# CQ NEWSMAKER TRANSCRIPTS

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# Research America Holds National Health Research Forum Titled "Straight Talk: The Future of Medical and Health Research"

LIST OF SPEAKERS

# WOOLLEY:

So, last evening (President Obama) emphasized in his address to the nation that the threat of terrorism is top of mind, a major concern for many and all Americans today. Something we ignore at our peril. It was clear that we must and we will act.

He further noted that we are acting to contain and cure, eventually, Ebola. American Public Health know-how is already at work and will be stepped up. And our scientists in both the private and public sectors are teamed up to develop effective treatments and vaccines ASAP. This is how it should be.

Now, you may have noticed that the President used cancer as an analogy to describe the scourge of ISIS, ISIL. Yet, we're going to act against ISIL with only imperfect knowledge about it even as we work assiduously to learn more. Seems to me that it's like trying to end cancer, there's a lot we don't know yet that we have to understand but we also have to act.

And that's true of other diseases that plague us, consider Alzheimer's. An estimated 5 million people age 65 and over right now are living with Alzheimer's. This number is expected to almost triple to 16 million by 2050. And then there's obesity rates remaining stubbornly high contributing to diabetes, heart disease, stroke, and other illnesses. Are we doing enough? Will the year ahead be a time of more action?

Now, add the facts on the ground about what else is ailing us. Unresolved immigration challenges and woefully inadequate funding both impact our ability to attract and retain the best and brightest young people to advance science and innovation.

The reality is that instead of nurturing it, we have put medical research and development on a kind of cruise control in many respects with the predictable result of an escalation in the pace here while other nations lure U.S. industry with more favorable tax and regulatory climates.

This afternoon, we're going to take a look at where all of this and more leaves us in terms of maintaining our nation's preeminence in science and innovation where it leaves us in terms of saving lives and improving the quality of life and where it leaves us in terms of continuing to drive our economy.

And speaking of drivers, keeping a finger on the polls of public opinion, as many of you know is a major driver informing our advocacy at Research America. New poll data, from just a couple of weeks ago, the end of August shows us that only about a third of the American public now say that the U.S. will be the global leader in science and technology by the year 2020, that's not that long from now. Almost as many say that that world leadership will be held by China and the rest chose the U.K. or another nation.

Another grim finding was that only 39 percent say the U.S. will be the world's health care in 2020. And in case you are wondering, this forecast is not OK with the American public. We're all in a hurry for better health, better treatments in preventions and cures. And we want those breakthroughs and those new products here now. And we want new industries like the biotech industry and its successor industries that we don't even know the names of yet. To be born here in America. To employ and be led by our children and grandchildren.

We all agree that the ultimate goal is the healthier more productive society. The American Heart Association's new brand, I think effectively articulates the whole point with their, quote, "Life is Why" unquote initiative having longer, healthier lives to cherish moments with family, friends, and loved ones. Isn't that why we all do what we do day in and day out? Isn't that why those who treat patients doing their jobs while those who protect the public health and who work to assure access to patients on an evidence-based platform do their work? Life is why.

Isn't it why those who conduct research and develop new products for better health work long hours everyday? It's why advocates continue to cram the corridors of Capitol Hill, continue to activate our grassroots networks, talk to the media, and urge decision makers to support research funding and policies that support medical innovation. Yes. Life is why. Thank you, American Heart Association.

Now, I'm worried about those policy makers. With the midterm elections drawing near, now is the must-do time to use our voter education initiative. Ask your candidates to contact Congressional candidates to ask them if and how they will support medical progress and collect it. We have laptops set up right outside the room today to help you. Send the message to candidates in your state and district. Please stop by and do that. And then spread the word. There's other ways you can help that important campaign.

Now I'd like to take a moment to thank our national forum sponsors. Thank you panel sponsors, Celgene, Johnson & Johnson, and Onyx Pharmaceuticals. And thanks to our lunch topic and science sponsors Teva, the University of Maryland School of Medicine, Genentech, and HudsonAlpha Institute for biotechnology. And thanks to our supporting sponsors, Astellas, Gilead, Novartis Oncology, the American Association of Colleges of Pharmacy, Bristol-Myers Squibb Company, and Northeast Ohio Medical University

And thanks to our media sponsors C.Q. Roll Call, The Hill and WebMD. We are very pleased to announce that WebMD is live streaming today's program to viewers across country. You can all join the conversation in social media using the hashtag raforum14.

And keep in mind that there will be a brief Q&A session at the end of each panel and we do encourage you to frame your questions and participate. So I'd like to introduce the first panel now. I see you all around the room. Please come forward. The moderator of our first panel is Corby Kummer. Corby is the senior editor at the Atlantic magazine where he edits articles on politics and public affairs.

And he also writes a regular food column. He's a contributor to Vanity Fair and the New York Times and the Smithsonian. And you can read a more complete Bio on Corby and all of our panelists in your program. And if you want to go up on the stage please, please do.

France Cordova will be with us. France is a director of the National Science Foundation recently assuming her post. Anthony Fauci, Tony is the Director of the National Institute of Allergy and Infectious Diseases. Bill Hait, the Global Head of Janssen Research & Development, the pharmaceutical companies of Johnson & Johnson.

Dr. Hait is a member of the Board of Research America. Richard Myers, the Director and President of the HudsonAlpha Institute. And John Seffrin, the CEO of the American Cancer Society. And Dr. Seffrin is also a Research America Board Member.

Over to you Corby. Thank you all.

# **KUMMER:**

Thank you Mary. Thank you every one for being here. So the mandate that I was given today was to talk about who to fund medical research in the future especially who's going to give money to blind alleys to the kind of trial and error that leads to actual new knowledge and discovery.

And I was being quoted and someone here will say exactly who said this. Remember its called research. You have to do things over and over again. They are often wrong. They often go no place before you actually find the new knowledge.

And I was asked to point out that Research America polling with the Battelle group at a projection of R&D funding will pass to the next 10 years. So before the next 10 years in 2023, China is projected to overtake the United States in research and development funding. The figure is going to be the scary figure in 2023 that China will be putting in \$602 billion compared to our \$593 billion. But right now we are all very aware of how fast China is moving.

So before we get into a bit on China, why don't we go down the panel and say how much have you seen the shift in basic research funding and as opposed to and whose actually funding innovation in the kind of blue sky research blind alley research that we most need to make new discoveries?

# CORDOVA:

All right, do you want me to start. I'm France Cordova, Director of the National Science Foundation. And...

### **KUMMER:**

A good place to start with that question.

# CORDOVA:

Yes, yes and of course our mandate, our mission is to further the progress of science by funding basic or fundamental research. And so the bulk of our portfolio funding really goes to fundamental research. And that lies as you all know appreciate at the basis of the discoveries that are made, they all start with basic research. And then that proceeds into innovation and tools.

And, you know, I always notice when I go to a hospital that all of the very fine equipment that they have that images then its used for diagnosis and finally cure, so palliatives for our ailments all started with basic research. Well a lot of times with physics or chemistry, materials research and so on.

And so I like to think that we are going to be great and continue to be great contributors towards what you asked for in the beginning who funds the (inaudible).

### KUMMER:

Well, we all like to think you're going to be great contributors and we know that you should be great contributors. But who's actually going to give you the money because what we hear is that it's ever more restrictive with these equestrian and dire strikes.

# CORDOVA:

Well I think I'll let my colleagues talk and we'll come back to that. But clearly that's where Research America has made such an impact is to keep reminding all of us and the public that they need to get the message about who makes discoveries which are namely the folks that we all fund and how that money comes to them.

NSF gives 94 percent of the money it gets which is just over \$7 billion right back to researchers mainly in our universities but also research institutes and even businesses. And we couldn't do that without Congress authorizing and appropriating those funds.

And so it's a virtuous cycle where we need to remind everybody where the money comes from and then get some messages about why these discoveries, how they are made and why it's so important to continue in this pane. And as Mary said in her really wonderful remarks is to keep

being great advocates for science and engineering to Congress who is a benefactor to all the American public.

# **KUMMER:**

Thank you. Dr. Hait, we have the opportunity to have lots of frank and useful exchange before the panel. And if you'd like to talk about your own trajectory it would be really interesting from research, the academic medicine too.

# HAIT:

Yes, and that's a good -- I love the quote of that research. And Einstein had another one. And he said something like, if we knew what we were doing we wouldn't call it research. And I think that's really important. My own perspective having come from academics and then joining the industry really has to do with an unintended consequence of an extraordinary development. And that was the era of molecular biology where we understood in sequencing the human genome.

We had these incredible tools to express proteins, crystalized proteins, making credible drugs. And based on that knowledge there was push to translate that knowledge into practical use. And I think what happened that pendulum swung so far over at the NIH that many, many grants are judged by the applicability or the translational aspects which really moves things away from the area where we really need to get back to I believe and that's uncovering fundamental knowledge.

And my perspective from the pharmaceutical industry is our rate limiting step is not making it highly potent drug. Our rate limiting step is a limitation on knowledge. And pharmaceutical industries are great at discovering drugs. People in academics and other types of institutes they're great at uncovering new knowledge. And I think we have to get back there.

# **KUMMER:**

You know when you say the metric, the importance, and the applicability and where will the practical outcome be? And would you have to demonstrate that to get a grant? Isn't that too bad? Well you're in an industry where everything is about making basic research useful to the public. But isn't it true also that foundations have moved away from thinking of funding basic research and they're all metric driven famously. So where's the difference?

# HAIT:

I hope not. I mean I think you are right. I see it in the area that I know best in cancer research where there's such a push because it's such a devastating disease that it's a natural tendency. But at the same time we have to remind ourselves that our shortcomings in the application especially in the pharmaceutical and biotechnology industry is not because we can't make very potent

drugs. It's we don't have the knowledge to what are the best targets for somebody's disease whether its cancer or Alzheimer, mood, diabetes, things that we just need more fundamental knowledge.

### **KUMMER:**

Fundamental knowledge, are you for or against it?

### **MYERS:**

Well I'm a scientist. So I'm for it. I'm in an academic institution. That's a little bit unusual. It's a nonprofit research institution that has biotech companies in the same building and the same campus and so the idea of interchange between that.

But and the dichotomy of applied versus basic knowledge research is a silly one to even argue about. If you're going to have a biomarker that allows you to detect whether somebody has early onset of ovarian cancer let's say, you have to discover what the biology is to make -- what the biomarker should be. So you got to do basic research in order to do that and if the public doesn't pay for this, it's not going to happen. The industry should not, cannot and will and should not probably be funding only then. They take the discoveries made in this combination of academic and nonprofit and other kinds of institutions and turn them into products. We are trying to be a hybrid between those so (inaudible).

# **KUMMER:**

Because this has always been two kingdoms, right? You know basic search and then applying it in industry.

# **MYERS**:

In lot of peoples minds yes, I think the problem is and a lot of time you hear this in the public but -- and with our legislators that I want to see an income from this immediately. And 90 percent of the --some huge portion of the discoveries that have been made are one step where people are imploring and trying to learn something that happen to be deeply interested in a problem.

Many of these seem like they're just esoteric. And the recombinant -- the whole recombinant DNA revolution and the whole industry was born out of two guys and others as well. But stand in the corner boy, you are playing around in their laboratories.

I don't actually call it playing. They were working really hard on something that didn't seem that interesting at the time that turned out to be phenomenal. The Human Genome Project is another

| KUMMER:  |
|--|
| But you are talking about basic research that was publicly funded?   |
|  |
| MYERS:   |
| Absolutely.  |
|  |
| KUMMER:  |
| Right?   |
|  |
| MYERS:   |
| Yes.   |
|  |
| KUMMER:  |
| And do you see the landscape now as being at all favorable to that kind of funding?  |
|  |
| MYERS:   |
| Well I'm an optimist always. And its certainly, certainly I have been doing this for a long time and I've seen it decline. But it's not zero. We spent a lot of money. I think this organization plays a really important role in doing that. I think our big problem is that we don't educate the public and our politicians very well. |

great example. There are many, many examples of that not just in genetics and genomics and

molecular biology but in all fields as well.

We just -- Most academic scientists are barely willing or even able frankly to talk in the public about what it is they do in everyday language so that you explain why it's so important. When I - I spent a lot of time talking to the public in our areas and actually elsewhere. And when you take the time to engage them they're really interested in it even if it's a very basic problem.

# **KUMMER:**

I wonder if that's the problem though and every one can chime in on this, even though I'm eager, eager to hear from Dr. Fauci and our other panelists. But isn't that scientists are not able to do it

or that they are trained to do something else. And they're not trained to communicate with the public and make things accessible on a very public scale or to have sharp elbows to get grants.

# **MYERS**:

So it's all of those. I mean, some and each of those. Most scientists haven't been trained to do this. Many learned or some learned to do it. Everybody's busy. I mean, it's more and more competitive. The competition makes it work well, I think. The sharp elbows means sometimes and often that means you re-board sometimes the best scientists in science and sometimes the most aggressive ones but it does -- it's a good system.

I fear I think all of us fear we've talked about this before lunch that and I have feared this for a decade at least we're scaring off young folks. They're -- This does not look as promising as it was when I was thinking about graduate school although it does seem to come up and down.

# **KUMMER:**

(inaudible) And Dr. Fauci we're going to take off on that point. Dr. Fauci.

# FAUCI:

What's your question?

# **KUMMER:**

The question was if you are good at advocating for yourself and advocating for both basic research and you oversee an enormous operation that has a lot of practical applicability as well. Have you seen the landscape shift away from money for basic research?

# FAUCI:

Well, yes, by necessity of the constraint resources its almost formulae that what we do is that we designate a certain amount of work for the fundamental basic on differentiated research that is officially known as an RO1 pool where you get investigator initiated.

And then you have what's called programmatic initiatives are things that you need to do. You need to develop an HIV vaccine. You need to find out a point of care diagnostic for Ebola. You need to do those other types of things.

When you have even a modest increase in a budget you can actually preserve the fundamental basic research pool at the same time as you do some necessary programmatic initiatives. The

problem we found ourselves in right now is that the budget has been flat for ten years and then superimposed what we all know was a sequestration. And we all know the numbers. We've heard it here many times that at the end of 10 years when you have a 2 plus percent inflation area index that you loose 22 percent of your purchasing power in 10 years.

So when you do that we do get asked all the time. Now what have you done with the money that we've given you? And it's very difficult to explain as eloquent as you can be to someone that its fundamental basic research is what we've got to do. People want to hear what you can do. I think what we need to do as a nation is to have a -- I mean everybody's got their own solution to it which just means that there's no solution.

Is to -- As a nation, make a commitment that fundamental research and science should not be part of a discretionary pool. I mean when we look at what happens to us you have the mandated budget. You have the entitlements and then you have the discretionary pool. And we're in the discretionary pool. So whenever there needs to be cutting of any budget it gets cut at the discretionary pool.

I think we have to have a complete transformation of how we look at science. And, you know, I have tried to articulate that at various levels and some people get it and some people don't. But at the end of the day the question always is, what have you done for us and it's very, very difficult to articulate what we have been articulating about basic research is the fount and the source of what it is we've done for you.

So whenever I get asked that question, I never unlink the two because if we keep talking about what have you done for me lately, five years from now if you shrink this in discovery pool we're not going to be able to tell anybody what we've done for them lately or we're going to tell you we've been doing the same thing that we've been doing for the last five years.

So it's a very difficult problem and I think we need a complete transformational change about how we look at science in this country. And as it come from above. I mean, it has to come from administrations. It has to come from elected officials. The trouble as well all know, I'm telling the choir how to sing here is that when you have a cycle of people who are elected anywhere from two to four to six years they're looking at two to four to six years. And research, you know, the molecular, biological revolution didn't happen in the two to four to six-year cycle that happened over a long period of time for people who are committed to it.

# **KUMMER:**

So two unfortunately big follow up questions. One a little bit of shaving in of the transformational change you'd like. And second bonus question, would that look like anything before? Was there a golden age in which politicians have the long view? And just let's fund things for the next -- for three generations away. We'll never know because we're philanthropist.

# FAUCI:

Well they did but they didn't know they were doing it.

# **KUMMER:**

That's exactly right.

### FAUCI:

So they did it. They gave a certain amount of money that allowed the scientists to do that delicate balance between fundamental research that is research thing that you don't know where its going to go and yet to be able to do things like develop a polio vaccine or develop this or develop that. And there was always that balance where you could actually do both.

The lesion, Corby, is that when your so restricted you can't do both. And the thing that cries out to be done is, what are you doing for me lately. And that's the reason why you see the other pool shrinking. Why you have success rates now that are preposterous. My success rate years ago was 35 -- 36 percent. Now it's 12 percent, 14 percent, 15 percent. I mean that's untenable.

### **KUMMER:**

I'm going to go back about the transformation of change and Dr. Seffrin has been very patient.

# SEFFRIN:

Well I agree with everything that's been said. Mary wants straight talk. I think first of all we need to put and stipulate right upfront we need to integrate and balance our research portfolio. And that means to be more for basic and it needs to be more for applied, more from professional research, more for public health research.

It probably wasn't called the NIH, National Institutes of Health because it could have been the National Institutes of Biomedical Research. But I think the implication was the American public wants to invest in something to get better health.

And so, we should be tough on ourselves in the following way. I think that the work of Research America is historic. I mean, we did double the United States budget in a five-year period of time, the only time that's ever happened in 100 years.

So I think we know we can increase the priority for research. But we have to sort of say have we really made the value proposition as strongly as we can. And I think the answer is no. So, 1600 people have died today of cancer. Different from when I got involved four decades ago. Most of them are suffering and dying needlessly. They don't have to die of cancer.

We now have cures for cancer not as many as we'd like but we have actual targeted therapies that work for a subset of patients. So I think we have to meet the value proposition. And value proposition for investing a hell lot more in research is better than just about any other value proposition out there including national security.

The President's speech last night, you think about national security. When the nation has been faced with a health, safety, or security issue of compelling interest and we have the evidence to back it up. We tend to respond. We have that evidence. If we do the right thing we can guarantee results. And you are right Tony, about the short term thing but we need to take the longer view.

And not every legislator is the honorable John Paul Vern (ph) and Michael and others. We have to then make that case then we have to make noise and get the word out there. I mean, when you think complimented time because you've done such a great job in the media balancing and getting it as an expert and also as a communicator not creating a frenzy of hysteria over Ebola. But also pointing out this is a serious issue we need to address and I think we will. I think he is.

What about the tsunami of noncommunicable diseases that's coming overtly in this country and worldwide? We have innovations at work and they're proven to work. We have to fund them if we don't, shame on us. So it's a clear and present danger if we don't beef up our investment in research.

### KUMMER:

So be even straighter in your talk because that's a value proposition everybody in this room agrees with. I mean, I don't think you have to make the case to all of us for that value proposition. Why does it remain that it needs to be made? Why is it so hard to make? What's getting in the way of transmitting that message to people not like us?

# SEFFRIN:

I think there are two things. I think again let me say to Michael Castle. Not every legislator is like that. And I think you have to go to them and draw a picture. And then you also have to say in the following which we now can say with the World Economic Forum report at Harvard University, oh by the way if you don't respond to this here's what you're going to pay for it, the reduction in economic productivity.

So now you've linked health, safety, and security with economic productivity. It's a compelling case. And then we need to able to say which were awfully sweet usually. We need to say and, oh by the way we intend to hold you accountable. Next week literally a week from today we'll have 600 cancer survivors and advocates from virtually 435 congressional districts in Washington. And we're giving them specific messages and those messages are we want something done. We want more for biomedical research, for cancer research and so on. And I just think we have to be -- play harder ball.

# **KUMMER:**

Play harder ball, OK. Well listen up everybody. That's one of the messages.

### CORDOVA:

And there's need to be new ball players too.

# **KUMMER:**

How do you mean?

### CORDOVA:

And well, I've been visiting with Congress a lot and of this past week I've got six visits. And they all tell me the same thing that it can't be just scientists and engineers scrap (ph) heads of agencies in their asking for more money for their agencies. But that some of the people that we affect should be in their talking with them. There should be more industry people for example they would like to see. And I know that every industry person I speak with has it on their list of priorities. But it's not like one, two or three. It's like nine or 10 and you only, you know, 10 or 15 minutes or something and you don't get to number nine.

And so while they're all for it and they all use it they don't really internalize the crisis that we're facing and make it a number one or two priority. So they say it would make a big difference if industry people from a small medium size and large that were in their districts or at least in their states were in there making the case.

And the other people they'd really like to hear from are -- and this is something I'll bring the message back to the Associations of University Presidents is that how about bringing some students along when a faculty member or a university president goes and visit Congress because the student's stories are very compelling about their sense of excitement in the discovery, where they're going to next and how they get funded is something that would really resonate. So they need to hear from other ball players.

# **KUMMER:**

How do you explain and we're going to pick on Dr. Hait here. How do you explain industry's reluctance to give time to this kind of advocacy if indeed they plan to continue relying on the kind of discoveries of basic research? Why aren't they looking at, you know, this golden goose or this necessary partner and saying we should be spending our time advocating because everybody is going to do a fine job.

# HAIT:

So it's to resonate. I don't think that is not a high priority. In fact it is. So, a company like J&J (ph) and I'm guessing many of the large companies we have big public policy groups in Washington pounding away all the time. But I do think there is an angle that we can do better on.

I think that as a -- when faculty members go and advocate it's quite self-serving. It's quite self-serving. When industry goes and advocates for universities, that's not as self-serving. And I think has enlightened self-interest and I think that's something we can take advantage of.

The other point that Tony was making about the golden year if that was the case. There were also leaders like John Porter, like Ted Kennedy, like Laura Wyker who thought that investment in research was important. They didn't get down into the whiz of how you invest it. They just were advocates and they were bipartisan. They'd go across the aisle.

Well I don't, you know, maybe you guys see it today. But I don't see much of that happening today.

# KUMMER:

Does any one on this panel see that or and advocating Congress for basic research?

# CORDOVA:

I've seen lots of them.

FAUCI:

Sure.

# CORDOVA:

I mean I in fact haven't met anybody and I've done dozens and dozens of visits since I started in April on both sides of the aisle. And to a person they get very engaged and enthusiastic. And often they'll have a picture of something, you know, to do with space or discovery in their office. And we'll get -- we'll talk about that. I -- They are under a lot of constraints fiscally, OK.

# **KUMMER:**

The two would come together across the aisle to make it happen.

### CORDOVA:

Now that's a real challenge. And in fact, to the extent if we allow in this room science to become political and we must really fight that very carefully and strategically without arguments that it's always been nonpartisan that was created.

Actually many of our agencies were created out of national needs and we shouldn't forget that. But point out how fundamental research addresses over some period of time this national needs.

# **KUMMER:**

Dr. Fauci I think you were going to add something. And does that cut any ice?

# FAUCI:

No, I don't think so. Not -- No. I don't think what you're saying cuts in the ice is I'm all for advocacy but, you know, having gone to virtually every congressional office trying to explain about the importance of biomedical research you are absolutely right, France, that every single person says they're in favor of it.

But I don't think that if you're in favor of it and it's self- evident that if two other people come in you're going to do something different. I am very sorry but that's not going to happen. They are telling you we can't do it because right now this is not the highest priority. The highest priority is budgetary constraints and getting the budget under control. That's the reality.

So although I am all for advocacy, I think that well if I go in and say something that I think is self-evident, well they may not do it. And then if you and you go in and say the same thing well maybe they're going to want to do it.

And then if that table goes in and says it yes, now we're going to do it. They're not going to do it. And they're not going to do it because of the budgetary constraints. And I think that's why I say you need to transform in the big picture where we as a nation put biomedical research because it's not the priority. And I think no matter how many people come in there it's not priority right now when the most important thing to do is to balance the budget.

# **KUMMER:**

But don't you think that when we have Ebola on our shores or SARS or?

# CORDOVA:

| That was my question. Why don't you ask it?  |
|--|
| KUMMER:  |
| Oh, I'm sorry. But I mean the problem is we're waiting until it's a crisis.  |
| FAUCI:   |
| Right.   |
| KUMMER:  |
| And I mean how many of these had been averted because we do have basic knowledge and (inaudible).  |
| FAUCI:   |
| Wait a minute are saying that I don't think we should have? I definitely think we do. But I think that they're not going to spontaneously give us resources.   |
| KUMMER:  |
| Sure, sure.  |
| FAUCI:   |
| That's the point.  |
| CORDOVA:   |
| But why?   |
| FAUCI:   |
| This can't shock them into seeing the need for basic research that well. Oh my goodness I think the opposite Corby this will shock them into thinking where was that vaccine that you should have gotten for me? |

The first person, you know, I'm sorry I could tell you a scene that's not going to happen. Somebody's is going to call me up and say, Tony, did you see there's an exponential rise in Ebola in West Africa? Why didn't we do basic research? Uh-oh, that's not going to happen. Its why didn't we have a vaccine? I see Julie shaking her head because she's been through that with me a few times when she was at the CDC. But anyway that's another story.

# **KUMMER:**

Let's go on to actuarials. Let's move on to a cheerier topic which is the preparation of students and getting them to think that basic research is going to be, you know, beautifully funded and an easy road for them to go down. So we had Dr. Hait. Why don't you start Dr. William.

### HAIT:

So the U.S. has been -- was and has been and probably will stay I think the leader in innovation and advances that have had major impact in biomedical and other sciences. And the reason is that we have had a culture that gets young people into science when their brains are still working really well as opposed to when you get a lot older.

### **KUMMER:**

That's flattering to the audience.

# HAIT:

I'm referring to myself but -- and gives them resources and a culture that is very competitive and that's why we've done so well. And I have done a training ground to students postdocs, undergraduates for a long time now. And they're still very -- the young people are still very excited about wanting to do something positive for the world and they see this and especially they're really smart ones see this as a great, exciting thing to be able to do and feel that there's not opportunity. So I definitely -- I think we've all seen a real decline.

It doesn't mean that we're losing them entirely. You still get great students and young folks coming in. But they don't see a career. And the one thing that has changed when I was in graduate school at least in the culture that I was in you are supposed to then go to a postdoc and then supposed to then go to -- be faculty member. That model has changed. And I think it's good that we change our models. I don't think they should always be stagnant and I'm interested in hearing about Tony is saying, how fundamentally we need to change some of this that the reason to this change is there are many other opportunities.

I'm glad we have people who have PhDs in the biomedical sciences doing policy things, doing things at NIH and NSF. Imagine them being not very smart and trying to do those things, it

would be terrible. So we need to have the -- and we have those other kinds of opportunities. Our biotech industry created lots of jobs and many, many other things.

I think what we are -- we should be training is people to learn how to think like scientists and be able to use that in a variety of areas.

# **KUMMER:**

As opposed to like investment bankers. So, Dr. Hait where (inaudible) scientists for students now?

# HAIT:

You know it's a striking change at least what I've seen. So, there is a time when the best and the brightest students would just love to go a great medical school where they were exposed not just to the state of the art of care but also to the physicians who are also involved in science. And that culture that's what (inaudible) and Tony said here other people in this room.

You don't see that as much it is, that's being depleted. And that was also a magnet for kids, young people to come from around the world. To train at these great academic institutions not only to get to the state of the art medicine and bring that back to their country or state but also because of their curiosity and they have role models to go into their lives, learn how do research and then take on a career in biomedical research.

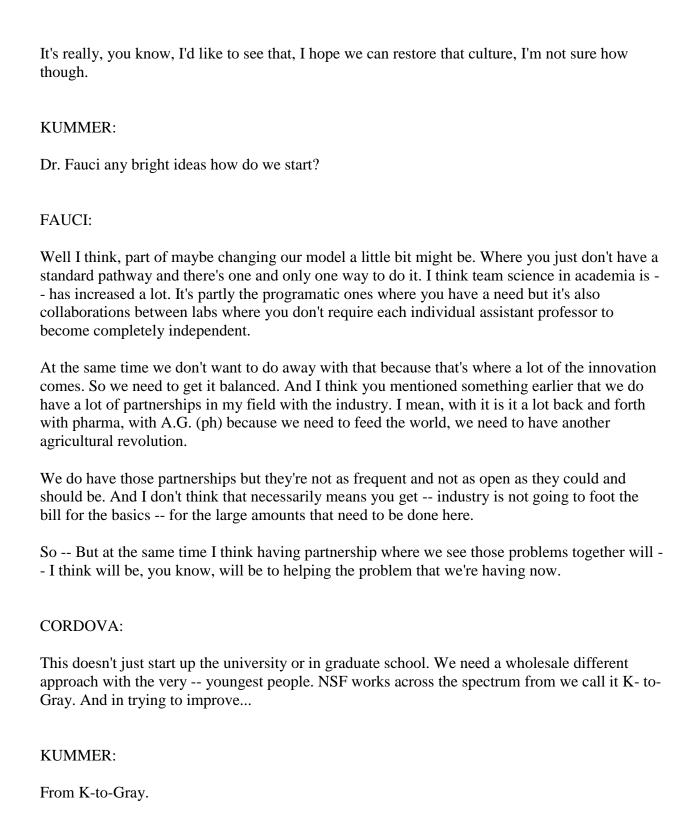
That was a phenomenal training ground for some of the best and the brightest, and that's being depleted I'm afraid.

# **KUMMER:**

So what's the way around it? Who is going to step in and make that? And I'm going to bring it back to China. Is that kind of system being instituted as well the enormous amount of funding which I would assume is much more pragmatically oriented.

### HAIT:

You certainly don't see it in China yet. But have no fear, there's a billion two people many of it -- a huge number of extraordinarily smart people, freedom is breaking out all over, there'll be freedom of thought, they'll get it. And they're traveling within the world as flat, it's going to happen. We need to restore that culture because it was just such an exciting. It is an incredibly exciting time to see a patient, see a problem that's not solved, and then being able to go into a laboratory and begin working on a project that you may take years to work on.



CORDOVA:

K-to-Gray, to improve our outreach for science. And we're more and more intrigued by the possibility of the changing conversation making science more local and doing more community building. We have, you know, teachers who are very enthusiastic about science. Who don't have often partners in order to learn more and what kind of tools they can bring into the classroom.

And I think all of you know, you're from different states that K- 12 is homeroom (ph) and it's very, very different and they're under much, much different constraints than we're out of the university. And -- In partnerships in our -- with community organizations, mayors, even governors, K-12 schools and their teachers with universities that they're really active partnerships, we can reach out and those kids can become a way of, I mean, I didn't know how to spell science as a kid. I actually majored in English when I was an undergraduate student and now I'm head of the National Science Foundation. But that happens because of a moment or an opportunity for inspiration. And we just don't have enough of them.

So we need to start building an infrastructure, and I think what the direction in itself is going to try to build regional infrastructures because every community whether it's a big city, an inner city or it's out in the suburbs, or it's in the country in some rural area has different opportunities for science, and to engage students in a real science experiments. And touching at -- and you just don't know where that's going to lead with.

You're not going to have, you know, some young girl who's never been exposed to a scientist become the director of one of the -- our agency.

# **KUMMER:**

Dr. Fauci, this idea of inspiration which could lead to lots of basic research and being able to pursue these fruitful new blue sky fields. What kind of transformation do you have in mind and how would it look?

# FAUCI:

Well, the transformation I'm talking about is a fundamental commitment as a nation. And I keep coming back, it has to come from the highest levels, it has to come from an administration and it has to come from the leaders in Congress that we're not going to diddle around with these little talking, but we can actually change the system. We're going to make a commitment, a long-term, 50-year commitment. Not a commitment for a budget cycle of one year that we as a nation feel that science in general, but for what we're talking about today, the health sciences is something that we absolutely need to support.

You know, it's very interesting, it's a shame because when you were talking about the Chinese and you were saying quite correctly that sooner or later they're going to get it because they are known to probably, I would say a little unfairly, they can do a lot of things when somebody else discovers it but they're the ones to discover it.

But, we do have in this nation, for reasons that are historical about how we will form that's in a nation of immigrants, it's a nation of people who are always been up with mobility in the sense of tying to do better, a very, very creative mindset that you don't see in almost -- in any other place as much as it is here. And it would be such a shame when you take those people who have the capability of being incredibly iconoclastically creative to go into something other than science or other than the biomedical aspects of science.

So, that's the thing that worries me most. If you stay on this track a bit longer and don't make that transformational change of saying that we as a nation are going to support this, that we're going to get people who are just no longer interested in it anymore, and that's really going to be a shame because it's going to take generations to get that back.

So what I mean by transformation is a real commitment that goes decade's commitment, not a two-year commitment.

# **KUMMER:**

You mean space launch kind of...

# FAUCI:

Yes. That's what I'm talking about, Corby, that kind of thing.

# HAIT:

If I may? Or perhaps and even more inspirational vision than we currently have, I think could be a rallying cry, can we envision the time, so you take some of the most serious diseases and you say, by 2030. Can you envision a time when there is no more type II diabetes? And if that -- If you can envision that, what do you have to do today to make that a reality? That inspires young people, especially if they've had diabetes in their family, cancer in their family.

That inspires them to get involve. And I think the idea that we can predict who will get diseases will become clearer and clearer. And the idea that we can preempt, we can prevent, we can intercept the process, that's a compelling vision that I think kids can rally around, young people can rally around, and God knows even Congress might rally around it but that's definitely what you say.

#### **MYERS:**

I was just going to add to this that -- how do we do what Tony just suggested, how do we get the nation, perhaps to inspire them, we have to teach them, we have to spend our time doing it. I do

spend time with some of our elected officials talking about how the impact that this is having on our economy.

At least 60 percent or 70 percent of our economy comes from science, math, and engineering not from -- I mean, we want -- everything can be met but that is a major, major impact. I don't know what the numbers are for NSF and NIH but every dollar spent is got to be at least \$10 or some -some significant number. In some fields even more, (inaudible) the study on genomics with and medically a new feel that's just starting to see and at least a couple of years ago the -- multiply it was 141 foes (ph) of different genome project.

# We won't see that in everything but -- and I don't want that to be the only argument we make to the public... **KUMMER:** It also has to be compelling. **MYERS**: But it is a compelling one. And it is the way that the U.S. will stay competitive. **KUMMER:** Well this has been an inspirational panel. We face threat, we face a great environment for discovery that you're all here to forward and promote with the kind of passion we have seen on this panel. So, I wish you all luck having your message received. Thank you all.

# CORDOVA: Thank you Corby. (UNKNOWN)

# WOOLLEY

Thanks Corby.

(Inaudible) the audience, then you would take a few questions.

# KUMMER:

I so wanted to but I was given constant and dire wrap up now. Yes, I'm afraid I can't.

All right, I was told to wrap up. So, that's why I wrapped up. Obey your orders...

(OFF-MIKE)

# **KUMMER:**

Oh OK, we've been given a special reprieve. Mary Woolley has arranged it. Let's have some hands and let's try to ask two or three questions at a time and at lightning rounds. Hand up, hand up. Let's ask both these questions at the same time. Go ahead.

# (UNKNOWN)

We appreciated the comment about a transformative change. The notion of shifting the budget, that's really -- can you comment on what you think it will take to accomplish that, meaning, duly from discretionary to mandatory (inaudible).

# **KUMMER:**

Right. OK, pragmatic, how to do it. I'll repeat your question while getting you (ph) the mike?

# (UNKNOWN)

I can talk loudly. You talked a lot about (inaudible) having the revenue about funding the system. It's all about the ALS ice bucket challenge which was on Facebook and Twitter and YouTube and it really got public interest...

# **KUMMER:**

The question.

# (UNKNOWN)

OK. So the question is, knowing about that, I'd like you to comment on how to expand these (inaudible) with that increased funding they've raised over \$100 million in to (inaudible) young people that might...

| CORDOVA:  |
|---|
| Ice bucket on every congressman's head.   |
| KUMMER:   |
| OK.   |
| CORDOVA:  |
| So, I have the answer to the second one, an ice bucket on every congressman's head.                 |
| KUMMER:   |
| OK, the first, how to make that transformational moment practical? Anyone who want to address that? |
|   |

FAUCI:

Well somebody's just got to do it. In 2002 when we were looking at the devastation of sub-Saharan Africa and the Caribbean with HIV, when President Bush -- he sent me to Africa and he says, go down and see if there's any way that we can make an impact that would actually -- that was the word that was used, transform HIV into developing world, for a world that's suffering disproportionately because of the extraordinary number of deaths in infection.

So I did and went down there. I spent a few weeks, came back and put together a program which ultimately became PEPFAR and I told him, he said, that's going to take billions of dollars, it's like \$15 billion over five years which was a start. Ultimately, it's much, much, much more than that. OMB went completely nuts, they though I was crazy and I kind of went into witness protection program.

But the decision was made by the President and by the Congress at that time that this was worth it and they did it. And there was a transformation of HIV in the world. We're actually the curve is starting to go down. Now, if we had been at the edges of that, we still would have been chasing it. But that's one transformation -- I don't know whether it's going to be the same model but that's actually what happened. There was a decision made at multiple levels that this was something, we absolutely had to do, and it was done.

**MYERS**:

That's often reactive rather than proactive. And I think that's part of the problem. But we can -- You were referring to doing things earlier. If you catch diseases early, you're going to be able to treat them a lot -- better even prevent them. But we -- if the only way then that's-- I mean, obviously we need to deal with crisis when they arrive.

# **KUMMER:**

But being proactive is -- requires much more boldness than being reactive. Do we have question on this side of the room? Gentleman?

### PARDES:

Well you said boldness, so let me just say, it's a great panel, a lot of good things were said. One of the things I'd like to underscore. Is that there's been people in leadership positions, namely Senator Specter, Congressman Porter, Mary Lasker who went against the grain.

It's always a big deal. The budget problem has always been terrible now. But they led and that leading voice was responded to. We've got to find who whether in the Congress or the Administration is willing to have the courage or boldness to say, this is very important despite what the context is, and therefore show leadership.

The question is how we help them do that.

# **KUMMER:**

It's up to everyone in this room to help them do that or are there other questions? I think we've reached our five-minute period of grace.

# (UNKNOWN)

I know your comment rather than a question.

### **KUMMER:**

Oh, no, we want questions.

# FAUCI:

In the beginning of the conversation about advocacy, you know, we talked about the -- so we talked to employees in talking about fortunately they have elected between the state level and in

Congress and without a doubt people who made the greatest impression on me in lobby were those who had a disease or a problem. It had been patients or whatever it maybe to maybe solve the terrorist to a degree.

Probably they would come in and they would lay out what their problems were. Sometimes they didn't understand all the funding connections (inaudible). But in my judgment we talk about advocacy. You should not leave out their situations for that...

# **KUMMER:**

Imagine how popular Dr. Fauci will be bringing in a group of people who are suffering. So I think that was...

# **MYERS**:

But how about their family members who've watched them die?

(UNKNOWN)

Yes, yes.

# **KUMMER:**

That could get a lot of attention. So we had many strategies. Thank you all very much for coming.

# CORDOVA:

Thank you Corby.

# WOOLLEY:

Ladies and gentlemen, if you could return to your seats please, we're going to begin our second panel momentarily so please take your seats.

OK. We're about to begin. I want to briefly introduce our moderator and panelists, if everyone could please tone down your conversation. This is quite a distinguished group of people.

The moderator for our second panel is Lori Montenegro, the Washington correspondent for Telemundo Network News. She's covered the White House, Capitol Hill, the State Department,

the Pentagon, the Justice Department, for two major Spanish language national TV networks and you can read more about her and for about all of our panelists in your program.

We are extraordinarily fortunate to have the director of the Centers for Disease Control and Prevention with us, Tom Frieden, who's been working if it's possible, you know, 48 hours everyday, a hundred hours everyday on Ebola and it is -- we thank you Tom, especially, for making time today.

We also have Georges Benjamin, the executive director for the American Public Health Association and a member of the Board of Research America. Lynn Goldman, the dean of the Milken Institute School of Public Health, The George Washington University. Richard Kronick, the director of the Agency for Healthcare Research and Quality. And Jack Watters, Pfizer's vice president for external medical affairs and a Research America board member.

Thank you, and Lori, over to you.

# MONTENEGRO:

Thank you everyone and I hope you continue to enjoy your lunch. I want to apologize to the audience in this part of the room. I don't mean to give you back, I'm sorry, but good, good, good, good. You have the monitors and I want to thank all of the panelists for taking time to be here.

I want to get -- start it off on a positive note. You know, a lot of times when we moderate these panels we want to attend and we talk about what the problem is, what has gone wrong, what's not going right, et cetera. So I want to start by asking our panel here who has done a lot of hard work for many, many years to give us one thing that maybe none of us in this room knows about, that is good news on the work that you and your groups has been doing that is currently benefitting us or will benefit us in the future health wise.

So I don't want to pick on anybody but I'm going to go ahead and pick on you.

### **BENJAMIN:**

Listen, you know, public health has been saving lives through prevention. You could get your hand around one thing. We've made a big attack on the second leading and preventable cause of death, tobacco. Tobacco utilization is down and we should celebrate that.

# MONTENEGRO:

Mr. Frieden. That's great.

(APPLAUSE)

# FRIEDEN:

He took mine so I'll say vaccination, because of vaccination and the Vaccines for Children program that's been active now for exactly 20 years, there'd been millions of fewer illnesses, hundreds of thousands of fewer severe illnesses and we're saving \$3 for every dollar we spend on immunization in a health care system alone and \$10 in society for every dollar we spend and industry and NIH and CDC all work together to bring vaccine into market and CDC works with state and local health departments and doctors from all over the country, in fact all over the world to get those vaccines delivered so that we save the lives that can be saved.

# GOLDMAN:

So I'm going to say something that's a positive that's going to sound like a negative to you and that is the opportunity that we have in prevention when we have every year still fight (inaudible) \$96 billion in health care related cost as well as more than 100,000 people every year dying from obesity and that sounds terrible, except for one thing, we know what those things are. We know what the health impacts are and we know that we need to prevent those and we need to get better at that but it's nowhere like the situation that we're in with so many other health care problems where we still don't even understand what's causing them, what we need to do without them.

So we have a tremendous opportunity, if we could only put it together and say boy, all that money that we need to spend to take care of those health care is a way to just -- just looking in obesity we need to draw some more of that into the realm of the behaviors that lead to those, preventing those behaviors. It's a golden opportunity that's right here in front of us.

| MONTENEGRO: |  |  |
|-------------|--|--|
| Perfect.    |  |  |

# KRONICK:

As a result of working with the agency that AHRQ has funded and whether it's our colleagues at the CDC and CMS and the tremendous energy in the private sector, hospitals are in many ways safer than they were 10 years ago. Central-line infections in ICUs have been reduced by 40 percent. We published results recently that showed that adverse events altogether in hospitals have declined by 9 percent from 2010 to 2012. There's still a long way to go but that represents 15,000 fewer deaths in hospitals, \$4 billion in lower health care cost. So much work still needed but progress as a result of evidence that public health research has produced.

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The happiest news is that we are all living longer and that is a cause for celebration and we're doing that for all sorts of reasons, many of which you've heard along the line. We are not a burden as some of the folks along the road would tell you.

Legislators tend to think that older people cost us more and are a burden. I am not burden. And I think one of the best things that is happening is that we are recognizing that healthy younger people have a much greater chance of becoming healthy older people. And recognizing -- in fact, if I may borrow France's expression from the previous panel from K to grey, that is the best summing up of a life course approach to healthy aging that I have ever heard. And I believe it behooves us to bring science and public health together to make sure that we take that life course approach to healthy aging.

# MONTENEGRO:

And I can attest that you are not a burden. My father lived into 95 years old. He was as sharp as a whip and worked until he was about 86 and the day that he stopped working he said, I'm tired and he kept on working after that, not as much, but yes, you're correct. We are living longer and we can live very healthy lives.

And with that said, with all these accomplishments and what we can look forward in the future yet we don't see the funding and we see that I'm moderating a panel that's called Code Red and how can we stop this assault, OK, on funding for research and development and so forth and I want to take time and have Dr. Frieden answer this question with regards to Ebola and is this not the prime example of why we need to really invest in this, you know, nature of science and prevention and so forth?

# FRIEDEN:

Well, let me first say, it really is wonderful to be here. I think the Research America Organization, the group, the commitment is critically important. As I told Mary (ph) only for you would I have taken an hour off from Ebola because that's about all I'm taking this week off from Ebola. It is really an amazing crisis. And of course, here we go talking about Ebola again, but I just would say that the cost of failure to establish a core level of public health services are mind boggling.

I think the Ebola epidemic is worse than is recognized, generally. It's worse not only in a number of cases, reported cases are a small and decreasing fraction of the total because systems are increasingly overwhelmed. It's bad not in terms only of the number of patients but the devastation it's causing to health care systems.

I was just in all three countries, empty hospitals, those are patients not being treated for pneumonia, malaria, not being vaccinated, not getting treatments that would protect themselves and their community and already we're seeing food prices increase and political stability decrease. This is a huge health and security crisis and it's increasing so rapidly despite maximal

effort. We have to date a hundred CDC officers in the field working on this. It's the largest international response in CDC's history and it's not going to be over for a long time.

Now, if we could just replay the tape. If two or three years ago we'd put in basic systems that would do three things, find, respond and prevent. These are three core things that every community needs to be able to do. Find health threats when they emerge, that didn't happen. Respond effectively, that didn't happen here. And prevent wherever possible. If we had done that with a tiny fraction of what we will spend on this in the coming weeks and months and years, we would have prevented these outbreaks from getting out of hand. And there is no more painful, tragic or moving an example of the failure to ensure prevention than the devastation that's happening in West Africa today.

# MONTENEGRO:

To any of you on the panel, do you believe that part of the problem with Ebola could be that many people see it as a disease that is not affecting us here, that it's because oh, it's across the ocean and that's why attention is not being paid to it?

# GOLDMAN:

I think that's definitely the case that in the U.S. we tend to feel pretty comfortable that we do have systems in place that do most of the things that Tom laid out. We were very good at finding them and interdicting. However, it would be very, very possible just a slightly different kind of pathogen for us to see an epidemic arise in a place like Western Africa that we wouldn't easily be able to protect ourselves from.

I mean just slight variations, for example, of the MERS virus which is similar to the SARS virus that most of us have heard of where there can be -- that where people can move around before they're infectious. It's more possible to introduce some of these in the population. An issue that I am particularly concerned about which is the development of antibiotic resistance among pathogens and the fact that worldwide the rate of antibiotic resistance among the most important human pathogen is continuing to rise. We're doing very little about it and if we are to see a rise in the United States spread of antibiotic-resistant pathogens we are not going to be able to control that very easily.

I don't think that we have the degree of concern that we ought to have because of the fact that, as she said, with the Ebola that we do have ways I think of securing ourselves from spread of that virus. At this point, that's what Tom told me.

# FRIEDEN:

Also, I think that our public actually thinks that we have a solid, rock solid public health system in this country because they haven't watched the degradation of the health system over the last

several years. Yes, we've made lots of investment in insurance coverage but at the same time we lost over 40,000 workers in public health than our own public health agencies in this country. We built off a very nice biodefense infrastructure over the last several years tragically since 9/11 so what do we do? Like we do for every other public health intervention, as soon as we think we've got kind our hands just a little bit around it. We cut the funding, remove the infrastructure.

So I am not convinced that we will be able to provide the kind of response that we would like to respond to, to an Ebola into this country. And by the way, we've already got dengue. We've already got Chikungunya. I mean, it's not like we haven't had new emerging diseases in the last few weeks. We absolutely have.

# MONTENEGRO:

Mr. Watters, I want to just ask you. Pfizer does a lot of work globally and so does this -- the fact that we see public funding being cut constantly and that's something I want to address later on but does that put more pressure on the private sector? Do you...

| WATTERS:                |  |
|-------------------------|--|
| Yes. It does.           |  |
|                         |  |
| MONTENEGRO:             |  |
| How do you handle that? |  |
| WATTERS:                |  |

You know, first and foremost, the public health of any nation is the responsibility of the government of that nation. It is no one else's responsibility. But no one can do this alone and I think what I see is a very positive response is that we're seeing far more appetite for public-private partnership, for governments and the private sector working closely together, whether it's in research or whether it's in delivering public health or you'll hear people talking about capacity building.

I don't like that term because I believe (inaudible) the capacity is there. It is a matter of unleashing it and freeing it up to deliver what it's supposed to be doing. I think it behooves us all to recognize that we should be in this together and working together in breaking those barriers down and I welcome the increased appetite to partner.

# MONTENEGRO:

One of the things that struck me while I was doing some research for this panel is just the seesaw, looks like a little rollercoaster, the funding year after year and so how on earth, Dr. Freiden, as somebody who directs the CDC, how do you plan? How, you know, I don't want to push on the stuff but do you even have enough money to confront this whole situation with Ebola? But how do you plan from year to year?

# **BENJAMIN:**

Let me (inaudible) he says that, no he doesn't.

# FRIEDEN:

Again, he took my line and I will say that public health really is a best buy. It's what protects all of us. It's what keeps us safe. It's what prevents problem from coming into this country and every dollar we invest is going to pay off. It's going to pay off in fewer infectious diseases. It's going to pay off in less cancer, less heart disease, less stroke, less diabetes and our challenge is try to make sure that we have the kind of partnerships and momentum so that we can build on the successes we've had so far and protect the country and the rest of the world from threats that emerge like Ebola and drug resistance which are going to be ongoing threats.

One of the challenges obviously is that year to year nature of funding but we always try to do is fundamentally make diligent use of every dollar entrusted to us and ensure that we can stretch that as far as possible. Part of that means partnerships, partnership with AHRQ, CMS. We have a very robust relationship with CMS now that never existed before and we're thinking about how we can be synergistic in getting the health care system, getting more of a public health approach, if you will, and partnerships with the private sector, philanthropic organizations but fundamentally, exactly as you say, public health is a responsibility of the government but the government can't do it alone.

# GOLDMAN:

And if I can chime in on the aspects that I think connects to the research and what a couple of them just said, the capacity that's out there needs to be mobilized, it also needs to be educated and it needs to be informed. And what I mean by that it's not enough to say, don't just stand there, do something. We need to make sure that what we're doing is going to be effective, it's going to be the best use of the resources that we do have. They'll never be unlimited.

And that's requires research, it requires research, it requires education. And we have a huge struggle with maintaining an adequate amount of funding for research, especially when it comes down to applying what we know. We can learn the fundamentals about what causes disease. We can identify potential avenues for prevention, but we need to be able to take those things into the field and do trials and determine where we have the evidence about what works, a scattershot approach, which is what we often end up doing.

Well, often, you know, we'll take down whatever we're trying to take down but we're wasting a lot of bullets and there are a lot of other problems that we aren't addressing because of the fact that we aren't sure how to target our efforts.

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Mr. Kronick.

# KRONICK:

I would add to. I think you're asking, you know, really excellent question to begin the segment about, is it a perception problem. And you asked was there a perception problem about Ebola and the threat to United States and Tom and others gave excellent answers to that. There is, I think, a much broader perception problem and that's that many people, I think, think that, well, maybe we have some problems with affordability that health care may cost too much. And there's some understanding that there are some access problems and certainly, the last couple of years 10 million new people, newly insured, there's some focus on access. But that, most people think quality and safety are just fine.

And there's a perception problem because I think everybody in this room probably knows that that's not the case. That, you know, as Beth McGlynn showed 10 years ago, 50 percent of recommended services aren't received by Americans. Lots of preventive care that isn't received, big problems with safety that we have made progress on. But there is a perception problem that practice is OK. And then, the second perception problem which is, we have not, I and my colleagues have not done as good a job as we need to do in explaining the effects of the research and the evidence that we generate on improving the practice of care.

And so, the Ebola perception problem that you ask about is certainly very important. Today, there's a much broader I think two perception problems that we need to be working on here.

### FRIEDEN:

And really just piggy -- If I may pick up on that for a minute, health care, we spend a lot of money on health care. And yet, just take two simple things, handwashing in hospitals. Not being done reliably, as a result, lots of hospital-associated infection that could have been easily and inexpensively prevented. Second, control of blood pressure. You know, if you ask a very simple question, what's the way to save the most lives with medical care? The answer is actually quite clear, improve blood pressure control. And yet, despite everything we spend for the 68 million people, Americans with high blood pressure, only about half of them have been under control. And most of those who don't have it under control have insurance, saw the doctor twice last year.

So, we have so much room to grow in improving quality and that will give us such a better health return on our health investment, \$4. And to get there, we need evaluation, we need programs that

are rigorously tested, we need to scale up what works, we don't need the boutique programs, we need the programs that are everywhere quickly, and understanding what works and how to scale that up. It's a critical role for public health, research, health care to do together.

# MONTENEGRO:

OK so -- I'm sorry, did you want to add something?

# KRONICK:

Just a very little advertising for the agency. We are issued a funding opportunity announcement and are moving towards awarding grants to work on exactly the problem that Tom is discussing. We'll be awarding grants to work with small and medium practices around the country, up to around 6,000 physicians will be taking care of 9 million people to try to figure out what kinds of supports these small and medium size practices need to make progress in improving control or blood pressure, lessen cholesterol and aspirin and smoking,, ABCS of heart health.

# MONTENEGRO:

So I hear what you're saying and some of the -- I think what you might be saying is that people don't really take this seriously. And a lot of the people who may not be taking it seriously are those who can approve funds in Congress and who do the voting. And for example, I understand there's legislation right now being introduced by Congressman Lamar Smith that would set a whole different criteria, I think it's for the Science Review Foundation, something like that, in order to get funds.

How do you feel about that legislation and how would that even begin to damage or hurt the work that your organization is doing? Go ahead (inaudible).

### **BENJAMIN**:

Yes, I don't know the legislation but let me just say that there's this somehow this belief that if you see your doctor twice a year or four times a year, that somehow magically, that's going to help you. It's wonderful to see your doctor four times a year but that's a check up. And, I think people need to understand that we haven't crafted a system which allows people to be healthy.

You know, we haven't crafted a community so they're walkable, bikable, green. We haven't crafted communities so that there's no wrong door for you if you go on for your blood pressure and it's high that there's a process that gets you to someone to help you understand why it's high and to bring it down. You're in your pharmacy a whole lot more than you're in your doctor's office.

You know some people and certainly, in the grocery store three of four times a week. And there's a little machine in most of them where you can take your blood pressure, but even if they take that blood pressure and it's high, there's no looping mechanism to get them back to get that taken care of. So, the problem is, is that we don't understand how to craft a system to ensure that people can be healthy.

And I think that's the kind of funding and research that we need to better understand. But when we talk about doing that, then they call it the nanny factor. And I always say, why would anyone spend money to do something that's not going to work? We're just simply trying to find out what works and find us then money to do that. And that's what prevention research is all about.

And, to the extent that someone wants to put in legislation to help us fund that, that's wonderful. But my experience has been, these -- a lot of these legislation -- and again I don't know about that piece, a lot of these legislation has wonderful titles which doesn't do exactly what we need.

| MONTENEGRO:  |
|--|
| Mr. Watters first and Ms. Goldman. Go ahead.   |
| WATTERS:   |
| I think seeing your doctor four times a year is better than not seeing your doctor at all. |
| BENJAMIN:  |
| Absolutely.  |
|  |

# **WATTERS:**

And I think there is an opportunity for you to talk. I agree about the pharmacist. I think -- certainly, I can speak for my industry. I think we've ignored the pharmacy professional and the nursing profession at our peril because -- I always remind my colleagues that doctors have not idea what our pills look like. Pharmacists and nurses do know what they look like. And I think that's -- reach anyway we can reach people because there's an incredible complacency about health.

If you look at the flu vaccine, and Pfizer doesn't make flu vaccine so I can talk about this. People just don't get it. They just don't get the flu vaccine. If you go to, if you go to Rwanda, you will -- they aim for 100 percent vaccination rates. And the human papillomavirus rate is at about 85 or something. And it's only that because they only introduced it a few years ago. Where there is political will, you can achieve anything. And I believe that is really what an organization that

research America and everyone in this room can do is make a difference, is sweep away that complacency and try to speak to raise political will.

### **GOLDMAN:**

I mean what I would say to Congress about that is that it's very important to make about diagnosis, you know, before coming up with the remedy. And it seems to me that what certainly people in industry are seeing which Congress doesn't seem to be seeing is the value of prevention to return on investment. So, more and more I think corporation investing and prevention among their employees. And munch more aware the linkage between prevention and ultimately, the productivity of their employees, how happy they are, the health care cost.

And that message has not gotten through the Congress. So, that does involve, unfortunately, more expenditures for research than they're making today. But the payoff in terms of the bottom line for us the American public, the taxpayer, is potentially tremendous, it's enormous. And how we get them to understand in a way that a company president can understand how this all impacts the bottom line. I think that that's a challenge that we have in communicating to policy makers because they tend to focus on only one piece.

And some will only be looking at the research while others are looking at the CMS cost and they're not putting that together.

# **MONTENEGRO:**

So, Mr. Kronick, I wanted to ask you, I -- you are all saying the same thing. There's -- the connection is not being made at all. So, where is it that we are failing? Where is it that maybe your organization is failing? I, you know, we all know that Congress can act if this pressure comes from the bottom up. And the bottom up are the voters. So, is that where we really need to start with about the community? But where is the failure do you believe, where is it that your organization might be able to do better and that you would like to see them do better. And then what timeframe? I don't mean to put you on the stop.

# **KRONICK:**

The easiest part of that question to answer and the timeframe is yesterday. I think the director at AHRQ for about a year and have been working hard with some success but more needed to very clearly tell the story of the effect of the work that we have funded. And also, to working on trying to make sure that we don't just produce evidence but that we work making sure that evidence is understood and used. And we do have some remarkably good stories to tell.

# **MONTENEGRO:**

So, where are -- why have those stories not gotten out and, you know, maybe the meeting I don't know but, you tell me.

### **KRONICK:**

We need the help of everyone in this room it is, you know, as you -- everybody knows there is tremendous amount of information all around and it is difficult to get attention to information especially when we are not so able to identify individual whose lives we've saved. So, you know we have funded work that has shown that well-income children are getting too many prescriptions for antipsychotics. And that has resulted in action by state Medicaid programs and others to reduce the use of antipsychotics. But it's hard to find a child who is so much better off now. So, it doesn't make such great headlines as potentially work that would find the cure for cancer.

So, it's somewhat more difficult story to tell. But, you know, I take responsibility and certainly, working as hard as we can trying to tell the stories clearly as we can as well as in, you know, trying to make sure that the evidence actually is understood and used.

We have in the past I think probably put too much effort on just generating the evidence. And we are pivoting now to working on dissemination and implementation. But we need help from everyone. We are a relatively small agency. We have, you know, one about one-one hundredth of a percent of healthcare spending in the United States to goes to AHRQ. There's a lot of other messages out there. So, we need help on this.

# MONTENEGRO:

I saw you shaking or nodding your head there for a minute.

# GOLDMAN:

Well, you know, I think that the question you're asking is really important question. I wish I had, you know, eight simple answers because I do think that what Research America does in terms of bringing us all together to address that question. It's very important, it's so easy for a speech to devolve into, you know, what's the best thing for my school, for my agency, for my company, for my industry, right? And/or my disease, the disease that I advocate on behalf of. And creating a larger vision and communicating a larger vision and finding a way to communicate the things that we know within that is what we haven't done well. You're absolutely right in pointing that out. And we need to be challenged to do that. It's one of the most important things that we can do.

# **MONTENEGRO:**

Dr. Frieden as head of the CDC.

### FRIEDEN:

I think we need to have an approach, come at this from multiple angles. What we've seen is that some of the best partnerships and the most effective ways of informing people are working with the patients and families. To give you an example, Consumers Union has worked with many individual patients who have been had to deal with hospital acquired infections. And they've really moved the ball. So, getting individual patient stories out there makes a really big difference. And we need to be able to tell those stories well.

Second, no one should ever underestimate your ability to ave an impact. I'll just give you three examples. One, all of you if you connect with educate, inform advocate with the people who you know in Washington or in state or in local government or policy makers or other areas, you can have a huge impact, especially if you're not in government. Because government always -- someone said well, you're saying that because you're out for your own entity. But if you see what's really needed and you advocate for that, that's going to have a much bigger impact than other advocacy.

And the story I'll tell about this is when I -- the first management job I had in public health was running the tuberculosis program in New York City. And there was a New York Coalition to Eliminate Tuberculosis. And when there was a change in mayoral administration, the president of the New York Coalition to Eliminate Tuberculosis wrote and said, there's a rumor that you're going to stop the renovation of the chest clinics which the prior administration is committed to.

That letter went to the mayor and deputy mayor and now the commissioner and deputy commissioner and ends up on my desk. I don't know what to answer because maybe they're going to cut our clinics. So, I wrote back kind of a mealymouthed answer saying well, don't worry. We'll look at it, blah, blah, and it went all the way back up and came all the way back down with a note from the deputy mayor saying no, tell them we're going to do it. And that one letter preserved our clinics. And the New York Coalition to Eliminate Tuberculosis was actually one person, Charles Alers (ph), a former -- a cured tuberculosis patient who made a one-man (inaudible). So, never doubt what you can do with the well-timed and heartfelt, sincere request.

| You told me you | were a troublemaker ( | ph). |
|-----------------|-----------------------|------|
|                 |                       |      |

BENJAMIN:

MONTENEGRO:

Yeah, I.

### MONTENEGRO:

So I'm going to ask you.

#### **BENJAMIN:**

The answer is we need to have resource allocators i.e. elected officials who don't talk about research with their mouth but talk of supporting research with their vote. And we need to hold them accountable for that. And we have lots of folks that say well, you know, we can't do it because we don't have any money. We have lots of money. This nation always spends money on what it wants to. My god, we just had 13 years of war and going on and we borrowed the money. I'm not so sure why we can't invest in research.

My father said to me when I got my first paycheck that you should pay yourself first. And I would argue that we should pay ourselves first with research. That is a sound investment. I'll steal Tom's line again. It's a best buy. And I don't get it. You know, when I hear someone says well, I support research and dah, dah, dah but they don't vote for it. They lose all credibility.

But we also need to make sure that we have committee chairman and these appropriations committees that support research. And that idealogically don't support the evidence. And when someone in leadership puts people in these jobs that really don't support research then we need to tell them, you know, we don't think that's a good idea. And we need to call them to task. And I think that it's good for advocacy organization to do that.

But the way to really get that done is this again, as Tom said is, you know, I just got to go there and talk to him, your cousins got to go there and talk to him. And when they see me coming in the door, they know exactly what I'm going to say. So, we need Auntie Sue and Uncle Jones to go in there and bang on the door and demand that they support, you know, improving the healthy communities and support the service.

#### **MONTENEGRO:**

You have here a room full of people who if you could put one seed in their mind that could get that done, what would be that step that you would encourage them to d?

### **BENJAMIN:**

I would tell them to just go ahead and meet the local elect -- a local or state elected official and begin the process of getting to know them. When you don't have an agenda, just get to know them. Because, you know, when you have a relationship with an elected official and they learn to trust you, when you don't need them for something, when you do need them for something, they're much more likely to listen.

### MONTENEGRO:

And that's just a reminder that this is not a federal problem, this is a problem at the local level. We have counties and we have cities and we have rural towns who are seeing their budgets cut and not being able to address the health issues in their community.

Mr. Watters, you're coming from the private industry, what would you say needs to be done that is not being done? Where is the disconnect where we can just pull people in and say, pay attention, this will pay off?

## **WATTERS:**

Well, I believe that we are seeing an improvement and the private sector has -- is very good at developing individual drugs, assets, we know that. But I am seeing a shift within my own industry towards an appreciation of the impact of our research and discoveries on public health. And I would like to encourage that within my own industry. So, everyone here in the pharmaceutical industry and the biotech industry I would encourage us all to recognize the impact that our research and our work can have on public health.

One of the problems that I feel public health suffers from is that it isn't nearly as sexy as science. You know, all the -- the billions that get spent in laboratories, people working in white coats and stuff like that. It's not nearly as sexy as going out there and vaccinating a village, or turning off a water pump in medieval London.

#### **BENJAMIN**:

It saves more lives.

# **WATTERS:**

But it has a huge impact. It saves far more life and I think that's the message that we need to get out there is again, we're back to Tom's it's the best buy. And I think one of the things I am seeing is a renewed interest in vaccine research that is happening in the private sector for hospital-acquired infections. I'm really seeing that and I would encourage my colleagues in the private sector to keep that momentum going.

#### MONTENEGRO:

Mr. Kronick, go ahead.

### KRONICK:

I'll just add that that if -- to Jack's point that the public health may not be as sexy as finding a cure for cancer but if you think that vaccinating people is not sexy, try selling, finding the sex appeal in changing the delivery system so that 70 or 80 percent of people with high cholesterol have a control rather than 50 percent. Now, that's really hard to get a lot of excitement about.

### MONTENEGRO:

Mr. Kronick, I wanted to ask you and I ask this question when they asked me to moderate this panel. One of the things that immediately struck me was well, if you're having budget's cut and you mentioned, I think, it was all the number of people that have been laid off, that have had to be laid off in the research sector. How does that impact a young student or maybe just even getting people to get involved? How do you attract people to this kind of science?

#### FRIEDEN:

You know what, I'll just comment that global health and public health have become some of the most popular undergraduate areas. There is a groundswell of interest in this area. We started the program for new entrants right out of college or master's degree called the Public Health Associates Program or PHAP. We only can leave the application open for five days. Because for 150, 160 positions, we get five, six thousand applicants in five days. And there is just an enormous interest and we send these people out to the front lines and they love it, and the people who they work with love them. But we're only able to scratch the surface of both the demand in interest and the need with the resources that we have available. And result of that is that the field of public health is at risk of not having a pipeline of future leaders.

# KRONICK:

And particularly, the challenge in creating researchers and we worked at the agency in funding

| education at a variety of levels and as Tom says, the demand is way bigger than what we can supply. So, there is a lot of interest but difficult financially for folks who are trying to roughen (ph) this area. |
|--|
| MONTENEGRO:  |
| Ms. Goldman.   |
| GOLDMAN:   |

I mean as a dean I have to mention that NIH pay line. And just because the fact is that most of the prevention work that we're doing as scientists funded by NIH. I wish more that we're funded by the CDC. I'd like Tom to be in charge (inaudible). And, but if you're not. And when young potential researchers, even people who are very serious about research and very enthusiastic about it, when they see the pay line and when they look at specifics such as the fact that the median age at which people receive their first award is what, hovering around 40. Right now, that's very discouraging.

And it's also true and I -- this is in my experience as well that a lot of our best research is done by young people. And this is not to patronize them at all. You look at people receiving a Nobel Prize, how old were they when they did that work? They were young, they're older when they get the prize. They were young when they get that work.

And so, we're waisting a lot of the creative energy that's available here in this country by making it so difficult for young people to do research, to become scientist, to come onboard in the enterprise. And this is something that I think is going to have a long-term detrimental impact on us, not only in terms of health and prevention but also our economy, because those our are leaders in the future who will be the next generation of say Tom Frieden. If it so discouraging for people to go into our field and that's the way it is right now with the pay line and grants unfortunately.

#### MONTENEGRO:

I wanted to take this into a different, Dr. Frieden, to a different direction. Health disparities is a big issue in this country and how does this impact into research and development?

# FRIEDEN:

So, we need to figure out two things one is, what are the very specific things that are going to reduce health disparities? The second is, what are the general things that are going to disproportionately benefit populations that are disproportionately affected, and let me mentioned one of each of those.

I mentioned blood pressure control earlier. Actually, high blood pressure and heart disease specifically is the largest single cause of the difference between -- life expectancy between black and white Americans in this country. So, if we can do this one thing right we would not have a large part of the health disparities and we would help everyone.

Second issue is teen pregnancy. Teen pregnancy all too often is the intergenerational transmission of poverty and we've seen teen pregnancy rates go way down. It is a tremendous benefit for society, it's a benefit for families. We want to do that in every way that works and scale it up and those are two examples of a specific program targeted to specific (inaudible) to provide more services and a general program that will help everyone but help people who need it most.

# MONTENEGRO:

You wanted to add anything or you OK?

### **KRONICK:**

I'm good with Tom's.

# MONTENEGRO:

OK. So, man, time flew because I just saw the sign for the five minutes go off which means we only have 10 minutes for questions, but I just have one last question and so, if anybody wants to have a question, please put up your hand, they have mikes all across the room but I wanted to touch on something before we finish here. You know, there's certain researchers -- research that has being going -- for give me, because before I got here I was speaking Spanish, Spanish, Spanish, Spanish. And so, when you -- and I'm going back and forth and I know that I've made up a couple of words. So, I'm sorry.

But I know that there are certain -- thank you for (inaudible) you know what I mean, probably. There are certain research disciplines that are not taken seriously. And that some people may think that it's a joke, it's a waste of money and a lot of it I think has to do, I think one thing I wanted to pinpoint, for example, was behavioral research.

Is that one of the ones that is most attacked but could be the most useful?

#### **BENJAMIN:**

It certainly could be and, you know, there was a time when health disparities research was not considered real. Social science research was not considered real research, only the quote, unquote, "hard science" were and you couldn't get tenure. Well, you know, now our college in the room can help us with that. All of you deans can certainly do that by promoting practice-based research, community-based participatory research, more behavioral research, the guild controls that. And I think one of the things we can do ourselves is begin to value that work a whole lot more.

After all, you know, if, you know, we can figure out how to make me look like Tom, sidewise. The research involved with that would save a lot of lives and reduce (inaudible) so it would make me a lot healthier. And I think that's the challenge. I think the behavioral research and all of that stuff is something we aren't paying enough attention to.

## FRIEDEN:

I think often, you know, people can attack something when they do it in general rather than specifics. I'll give you two specifics. We've been trying to increase HPV vaccination rates, why is it not happening? So, behavioral research is with everyone's consent, we need doctor's practices that can listen to what pediatricians and parents said. And they weren't like oh, you may not want to get this. It was -- You don't want to talk about HPV now, do you? That was the common -- That was an important thing for us to understand, for us to re-approach how we get HPV given.

Second example, Ebola, one of the biggest challenges we have is burial practices. Remember, these are countries that don't have an undertaker system. So, if somebody dies, someone's going to help that person pass and, you know, respectfully. And we need to understand what the traditions are so we can change them in ways that are respectful but are not spreading disease. Those are behavioral research and they're life and death questions.

# **MONTENEGRO:**

Ms. Goldman, Mr. Watters and then, before we can -- Anybody has a question yet, OK. Go ahead.

### GOLDMAN:

So I would say nothing has helped behavioral science more than human genome research project in sequencing genome and realizing that while there is a major contribution of genes to most diseases that we can't understand genetic causation of disease without understanding the environmental and behavioral triggers.

And my own brother who's a geneticist at the NIH and he and I used to fight and fight about this. He now has behavioral's finest, brightest lab. So, that's my evidence for that. But also that we are getting, we are able to fund that kind of research today and because people are -- have become aware that, no, we're not going to fix this just by understanding about genes, that we really do need to get down into the nitty-gritty of human behavior to present with these.

#### **WATTERS:**

Lori, making up words is an essential requirement for science. So, you would be a great scientist.

# MONTENEGRO:

Thank you. Thank you.

## **WATTERS:**

In terms of behavioral science, the -- one of the most important noncommunicable disease that gets completely forgotten about is depression. And that needs to be focused on. We're talking about heart disease and I completely agree with everything that has been said and blood pressure and smoking. Depression and a very simple scale of knowing whether someone is depressed or not is to ask them, are you depressed? And we don't do that. We've learned -- one of the first things you learn at medical school is don't ask leading questions like you don't want to do -- you don't want to talk about HPV today. Well, ask a question, are you depressed? And I really do believe that just -- would make a significant public health (inaudible).

#### **KRONICK:**

I would add only certainly behavioral research has come under attack but there have been sort of equal opportunity attacks on a variety, a variety of other kinds of research as well including comparative effectiveness research and others. And that kind of main task we have is to uphold the highest standards of science and to demonstrate that the results of the research that we fund and conduct are really useful and creating change. And as Tom has discussed, there are examples of behavioral research. We have many examples from comparative effectiveness research also. We need to work that.

### MONTENEGRO:

OK. Go ahead. We're going to -- and I have a question here and a question here.

### MAINE:

Thanks. Lucinda Maine from the American Association of Colleges of Pharmacy and so, I have to say, thanks Jack and Georges and the others that brought the pharmacists into the equation. And a particular shout out to CDC and then, I'm going to have a question that really picks up on this last stream.

CDC believed that pharmacists could expand access to immunization. And there wasn't a heck of an awful lot of evidence to go on. But now, you walk down the street and you can get your flu shot in virtually 55,000 locations without an appointment.

But the problem that I have found, I'm a social science researcher myself, historically throughout my career, the funding level for that work has been the lowest in comparison to lots of others. And there really are issues related to methodological credibility. But when your laboratory is the world, that's different research than when your laboratory is a pristine lab and it's a randomized controlled trial.

I just appreciate you're talking about what we could do to really push the envelop forward, both on funding adequacy because the deans will pay attention to that and the credibility of the science.

### KRONICK:

On the credibility of the science, it is the work that you and your colleagues are doing to train the next generation and to put forward incredible research design and we, you know, fund, not as much investigator initiated work as I'd like to but about \$45 million a year of investigator-initiated work and we see a lots of very high quality applications that come in, many more than we are able to fund. In terms of raising the pay line and the funds I'm not allowed to lobby. I (inaudible) that to, you know, I'm delighted that Research America is here.

# MONTENEGRO:

I want to go ahead and get this other question in because I know that sign is going to come back up any minute. And I give you...

### SHAYA:

Thank you. Thank you, yes. Fadia Shaya, University of Maryland and also here on behalf of AACP Fellowship Program.

So, thank you for the comments and question about if our mandate for public health is going to be to find, respond and prevent and all of that is going to be overlaid on a fabric of a public health system that's rooted in primary care networks where mental health is integrated, how do we know that we're doing it right and when? When can we leverage or how do we leverage our knowledge of HIT, the tools that we have available, social media, et cetera, to make sure in real time we're producing results so that we're continuously improving those systems?

## FRIEDEN:

Yeah, absolutely. This is about surveillance. Surveillance is the core of public health, it's what we do. It's fundamentally, what we're trying to do if there's something you'd want to say in one sentence in a kind of meadow (ph) way, it's helping people base decisions on data. We spent the last two or three years studying which practices can get to good rates of blood pressure control and we found that one of the key ingredients was a feedback loop that wasn't annual, wasn't quarterly, it was monthly.

So every month, every provider was finding out how they did and how they did with respect to everybody else. And with that kind of feedback loop, you could get dramatic improvement in a year. If you do it every year you might get improvement in a decade. So what's really important is investing in the systems that are going to give us real time information for the decisions that needs to be made that really are life and death decisions.

### MONTENEGRO:

I know you wanted to say something Ms. Goldman. You wanted to add something.

#### **GOLDMAN:**

On the last point that I think's gone by.

# MONTENEGRO:

Anybody else has a question? We have three, four more minutes. Are you sure? Oh, come on. OK, that's how good you guys are. You answered all draw their questions? We have one more, OK.

### SAINT-HILL:

Thank you for that very informative panel. I'm Catherine Saint-Hill (ph) and I'm also a member of the AACP Fellowship Program. My question is, in terms of science, we've talked a lot about different aspects of science. And so my question is, how as scientists do you pull from the various levels of expertise that different disciplines may have, different professions may have to solve some of these tough scientific questions?

#### **BENJAMIN:**

Yeah. You know, public health is a team sport. We've been doing it for, you know, hundreds of years. I mean the concept of bringing together people from multiple disciplines and focusing on a single problem. You know, that's exactly what's happening with tobacco, that's exactly what is happening now with the Million Hearts campaign that Tom and others are leading. That's really the centerpiece of what public health do -- does is working on multidisciplinary way to focus on a problem.

And now, our medical care colleagues are beginning to do a much, much better job of doing multidisciplinary management of patients. And we're learning a lot from that as we share experiences. And again, we break the walls down between the guilds and create a system which anyone can start the assembly line and anyone can stop the assembly line.

### KRONICK:

I would add only that in addition to the kind of traditional mix that we have had and that Georges talked about the various kinds of social scientists and physicians, we're increasingly realizing the

need for bringing kind of systems engineering and operations research approach into the mix, which we are doing at AHRQ and a variety of health care organizations are doing as well. But, you know, very exciting and needed addition to that mix that we've had in the past.

### **WATTERS:**

Public health is a team sport, but it shouldn't be a competitive sport. And I believe we're all in this together. I think we're seeing that certainly in the universities with improvements in interdisciplinary partnership. And I think that that behooves us to see that we truly are working in this together.

### MONTENEGRO:

We have gentleman here and a young lady, over back there. And so, I think the microphones are making their way.

# **MYERS**:

I can make it loud. Your (inaudible) from when you're successful, lot of times people don't know about it. You prevent something from happening, (inaudible) so what, right. Do you have metrics or methods or ways, mechanisms for sort of showing what you either might have saved or did save? It seems like that's --That would be compelling to the public, certainly, and maybe to politician.

## FRIEDEN:

We have been doing that increasingly. I think Rick mentioned the same thing, is making apparent that which is not so apparent. So, the tens of thousands of deaths that didn't happen from vaccine preventable diseases, the tobacco deaths that didn't happen because of progress there. That's absolutely something we're doing more of and need to do even more of.

# **BENJAMIN:**

And let's do a field test. We'll count after this meeting how many people get sick from drinking the water, probably not going to happen.

### MONTENEGRO:

Yeah, go ahead.

# (UNKNOWN)

I think we can all say that we weren't quite ready for Ebola. And that we didn't spend enough money when we could have to get therapies and other things online. I remember working on that eight years ago. So my question to you as public health people is, what should we be focusing on now, what's coming? What's going to happen in the next three to five years that you know we're not ready for now?

### FRIEDEN:

Globally, the number one issue is global health security. We've been talking about this for years. We've had a pilot project with tremendous success but we're not at scale. We need systems in all of the weak links, all of the blind spots, all of the places around the world where the next Ebola or MERS or SARS or H1N1 may emerge so that right there, it can be found quickly, responded to quickly and then we can all together prevent it. That is the leading need and as we work to stop Ebola. We're going to have that put into place systems that would have prevented the Ebola in the first place and that will prevent the next Ebola or other health threats in countries all over the world.

#### MONTENEGRO:

And I want to take upon -- thank you for your question. To end on that note and each one of you to address that, that question and wrap up. And once again, it boils down to one thing and it's about funding. And how do we get the level of funding that you need to go on doing the work that you're doing and confronting the thing that we are not talking about right now, but that you have the knowledge that we could confront as a nation in the next year or so, the next five years, or the next 10 years. And I'm going to start with you Mr. Watters, I'll give you a break.

# WATTERS:

Antibiotic resistance, without a doubt. And there needs to be incentives to those who will develop and discover the next antibiotics, which is largely the private sector.

### KRONICK:

We need to tell the story more clearly and more effectively than we have about the effects of the evidence that the research creates, the tens of thousands of lives saved, the improvements in health and the reduction and rate of growth in spending. And we need your help in getting that story to people who are making decisions about funding.

### GOLDMAN:

I think it's a matter of return on investment, and that prevention is the best investment that you can make and whether that has to do with keeping antibiotics perspective globally. If you've seen childhood obesity which we know is -- what I mean disaster or for that matter, how do we get the people who continue to smoke to quit smoking? How do we help people quit smoking?

And those are questions that all of them have enormous consequences financially, economically not only in the U.S. but also globally.

#### FRIEDEN:

I would just add, protecting Americans from threats and that includes things like drug resistance and global health security and then, ensuring that we're maximizing the value we're getting for our health care investments because today, we're not.

# **BENJAMIN**:

You know, we're not the healthiest nation that we can be so, clearly, we need to create a movement so that every American believes that. And then, that they're demanding on our resource allocators to (inaudible) funding.

### MONTENEGRO:

Thank you very much. So, I guess, we're all challenged. All challenged to see how we can tell the story. I need to do better in telling the story and paying attention when I do get those press releases. But I think that you all have such done something.

There has to be a better way. You know, everything is about a pitch and how you pitch. And so, maybe we need to start with the organizations that you have within you own entities that are the ones that are suppose to communicate to everyone else the message.

So maybe it's the way you've been crafting the message, I don't know. I'm just throwing that out there. But, just to, you know, sometimes, look, I can tell you that sometimes we do make that call about something that is medical and you'll call at 9 AM and I may not get a callback until 5 PM.

And then, you have missed out on, you know, communicating your message, on what is important. So, those are all just -- It's a very complex issue. There's a lot of components to it and I want to thank you all for the work that you're doing. I pray God continue to guide you and that, you know, we'll have many more successes in protecting our nation from diseases. And that, you know, we'll be a healthier nation. Thank you, thank you and thank you all...

#### FRIEDEN:

Thank you very much.

### **MONTENEGRO:**

Thank you so much. Good job (inaudible).

# WOOLLEY:

If everyone could be seated please, we're going to begin our final panel. Will you please take your seat and hold down the conversation level?

OK. We're now about to start our final panel of the forum afternoon. Our moderator is Margot Sanger-Katz, correspondent of the New York Times where she covers health care for the upshot. She was previously a reporter at national journal and a concrete monitor and an editor at Legal Affairs Magazine. There's more about Margot and all of our panelist in your programme.

And in fact, the panelists are Janet Woodcock, the director of the Center for Drug Evaluation and Research at the Food and Drug Administration. Pablo Cagnoni, president of Onyx Pharmaceuticals. Robert Hugin, the chairman and CEO of Celgene Corporation. Albert Reece, the dean of the University of Maryland School of Medicine and vice president for medical affairs and a member of the Research America Board. Not here in your programme but not able to join us at the last minute is Kathy Giusti.

Because we want to be sure to hear firsthand the patients' voice, the voice that Kathy would certainly have represented forcefully on this panel, we have asked our moderator to make more time at the end of this particular panel to take questions. Those of you in the room who are patients yourselves, and we all, really, or represent patient groups, we want to particularly encourage to speak up.

But now, Margot, let me turn it over to you and your distinguished desk.

#### SANGER-KATZ:

Certainly. So I was so delighted to hear that everyone thinks that the Whitecoat research is the sort of sexy part of medical science because I think that's certainly what we're going to be talking about and, you know, this is a time when there's a lot of changing both in regulation and the way that science is progressing and in the funding streams that are available for that. And so that's what we're going to talk about.

But just to open it up, I, you know, was hoping that you guys could talk a little bit about what you think is distinctive and maybe particularly wonderful about the U.S. research environment when you think about how we do things here compared to the rest of the world and also perhaps (inaudible), kind of how do you view the U.S. system in comparison to the rest o the world.

### **HUGIN:**

I'll be glad to start with that. First of all, you have to know, I'm an optimist. And I think the system in the United States is by far in a way the best system in the world. And that's -- I don't think that's an opinion. I think -- believe to be a fact when you think about the quality of our higher education institutions and the basic research institutions. Even though we hear all of the troubles, the government does care about basic research and support.

We have the most sophisticated regulatory environment in the world, though we have a lot of work on how to improve in some research science, et cetera, but we have the best system and one we need to work on.

We have, in most cases, the best intellectual property system, not the best in all cases. We've got areas that do. We have a gem in our economy from a biomedical research industry. Academic medicine is the strongest. It has the -- our culture of America is to find solutions. Our culture is a competitive one that allows people to do things in very different ways in experiments, not like other countries where the government says, "You're going to do it this way and that's the way it is."

So, I think we've got a great spirit, we have incredible challenges, but I think the premise we have the best system and we will -- we're evolving. It's very different today than it was even five years ago because of the financial crisis and positive in many ways of focus on more integrated solutions. So I think that's my first premise, we have a very, very strong system, we've got lots of work to do to meet the future challenges, but we have to be careful that we don't jeopardize the success and build off of that.

(OFF-MIKE)

### WOODCOCK:

Well, I'll second what you said, OK, but then I'm a born critic and let's talk about -- all right. So what are these challenges? I think we've had a huge investment in basic biomedical research. And actually I don't totally agree with you. I think we're not defining it too narrowly because I do think we don't have the translational infrastructure in place that can easily and effectively evaluate the research and then bring it to patients and to consumers in an effective manner.

And I think that we are in a verge of therapeutic revolution due to the discoveries and genomics and just molecular biology and this plain old biology. And yet we have anemic translational and

implementation, as was talked about in the last panel, arms to take all of these fruits of all of this research and all of this investment and actually translate it actionably into benefits for patients.

So I think, you know, in business and in government resisted (ph) talk about having a balanced portfolio so that we're not over spending on one area and then we end up not being effective because we've constant -- we've under-funded certain areas. And I think we are at the verge of recognizing or actually being, you know, punished sort of for the lack of really substantive and systematic invest and translational infrastructure and then actually the implementation people.

| SANGER-KATZ:   |
|--|
| Can you just just for the way a person who doesn't know what translational means |
|  |
| WOODCOCK:  |
| OK.  |
|  |
| SANGER-KATZ:   |
| what are you talking about?  |
|  |
| WOODCOCK:  |
| All right.   |
|  |
| SANGER-KATZ:   |
| What's an example of that?   |
|  |
| WOODCOCK.  |

## WOODCOCK:

So our great scientists and all of the medical schools and labs around the country, OK, they discover new pathways that cause disease, OK. And then the industry picks that up perhaps in (inaudible) of targets, maybe through a vaccine or a treatment for the disease and then what do they have to do? Well, they have to go and find a way to evaluate that in people. And that's the most expensive, the slowest, and the most ineffective part of the process, right?

And then when that's done, and you heard this in the last panel, they have to make sure that if there is this tremendous health breakthrough, say, control a blood pressure which has been around for a long time, OK, or control cholesterol, that it actually is applied to people to benefit

| their health maximally, all right? So those are they would call different translational steps, one is evaluation and then the other is application to people and making, you know, actually making it happen. And these are not strong. And so I think we're going to see all these discoveries and already we're seeing that the clinical evaluation is getting too expensive for companies to be able to afford it. |
|---|
| HUGIN:  |
| You know, I would disagree with regulators.   |

HUGIN:

(OFF-MIKE)

But I have to disagree a little bit. I mean, we're not going fast enough, but look at the NIH though, you know, Chris Austin and the folks there in translational medicine centers who really do it. And I think you don't see as much because it doesn't get the visibility and researches that get designated by that name, but I can't think of a company or an academic medical center that hasn't aggressively moved into this field because they realize they won't capitalize on this. So I'm more optimistic than you are that, I mean, it's not fast enough but it is absolutely the world is going that way in terms of investment dollars.

### WOODCOCK:

You know, I'm not optimistic, I'm just ruthless realist, OK? And we see all of the clinical research so we actually know what's going on at FDA and what ain't going on. So, anyway, I'll stop there. We can talk about late (ph).

HUGIN:

Absolutely, we will.

CAGNONI:

So going third, I have to agree with the previous panelist.

(OFF-MIKE)

WOODCOCK:

That's hard.

### **CAGNONI:**

... safe place to be right now.

So it's hard to disagree with Bob's comments about the U.S. ecosystem. I mean, we have the best infrastructure in the world be it from world-class academic institution, access to capital, the biopharmaceutical industry and our regulatory landscape has evolved fairly rapidly over the last 20 years. So that's wonderful.

I do have to agree with Dr. Woodcock though. I think that the way we test drugs in patients, the way we conduct clinical trials has not moved, advance as fast as the way we do in terms of discovery. And what that is presenting in the biennial (ph) term is a problem, is, you know, the amounts of capital that requires to go from the lab to the marketplace is requiring enormous investments and timelines haven't gotten any shorter. And the system of incentives at the backend is under pressure, as we all know.

So when you put all of that together, I'm an optimist, I think that we do still have the best system in the world. I am absolutely convinced that we're going to find a way to fund this innovation but I don't think it's going to be that simply and I think we have to somehow become a lot more efficient in the way we conduct all of those clinical trials which bulk of investment takes place.

### REECE:

Well, I agree with everything that was said so far. But I think that in a more serious vein, I really think that one of the strengths that we have is our infrastructure. And what I mean by that, we need a configuration of our research enterprise.

The way we train scientists in this country is very methodical and has great promise for success on a very recurrent, repetitive basis. We are rigorous. The way we conduct research, the design, the infrastructure is also a very systematic and very methodical. There is a peer of -- a very rigorous peer review process, not perfect but it's very rigorous. There is a grand application process that's also relatively neutral and works very well.

So, again, it's not perfect. I would not even -- there are ways that we could improve our system, but those are the strengths and its fundamental fabric as well as the weakness being the sustainability.

### SANGER-KATZ:

Well, I'd like to follow up on something Dr. Woodcock said. You know, so we -- I'm sure that everyone would love if there was more money for medical research both coming from

government sources and also, you know, in industry, but, you know, the United States does make a very large investment in research. Are there ways that the money could be better spent? Are we over-investing in some areas and under-investing in others? Is translational medicine a place where we need to put more resources or how do you look at kind of the distribution of resources and the kinds of projects that are being funded or not funded?

# **HUGIN:**

Innovations too for private sector organizations, when you collaborate with academic medical centers, can you find two or three to do together? So there are lots of initiatives going on that will help us be more efficient. So I do think we have to be ruthless to see everyone lose a spirit but we cannot over-invest in places where we're doing the same thing. So we've got more transparency, more clarity on that, provide incentives for integrated research efforts in that and for those many others.

## WOODCOCK:

Well, I have just a few little points I'd like to make but, you know, they're probably -- number one, you know, to the rigor. As you well know, a fair percentage of published results from basic biomedical research is not reproducible. That's a big problem, OK? That's a rigor problem, all right? And it isn't a small percentage, it's a big percentage.

OK.

(OFF-MIKE)

#### WOODCOCK:

Pardon me? OK. So I agree then when the cancer center docs told me 70, OK? So, you know, it depends on who you ask and what university you're looking at, but it isn't minor.

Number two, we have to ask if certain areas of biomedical research or not overbuilt. Why? Because I get hundreds of applications from newly built (ph) basic science post doc, all whom have been rigorously trained and given like eight years of their lives to post, you know, post-graduating from college to get a PhD in molecular biology or something. I don't really have jobs for those people at the FDA. Now, other places do but I'll bet you, some of them are driving cabs in New York City.

And see, we really have to think about, you know, rather than just to say we had need more of it, we have the best the world, I agree. But, you know, what are we being intentional in some ways, I agree we have competition and allowing different things is good. But really, some of this enterprise, in my opinion, is overbuilt compared to other parts.

### SANGER-KATZ:

And what are the parts that are overbuilt?

### WOODCOCK:

Well, probably the -- you know, there's an endless machine of basic biomedical research, OK? And, you know, it has to -- and if you have the pay line at age 40 and you make -- it's a -- those of you who are familiar of the story about the checkerboard and, OK, you double each, you know, you put twice as many on each square and pretty soon you're like an incredible -- well, that's -- if that's kind of scheme, OK, if everybody has five post-docs, the next generation is going to be much bigger, right? So, yes, I think you have just to think through things like that.

And then the third thing is we are trying to really change how clinical evaluation is done. And, OK, we are trying to -- we need a coalition of people who feel the current way that the clinical evaluation is not sustainable because it's too expensive and it's too inefficient. And that is we're trying to turn the paradigm around and make -- put standing protocols, master protocols or clinical trial networks in place, fund those researchers kind of semi-permanently, and that's where Kathy would have been helpful because the patient groups are helping us with this, because it's in their best interest, and build a machine that can rapidly do the clinical evaluation of many drugs, investigational drugs or vaccines or whatever coming through so that you don't build a new clinical trial or set of clinical trials for every single investigational drug you have a standing infrastructure that can do that.

So I've probably talked and I have of course very controversial opinion.

#### SANGER-KATZ:

I see Dr. Reece shaking his head, so I want to give him that.

# REECE:

I don't entirely disagree but I believe that there are -- there's something fundamental to our system. And as I said, the fundamental framework I believe is one of the best, the fundamental framework.

(OFF-MIKE)

### REECE:

And that I think is our strength and we had to acknowledge that and celebrate that.

| mean                                |
|-------------------------------------|
| HUGIN:                              |
| That's our whole industry.          |
| (OFF-MIKE)                          |
| REECE:                              |
| There are those exceptions, yes.    |
| HUGIN:                              |
| So we'll take that as an exception. |

But here is what I think is a problem for us, and that is no one runs a business at home and

### REECE:

And the problem is that we have boom or bust, boom or -- there are times, and again with research, to get young people trained, it takes many, many years. And if there isn't a main -- a method by which you can maintain them, they'll be gone, gone to something. And then one thing as a boom again, another decade from now, there's no way of getting it back and it takes a while. So, it's a constant rollercoaster that made huge swings.

So I do believe that is a major issue that we have in our system and that is the lack of predictability in terms of how we fund. Again, it doesn't have to be precise, but there is no -- there is this huge boom and there's a bust, there's a dumpling (ph) and then there's -- it's a major problem.

# **HUGIN:**

I have to add something to this because I think -- I worry about us giving the wrong impression here that we have to be efficient in all of our ecosystem and the whole ecosystem we're talking about here. But we let the debate get away from us if that's the debate. We do not spend enough on R&D broadly defined as a society to deal with the problems that we're facing, the Alzheimer's issue, the metabolic disease issue, the cancer issue, all demographic curve is so against us and innovation needs to be accelerated not rationed down.

So we shouldn't let anybody be confused. This should not -- this discussion of efficiency and improvement is absolutely essential to justify more investment, but we need more investment. And that's why I was a little discouraged by even the panel before that we need as a group to be more effective with specific plans that are going to reduce the cost of health care in areas where we should be reducing it, improving digital health, getting the Congressional Budget Office to recognize that prevention and wellness does score as opposed to preventing any congressman for voting for prevention because the Congressional Budget Office will give it only a cost and no benefit into the 10 years cycle.

We have to be talking about how to reduce the cost of health care, make it more value-oriented in the areas that don't affect the future of solving the problems. And so I'm glad to participate in this panel but this is not an acceptance that we need to reduce the amount of R&D, we need to fix health care broadly defined in the best way it can, we need to invest more here, even if we have not so perfect world that we operate.

## CAGNONI:

I completely agree. Look, a system that is fundamentally based on competition where there is two post-docs competing for (inaudible) or two companies competing for share on the market, by definition, is going to have some overlap and efficiencies. And it's very dangerous to try to understand or to pretend that we understand exactly how to fix those inefficiencies and go proactively.

I think that one of the things that Bob mentioned, we fundamentally have a healthcare system that has some of its incentives, you know, most of incentives is in the wrong place which is to deliver care. And as a result of that, I think that, yes, we are seeing inefficiencies with the system because more money is spent in areas that provide minimal benefit as opposed to things like prevention and keeping people healthy which is not incentivized the right way.

So I'm not sure whether some parts of the ecosystem are overbuilt but I certainly see areas for improvement to such as those.

## SANGER-KATZ:

When you guys look at the regulatory system, how is that changing and how does that need to change? Do we -- you know, is it keeping up with the way that science is developing with more personalized medicine and, you know, more development of drugs and other treatments that address small population...

#### REECE:

I'll get to it first.

# (CROSSTALK)

### **SANGER-KATZ:**

Do you feel that you have the resources that you need in order to accomplish these new things and to keep up?

### WOODCOCK:

Yes, well, I don't think it's a resource issue as much as it is. We have to evolve our policies rapidly. What we're going to see in medicine, to some extent, for pharmaceuticals, is we're going to see them target smaller, more genetically defined or other biomarker defined populations. And so we're going to see larger treatment effects and probably drugs that are somewhat safer because they're targeted towards people and towards the pathways that are out of whack and whatever disease it might be, OK. And that creates -- that's a whole different paradigm than large drugs that treat like a zillion people and you don't, you know, anybody, all comers should be treated.

And so especially for the very closely genetically targeted drugs where only one mutation in gene might be a candidate for that drug, right, we're going to transition phase right now and that's, you know, it creates policy challenges.

Now, you know, a government doesn't have competitive salary, so that's another issue. All right, that's just a broad issue about attracting the most up to date and best talent to deal with these. But I think it's really -- we're seeing a shift in how drugs are developed and they're very intentionally developed toward genotypes or specific phenotypes in a much more targeted way. And people call that precision medicine or personalized medicine but that shift is upon us right now and...

## **SANGER-KATZ:**

Do we need different processes to address those kinds of innovation?

### WOODCOCK:

Yes, we need to make the policies. We don't need new legislation I don't think or anything like that. We simply need to evolve our policies, understand the science that we're regulating so we're not doing that line and make sure the policies match the kind of therapies that are evolving.

### **CAGNONI:**

So drugs have been developed now differently than they were 25 years ago, and this is going to continue to change very rapidly, specifically in oncology whether it's through target and specific

molecular defects and cancer specific targets in the cell surface or both, we are going to continue to evolve this. A lot of examples already out there.

I think what we need -- one of the things that could certainly be improved is all the great work that Dr. Woodcock has done in CDER should extend to CDRH and coordination between those two agencies as we more and more have to develop every -- many of our new medicines with a companion diagnostic. And I don't think that is yet where it should be. And so my plea to Dr. Woodcock is, again, to extend all of the great work that CDER has done to update a regulatory framework for approving medicines to approving co-diagnostics and combinations with those medicines.

### WOODCOCK:

**HUGIN:** 

Fair enough, I mean, don't forget the genetic diagnostics, it was changing very rapidly and those changes are upon us with next generation sequencing. Pretty soon, we're going to be -- we don't have to just take tiny little samples of your genes if you're getting a genetic test. We get your whole genome sequence right at once and it'll be affordable.

And so that is a game changer for diagnostics and (inaudible) and we really need to figure out how to use that as a platform technology because pretty soon in 10 years, you could see many people with genotypes.

| CAGNONI:  |
|---|
| OK.   |
| HUGIN:  |
| I have to disagree with Dr. Woodcock about something. I think there is a need for legislation |
| SANGER-KATZ:  |
| OK  |
|   |

And I think the 21st Century Cures Act that Chairman Upton and Congresswoman DeGette are working on is an opportunity to take a very rigorous fresh look at things. I think -- and I agree with what you said, I think there's things that we should consider in this and I know that people are participating in getting ideas out there. Why are drugs part of the food and drug -- why are drugs and food together? Why are the funding for the FDA out of the agriculture department?

Why is the FDA not legislatively authorized the same way certain parts of the NIH are to be exempted from government pay scales and things?

So I think there are absolutely legislative things that we should be taking a very fresh look at things. And so I think there are the funding opportunities, organization design issues that would give the FDA even more independence, more capability to advance the reforms that you're talking about. So I would argue that we have an opportunity now and we should be very aggressively challenging the White Board as opposed to saying the changes are acceptable because I think we all know we want that -- we're the best but we want better.

I am a little concerned that we also, as we -- if we're able to accelerate the pace of change that you're talking about and leading, we have to do -- have to be careful that we're not going to have a revolution and change things because we're in the middle of so many things under one set of standards and all of a sudden we change things. So we've got an opportunity I think to look more aggressively than we've ever looked before under the environment of the 21st Century Cures Act in a very positive way that would enhance the FDA and make sure that we've completed advances outside of that

| standards and all of a sudden we change things. So we've got an opportunity I think to look maggressively than we've ever looked before under the environment of the 21st Century Cures in a very positive way that would enhance the FDA and make sure that we've completed advances outside of that. |
|--|
| WOODCOCK:  |
| WOODCOCK:  |
| You know, I don't think you're disagreeing with me. I was really talking about   |
| HUGIN:   |
| I was kidding that I disagree, but I (inaudible).  |
| WOODCOCK:  |
| regulatory standards are not sort of organizational structure management, all those sorts of things, different issues.   |
| HUGIN:   |
| Right, yes.  |
| WOODCOCK:  |
| Do you think that there needs to be changes in regulatory standards?   |
| HUGIN:   |

I think the world has changed totally, right? I think that we're all -- I think we all agree with that. I think that the challenges is the science where it needs to be so we can have confidence in the biomarkers that tell us that is going to be the ultimate outcome and so we're advancing very quickly. The standards have to change. We cannot take \$1.5 billion to develop a drug with only 2 out of 10 drugs ever reached the conversational potential to pay off the investment. 2 out of 10, 15 years, you've got to be kidding me. We have to make changes as a society, otherwise we won't produce the solutions for the Alzheimer's, the cancer, the metabolic diseases, and we just won't make the investment.

Who's going to -- who wants to put money upfront when the odds are so stacked against you, we've got to encourage people to invest more in risky ventures by making them a little less and giving the answers more quickly. So we have to, it's just how we do it and when we do it.

## WOODCOCK:

HIIGIN:

REECE:

But do you think that's regulatory or now I'm going to (inaudible) my possession, OK. The reason we're having so much success now in cancer drugs, OK, and antivirals, why is that? It's because of 30 years of focus research in those areas where on cancer started a really long time ago and everybody is starting like, "We're seeing that we can get something out of this, right?" Well, it's bearing fruit now. That war on cancer, we understand the pathogenic mechanisms of cancer, we're going to elucidate all of the targets, we can sequence the genes of a person's cancer, determine what's driving that tumor and then choose the correct intervention to intervene in that.

And so in that sense, I think we definitely have to push. I don't think us regulators saying, "Oh, we're going to have different standards for Alzheimer's. It's going to do it." We need a fundamental research findings that will give us the biomarkers and give us the targets to we understand how to intervene in Alzheimer's. That's what I...

| noon.  |
|--|
| So simple work and I agree with it. That's first and furmost |
| SANGER-KATZ:   |
| Dr. Reece.   |
|  |

Yes, I just want to -- I just want to follow up in some of that offset which I totally agree with. I think that there is a need for some review of a regulatory process.

Again, we have sort of accepted our regulatory processes over the years and we have sort of built on it. It comes like an onion (ph) where we just sort of build on it. I do believe that it is served as well. I don't want to -- no that, but at the same time, I think to the extent that we can use new legislation or when I think that when it (inaudible) the new era of regulatory science as a means by which they can maybe partner with universities and try to study what approaches may be used in order to accelerate the pace or might advise (ph) some of the regulations.

I do think that it is something that becomes -- at the present time, may inhibit or impede to some extent those who may have -- may reached a fast track growth. So I think that it's one -- it's something that needs to be reviewed and those had, to agree with Bob that there needs to be reviewed legislation regarding how we can be helpful to FDA to make certain the processes are more compatible with fast cures, fast processes, not to the extent of entering patients but efficiencies. And I do believe that that could be looked at.

# **SANGER-KATZ:**

So we're just talking about, you know, big breakthrough then oncology and antiviral drugs and certainly there have been, you know, quite a few over the last few years that have been, you know, very important in helping certain populations but they've also been tremendously expensive, very large price tags attached to these drugs. And, you know, there's been some of a backlash in the oncology space. And most recently, I think there's been just a lot of public conversation about Sovaldi and the cost of treating Hepatitis C.

And I'm just curious about how you guys view this environment, you know, to what degree are -is the ability to charge a very high price for a very effective drug that, you know, that is
potentially a real scientific breakthrough? Does that motivate you and make it able to bring you
to get through this would be process? And to what degree do you worry that drugs are becoming
so expensive that it (inaudible) for the health care system or it limits access for patients who may
not have the ability to pay?

# **HUGIN**:

Well, I've spent an hour on this because I think it's a fundamental question and a very important one, and I think we look at this incredibly in an inappropriate way. I think that if we're talking about research, first of all, we have to recognize that the only way a pharmaceutical company gives any money to invest in research, not government funding, it comes from a reimbursement of products. So, it's a very complex equation and there's no doubt that every drug should be value. It should be value. We need to look at the value proposition, if you can't justify the impact of it, you shouldn't be able to charge that price.

But let's think about a few things, right? If someone discovered a capsule you could take that would cure a drug, cure a cancer, a certain cancer, what would we charge for that? What would you charge for that? So we're talking about -- and I'm not here to defend any specific company. We don't have anything that cures Hepatitis C or anything unfortunately, but the cost and benefit.

We have to remember also the way we look at this, the economic impact that our country has benefited from from this whole system is overall the economic impact is a very positive one. One of the reasons the U.S. economy is better even in the last five years over Europe is because we do a better job of encouraging risk taking, do better access to medicines than other countries.

There's an incredible important value proposition that has to be determined. We should never be embarrassed to talk about it because there is such rigor in all systems about -- it's not only free pricing. I mean, there's a couple of examples, but there's no -- you don't get paid if you don't make a big impact on patients.

So I think we have to make sure we talk about this in the right way that it has to be a value proposition, we need to support it. And let's also remember, let's say cancer, for example, in 1970, the cost of oncology drugs was about 1 percent of health care spending in America. Last year, the cost of oncology drugs was less than 1 percent of health care spending. Pharmaceutical overall absolute dollars have virtually been flat in the last three or four years. Per capita, pharmaceutical spending is now 3.7 percent. We invent so many freaking generics, 85 percent of drugs dispensed at America are generics.

| WOODCOCK:          |
|--------------------|
| 86 percent, that's |
| (CROSSTALK)        |
|                    |

### **HUGIN:**

We discovered those generics. Nobody -- no generic company discovered a generic. You wouldn't have those low-cost drugs if we hadn't invested in R&D and made them. We put all of that cost together. We're letting people because we restructure the insurance system very inappropriately and put caps on things, we put the wrong incentives for low premiums and denied access to patients for -- and with 50 percent copay, every age drug is on a specialty tier under this -- under the exchange programs.

Do you know in Texas, under the -- every exchange program, 77 percent of those programs exclude MD Anderson from cancer care for patients that are working poor that are under those exchanges. In New York City, 81 percent of the New York exchange insurance program excludes Sloan Kettering from care. In the state of Washington, 100 percent of the exchange programs exclude the Fred Hutch Cancer Center from those. It's discriminatory against the working poor, it leads to terrible care, and they focus on the price of the drug when it's not -- it's still invented pharmaceuticals, 8 percent of total health care cost.

We had to get together to support the NIH, to support good reimbursement, insurance reform, we need success on the whole system. And I think that we allow people to talk about, and I have a

slide in my speech at (inaudible) University yesterday, we've been talking about growth prices since 1860 in the New York Times about drug prices being too high.

Anyway, I don't really care about this issue that much but...

(CROSSTALK)

#### **HUGIN:**

... it's the same with overall research space. We don't invest in our -- we people should think more gross. The CBO two years ago finally came down and said, "We've got to get them to change about prevention and wellness." Well, a miracle happened. The CBO said, "When prescription drug uses rise, other medical costs go down." And they've used the most conservative ridiculous estimate, but that's what's happening. They finally changed that. More drugs lead lower health care cost.

We got the debate all wrong because we want to talk about Lindsay Lohan and rehab instead of Alzheimer's research and development or drug price of something that gets somebody's headlines and we don't really talk for the substantive issue about access to good medicines for patients leads to better economic productivity, leads to investments for our solutions for our society. We have this discussion asked backwards, so let me tell you.

(OFF-MIKE)

### SANGER-KATZ:

If that's the problem, do we need -- is it just that there needs to be better communication about value or are some of these prices too high?

# CAGNONI:

I think this is a legitimate debate, right? And one could say are we rewarding innovation the right way, right? I do happen to think that a critical point here is innovation and drug discovery and development has to continue to be incentivized. And any discussion that leads to the wrong changes and change in that sort of incentive that Bob described is going to be a big problem.

Let's just take a couple of examples and you can take -- I'm sure everybody in the room has a favorite one. We can take chronic myeloid leukemia and partnership from a lot of academic research with a lot of pharmaceutical investment has made a disease that was uniformly fatal without bone marrow transplants into something as a chronic disease, 85 percent of patients would tend to use.

Take most of myeloma to see that Bob's company and our company focus on used to be fatal in 3, 3.5 fears (ph), now the survival of patients with newly diagnosed myeloma is probably over 10 years. These are concrete advances that have been delivered through the system we have in place that we started the panel discussing which requires massive amounts for capital investment at risk. There's no other way to get to that point.

So now, I'm not going to sit here and pretend that every single medicine launch by the pharmaceutical industry provides true benefit. We agree. And probably those shouldn't be rewarded the same way as provider real benefit. So it's about value, the value proposition of the medicines we develop.

| SA                          | NC     | ER-  | $\mathbf{K}A$ | <b>T7</b> | • |
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Yes, I'm sorry.

### WOODCOCK:

Yes, well, I think there are three things that can be done actually about this leaving aside the debate. A long time ago -- a decade ago, Mark McClellan and I put out a paper called "The Critical Path to Drugs", pointing out that, you know, with all of the biomedical discovery that was going on, unless we changed the costs and efficiencies of drug development, we may have -- not have any innovation or if we have innovation, we might not be able to afford it, OK?

And so other things that can be done that we've been working on, number of course, we have to keep investing a biomedical research enterprise because it's the uncertainty that leads to the fact that only 2 out of 10 end up getting on the market. We don't have enough predictive value from biomedical science to design the right drugs, OK, right away from the get-go. So, nobody built airplanes when 8 out of 10 are going to fall out of the sky, right? We hope not, OK.

But that's the state here that many dropped by the way and it's very expensive. Number two, that we need to, as I said earlier, we ought to decrease the cost of the clinical evaluation by setting up networks in other standing protocols and so in cities and investigational drugs can be evaluated very efficiently.

And then, number three, I think, well, it sounds like (inaudible), but I think there are many things that can be done in fact that will improve the efficiency. We can also improve and no one has brought this up because no one was interested in this, but I'm very interested in it, the cost of manufacturing these drugs is extreme. And new advanced manufacturing methods can actually cut cost by a tremendous amount. And the FDA is really going to go on a very big effort to do that, but we will require public partnerships to get that done.

# **SANGER-KATZ:**

I want to make sure we have enough time for questions and especially want to hear from patients and consumers who feel that their voice was not included in this panel.

So can you step here in front? I think there's a microphone coming.

(OFF-MIKE)

#### PARDES:

I want to just raise one comment. There was a comment before about redundant laboratories. And I'm sure that you are -- you want to be cautious that you don't wind up with a system in which you have too few laboratories investing and we've been down the road of one laboratory producing a result which then was found to be wrong when other laboratories got in. So I would assume I raised a question as to whether you might not think that there's a balancing act there, not excessive but not too narrow.

And let me just make one other point, and that is that I also appreciate some of the comments about some things that have gone better. And there are costs being taken out by people in many different sectors of the health care world, the teaching hospitals agreed to \$155 billion reduction in cost where the Obamacare was put in place and we are doing that and that's costing (inaudible) \$1 billion is being taken out. Other place is the same thing.

I think sometimes we get so hooked on this notion that it's cost, cost, cost that we fail to recognize that there is some progress being made.

#### SANGER-KATZ:

We have some over here.

# MAINE:

So (inaudible) from Stanford did the plenary at our annual meeting this summer. And it was asked to focus on the educational and the clinical and the research implications of Big Data. And he talked quite a bit about the phenomenon of pulled data from publicly funded research and whatnot. And I haven't drilled deeply into that topic yet to know how it actually is playing out in your various sectors.

#### CAGNONI:

So the day before yesterday, I was asked to sit in a roundtable for the Personalized Medicine Coalition and this was the question, how Big Data is (inaudible) by what we do.

For me, it's very clear that there's two areas where I see Big Data played out, one is a way we do research on discovery. I can understand how difficult (ph) to analyze and compile massive amounts of data and multiple permutations will lead to better targets and better understanding of molecular of disease and across the board. And I can understand how Big Data can be utilized at the backend in terms of access and how drugs are actually utilized in the marketplace.

My concern, first of all, I think this at least in the backend is coming and it's coming fast. I think the question is how is it going to be utilized? It's going to be utilized to make sure that we use the drugs, we have the medicines, we have the right way and the right patients. That is obviously a welcome advance. Obviously going to be utilized to circumvent the regulatory system which we're already assigned to which patients are supposed to receive a certain medicine for their disease. Are we going to get around the regulatory system with the utilization of Big Data or not? I don't know the answer to that but that is one concern that I would put in and I would love to hear Dr. Woodcock's opinion.

Now, in the middle part which, as we've discussed earlier in the panel, I think we have the fundamental problem of timelines are too long, inefficiencies and cost, despite discussions with many Big Data companies, I'm still not convinced that Big Data can address the fundamental problems that we have. But I'm waiting to hear that answer.

| SANGER-KATZ:              |
|---------------------------|
| Dr. Woodcock, do you have |
| WOODCOCK:                 |
| Sure.                     |
| SANGER-KATZ:              |
| any visions for Big Data  |

# WOODCOCK:

To me, it's kind of buzz where it always gets me a little hostile because we know people should say what they mean, not you, OK, but you heard about and I have lots of people coming to me too, "Oh, Big Data," and I was like we have a sentinel network, OK, that we have built. There's 150 million lives, has a health care information of 150 millions lives that we can query behind the firewall so this personal privacy is maintained. And we're using that and even my greatest skeptic, Bob Temple, who is a Mr. Methodologist for randomized control trial, said, "We can use the system to find safety signals after marketing, OK, and to assess them."

So we are already -- that is up and running. We are advertising the contract for this actual sentinel system which will be even larger. And we will be able to query very rapidly. And when the drug is launched, we'll be able to call the information and experience from the patients who are taking it and see if anything untoward or the things that we had not predicted. So that's a very early win I think.

I agree also on the molecular side, we still don't understand how people get disease and what their genes have to do with that in general, right, except in very small instances. So there's going to be a revolution, it's already coming out in medical journals where they're looking at this and that and they're finding the gene that's causing this rare thing or that, and they're going to try to do that on a very large scale to figure out on a population scale what is the relationship between genotype and what happens to you. And that's going to be very interesting.

There's no -- I agree. It's not going to help drug development and it'll provide perhaps many more targets. But if we have this constriction in the middle that cost \$1.5 billion to assess whether the drug is effective or not, well, that's going to -- that's a pretty small thing to get through and Big Data is not going to help us here.

### **HUGIN:**

I think the broader question about technology is incredibly important. I think we've already seen the value -- if we think about the financial services industry, 1980, technology was finally applied to official service and you'd end up securitization derivatives and you saw tremendous growth of that industry and that become a commodity, that's one of the reasons why the financial service industry has to struggle for revenue growth, is that's a commodity now. We are finally bringing technology to the health care world and one of the reasons I am optimistic that we will get control of cost, et cetera.

Then finally, the whole technology industry realizes, this is 17, 18 percent of GDP and we're in the 1950s with technology generally, we can make so much more of the value of our techniques, our products to be able to understand really what value is, understand what the costs are in our system. We're going to be able to care for people so much better. I think our -- 10 years from now, our lives will be fundamentally different. What we know about our own health and how technology impacts both the prevention, the wellness, the care of people, and all the different aspects of being able to provide care in a more cost-effective, more value-oriented way, technology is a big, big part of the next 10 years of the crisis that we face.

And we'll have -- hopefully leave money for leaving -- they had more money to R&D, that's the goal.

### **SANGER-KATZ:**

Dr. Reece, did you want...

## REECE:

Yes, I want to make just a few points, one to follow in Bob was saying. First of all, I do believe that the wave of technology that is really across the country, let's say the electronic medical records, for example. That is being installed in virtually all major hospitals through United States. That is going to have a significant impact. I mean, this is relatively -- even though we knew that it was an important aspect, it was -- it's a relatively newly adopted or embraced. That's the first part.

Second one I think is the one that Dr. Frieden (ph) has raised earlier regarding the taking credits and take with cost and the system. And I'm very skeptical about this way of trying to reduce cost and reduce cost. It's always good to be efficient. Nobody can argue about that. But I think that -- or the system try to focus so much so heavily and try to reduce cost from a research enterprise. And I'm referring to the research enterprise. We could potentially do that at our parallel simply because this is -- the research in this country, research doesn't pay for itself. And I'm referring to, in an academic setting, research does not pay. It has to be supplemented with margins from clinical dollars.

So if there is further diminution in the -- in funding for research, for example, that has to be further supplemented by dollars from elsewhere. And for the academic institutions, like my own, for example, we fund research. It's important aspect of who we are. But it depends, it requires a certain level of funding. So to the extent that we can be investing in research, and again, if we want to continue to have our leadership role, we have to at least be competitive with those -- with our competitors, China, Russia, the Brit countries, for example. The rate -- the pace of research investment is several or there's a magnitude above ours, several orders.

So at some point, we -- there's a prediction that we will fall behind. At the present time, we're enjoying some leadership role. But if we do not continue to invest in, so I'm very skeptical about this very, very heavy emphasis on reduction in our expenses.

| SANGER-KATZ:       |
|--------------------|
| We have back here. |
| (OFF-MIKE)         |
|                    |

## **HOUSE:**

Hi, my name is Linda House. I represent the cancer support community. Thank you all for you feedback and your comments here today.

I have a question, when I think about the topic of this panel in particular speaking about research as an ecosystem. And we've alluded to in the previous panel depression and the importance of

impact and depression. We know from Barbara Andersen's research out of the Ohio State University that women who go through just a 26 session support group not only reduce their risk of recurrence for breast cancer by 50 percent, those who do recur reduce the risk of death by 50 percent, and who do die from their breast cancer live 1.3 years longer than those who aren't in the intervention. If that were a drug, that would cost a lot of money.

We also know from (inaudible) state out of Canada that psychosocial intervention reduces overall cost of care by about 25 percent. So, when I think about the ecosystem of research and particularly drug device development, and Janet, I'm sort of coming to you because at some point in time, I like to have a conversation with you about how do we make this really happen in your organization. How do we get to a point that, in addition to companion diagnostics, we also incorporate psychosocial research alongside of development of solutions?

### WOODCOCK:

Well, I think the problem you're alluding to though has to do with the fact the adoption of demonstrated beneficial interventions that are not conventional medical products, OK, and our healthcare is poor -- healthcare system is poorly designed. In my field in rheumatology, the same way. We know that there are certain types of interventions that really improve osteoarthritis and so forth. However, often the patients are given opioids which, as we all know, is not really the best thing for them, right? And research has shown that.

So, it's that final translational arm translation into practice that we -- it's less of the research and actually how do we make this happen, and that's sort of what you're asking me, can we piggyback at -- on to drug development so that then it'll happened at least in those trials.

And, you know, I think some of those things are possible starting to try to incorporate patient reported outcomes and more patient- centered measures in drug development so that we understand the real -- we talk about value, it has to be a value to the patient. And we understand the actual impact on the disease and on the quality of life of the person.

So, where there are proven effective interventions that are not being used because they're unconventional, that's a really interesting question. But I think it does show this other translational gap that we have in care.

## SANGER-KATZ:

Well, thank you so much to all panelists and everyone for being here. This is wonderful.

### WOODCOCK:

Great, thank you.

| HUGIN:     |  |
|------------|--|
| Thank you. |  |
| (OFF-MIKE) |  |

### WOOLLEY:

You -- I think you'd have to agree that our panelists on all three panels have given us lot to think about. There's plenty of straight talk, a lot of passion, a little bit of disagreement, a little edge. I'm not going to attempt to sum up what we heard but we will be highlighting key points on our website and otherwise and this has all been taped and can be accessed so you can go back and take a look.

But I think we did hear some things that are pretty important and pretty -- yes, I would say definitely critical for us to all embrace. We're not the healthiest nation that we can be or that we want to be, we're not. So, how are we going to get there? Transformational change is overdue about health in a lot of ways, I would say. But the point was made, and I think it was Dr. Fauci who did this in such a powerful way that transformational change and how this nation prioritizes research discovery is essential. And getting to that point is a goal worth pursuing.

We also have to get across this simple truth that public health and prevention is a best buy, it's a best buy. We have to tell that story better, more effectively, with a lot of impact. We have a crying need to change some parts of our current ecosystem, not wholesale, carefully. But there is some room for improvement. And we need success in the whole system, in the whole ecosystem. We've got to have success altogether.

And that means we have to stand shoulder to shoulder, every aspect of the research ecosystem, if you will, starting with the patient groups, academia, industry, scientists themselves, the public health community, government. We have to stand shoulder to shoulder, learn how to make each other's case as well as our own, not point fingers across the ecosystem but take it on together and tell our story in a combined high impact relentless way.

I think if we do that, it will be irresistible and we'll get to that transformational vision that I'm pretty sure everybody in this room shares and cares about.

Thank you for being here today. Thank you for being part of Research America. Thank you fore what you do everyday because life is why and that I think that American Heart Association for. But thank you again and again, talk to us all the time at Research America. That's why we're here, we're proud to work or you. Bye-bye.

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