11th Annual State of Personalized Medicine Luncheon Address

TRANSCRIPT

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Ballroom
National Press Club
Washington, D.C.

12:55 p.m. ET
Thursday, May 14, 2015

EDWARD ABRAHAMS: Good afternoon, everybody. Good afternoon. My name is Edward Abrahams, and I'm president of the Personalized Medicine Coalition.

And as we all know this an important moment for personalized medicine. According to Congressman Upton, chairman of the House Energy and Commerce Committee, personalized medicine has been a recurring theme throughout the discussion of the 21st century cures bill, about which we will hear later this afternoon from our guest speaker. Congressman Upton, by the way, expresses his regret that he could not be with us today because of the committee's markup earlier this morning.

According to President Obama, not to be outdone by the House Energy and Commerce Committee, something called precision medicine or, as he said, in some cases people call it personalized medicine, gives us one of the greatest opportunities for medical breakthroughs that we have seen. So if we're looking for something to unite the two parties, this seems to be it.

Personalized medicine is popular because it does not – it offers the ability to improve patient care, while also making the health system more efficient and more cost-effective. It is good, therefore, and appropriate that both Congress and the White House are trying to put in place policies that will stimulate its development. This is why, as you all know, PMC was created, to make the case for creating an environment that encourages the development of what we call personalized medicine, and why I am pleased to welcome you to our 11th Annual State of Personalized Medicine luncheon at the National Press Club.

In many ways, as you will see, this is probably our best luncheon, though it was not the easiest to put together. And it is in that context that I would like to thank some of the people who made it possible. First, Ken Cole of the Pfizer's Washington office was indispensable, and Pfizer is also our sole sponsor. And we are deeply grateful to you, Ken. Bill Dalton, chairman of the PMC, was also very helpful in ways he doesn't know. (Laughter.) Greg Downing at HHS was very helpful. Margaret Hamburg was helpful putting this luncheon together. Brian Munroe was extremely helpful to me, personally. Ellen Sigal and, most importantly, the PMC staff, including Amy Miller, our public policy director. Every one of these people above and beyond, and I'm grateful for all that they did and I'm really grateful to be standing here today.

I also want to acknowledge that ACLA, AdvaMed and the National Pharmaceutical Council have all bought tables, representing, as PMC does, the full spectrum of health care interests in Washington. That is our value-add, and that's why we think we have a very important voice to advance personalized medicine. This commitment, as does that of everyone in this room, helps makes PMC's educational and advocacy work on behalf of patients possible.

Before turning the podium over to Ian Read, Pfizer's CEO who will introduce our guest speaker, I want to acknowledge Pfizer's long-standing support for the Personalized Medicine Coalition, as well as for personalized medicine. Ten years ago, Pfizer was a founding member of PMC. It was represented on PMC's board then by Denny Van Liew, who was succeeded by Aidan Power, and as of today, Hakan Sakul, executive director and head of diagnostics at Pfizer. And all, I'm pleased to say, are here with us today. Thank you for your leadership.

It is now my great pleasure to turn the podium over to Pfizer's CEO since 2010, Ian Read. (Applause.)

IAN READ: Well, thank you, Ed. And thank you for your leadership of the Personalized Medicine Coalition. I have never – actually never heard Ken been described as indispensable, but I would describe him as irreplaceable. (Laughter.)

I'm delighted to be here today and welcome the opportunity to introduce Congressman Michael Burgess of Texas, one of 19 physicians – seems too few in my opinion – only one of 19 physicians in Congress, a champion of excellence in health care, innovation and research, and in modernizing public policy to keep pace with science and the health needs of our country.

I'd like to begin with a few words – well, to be truthful, a lot more than a few words – about the key role that Personalized Medicine Coalition plays in educating and advancing the importance of personalized medicine and policy leaders. Since 2004, you've been at the forefront of driving the dialogue and raising the level of awareness on the benefits of personalized medicine. You are the one place where innovators, scientists, patients, providers and payers all come together to collaborate, debate and educate the public and the private sector.

Firstly, you do that on the potential of personalized medicine advancing care for patients and, secondly, in making health care systems more efficient. For example, in a study by the Mayo Clinic and Medco, hospitalization rates for heart patients were reduced by about 30 percent when generic – when genetic information was available to doctors providing a blood thinner. Another study found that 604 million (dollar) annual savings amongst all patients when oncology drugs were limited to patients with metastatic colorectal cancer whose KRas gene was not mutated – huge savings resulting from what you may call precision medicine or more broadly personalized medicine.

And targeted therapies for tumors with mutations and specific genes has revolutionized treatment of certain cancers, including some leukemias and sub-types of lung cancer. I see this every day in our laboratories when I get presentations from our scientists in oncology and other areas, where the power of precision and personalized medicine is becoming so important to us. And the pharmaceutical industry stands with you and supports your efforts. They go to the core of why we exist as an industry, to create therapies that significantly improve people's lives.

In fact, for over 50 years, we've been creating value for patients. Consider that pharmaceutical innovation has accounted for 73 percent of the total increase in life expectancy between 2000 and 2009. That's in 30 developing and high-income countries. And while there has been tremendous progress reducing disease and infection, there is important work to find cures for some of the most devastating diseases of out time, such as Alzheimer's, Parkinson's, rare diseases and certain cancer types.

I am excited about the future as I look at the science that's being done. And I believe that we are in the midst of a scientific Renaissance that will lead to a paradigm shift that is spawned by vastly more knowledge and data about biology and the genome, and potentially mechanisms and targets, allowing us to design therapies addressing the right targets and mechanisms in the right patients – something that most pharmaceutical companies now take as a mantra as they look at their research.

Emerging therapeutic modalities, such as gene therapy and cell therapy, will play an increasing role in generating real cures at the same time that small molecules and antibody drugs will continue to play key roles. And in fact, as we produce real cures, it's going to challenge our system of insurance and our society of how we pay for real cures. So this Renaissance is transforming drug development and patient selection, also through molecular diagnostics.

Precision medicine gives us the ability to integrate clinical and molecular information to better understand the biological basis of disease. Precision medicine has transformed cancer treatments of tumors and specific mutations and certain hematological cancers and lung cancer. And with real world data and interconnected health systems, we can develop more sophisticated tools to ensure the right patient receives the right medicine at the right time, while also increasing our ability to allocate resources more efficiently.

I want to assure you that the pharmaceutical industry is deeply committed to delivering on the potential of personalized medicine, of which a precursor is precision medicine. For example, just this week the Tufts Center for the Study of Drug Development's Impact Report commissioned by the PMC was released. The study found that 73 percent of all cancer compounds in development, and 42 percent of all compounds rely on biomarker data, that 13 percent of marketed drugs have pharma – genomics information in their labels – this is up from 10 percent of 2010 – and that pharmaceutical firms say they expect to invest in personalized medicine – they expect their investment to increase 33 percent over the next five years. I would probably think that's an understatement given what I know about the way that Pfizer's investing its research money.

While I know there are growing concerns over the cost of these therapies, they are targeted to the patients who will benefit most and they will return value to the health care systems over time as they improve patients' health. To accelerate the potential of precision medicine, we need to – one, we need the support of leading academic and medical research by NIH and others to dissect the mechanisms of disease and disease progression, paving the way for the development of better therapies.

And secondly, we need dedicated support for the generation of large-scale databases of patients' data to enable a better understanding and assessment of disease risk. It requires people who agree to share data and bio specimens, so researchers can find patents that can lead to new discoveries. It requires partnership across health care stakeholders, patient organizations, providers, payers, researchers, clinicians and drug developers. And it requires aligned public policies that regulate and pay for these new medicines so patients can have access as quickly as possible to the medicines they need.

For example, I believe we need to advocate for policies that ensure market-based pricing of these medicines based on the value that these innovations provide to society and will continue to provide to society. We need policies that can fund advancements in precision medicine across difficult-to-treat therapeutic areas and support by a robust insurance system that allows coverage without restrictive barriers for patients most in need of these treatments. This will require robust discussions between regulators, governments and health care companies to get to a solution.

It was encouraging to see, during the State of the Union Address earlier this year that the president shares our commitment to personalized medicines. And it's why 20th century cure initiative is important. If enacted, it will help improve our ability to deliver treatments to patients much sooner. It will accelerate new drug development by modernizing the clinical trial process and increasing the use of biomarkers, and increase our ability to perform patient-focused drug development.

I commend our guest speaker, Dr. Burgess, for his leadership in 21 CC and for provisions in the bill to improve the discovery, development and delivery process for drugs and devices that are needed to foster continued innovation for personalized medicine, and to unlock the full value of targeted medicines and diagnosis for patients.

Before coming to Congress to represent the 26th district of Texas, Dr. Burgess spent three decades practicing medicine. That background and focus on patients has guided his record in Congress. He has supported legislation that improves patients' choice and that reforms liability laws to put their needs first. As a senior member of the Energy and Commerce Committee, he is engaged in all of the key health care proposals developed by Congress.

Notably, Dr. Burgess helped lead the fight to pass legislation to finally fix the flawed Medicare sustainable growth rate formula that I guess nobody at the beginning of this year would have guessed we could fix. So that was an incredible achievement. So thank you very much for that. (Applause.) Given this fix, given this reform, doctors may no longer wait and wonder every year if they will be paid, and beneficiaries must no longer wonder if they will be able to see their doctor.

He has also been a leader when it comes to FDA policy, specifically through the prescription drug user fee authorization bill that his committee works on every five years. It is one of the most critical pieces of legislation that lays out the parameters for how the biopharmaceutical industry will work with the FDA to get our products to patients and is an essential piece of legislation that allows us to make progress with our regulators on a five-year cycle to bring drugs faster to patients.

We could not ask for a more credible voice to help us drive polices that foster ongoing scientific innovations that enable us to conquer the hardest-to-treat diseases. Patients are waiting and they depend upon us. It is my pleasure to introduce Congressman Michael Burgess to the podium. Thank you very much. (Applause.)

REPRESENTATIVE MICHAEL BURGESS (R-TX): Well, thank you, Ian, for that very kind introduction. I'll give people just a minute because I know you're checking your notes – what did he say? A Republican from Texas – Ian, who cancelled on you at the last minute and you had to get – (laughter). Sorry, I couldn't resist.

And you know, every time I think about the contributions of Pfizer to certainly my time in practice as a physician, but even going back further – here we just had the 70th anniversary of VE Day. A year before that was D-Day. And D-Day – the course of D-Day and the survivability of those injuries was affected in a positive direction, not because Pfizer discovered penicillin – Sir Alexander Fleming had done that in 1928, got a nice statue up in Barcelona, Spain because the bullfighters love it – but penicillin had been kind a parlor trick.

It was available to just a few people. You made it commercially viable and available to everyone. And that, while we're here today to talk about precision medicine, I'll be honest with you, I trained at Parkland Hospital, my specialty was shotgun medicine, right? I mean, we – (laughs) – never used one drug when three would do. That was kind of our mantra at Parkland Hospital. (Laughter.) But you – the commercial availability of penicillin from the Pfizer Corporation, your development of the technology that made that possible, really did – I don't think just altered the outcome of the Second World War, but I mean it altered the practice of medicine forever after.

Now, I was on the plane on the way up here on Tuesday morning, 5:00 flight from Dallas, I do it every week. And looking on my iPad, and actually this was – this is The Washington Post from Tuesday. Below the fold: Sedation device could replace doctors. It's an interestingly little story, you know, kind of catches your eye. (Laughter.) But actually, it was more than interesting to me because I actually had

met the doctor, an anesthesiologist, who had developed this sedation device and came to me sort of late in the development of this because he just needed advice. He didn't know really where to turn.

It turns out Dr. Hickle – it had occurred to him that as an anesthesiologist there were perhaps – there was perhaps more that we could make available to patients who were undergoing uncomfortable procedures in an outpatient setting. And it occurred to him during the – you know, he had a newborn son in the newborn nursery and was having a procedure done that they do sometimes on newborns. And this device would have never been appropriate for a newborn, but it set him to thinking: Are there ways that we could do this and manage this in a more effective way?

And he ultimately came up with this operation called SEDASYS or this technique from SEDASYS, which is a – sort of a feedback look, the patient is continuously monitored and questioned through headphones, asked to squeeze a little a rubber ball, all the time being administered propofol through an IV. So for example, a procedure like a colonoscopy and, you know, who wants to remember their colonoscopy? Not this kid. So it's great to have that available and it reduces the cost then of providing that procedure because the SEDASYS is about a 10th of the cost of having an anesthesiologist or an anesthetist on standby.

Dr. Hickle, the idea had come to him while his son was in the newborn nursery. When he explained to me the difficulty he was having, his son was packing up to head to college. So that's 17 or 18 years this thing had been sort of trying to work its way through the regulatory structure at the Food and Drug Administration. And it just struck me that that's too long. Now, it eventually did get approved, but three or four years even after that. So what can we do to affect that arc from the idea, from the discovery, to the development to the delivery? What can we do in public policy to affect that arc in a positive way and certainly how could we prevent ourselves from putting even yet more impediments in the path in that obstacle – more obstacles in that path?

Now, this morning we did markup the cures for the 21st century, the subcommittee markup. It passed on a voice vote. Pretty – at the end of the day, pretty non-controversial because so much work had gone into it before hand. Fred Upton and Diane DeGette had made the announcement about 21st century cures May of last year. Through the spring and summer last year, through the fall multiple roundtables and many of you participated in those.

Many field hearings, many site visits, and listening to people – not trying to write legislation, but listening to, yes, people in academic medicine, yes, people in commercial development, yes, people in the investment community about what are the barriers to investment. Surely there is investment that's going to come from the federal government, but how do we make it attractive to outside investment and how do we keep from frightening them away when we do things that are counterproductive?

So when Mr. Upton talked – Chairman Upton this morning talked about sort of the history of the NIH, going back to the 1800s, the FDA, going back to the early part of the 1900s, I actually remember a conversation I had with Michael DeBakey right before he died. He came up to Washington. We gave him a gold medal. We went over to the VA one morning and had quite a lengthy talk. And one of the things he told me was: You need to take care of the National Institute of Health, because it is one of those things that has set us apart from the rest of the world.

He said: When I graduated from medical school – he's talking about Dr. DeBakey – when Dr. DeBakey graduated from medical school in – I guess it was the 1930s, he said: I knew I wanted to go

into research. But the only way I could get the credential to be a reasonable or viable researcher was to go to Europe. There was no place in the United States to do that. Now that equation is completely turned around. The NIH is the gold standard. The NIH is a national treasure. And as Dr. DeBakey explained to me that day, this is an asset worthy of protection.

Now, Newt Gingrich, when he was speaker of the House of Representatives, managed to balance the budget – quite a feat. Certainly during my political lifetime I've not seen that repeated. But during that same interval, and he is quick to tell you this, he doubled the funding at the NIH because it was important and it was important to the future. Yes, we've got to cut spending, but we've also got to invest in the future. Attrition through biomedical inflation, whatever the cause, level funding certainly had affected the dollars that were available.

Joe Barton, as chairman of the Energy and Commerce Committee in 2006, said we are going to reauthorize the National Institute of Health. It hadn't gone through a reauthorization process in quite a while. So we did. We reauthorized the National Institute of Health in 2006. It was in a lame duck session, late in December, everyone's ready to get out of town. But by golly, we were going to stay there until we got that done. And it provided a base funding of $31 billion to the National Institute of Health, a fair amount of money, and it increased that funding by 5 percent every year.

Now, we were criticized during that reauthorization that that's not nearly enough money to keep up with biomedical inflation. NIH has been level funded for years. You're going to have to do more. OK, I don't know if many of you remember 2006. I do, because the Republicans lost the majority in that 2006 election. So 2007, 2008, 2009, 2010 – Democrats were in charge of the appropriations process. The same Democrats that criticized us were only providing a 5 percent increase every year for the National Institute of Health. By the way, that is $1.5 billion every year added to that $31 billion base, never appropriated anywhere near that amount of money.

Now, I say this with some sensitivity because every year that I've been in Congress I've tried to go – or every term that I've been in Congress I've tried to go up to the NIH and visit one of the institutes, become a little bit better acquainted with what's going on, what people are looking into, what the state of the art of research is. And I go up there, and I always marvel, they got some beautiful buildings out there. And they're all named for representatives and senators – representatives and senators who are on the Appropriations Committee. (Laughter.) We are humble authorizers, but we authorized more money than the Appropriations Committee has ever appropriated. And I don't know why the naming is the way it is, but nevertheless – (laughter) – it's a reality that I live with on a continued basis.

Look, my first term I went out to the National Institute of Health. I spent a good deal of time with Dr. Zerhouni. He was very generous with his time. He talked to me about what you hold dear, personalized medicine. He talked about medicine that was personalized. He talked to me about medicine that because it was personalized it could be so much more predictive, because it was predictive it could be so much more preventive. And then the last part of those four Ps was, it is going to have to be more participatory. We are going to have to depend upon activated patients.

That struck a chord with me because during the time I was in my medical practice, I always provided insurance through – to my practice through what's called – what used to be called a medical savings account, now it's called a health savings account. And really that – even the Commonwealth Foundation about a year ago said this type of structure will help you in produce that – producing that activated patient. So rather than just everyone gets the same benefit and goes and cashes in at the

same time, no, you got to think about it before you're actually spending some of your own money, even though it's money that's held in a health savings account.

For an example, Mitch Daniel, when he was governor of Indiana, created the Healthy Indiana Program. I remember this, because I had hoped we could get him into our committee in 2008 or 2009 to talk about how he had managed to save the amount of money that he did in providing insurance coverage to his Indiana state employees. Healthy Indiana plan meant that he purchased a high deductible, catastrophic, if you will, plan for each of his employees. And then he put into a health savings account every year the amount of money that would be required to meet that deductible. So, really a pretty generous plan when you stop – these are $3,500 deductible generally. So he would place that amount of money into a health savings account.

And what he found was something magic happens when people spend their own money for health care, even if it wasn't their money to begin with. They become very wise stewards of those dollars. Well, think of the power of coupling that with personalized medicine. So Dr. Zerhouni's admonition that medicine is going to be more predictive but it was to be more participatory, doesn't do any good to predict if the patient is not activated and going to participate in those decisions. That's why in 2007 I became quite excited about the fact that there were companies that were marketing your own genetic information to you. They would take a sample and – a saliva sample and run it through a certain number of single nucleotide polymorphisms and return it back to you and talk about your relative risk for various conditions.

I did that. It was pretty expensive, but hey it's my information, I want to know. It became available through another company at quite a reduced price just a couple years ago. And I thought, well, what the heck. I'll do it again. I'll kind of compare notes. Some things were comparable, some things were not. But it is an ongoing and a learning process, but how powerful for me as a consumer to be provided with that information? Around about that same time, 2006, 2007, 2008, I had two staffers and a family member of a staffer who were affected by multiple sclerosis. And I remember very well my staffer down in Texas, who – it was a very difficult diagnosis to finally pin down. And she went through a lot of tests and hospitalizations, a lot of pain and agony.

You know, if there were a way to know here is a subset of the population where when they come in with these complaints that don't add up, you might want to think about MS. It would have saved her a great deal of time and trouble and emotional turmoil. So I became very excited about the concept of providing genetic information to individuals on an individual basis. Unfortunately, when the president talked about precision medicine in his State of the Union Address, he failed to mention that two months before he said you can no longer have that information because for whatever reason you're not capable of dealing with it.

So the money that I sent to this company now has provided me only ancestral information. No longer do I get health care information. It is useful to know that my mother was related to Jessie James through the X chromosome analysis and the mitochondrial DNA. I've always suspected that fact – (laughter) – now it's great to have it approved. But at the same time, I think there's other more useful information. I look forward to the day when people will be really active participants in their own care.

I'm a big consumer of health care stuff. My iPhone can take my EKG. I've got a little peripheral that can take my blood pressure. Yes, it can take my weight. I don't care of the NSA finds out. I don't care if someone in Eastern Europe and tries to market it. I'm good with that. But you know, I stop

and think, when we think of precision medicine and personalized medicine, we think of some of these very fine distinctions we can make in a diagnosis or treatment.

I got to tell you, in the days I was practicing OB/Gyn back in Lewisville, Texas, what I would have given for someone to be able to put a little blood pressure cuff on their wrist, take their blood pressure, email it to me a couple of times in a weekend. It never fails, 4:30 on Friday afternoon, your last patient of the day, 36 weeks gestation, about a month away from delivery, blood pressure's been stone-cold normal all the way through pregnancy, and here it is 88 millimeters mercury diastolic.

You still hear Dr. Pritchard in the – you know, if that diastolic goes up more than 15 millimeters of mercury, watch out, that person could be getting into trouble. It could be. Or she could just be mad at her husband who didn't leave enough time to find a good parking place when she got to my office and I'm so cheap I wouldn't make more parking places and why do I still go to this guy? (Laughter) So here's a way then – it's a – you know, you could say, well, this is not very sophisticated, being able to take a blood pressure and email a number to the doctor.

And I grant you, in 2015 it doesn't sound that sophisticated. But I promise you, in 1995 it was because what were my options on a Friday afternoon in 1995? One, I could bring the patient into the hospital and say, I'm so sorry, your blood pressure's up. This can be a dangerous situation at your point in pregnancy. And I need to keep you in the hospital and monitor this situation in case we have to intervene. You know that story, most of the time Saturday morning you'll come in rather sheepishly. Every blood pressure that's been taken over the last 24 hours is absolutely normal. I'm so sorry about that. Sorry that I caused a difficulty and disruption in your family and you had to hire a babysitter for the other kids. But, hey, you're healthy and you should be grateful. Sometimes they were. Sometimes they weren't.

But what's the other side of that story? It's 3:00 on Sunday morning. That patient comes in with a platelet count of 12,000. That patient comes in with a bleed in the central nervous system. That patient comes in with a placental abruption. That patient comes in with malignant hypertension. That's the difficulty. And on Friday afternoon at 4:00, you can't tell. They look identical. So to me, precision medicine can mean something as simple as being able for a patient to take her blood pressure at home, email me the result more or less in real time, and for me to be able to then access that intervention in a more timely fashion and not have to wait until something dreadful has happened.

Precision medicine, we all know, can run the gamut to much more sophisticated interventions. We all remember the arguments a few years ago. We had Avastin at the FDA, Provenge at CMS. Wouldn't it be great to know the population of patients who's going to be benefited from Avastin and the population of patients that is going to be benefited from Provenge, not the ones who are going to benefit from two or three weeks of extension of life with severe prostate cancer but those that are going to benefit long term? It would be great to be able to have that information as a clinician, I will tell you. It would be great to have that information.

Now, the bill we marked up today was big. It was wide ranging. Certainly all credit goes to Fred Upton who a year ago said he wanted to do this, he wanted to do something meaningful in this Congress and he wanted the committee to work in a bipartisan fashion, the way we are supposed to, and he wanted us to come up with solutions. So that's what 21st century cures really embodies. You mentioned about data sharing and one of the important things to me in 21st century cures has been the interoperability concept with electronic health records, not just so doctors in hospitals can talk to each

other, but so the data can be shared amongst research institutions. If we are going to deliver on the promise of electronic health records, we've got to be able to have that ability – that interoperability and that ability for data sharing.

There are provisions in the bill that deal with ways to bring drugs to market with clinical trials that are less involved and less expensive. Those are still in development, but I believe that they will ultimately deliver on that product in a more – in a more timely fashion. This past weekend I attended a medical school graduation down at Texas A&M. My nephew as graduating, thank goodness. It's been a long time. But as I sat there a few rows back from the graduating class, and you look out over that – those young doctors who are going to walk across the stage and get their diplomas, because of the work we've done in the Energy and Commerce Committee this year, they will never need to know how to spell SGR. I doubt it would be important to them in any case.

But what will make a difference to them is that they are going to have tools at their disposal that will allow them to alleviate human suffering that no generation of doctors has ever had before. And that is the promise that we are delivering to the patients and the clinicians and researchers of tomorrow. This is the work that the committee should be doing. I'm grateful that Chairman Upton took it on and we have heard from a lot of you during the development stage of this legislation, subcommittee markup today, full committee markup sometime to be determined. But to the extent that those telephone lines are there, they are available, it is a two-way street. We are happy to hear from you. We're happy to get your information and this is a work in progress. We do fundamentally want this to be right when it is done.

Thank you very much for your time and attention. I appreciate the invitation to be here today. (Applause.)

MR. ABRAHAMS: Dr. Burgess has agreed to take some questions. And let me –

REP. BURGESS: So don't misinterpret my lack of specificity. (Laughs.) I'm sure you have specific questions and make sure they're positive in a true/false format. That'll make it easier for me. (Laughter.)

Q: If you could add one to the cures bill that fell out between the first draft and today, or some idea that you've heard but didn't make it in, what would it be?

REP. BURGESS: If I ran the zoo, what I would really like to do is to be able to talk to the Congressional Budget Office about having to score everything with a 10-year budget window. It makes it extremely difficult. We all talk about, hey, a stitch in time saves nine. Unfortunately, if the saves nine doesn't occur in the 10-year budgetary window so the CBO always just says: You got to pay for the stitch. You can't take credit for the nine you're going to save in the out years.

And the case in point, Center for Medicare and Medicaid Services just this week said one of the number-one expenditures we have is for Nexium. OK, Nexium, I get it. That was a favorite target of Henry Waxman's when he was on the committee: make one little alteration in the preparation and you want to go back and do a period of exclusivity, and shame on you for doing that. But the change that they made was – and I'm not smart enough to know whether the Nexium is the L isomer or the D isomer – but you just have the single isomer which is the active ingredient – doesn't make a difference. I would suggest to you that it does.

But I will also suggest to you that when I was in medical school, you go look at the surgery schedule a lot of mornings and you'd see five operations that were highly selected vagotomies and partial gastrectomies. People in their 50s got peptic ulcers back in the 1970s and if they failed conservative therapy – read: Maalox – then the next step might very well be surgical therapy. Either they were going to have to have a oversewing of a bleeding ulcer or they would go through one of these – one of these procedures to strip the vagus nerve off the lower-third of the esophagus and big operation, big incision, six to eight weeks off of work, probably altered gastrointestinal function forever after that. Hey, I'll take a Nexium every day. I got no problem with that. I'll spend my own money for it, if you won't let me have it through insurance coverage because I think that is a valuable tradeoff.

What is impossible to know – I forget the dollar figure, it was under $30 billion a year that's spent on proton pump inhibitors. What's impossible to know is what would the dollars that would have been spent on highly selective vagotomies and partial gastrectomies had proton pump inhibitors not come along? So it's very difficult to know that. I referenced Newt Gingrich earlier and he likes to tell the story of he's sure that at some point in a windowless room in the Capitol in the 1950s there was someone with a green eyeshade on who was trying to calculate how much it was going to cost in future expenses to provide iron lungs for all of the victims of polio that were likely to happen over the next 10 years. Except that reality never occurred because something happened along the way that said we're not going to have to deal with that.

So there are things that happen along the way that will change things. We can't ever get the benefit of the savings that are affected by the treatment that's given. The only thing the Congressional Budget Office can tell us is how much are you spending on this drug right now. They cannot tell us how much are you saving in 10 years time. The interesting thing is here – and we are right now on the cusp of the 10-year anniversary of the Medicare Part D program. You look at Medicare expenditures, and they have been drifting down.

The break point was about 2005. People who say, well, it's the bad economy and people aren't going to the doctor as much. That may be true. But in 2005, the economy was actually OK. Some people say, well, it's the Affordable Care Act, it's starting to kick in. And again, there wasn't Affordable Care Act in 2005, 2006, 2007. So that drift downward has been relatively consistent. And my thesis is that this a result of the Part D benefit in Medicare. It's – these are Medicare expenses that I'm primarily talking about.

And we all talked about it in the run-up to voting on Part D that if you pay for the Lipitor, you're going to have to buy less treatment for congestive heart failure. And we may be seeing that benefit begin to occur. Right now I don't have hard data. I would love for the Congressional Budget Office to help me with that. But more importantly, I would like for us to have certain instances – not in every instance, because I realize we could blow the budget up if we do this – but where the chairman and ranking member of the Budget Committee, House and Senate, agree on extending that window for a certain procedure or therapy, that that be allowed to happen, and using the savings or be able to offset the expense with the savings. This bill would be a lot easier to offset if we had some of those capabilities.

MR. ABRAHAMS: Ellen (sp).

Q: Thanks. So, first of all, I want to thank you for your extraordinary work and your wonderful, wonderful speech today and the 21st century cures. But there is a little bit of a "but." So very pleased with the $10 billion for the NIH, but to execute this bill the FDA will need the resources as well. And

we were – we were very disappointed that there was not a resource allocation because much of this to get to patients will have to be through a robust regulatory system and we'll be able to work with these drugs. So can you maybe address what's going to happen on that?

REP. BURGESS: I can tell you historically – of course, we reauthorized the National Institute of Health. It didn't – the monies never really got through the appropriations process. Arguably Food and Drug Administration, which is dependent upon Ag appropriations for their money, sort of a similar fate along the way. The stimulus though is what sticks out more in my mind, because here's $10 billion that comes right now – right now into the National Institute of Health. It's a little difficult to know what the return on investment was on that $10 billion. It's just been – I've had a hard time tracing that and no one has really offered to help walk me through that.

But I do remember talking to Josh Sharfstein one morning, who at the time was the number-two man at the FDA. And I said, look, they just put all this money into the NIH. Aren't you going to need something at the FDA to deal with the product in the pipeline? And he assured me they had the money – all the money that they needed. I asked somebody, please, take the man's words down because I want that on the record. Look, we are asking the FDA to do more and more every year with food and drug safety – food safety, the enormous dependence on food that's imported. And we had those discussions when some trouble occurred in the late 2000s. It is an ongoing – an ongoing evaluation.

This bill, although it's labeled the 21st century cures, is – really it's an NIH reauthorization bill. Will there be other opportunities in the appropriations process? There always are. This is – I guess my concern on the regulatory side is I want to be certain that we're getting a return on the investment that's made. And that has been hard to do. I will tell you that the 21st century cures – the template for 21st century cures was the Food and Drug Administration Safety and – FDASIA, that passed in 2012, that ramped up the money for user fees.

I don't know how many of you remember the summer of 2011, Congress and the president were fighting over the expansion of the debt limit. We were all pretty mad at each other. Nobody was talking. And so certainly I'm sure it occurred to people in this room in September of 2011, oh my gosh, we got one year to go till the end of the fiscal year and suddenly we are out of money at the Food and Drug Administration because if we don't reauthorize it, all the companies that are putting in additional dollars for the user fee agreements, that all goes away.

So unlike the highway bill, where we can say, oh, the dog ate my homework so I'm just going to reauthorize it for a couple of months, you don't have that option in the FDA. The user fee agreements are what they are and those monies are dedicated to the FDA. They don't go anywhere else. As long as you can convince the Office of Management and the Budget to release them, those monies go to the FDA and nowhere else.

So it was really FDA funding that set the template for this because of the harsh reality of not doing the reauthorization for the FDA was that the money went away. And that did focus people, certainly on the Energy and Commerce Committee, comparable Senate committee as well. And we got it done and it was signed into law three months ahead of schedule. You didn't read about it in the newspapers because there was no signing ceremony. It was July of 2012. President was running for re-election. He was running against us. We were running against him. Nobody wanted to be in the same room with each other. But this was important work and it got done.

That was sort of the template I used on the SRG, in bringing the Democrats into the room where we all talked together. It's sort of the template that I think is likely to be used with 21st century cures. Doesn't mean that there won't be more money for the FDA, but there's got to be – you know, it's been difficult to get the demonstrable metrics that we were supposed to get from the last reauthorization bill from the FDA. It has been hard to come by, that information. I hope they will be more forthcoming. That might make the job easier in the future.

MR. ABRAHAMS: We promised the Congressman that he would be allowed to get back to Capitol Hill as soon as possible. So one last question, over here.

REP. BURGESS: You got to let her too.

MR. ABRAHAMS: OK, two.

REP. BURGESS: But it's just the defense of our nation that we're going to be voting on, so bear that in mind. (Laughter.)

Q: Last week Jeff Shuren spoke at the Senate HELP Committee, where he said that in order to make precision medicine a reality that FDA needs authority to regulate LDTs, and I know in 2011 you proposed legislation in LDTs. And I was wondering, has your thought on that evolved, changed since then? Because you haven't reintroduced that bill. Where are you on that issue right now?

REP. BURGESS: I still feel exactly as I did then. I recognize some of the political difficulties of achieving that. And if you'll remember, in the FDA reauthorization bill, I wasn't really completely successful. I was only successful in getting a stay of execution for I think it was 90 days. I thought that would take me through a presidential election, which quite honestly I thought was going to turn out differently. And then when it didn't, I realized that I was up against a very difficult situation. And sure enough, right before – two or three days before the August recess last summer, Dr. Shuren announced that he was going ahead with what we had asked him to let us know when he was going ahead with it. Again, he chose right before the August recess, recognizing that no congressional hearings were going to happen for at least 35 days and he had a window of opportunity.

I think that's still important. I realize this community is divided on that issue. But again, you know, I come at this from the perspective of a clinician. If I've got a laboratory developed test that I can have done relatively easily, relatively inexpensively and it will make a significant impact on my decisions for treating that patient, I want that. I can't tell you – I mean, I showed you the article about SEDASYS. Eighteen years to get it through the device guys at the FDA. Are they doing a great job with everything they've got right now that I want to give them more? I'll let you answer the question. (Laughter.)

And I'm sorry, you had a question over here?

Q: Thank you. And thank you for your time.

My question's a little less policy and a little more high level, but you're asking for participation to test and to treat patients. In your bill or in your thinking, do you see or envision a world by which we will be testing – asking for participation, testing patients and preventing disease? And what does that look like?

REP. BURGESS: The short answer is yes. And you know, we do – we do talk a lot about privacy and data security and protecting the privacy of the patient. But I will also tell you, when I signed on to 23andMe I clicked the box that – you know, use my information. Use my information, and then I'll answer all of your crazy questions that you have on here on the questionnaire. If at some point somebody as smart as Google can put together an algorithm to really have a deliverable for here's a way to have – pick out a person who might have a problem, here's a pathway to an intervention that would be useful – I'm all for that. I want that.

Now, I realize that constructing such studies at – you know, within the constructs of a federal agency are much more difficult and you do have to be sensitive to things like privacy and disclosures on participation – I get that. At the same time, I'm a big believer in consumers of this kind of data and I'm a big believer that the fact that the computational power that exists right now outside of the federal agency is massive compared to the relatively prehistoric computational power that's available in the agency. I realize that's our fault, but nevertheless the reality is what it is.

And I'd vote for letting people have their information and allowing things to be developed – full disclosure, let people know what they're putting at risk, but at the same time allow them to participate if they would like. Right now it's much more restrictive and I think that's to our detriment.

MR. ABRAHAMS: Please join me in thanking Dr. Burgess. (Applause.) Thank you very much.

I hope you'll stay around and network a little more, but thank you very much for coming, for working with us. And I hope to see you all next year if not many times before. (Applause.)

(END)