it was in response to all the people saying the standards aren't specific enough around interoperability. And the big push for stage two, and what people are having the greatest difficulty with, that's sapping innovation out of, is the ability to move data. Those are the two big requirements that step ups for stage two are -- share data with other providers and share data with the patient. And that's the thing, that's the same thing -- this kind of schizophrenia that we have here -- it's the same thing that people are so upset about, is the limits of us using certification as the only hammer to get people to share information and do it interoperatively.

So I think the main thing I want to convey here is it's convenient to criticize the regulations, and I guess it contains within it valid criticism that you cannot regulate your way to business practice. And if the fundamental issue is it's not profitable to share information, and however much the capabilities have now increased, we're seeing an increase in complaints about it. I guess it points to the limits of certification.

STEVEN STACK: You engendered more response than I did.

DANIEL GILMAN: So maybe, quickly, Jodi, quickly Curt, and then move on.

JODI DANIEL: So Farzad actually made a couple of points that I was about to make. But we talk about -- we've been working together for too long -- when we talk about interoperability, we think about it as a multitude of activities that have to come together for exchange to happen, and standards is just one of them. Obviously, adoption of technology is one of them, but also having the services in place, having some rules of the road for exchanging that information. And I think the most important one that we're seeing lacking is the incentives for that exchange to occur, for people to actually want that information to move.

And so, as Farzad said, our goal at ONC is to try to create the infrastructure to enable the information to flow. But that doesn't necessarily mean that we can compel folks to share information. I think our certification program helps in many ways, and not only in creating the standards, but one of the things we've tried to do is try to build increased transparency, like price transparency, and have folks make that information available.

We've tried to use or certification program somewhat creatively to try to encourage some transparency, usability, some of those things that are hard for a certification program to do. And we're trying to use that to establish our priorities and things that we think we need to happen, and doing the piece that we can, but understanding that others have to contribute to that as well. We're trying to build safety and usability and transparency and things like that into our certification program, but as Farzad said, it is one tool, and it is not alone going to address all of the challenges that we face in this space.

DAN HALEY: Can I just jump on this for a second?

DANIEL GILMAN: You bet.

DAN HALEY: Because we're actually tying together a number of things that have been said without necessarily recognizing it. It's not just that there's no market incentive to share information. There are actually numerous market disincentives to share information. I can't remember who it was -- it was Farzad who talked, I believe in your opening statement, about the fact that health information technology vendors will often charge their clients, their doctors, to send information outside of network.

And I'm not saying that as a criticism of those vendors, because, frankly, in order to send trusted data, to get to the curation of data and the ability to trust it, to know where it went, where it came from, who's responsible for it, the vendor has to do some work on that data to be comfortable sending it out-of-network. And they can't charge

the receiver of that data because that's -- in the context of a referral, it could be deemed a kickback.

And so there is actually a market disincentive, to some extent driven by unintended consequences of law that is maybe over-broad in the 21st century, to some extent driven by vendors who are -- I don't want to go too far -- they are only too happy to charge a premium for sending information outside of network. More and more again are not doing that. We don't do that.

We build interfaces at our cost, because we believe that information sharing is something that's important. And over time, we'll be able to recoup those costs, as the system becomes more and more interoperable. But that's a big lift, and that's not something that a new entrant into the market can afford to do.

DANIEL GILMAN: So I wonder if I can ask a vendor-focused question? We've got two vendors at the table, both successful entities. One of you is actually a software developer, at least part time, and -- not today. And so we've heard about a huge shot in the arm. Obviously tens of billions of dollars in program expenditures has pumped up the demand side of your business. We've heard about some regulatory issues, maybe with certification, maybe with meaningful use, and I don't want to harp on those, despite the fact that that's not the purview of our agency.

But I think you're both vendors competing in the vendor space, and you're both innovators, right? And so my question is, as vendors and as innovators, if you had to identify: a) one primary commercial challenge and b) one primary regulatory challenge, maybe from well-intentioned regs, maybe from regs that do have some benefits, but also some costs. What would those be?

JANET CAMPBELL: Primary commercial challenge. I'm going to start with the primary regulatory challenge, I think, because I probably already alluded to that a few times. Certainly, as was pointed out, when we looked at the stage one criteria it was

pretty obvious what should go into that, right? There's a tightly held nucleus of things that an EHR can do, and it's pretty easy to draw a small orbit around that and say, OK, these things are going to be how we define an EHR.

And as you continue to move out from that nucleus, though, that's when a lot of -- this group thinks the EHR should do this. And that group may or may not be provider users, it may be someone with some other interest in it. But what we see is that the functions of an EHR get more dispersed as we tend to expand, to the point that now as we look at some of the stage three regulation, we couldn't include all of it, that would just be impossible. And so then we ask the question, well, what makes the particular orbit that we've chosen to include better than any other particular orbit?

I think that that's probably one of our biggest concerns as we continue to look at not just stage three certification or 2015, 2017, et cetera. But time is going to keep going on, and where do we draw the line, where we say that it is no longer the place of regulation to say what goes into an EHR? If history informs us at all, I don't know that we would draw the line. We'd just keep adding things.

DAN HALEY: Yeah. I'm again going to go back to something that Farzad said to me. Our primary commercial challenge is lack of awareness of what exists in the marketplace. And I sit here stewing in that frustration as I listen to Steven talk about existing technology with such frustration, as though technology that alleviates that frustration doesn't exist.

If the government were to come to me and say, you need to drive, you need to get from Massachusetts to California in one day, and they were to give me an automobile, that would be a problem. If they were to give me a plane ticket, that would be the reality of the 21st century, and the 20th century. But the point is, there are airplanes.

Our clients do not express frustration about meaningful use. They don't particularly like all of the criteria and the certifications and the attestation standards, but they don't complain about them because they're able to meet them, because our platform allows them to meet them relatively easily. And so that's our primary commercial challenge, and that's on us, that's not a government thing. Building awareness is on us.

Our primary regulatory challenge? I've already talked about it. It is the fact that too much policy is still geared, future-oriented policy, is still geared toward accommodating technology platforms that in a free and unfettered market just would not still exist. They don't still exist in any other sector of the information economy. They would not exist in health care, but for the unintended consequence of government policy that is essentially giving them a shot in the arm and continues to cater to their concerns, their expressions of anxiety going forward, their inability to meet standards that are perfectly rational and perfectly meetable, and timelines that are perfectly rational and perfectly meetable.

I don't think that's a word, and I said it twice. And I feel bad -- my mom's an English teacher. Terrible.

DANIEL GILMAN: Maybe, well, sorry. Danica, did you have a question from the crowd? Did anything come in as people passed up cards? Or just passed out?

[LAUGHTER]

DANIEL GILMAN: I mean I have -- you got anything?

DANICA NOBLE: I have a question, based on the submitted comments.

DANIEL GILMAN: Go for it.

DANICA NOBLE: And that is just, I'd like to ask anybody on the panel who wants to tell us, is there a direction that you'd like the FTC's competition authority to take a look at? Maybe you could set some flags or some markers. We're all ears.

DANIEL GILMAN: Maybe just to add a wrinkle to that, turn this on us, OK? Not to pick on CMS, not to pick on ONC, we're a competition agency. We want to understand what's out there in the market. We've got a tech market. We've got a health care market. We've got the intersection of these markets. We want to know what's out there. We want to know what's working. We want to know about both private conduct that maybe intentionally, and maybe public conduct, public regulation, that perhaps unintentionally create impediments to competition, barriers to entry, impediments to innovation.

We've asked you a bunch of questions, we've had a nice conversation here. But what did we miss here? What did we fail to ask that we should be asking? And maybe just go down the table and ask what people think.

UNIDENTIFIED SPEAKER: Which end?

JANET CAMPBELL: You put it that direction, right?

DANIEL GILMAN: Sorry. Sorry. Right. No. Yeah. We're starting by some complete geometric -- No, let's start at the other end, with Micky.

MICKY TRIPATHI: OK. Direction to FCC? I would look elsewhere. I would look to the other panels that were here, actually. I think that the issues -- I don't think that the issues, except they're anti-competitive issues, I don't think that they're in the technology area. I think that they are bigger questions that -- some of which what Dan was alluding to -- that are about the way health care is evolving, accountable care, other things like that. And do we have arcane regulations that are impeding progress in the flexibility of health care models going forward?

But that's not about technology. Technology should follow those models. It shouldn't be the leader. And I don't see, directionally, that we have significant issues that would warrant more regulation in the technology space.

STEVEN STACK: I actually agree with Micky. I'd look to the other panels. I am glad and thankful to have the opportunity to talk here today, but I don't think this is the big issue for the FTC. There are big issues here, but this is not, I don't think, the primary venue, or even the venue. There are other venues to dialogue on these technology challenges and legislation and regulation. So I really, I don't think that this is an anti-competitive issue, this market and the things related to it of substance enough for the FTC to really --

DANIEL GILMAN: Well, not just the tech market, but for instance, both of you raised this question about health care consolidation. What implications there should we be looking at? Does this foster consolidation, foster integration?

STEVEN STACK: I don't see that this particular technology tool is -- it's obviously central to coordinating care better. But I don't necessarily see it at this point as central to the market evolutions that are competitive or anti-competitive. And so I'll reserve any other detailed comments we'd have on that to the comment letter we'll submit that will be more thoughtful and more substantiated.

FARZAD MOSTASHARI: I would echo the first part, that I broke it up into the hospital consolidation and competition issues and the vendor issues. I would agree that on the hospital consolidation issues, it's part of a much bigger story, actually. And the consolidation can occur without clinical integration, and that's probably getting all stick and no benefit, right? So at least with the technology you gain some advantages from that. But I think the FTC clearly is interested, and based on the St. Luke's case, is leaning forward on some of the hospital consolidation issues, and that's probably a good thing.

On the vendor issues, I do think that -- as national coordinator, I heard all the time, all the time -- people complaining to me about what they believed were anti-competitive behaviors on the part of their vendors. And I wasn't the right agency to deal with it. So what I would like you to do is not just ask a lot of questions, but actually share back with this community that is not familiar with the fact patterns and with the way you guys think, about what is concern for fairness and competition and barriers to entry in switching costs, actually help educate us a little bit about how you think and what are the kinds of things that you find somewhat concerning, and other things that, you know what, that's just competition. And that's OK.

Because I think that education has to go both ways. And right now you've gathered a lot of information but you haven't given a lot of information back yet. So I would ask you to share back some of your thoughts as well. I know sometimes for an enforcement agency it's difficult. You want to get a letter, that you respond to the letter, and it's all great. But there are ways that you can do that.

And I do think that the mere interest on the part of the FTC in this area could be salutary in terms of making sure that some of the worst behaviors do not occur. So I'm thankful that you are leaning forward.

DAN HALEY: I'd go back to where I started and say that in the ACO context, I don't think there's any doubt that there are consolidations happening, but for the antitrust waivers built into the enabling statute would get much more scrutiny than they get. And that technology is used as a lever to lock in, to enable, and then cement those consolidations.

We hear all the time from docs affiliated with large hospital systems, particularly in the context of our offering to build interfaces for free, that they have effectively been told if they don't get on the platform that they won't be able to get referrals. I don't

know if that rises to the level or if it doesn't, but it's certainly a strong commercial disincentive toward participating in models that share information freely.

JODI DANIEL: So I echo Farzad's comments. We do hear a lot of anecdotes, at least, not necessarily -- we don't have the data to support whether it's an anecdote or it's just the tip of the iceberg. But we do hear a lot of concerns about business practices that may or may not be anti-competitive, or may or may not be fostering a competitive market for health information technology and exchange.

So specifically we are interested in, we keep hearing over and over again, about a lack of transparency in the marketplace which makes it hard to have a competitive marketplace for products as well as for exchange. So, interested in anything that you all might be able to uncover with respect to transparency of price, safety and usability, reliability of products, as well as support services.

A lot of times what we hear is that providers who are purchasing systems don't always have all this information, and had they known x, y, or z, they might not have purchased that product. And so finding ways to have comparative user information available, having more of that information available for purchasers so that they are making informed decisions when they're purchasing products.

And then also, we are particularly interested in some business practices, again, that we're hearing about from stakeholders, and whether it's one-off comments or anecdotes or if it's just the tip of an iceberg of practices that may be occurring, more probably. But things about restricting, going back to transparency restrictions that may be either in contract or implied, about sharing information, about user experience, any business practices or contract terms that may deny customers access to their data if, in fact, the product goes out of business or something like that, or they choose not to renew their license. Or any practices that may lock in customers or limit data portability that the provider would like to have to share that information.

We are also interested in practices that may be related to HIE pricing, which I did mention at the beginning. But we need a better understanding of how folks are -- how the HIE market -- is charging for exchange of information, and whether or not their practices in the pricing of exchange services that may be anti-competitive or may not promote a competitive marketplace or innovation in the exchange market. Again, we don't have facts to back this up, but these are things that we're hearing about that we would love to work with you all to learn more about, and understand where things may be perfectly fine and just part of a regular competitive market versus maybe in a gray zone or crossing a line.

So just to reiterate, we're really thrilled that you all are engaged on this topic. And we hope to work more closely with you all to think through some of these issues.

CURTIS COLE: I'm afraid the things I want are impossible. I mean, I do long for the era when we were able to innovate in academic medical centers against electronic medical records. We were able to build our own. Nowadays the issue -- third party vendors, let alone the providers themselves -- are not allowed to touch the systems. But, truth be told, I can't touch my iPhone either. In fact, if I write an app and Apple doesn't like it, I'm not even allowed to sell it. So I don't think the government is going to be able to legislate in that space.

So then I'll go to the other extreme, which is to ask the government to stop doing things that I think are bad. We keep being told you want us to exchange health information, but Congress, in its infinite wisdom, has banned the creation of a national patient identifier, which is probably the single most valuable thing that we could do to assist the exchange of health information. And government is actively in the way of doing that, and so instead we all have to spend millions and millions and millions of dollars reconstructing the identity of each patient before we exchange the data. So it's a ridiculous waste.

JANET CAMPBELL: So I guess I'll finish it up. I don't know the reason why, but regardless, it is a fact that vendors are dropping out of this market, innovative vendors. That means there's less innovation in the market, means there are fewer choices out there for health care organizations, and it means that those organizations that had a vendor that was certified who really, really liked that vendor, are not able to use them anymore. And that they will incur switching costs not in moving the data, but in moving the workflows and understanding yet again how to put it in another EHR, and that's not a competitive market.

DANIEL GILMAN: Well, thank you very much. Thanks to our panelists for their input and their discussions. Thanks to the remaining people in the crowd. And we hope to continue all these conversations. Thank you.

[END OF WORKSHOP, DAY 1]