LOST OPPORTUNITIES FOR VETERANS: AN EXAMINATION OF VA'S TECHNOLOGY TRANSFER PROGRAM

HEARING

BEFORE THE

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Wednesday, February 3, 2016

COMMITTEE ON VETERANS' AFFAIRS,
U. S. HOUSE OF REPRESENTATIVES,
Washington, D.C.

The Committee met, pursuant to notice, at 10:30 a.m., in Room 334, Cannon House Office Building, Hon. Jeff Miller [Chairman of the Committee] presiding.

Present: Representatives Miller, Lamborn, Bilirakis, Roe, Benishek, Huelskamp, Coffman, Wenstrup, Abraham, Zeldin, Costello, Bost, Brown, Takano, Kuster, O'Rourke, and Walz.

OPENING STATEMENT OF JEFF MILLER, CHAIRMAN

The CHAIRMAN. I would like to welcome everyone to today's hearing and we have entitled it Lost Opportunities for Veterans: An Examination of VA's Technology Transfer Program.

Let me begin today's hearing by stating that the issues that we are going to address show how that despite VA's objections, it is really critically important for this Committee to look at both the past and current failures that exist within the department in order to improve the future of veterans' care.

Without our investigative effort and our notice to conduct this hearing, VA would not have reviewed what we are going to talk about this morning. Moreover, VA would not be aware of the apparent exploitation of its Technology Transfer Program from those that are inside the Department of Veterans Affairs.

My concern is that the issue we will discuss today may not be limited to one single researcher. For those who are unaware, Federal agencies are, in fact, authorized to assert ownership in inventions made by Federal employees using Federal resources.

VA's Technology Transfer Program was developed as the mechanism to determine ownership and then to transfer the benefits of VA-owned technology to veterans and the public through patenting and licensing. Unfortunately, this program appears to be habitually underused resulting in tremendous losses to veterans and American taxpayers.

A glaring example of where the Technology Transfer Program perhaps should have been used is in connection with the hepatitis C drug Sofosbuvir which is claimed to cure up to 99 percent of those infected with this ultimately fatal disease. This drug report-

edly developed by a VA employee resulted in an $11 billion sale and a $444 million personal profit to that VA employee.

However, VA appears to have nothing to show for it except a bill from the drug's current owner for VA's use to treat veterans. More than 200,000 veterans have been diagnosed with hepatitis C and VA pays upward to $40,000 for treatment for each veteran that is infected with this disease. That is about $8 billion to treat veterans with a drug reportedly developed using VA resources.

During last summer's financial crisis, VA had to ask Congress for additional funds to pay for the treatment. So the question is, why is VA paying so much? What we know is the drug's reported creator, Dr. Raymond Schinazi, was a 7th VA employee when the hepatitis C drug was developed. He worked for VA for more than 25 years and retired shortly after we asked him to testify at this hearing.

In fact, we sent an email over to VA on January 20th informing them that we would be asking him to participate and testify along with Dr. Shulkin. We sent a hard copy to Dr. Shulkin on the 21st. Dr. Schinazi put in his papers to retire from the department on January the 21st. He retired two days ago.

He's listed as a senior career researcher and has received hundreds of thousands of dollars in VA research funding. Yet in a letter to me dated the 1st of February, the day of his retirement, VA asserts that no money was given to Dr. Schinazi for his research on the drug.

But questions remain whether earlier research on a different drug was used in the development of the hepatitis C treatment. Additionally, Dr. Schinazi filed patents while he was a VA employee, but he never disclosed those inventions and patents to the VA.

So how is it that none of his claimed life-saving inventions belonged to VA or our veterans? Interestingly, as I mentioned earlier, I asked Dr. Schinazi to appear at this hearing, but after being requested to testify, he did retire from VA effective two days ago.

Secretary McDonald rightly promotes VA as having invented many cutting-edge technologies like the Nicotine Patch, the cardiac stent, and the CT scan. And although these inventions were developed prior to the inception of VA's Technology Transfer Program, I think these lost opportunities should serve as a lesson to be learned by everyone that VA should be supporting and developing the program so that no other potential opportunities are lost. Our veterans and taxpayers should be benefitting from these inventions. It is as simple as that.

VA oversees $1.8 billion in research every year. Yet in 2014, it only received 304 invention disclosures, filed only 25 patents, issued only 15 license agreements, and earned only $375,674 in royalties.

To put that into perspective, the National Institutes of Health has a $3 billion intramural research budget and in 2014, they received 370 invention disclosures, filed 153 patents, issued 222 license agreements, and earned $137 million in royalty income or about 360 times more than VA's reported royalties.

Similarly at the USDA, they have got a billion dollar research program. In 2014, they received 117 invention disclosures, filed 119

patents, signed 412 license agreements, and received $3.6 million in royalty income or about nine times more than VA.

So it begs the question why has VA not seemed to capitalize on the many research successes that it claims? We have already seen the results of one potential lost opportunity regarding the new hepatitis C drug. How many more are there out there, and how many more will there be? If VA wants to take credit for the tremendous medical accomplishments, it should have something to show for it, certainly more than just talking about it.

Veterans deserve the right to reap the benefits of those inventions given the fact that they were created by employees and with taxpayer resources specifically designed for their use.

With that, I now yield to the Ranking Member, Ms. Brown, for any opening statement she may have.

[THE PREPARED STATEMENT OF JEFF MILLER APPEARS IN THE APPENDIX]

OPENING STATEMENT OF CORRINE BROWN, RANKING MEMBER

Ms. BROWN. Thank you, Mr. Chairman.

Since 1980, the Federal Government has worked to make taxpayer-funded research more available to the private sector while making sure that taxpayers also gain from these research investments.

This allows all of us to share in the important research breakthroughs.

University of Florida developed Gatorade and got a patent for it, so anybody who used it had to pay University of Florida royalties for its use. This concept of VA keeping its intellectual property rights for its employee's invention can't be hard.

But we need to strike the right balance here so academic institutions want to partner with VA to conduct research and get funding for research from royalties from inventions, and so research is available for businesses to develop products that help veterans and the public.

This important program that should be overseeing, this balance may not have received the leadership focus that it needs and employee turnover has been high.

There are questions as to whether the process in place is sufficient to strike that balance from the Veterans Health Administration to the Office of General Counsel.

For this reason, I believe we should have an outside organization look into this program. I believe we should request that the GAO to look into this program and provide us with the facts so that we can make sure the program strikes the proper balance.

Finally, I believe that if this program is not working as it should, VA, the taxpayers, may end up holding the bag.

Just last week, the Chairman raised questions and concerns over the price paid by the VA for hepatitis C drugs. He also pointed out that the drug was invented by a team led by a VA doctor.

This doctor subsequently sold the company that developed the drug to Gilead Sciences.

According to the Chairman, Gilead is charging the VA "upward $40,000" while Egypt, the same drug costs $900.00.

VOICE. Nine hundred dollars.

Ms. BROWN. Oh, I am sorry, that is a big difference. Let me go back and make a correction on that. We charged 40,000.

VOICE. Forty thousand.

Ms. BROWN. I am sorry. Forty-thousand. That is a lot of money.

VOICE. Egypt pays $900.

Ms. BROWN. And Egypt pays $900. Let me try that again. We pay $40,000 per individual and Egypt pays $900 per individual. And this is for the same drug? Uh-huh. The milk isn't clean in that one.

Without the VA, this drug would not exist.

In this case, we do not know if the process worked and whether the VA properly asserted its rights in this matter.

I believe that we should have a hearing on drug pricing and how, moving forward, we can make sure that veterans are getting the drugs that they need and the VA is paying a fair price.

In addition, according to the recent New York Times article, drug manufacturing issues have caused shortages and rationing. We need to make sure that we get to the bottom of this to make sure that veterans are not unduly affected. Let me repeat myself. We need to get to the bottom of this and make sure veterans are not unduly affected.

Making sure that taxpayers are not ripped off, and that the veterans get the medicine that they need is vital.

I look forward to working together to explore these issues in the weeks to come. Thank you, Mr. Chairman, and I yield back the balance of my time. One team, one fight.

[THE PREPARED STATEMENT OF CORRINE BROWN APPEARS IN THE APPENDIX]

The CHAIRMAN. Thank you, Ms. Brown.

Members, I would ask that you waive your opening statements as is customary in this Committee.

And I would like to welcome Dr. Shulkin to the table as the only witness testifying today. Of course, he is the Under Secretary for Health of the Department of Veterans Affairs. He is accompanied by Dr. Kyong-Mi Chang, Chief Research and Development Officer for VHA, and Doctor, is it Marisue, Marisue Cody, Director of Operations for the Office of Research and Development.

And as I have already told you originally, we had requested that Dr. Schinazi who retired on Monday and another physician, the Deputy Under Secretary for Health and Policy Services, to attend. Dr. Agarwal is out of the office and won't be available for a couple weeks. I understand the reasons for that. And, of course, we have already talked about Dr. Schinazi retiring two days ago.

I have made numerous requests, and I think Dr. Shulkin is aware of that, for answers to several questions that were sent to VA starting back in December of last year, but after those attempts by the Committee staff to get VA to provide this information, you only provided some of the requested information as of Monday.

So I would ask, if you would, to stand, so I can swear you in, and if I could have the two folks that are joining as well stand, so I can swear you in as well. If you would raise your right hand.

[Witnesses sworn.]

The CHAIRMAN. Thank you very much. You may be seated.

Dr. Shulkin, your complete written statement will be entered into the record. You are recognized for five minutes.

STATEMENT OF DAVID SHULKIN, M.D.

Dr. SHULKIN. Thank you.

Good morning, Chairman Miller, Ranking Member Brown, and Members of the Committee. Thank you for the opportunity to discuss the Technology Transfer Program at the Department of Veterans Affairs.

The Chairman has already introduced my two colleagues to my right and my left.

VA's Transfer Technology Program is housed within the Office of Research and Development through which VA conducts a robust research program whose fundamental mission is to advance the health care of veterans.

VA research supports over 2,000 research projects at over 100 VA medical centers throughout the country with a fiscal year 2016 direct appropriation of $620 million. The VA research program is further enhanced by private and Federal funds awarded to VA researchers, meaning total resources available to VA researchers will exceed $1.8 billion this year.

VA research projects focus on VA relevant biomedical laboratory, clinical rehabilitation, health services research through four research services, a cooperative studies program for large clinical trials, and a quality improvement program that uses research evidence to improve clinical care.

For over 90 years, VA research has worked to improve the lives of veterans, performing the first successful liver transplant, developing high-performance prosthetic devices, establishing the value of aspirin therapy in improving heart health, and showing the effectiveness of the shingles vaccine, as well as developing the Nicotine Patch.

Established in 2000, VA's Technology Transfer Program reflects our research focus on the veteran, ensuring that products and innovations created by VA researchers are accessible to all veterans.

Prior to the establishment of this Technology Transfer Program, VA had no policy on intellectual property rights and generally waived ownership rights to inventions tasking the inventor and usually the academic partner with patenting, marketing, licensing responsibilities.

My written testimony includes the specific details of the Technology Transfer Program. The primary goal of the program is to ensure veterans have access to cutting-edge technologies and to enable VA to effectively partner with academic and private organizations.

To support this, the program manages over 1,500 cooperative research and development agreements per year, most for clinical trials that grant veterans access to new and potentially beneficial medications.

Often as opposed to patenting inventions and delaying their availability in the public domain, the Technology Transfer Program works to ensure veterans have immediate access to these technologies by releasing them publicly.

The program is crucial to the dissemination of products that are of limited commercial value to private institutions, but can greatly improve veterans' quality of life. This has included the development of several kinds of prosthetic feet such as a foot that allows veterans with lower leg amputations to easily change shoes without experiencing balance issues. This allows for easier wear of high heels or cowboy boots.

This is an important quality of life issue for veterans with lower limb amputations, but is not particularly commercially viable. Every year, VA researchers develop dozens of new health care related technologies and other inventions like these that benefit VA patients, other veterans, and all Americans.

Research at work at more than 100 medical centers conducting research, most of which have formal affiliations with academic institutions and hospitals. Many full and part-time VA employees also have academic appointments. Many clinicians and researchers have laboratory access at both VA and academic affiliates.

Because of these arrangements, most VA inventions are jointly owned by the VA and its academic affiliates making technology transfer a collaborative effort.

VA research relies on researchers self-reporting invention disclosures. This process is very similar to the one used by academic partners. Without proper filing of invention disclosures, VA is unable to review and appropriately make a determination of rights.

VHA will review the Technology Transfer Program to ensure compliance with regulations and statutes concerning invention disclosures.

VA recently reviewed the Technology Transfer Program materials related to Dr. Schinazi, a Ph.D. scientist who has retired from VA service. As you know, certain information regarding Dr. Schinazi's employment and invention disclosures made to the department are protected from public disclosure under the Privacy Act. This includes discussions of Privacy Act protected information in public oversight Committee hearings like this.

I did provide specific information in a letter to the Committee pursuant to the ccongressional exception to the Privacy Act in furtherance of your oversight function. While I'm happy to address any specific additional questions regarding Dr. Schinazi in a Committee briefing or a closed hearing and, in fact, offered to do so in advance of this hearing, I am prohibited from disclosing protected information in this public forum.

I recognize the Technology Transfer Program requires an in-depth evaluation, and I have directed VHA to begin that evaluation internally, but also requesting assistance from academic affiliates, other Federal agencies, and industry leaders to advise VA on the current role, scope, and configuration of our Technology Transfer Program.

Thank you for the opportunity to testify before you today. My colleagues and I look forward to any questions.

[THE PREPARED STATEMENT OF DAVID SHULKIN APPEARS IN THE APPENDIX]

The CHAIRMAN. Thank you very much, Doctor. I appreciate you being here and your colleagues that are with us to testify today.

I just want to, for the record, make sure that the dates that I am using are correct. We emailed your office and followed up with a hard copy on the 21st inviting Dr. Schinazi to be along with you while you testified. I received information this morning and I just want you to confirm that he officially put his papers in to retire on the 21st, so that would be the day after we asked you to testify; is that correct?

Dr. SHULKIN. I think that is correct.

The CHAIRMAN. Okay. Although his retirement went into effect a couple of days ago, he did have a research lab and a program at the Department of Veterans Affairs. So what is the status of that facility and laboratory at this time?

Dr. SHULKIN. My understanding is that he had numerous active research programs and grants and that they will be appropriately transferred over to other researchers who will assume those responsibilities.

The CHAIRMAN. Does he have any access at all to any of that laboratory or any of the information that you are aware of?

Dr. SHULKIN. After a person leaves Federal Government, they—they relinquish their access to Federal information and resources.

The CHAIRMAN. And so you say he has got a couple of active projects now and those will be picked up by—he can't carry that with him? It stays within the VA?

Dr. SHULKIN. Anything that's done with VA resources or time or effort will remain with the VA, cannot be transferred, no.

The CHAIRMAN. I don't think this is going to affect privacy rules and regulations, but did Dr. Schinazi make any disclosures of what he was doing at the VA?

Dr. SHULKIN. As you know, Mr. Chairman, I have sent you a letter and—and a couple to the Ranking Member as well that has given that specific information to you, but I am not able to discuss any specific disclosures in a public hearing. I certainly would be glad to discuss in a closed hearing or any other forum that's private for that information.

The CHAIRMAN. And I do appreciate that. I am not asking about any specific disclosures. I am saying did he make any disclosures?

Dr. SHULKIN. I—again, I've provided that information to you. There is a listing of those, yes.

The CHAIRMAN. So he did make specific disclosures?

Dr. SHULKIN. In the—in—in the letter that I sent you, I provided you that information.

The CHAIRMAN. Help us understand a little bit. If, in fact, it is found that he didn't make appropriate disclosures, is there any statute of limitations that would prevent the Department of Veterans Affairs from going backwards after the appropriate licensing and recoupment of any of the dollars that may be out there?

Dr. SHULKIN. Yeah. I am equally as concerned to make sure that the rights of the Veterans Administration and the taxpayers are being upheld here. As you are aware, I am asking that this entire situation be looked at.

I am not aware of a statute of limitations, although that may be in a statute that I'm not aware of. But it would certainly be my intent to understand this situation in complete detail so that we could make sure that everything that should have been followed was followed.

The CHAIRMAN. And if, in fact, when there is a look-back and it is found out that disclosures were not made, that there are some rights that can be asserted by VA, does VA intend to assert those rights?

Dr. SHULKIN. I don't want to make any presumptions about what we will find. As I said, I want to do a thorough review, get to the bottom of this. But I can assure you it would be my intent to fully pursue every option that would be available to the government to protect the rights and to make sure that everything that should have been done was done.

The CHAIRMAN. Okay. Thank you.

Ms. Brown.

Ms. BROWN. Thank you.

During the summer, I think, we put up an additional billion dollars for this drug which is one of the best drugs out. It has a 99 percent rate and it is very, very good. But you see I have a little problem with figures. I don't understand why other countries can spend $900 and we are spending $40,000. I mean, it was very confusing. I can't see the disparity.

Can you explain it to me?

Dr. SHULKIN. That would definitely be beyond my expertise to understand the pharmaceutical industry's pricing schemes. But, you know, I think—I think that everyone who knows even a little bit about this topic understands that the prices charged by many companies in the United States are higher than what's available in many third-world countries.

Ms. BROWN. Are we talking about the same formulary, though?

Dr. SHULKIN. Yes. Yes, it's the same—it's the same molecule. There is pricing differences between what U.S. customers are charged and the—and, as you know, most of the press focused on the Canadian drugs that—that you can get the same drugs in Canada often cheaper as well. But, you know—

Ms. BROWN. And Mexico, too?

Dr. SHULKIN. What's that?

Ms. BROWN. And Mexico, too?

Dr. SHULKIN. Yes, yes. So—but, you know, that—that certainly is not determined by the government. We're a customer. We make sure that when the government buys drugs through the VA that we obtain the very best pricing possible, but we don't get to determine the price.

Ms. BROWN. I am going to ask that the Chairman, can we have a hearing just on the drug pricing because one of the things that we do, we push that the Department of Defense and the Department of VA negotiate the prices of the drugs so we can keep the costs down.

I think that is extremely important because if we buy it in volume, the taxpayer, the veterans or the military or the spouses should benefit from the research that we are doing. So this is very

disturbing to me, Mr. Chairman. I hope we can have a hearing just on drug pricing, in the immediate future

And with that, I yield back the balance of my time.

The CHAIRMAN. Thank you very much, Ms. Brown. We will look at that possibility. You and I can have an opportunity to discuss it.

And I would let you know that even at the $40,000 number or $42,000, that is a discounted rate of what the drug actually retails for out there. And that is another discussion. I am not into price fixing. I am not into setting the government doing that.

But if, in fact, it is found that it was a Department of Veterans Affairs' employee that did, in fact, discover the drug and did not do what was appropriate, I think that it is important that this Committee do its oversight. And I appreciate Dr. Shulkin and certainly the secretary and the deputy really trying to get to the bottom of it by going to the inspector general.

And with that, Mr. Lamborn.

Mr. LAMBORN. Thank you, Mr. Chairman, and I really appreciate your leadership on this issue and having this hearing today. And I appreciate the hard work of the staff and their research in bringing this to light. And I am really concerned about this.

Dr. Shulkin, are there other possible inventions, whether it is pharmaceuticals or prosthetics or anything else, Nicotine Patches, that we rightfully claim as part of the heritage of what the VA has researched and developed that might be out there that we have not gotten the fair share for the taxpayer and for your budget?

Dr. SHULKIN. Congressman, I, too, am equally concerned about this. And I can't tell you today that I have a good enough understanding to say that I can assure you that there aren't other issues out there. That's one of the reasons why I am going to take a thorough review of this both internally and externally and I want to get to the bottom of it to make sure that I can tell you that there aren't issues out there.

Anything that was done prior to the year 2000 like the Nicotine Patch and other inventions that we've talked about, we have no claimed intellectual property. That was our policy pre 2000 that VA didn't want anything.

Since 2000, though, if there was VA resources and time, we would expect that information would be disclosed and that we would have our right to assert or not to assert ownership over that. So I'm—I'm going to get to the bottom of this.

Mr. LAMBORN. And I know the Chairman has already started probing on this, but if there were any disclosures not properly and fully made by Mr. Schinazi, does that give grounds to review and perhaps claw back some of the money that it sounds to me should have gone to the taxpayer?

Dr. SHULKIN. Yeah. You know, Congressman, although I'm going to—I'm not going to comment on any specific individual here, there is enough concern that has been raised here that I am asking for a review of all these facts. And should there be anything that comes out of that review where we have violated the policies or procedures including disclosure or anything else, we are going to take full rights to make sure that VA does get its proper ownership.

Mr. LAMBORN. And I have no objection to people working hard and becoming wealthy as a result of that, but I think the U.S. Government, the taxpayers, and the veterans should have their share if they were entitled to that.

Dr. SHULKIN. That was the purpose of setting up the Technology Transfer Program, absolutely.

Mr. LAMBORN. And I am glad that the VA is now starting to get behind this. It sounds a little belated to me, a little behind the power curve. I wish the VA had been more on top of this from the year 2000.

Okay. How can we be assured—I know you are saying some good things and I appreciate it—

Dr. SHULKIN. Yeah.

Mr. LAMBORN [continued]. —but how can we be assured that this is not going to be a pattern in the future like it has apparently been in the past?

Dr. SHULKIN. Well, first of all, I just want to make sure you have the right information. I think the Chairman gave—gave some statistics. But we have been disclosing, our researchers have been disclosing, VA has been asserting its ownership. We have been patenting and licensing inventions.

But I think you're asking about the internal controls. How can we be assured that we're not missing anything? And today, I cannot tell you that I have good enough confidence that we have the right internal controls in place.

We absolutely have internal controls. I just can't tell you that I think they're robust enough and that they're working well enough. And that's one of the reasons why I'm going to be doing this review to make sure that I have confidence that those internal controls are in place. And it's something that I absolutely will get back to you on.

Mr. LAMBORN. That is really good, but it sounds like when other agencies have ten times the amount or way beyond the amount of royalties coming back, it sounds like VA has dropped the ball.

So you say that you have been taken advantage of this program. It doesn't really sound like it has been taken advantage of very much up until now.

Dr. SHULKIN. Well, let me just give you my perspective which is—which is—I share this with you which is that—which is that, again, until I have confidence that we have the right controls in place, I can't tell you for sure that we are doing everything we should be doing.

But as—as the Chairman said, we have $1.8 billion in funding. One point two billion are external funds into the VA from NIH and outside grants. Six hundred and thirty million, $637 million to be precise is internal VA money. That internal VA money isn't like other research labs in the Federal Government.

We use $93 million for health services research which never generates really patentable or licensable ideas. We use internal money for prosthetics research which when it generates licenses or patents, it doesn't generate commercially very financially viable ones. They help veterans. That's what we're doing, but they're not really meant to do that.

The money that you would look at that would say is comparable to other agencies is about $171 million for biomedical research. So—so our number is a little bit smaller in comparison. That's not to say that—that we're not going to look at this very hard.

Mr. LAMBORN. Okay. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. O'Rourke.

Mr. O'ROURKE. Thank you. Mr. Chairman, thank you for bringing this issue to the attention of the Committee and to the public.

And, Dr. Shulkin, thank you for your commitment to try to resolve this.

I think some of the questions that I would like to know the answer to, you have already said you cannot answer. I would like to know what additional controls need to be in place, and you said that you are going to review that process and make that determination hopefully soon or shortly.

You mentioned earlier that what the VA is doing when it comes to technology transfer is similar to what the academic world does. I would just ask that you ensure that we are absolutely following the best practices and precedents from the academic world where we have seen tremendous success in transferring marketable technologies.

And then, of course, I think all of us want your assurance that you are going to aggressively pursue the interests of the taxpayer and ensure that their rights and returns are protected and sought after and that we actually receive that benefit if, in fact, it is owed.

Lastly, I will say that there is no one in Federal service that I respect more than you given your commitment to come into the VA with very little time to implement a significant transformation. And you have hit the ground running, have come up with some very bold proposals which I think the majority of this Committee supports. You had a tremendous conference yesterday on veteran suicide which I thought was great.

And it is too bad that Dr. Schinazi can't be here in person, but just his story, the selling this company for $11 billion after working at the VA ostensibly to help veterans, a company which then charges $40,000 per treatment, just to put it in context, one of the gentlemen sitting behind me, David Combs who is himself an Iraqi combat veteran and is on my staff and supports me here, makes just a little bit more than one of those treatments. But he is here because of his sense of purpose and service to his country.

And you and I have had this conversation when we try to address veteran suicide, for example. We need more mental health care providers. If you are just graduating from medical school, this is probably not the most desirable place to work right now.

How do we connect with people's sense of public service to draw them in to help prevent more veteran suicides, to provide more mental health access, to pioneer the kinds of treatments that we see here that truly are life saving and transformative?

You almost don't want to have to have the controls in place. You want the people in there who are doing this for the right reason. So I don't know what questions, frankly, you can answer today, so I just thought I would use my time to make that appeal, commend you for your service. I know that you are going to aggressively pursue this.

I have got a little over a minute and a half left. If there is anything you would like to add on any of those themes, we would love to hear your comments.

Dr. SHULKIN. Well—well, thank you and thank you for your commitment to veterans' issues. And—and I think that our passion for making this better is very much appreciated.

I would like to add I take this very seriously. As I said, I'm going to get to the bottom of this. As you also said, I come from the private sector where I have a lot of experience in this. And I have already begun to reach out to my academic colleagues because I want to make sure that the VA has the very very best processes in place for technology transfer. And I do believe that that exists among our academic affiliates and that we will come up with improvements that we're going to put in place. I'm pretty confident of that.

I also appreciate your concern making the VA a place where physicians and other professionals in health care want to come to serve because this is a terrific place to spend your time and to do something very meaningful and to give back to your country. And I want this to be the type of environment, and that's what we're working hard to do, where people do want to come to work. And I hope that together we can create that environment.

Mr. O'ROURKE. Thank you, Mr. Chairman. I yield back.

The CHAIRMAN. Thank you very much.

Dr. Abraham, you are recognized.

Mr. ABRAHAM. Thank you, Mr. Chairman, and thanks so much for holding this hearing.

Certainly the taxpayers should be outraged and certainly even from a moral bankruptcy point, I think we could argue that this hearing is very important.

Dr. Shulkin, thank you for being here. I know you aspire, and I truly believe that you do aspire to make the VA a better system. And I understand you are treading water on a daily basis on some of these issues.

Let's go back to Dr. Schinazi just for a minute and then we will move on. When an employee at any company, whether it is Federal, civilian, it does not matter, if he works 26 years and he is going to retire, there is usually a big party and a watch. There is usually notice of months of advancement. And certainly in his position as a lead researcher where you have ongoing projects, he needs to groom those under him to take the torch, so to speak, carry that research on to make sure that all the research before that is not repeated not so much for the money, just for the expediency of time.

So my question was, did Dr. Schinazi, did he give a two-week notice, a four-week notice, a six-week notice, or did he just go?

Dr. SHULKIN. I think—I think the Chairman already gave the dates that—that I am aware of. I—-I got—I've never spoken to Dr. Schinazi.

Mr. ABRAHAM. We got an email and he was out the door the next day. Is that a fair statement?

Dr. SHULKIN. I'm sorry. Repeat it again.

The CHAIRMAN. Excuse me. If the gentleman would yield. For the record, he put his papers in on the 21st of January and retired on the 1st, so less than ten days.

Mr. ABRAHAM. I understand. Thank you. And there was no prior notice that we know of. Okay. Thank you.

Go back to the post 2000 internal reset, so to speak—

Dr. SHULKIN. Uh-huh.

Mr. ABRAHAM [continued]. —about the patents, royalties, those types of deals. Is there anything now in place where if a researcher develops a home-run drug—

Dr. SHULKIN. Uh-huh.

Mr. ABRAHAM [continued]. —that can saves lives of veterans and civilians, just a great drug like Harvoni, these types of drugs—

Dr. SHULKIN. Uh-huh.

Mr. ABRAHAM [continued]. —does the VA have in place a policy to incentivize for that research if it comes to fruition that it is a great drug or does that researcher get a percentage of the profits now as compared to pre 2000?

Dr. SHULKIN. Yeah. First of all, the VA currently and since 2000 has in place a number of controls to make sure that it is the investigator's obligation to disclose information such as that. Once—once a disclosure and a form is completed, it then goes to our Office of General Counsel and there's generally three decisions that happen.

One is, is that the VA asserts no rights and says you didn't use VA resources. You didn't use any time. We're not going to assert rights. The VA can assert its right of ownership total—

Mr. ABRAHAM. Okay.

Dr. SHULKIN [continued]. —totally, absolutely.

Mr. ABRAHAM. So the researcher, he just gets his or her salary?

Dr. SHULKIN. The—the VA could do that, absolutely, and assert a hundred percent ownership. What typically happens, 95 percent of our researchers are called duly appointed. That means that they share an appointment with an academic affiliate.

So for 95 percent of these, they actually go between a negotiation. We have a—what's called a cooperative tran—transfer technology agreement with the academic affiliate where we negotiate with the academic affiliate. We say you're going to get a piece of this. VA is going to get a piece of this. The research potentially could get a piece of that.

Mr. ABRAHAM. But whether the researcher gets a piece of the pie is up to the academic institution and not the VA. Is that a fair statement?

Dr. SHULKIN. A duly appointed—a duly appointed personnel which, again, 95 percent of our researchers are, would have to negotiate that with their academic affiliate and with the VA.

Mr. ABRAHAM. Okay. Thank you.

Mr. Chairman, I have three more questions I will ask to submit for the record for a written response later if that would be okay.

The CHAIRMAN. That would be fine.

Mr. ABRAHAM. All right. I will yield back. Thank you, sir.

The CHAIRMAN. Thank you, Doctor.

Mr. Walz, you are recognized.

Mr. WALZ. Thank you, Mr. Chairman.

And, Dr. Shulkin, I am going to also echo a little bit what my colleague, Mr. O'Rourke, said. I think it is important for folks to know what you were doing yesterday convening a national summit on veteran suicide, everyone from the Chairman, Mr. O'Rourke,

others in this Committee, Elizabeth Dole, the work she has done, and this Nation's leading researchers as well as Clay Hunt's family and Daniel Somers' family.

So thank you for that. We are very grateful. I think what you have heard here is reestablishing the trust in the VA is a critical component as well as the delivery of health care and everything else.

And looking at this, and it is premature, and I think I have no frustrations with your inability to answer because this is all fast and that is what you are supposed to do and there are rules for that, I totally get that, but you can see where this thing is made for TV and the frustration of the American public that, again, feeds back into the idea that the VA is not doing things right.

The sad part of this is, this is a huge success story or should be for what the VA does, from the research we do, what we do collectively as a Nation to solve problems. There should be a mechanism to move these for efficiencies into the private sector.

The interesting thing is, is that we socialized the risk and the investment and privatized the rewards to this. And there is an irony in this discussion going on here that I am sure is not being missed on anyone.

For me a couple things, though, really stand out. My first concern, though, comes to this issue, the cost of this drug and delivery of life-saving care to our veterans. That is the main priority here. We will go back and figure out what Dr. Schinazi did and there is need to recoup, fix the system, but that is the one.

And I know you have spoken a little bit about it. We as a Nation, I would say not just the VA, have to get a handle on this. It is unacceptable. It is stunning to me that you have a veteran. You have this miracle drug. We are going to have to have the discussion of life-saving principles or how expensive they are and the care we give.

So I know you are very aware of that, but just the second part is just, I mean, it is mind boggling. I was thinking of this one-eighth of the time to develop this. I was thinking to myself, Vice President Biden needs to get this guy on board for the cancer project because this is a go-getter apparently. And it is frustrating me because you see where we are coming from.

I am pontificating to you, but I just want to be clear on this that, again, it is another good thing that is happening in the VA. There is life-saving ability here. There are some things we can do to streamline the system to get this drug to our veterans, and to the private sector who need it, at the same, time understanding that collective research that can't be done or won't be done by the private sector in many cases is still a role of government, but not at this type of expense.

And I know you have articulated. I don't want to ask you anything specific. I want you to know we get it. I think the Chairman is right in calling this and bringing it to the public's attention. They want to hear about it. There is a lot more that needs to be done before we can say what happened.

But, again, I can't stress enough that the public's perception of the VA is tenuous right now. Any story like this comes out, sets

us back and it sets back the great work that you and your team and others were doing yesterday.

So thank you for that and please know we know it.

Dr. SHULKIN. Well, thank you. First of all, I do want to thank you for your leadership as we approach the anniversary of the Clay Hunt Act. It was you who was the cosponsor in the House and thank you for that.

And thank you, Mr. Chairman and Mr. O'Rourke, for being there yesterday as well and Ms. Brown.

But establishing the trust with the American people and our veterans is our top priority and I couldn't agree more. That's why I take this very seriously. I do appreciate the Chairman's leadership in this, and we are going to make sure that we get to the bottom of this with all the facts, with the external reviews that we've set in place and the internal reviews.

The issue of hepatitis C, this is truly a miraculous new drug. We have, thanks to the support of Congress, have the resources now to make sure that we are going to treat thousands. In fact, this year, 36,000 veterans we are going to be able to deliver this drug to and hopefully cure at very very high rates. So thank you.

Mr. WALZ. No, we appreciate that. And, again, I can say this is a great story. And I don't know and I don't want to pass judgment on Dr. Schinazi.

Dr. SHULKIN. Uh-huh.

Mr. WALZ. This is a miraculous achievement and it is one that it is unfortunate that we are in a position where things seem to be clouded and we can't all celebrate this. And he should see the fruits of his labors to a certain degree, but not to the numbers we are talking.

So I yield back. Thank you, Mr. Chairman.

The CHAIRMAN. Before I recognize Mr. Huelskamp, is there anything that would prevent the VA from buying a veteran a first-class ticket and allowing them to fly to one of these countries and purchase the drug for $900?

Dr. SHULKIN. I am sure there is something that would prevent us in—in spending our money that way, but—but—but—but I understand. I understand the point of your question. And so I'm going to give you my personal opinion as a physician having practiced for as many years as I have and patients asking me this question.

I tell my patients that you are safest when you get your drugs in the United States of America with the FDA protections and our controls and our systems. When you go to a foreign country, we don't have as many protections as we have here in America for safety.

And so you're not always sure exactly what you're getting. So I wouldn't recommend that a policy that we send our veterans to Egypt for that, but—but—but certainly it's hard to understand the price differential. I understand that point.

The CHAIRMAN. I don't believe you would find a whole lot of argument from the Congress that would allow you to purchase a first-class airline ticket at $7,000, $8,000 to reap a $900 drug regime. And, you know, maybe we ought to look at it. I understand the efficacy issue, but this is the exact same drug made by the exact pharmaceutical company and so I asked that question.

Mr. Huelskamp, I will tee it up for you. You are recognized.

Mr. HUELSKAMP. Thank you, Mr. Chairman. I don't know if you were suggesting a one-way first-class ticket for me, but thank you. I appreciate the doctor being here.

But based on what I have heard now, I just want to make a statement. If I understand correctly, if the VA would assert ownership on just a few of these issues such as the hep C or HIV treatment, that could create an influx of billions of dollars into the VA for our veterans. Is that accurate?

Dr. SHULKIN. This is—this is all hypothetical because—because I don't know what percent ownership we potentially could assert. But potentially, this drug is a—certainly a multi-billion dollar drug, absolutely.

Mr. HUELSKAMP. Have we asserted any ownership in this drug?

Dr. SHULKIN. No, we haven't.

Mr. HUELSKAMP. Okay. Five questions I would like to quickly get through just for the record, Doctor. What were the total number of invention disclosures received by TTP for fiscal years 2013 and 2014?

Dr. SHULKIN. I believe that we disclosed in '13 272 and in '14 304.

Mr. HUELSKAMP. And how many inventions did VA assert in ownership interest in fiscal year 2013 and 2014?

Dr. SHULKIN. How many—

Mr. HUELSKAMP. Ownership interests.

Dr. SHULKIN [continued]. Oh, of those, 100 in '13 and 98 in '14.

Mr. HUELSKAMP. Okay. Is there a backlog or what is the backlog of invention disclosures waiting to be processed by TTP?

Dr. SHULKIN. There is a backlog. In '13, there was still five pending and in '14, there were 23 pending.

Mr. HUELSKAMP. Okay. And how many of these VA-owned inventions are jointly owned with the academic affiliate?

Dr. SHULKIN. Most are jointly owned with the academic affiliate. Around 95 percent are jointly owned.

Mr. HUELSKAMP. And you are able to identify what percentage is owned by the affiliate?

Dr. SHULKIN. Yes. Yes. It's a high percentage. About 95 percent are owned jointly with our affiliates.

Mr. HUELSKAMP. And what percentage is generally owned by the affiliate? Is that variant?

Dr. SHULKIN. Oh, oh, what percent. That would—that would really vary, depending upon where the research was done and where the time and effort was—was put in. Sometimes VA has a small amount. Sometimes VA has the majority amount.

Mr. HUELSKAMP. Okay. And how many patent applications did VA file in fiscal year 2013 and 2014 for solely owned inventions?

Dr. SHULKIN. In both fiscal year 2013, 25 and also the same number, 25, in '14.

Mr. HUELSKAMP. And were those patent applications approved?

Dr. SHULKIN. They were filed. They're not approved. So—so, you know, the patent process, as I'm sure you're aware, often takes a couple years, but those are the numbers that were filed. I think that three patents were approved in '13 and four in '14.

Mr. HUELSKAMP. And, Dr. Shulkin, how long have you been in this position again?

Dr. SHULKIN. Almost seven months.

Mr. HUELSKAMP. Almost seven months. And were you with the VA before and what position?

Dr. SHULKIN. No, no, no. I'm—I have spent my entire life in the private sector. I had a pretty good job before doing this, and I was asked to come in to help turn around the VA.

Mr. HUELSKAMP. Apparently not as good as Dr. Schinazi had as well, Doctor. But what is bothersome to me amongst many of these things is the fact that the sale was, I guess, public four years ago.

I mean, what has the VA been doing to establish an ownership interest? I mean, could you describe what has been occurring? And obviously you have only been there six months, but this occurred three years before you even came and we are talking about billions of dollars. Can you describe the process that the VA has done to establish an ownership interest and to investigate this issue?

Dr. SHULKIN. I—well, I'm going to—I'm going to refrain from—from anything specific about Dr. Schinazi. I think that much of what we've been looking into when I became aware of this is a result of the Chairman's letter to us. So—

Mr. HUELSKAMP. And that raises the question, the concern. Again, this is four years ago when he sold this $400 million profit. And we are sitting in the hearing today and this is the first time I heard about it.

When did you first hear about this and, again, has the VA done anything until January of 2016?

Dr. SHULKIN. I—the Chairman's letter to us was dated December 17th of 2015. I first became aware of it January 15th of 2016.

Mr. HUELSKAMP. What is the status of an investigation and did anything happen before you were made aware of it? Again, three years after the sale. I mean, this drug has been on the market and the VA finally discovered this guy works for you and was working for you a year ago when you first discovered this.

Dr. SHULKIN. Yeah.

Mr. HUELSKAMP. And tell me what investigation has occurred.

Dr. SHULKIN. So we were certainly aware that Dr. Schinazi has been an employee of VA for 33 years. No question about that. That wasn't a surprise.

Mr. HUELSKAMP. But he just sold a company for $400 million. Did anybody know about that?

Dr. SHULKIN. I'm not aware of who knew what three or four years ago. That's one of the reasons why I'm going to make sure that we take a look at everything that's involved in this to make sure that we do get answers to the types of questions you're asking.

Mr. HUELSKAMP. Well, I want an answer. The question is, why an investigation has not occurred more quickly? Why are we talking about it years after the fact? We are talking about millions of dollars that should go probably to the VA.

I mean, what we also need to investigate is what did he leave with in the last ten days. He is seven-eighths of his time. I can see where he walked out with a lot of stuff. I don't know.

Dr. SHULKIN. Yeah.

Mr. HUELSKAMP. Is he allowed to maintain an email network on his own that—do we even know any—

Dr. SHULKIN. No.

Mr. HUELSKAMP [continued]. —answer to these questions?

Dr. SHULKIN. No. Once you leave Federal employment, everything will stop in terms of that. There—there—

Mr. HUELSKAMP. Unless he took stuff home beforehand or took it to the affiliate. My question is we are talking about millions of dollars and I still—Mr. Chairman, I don't know why they didn't look into this before your letter. Thanks for the letter. I mean, this is shocking.

Dr. SHULKIN. Yeah.

Mr. HUELSKAMP. And we are talking about billions of dollars. So I would appreciate if you would provide the Committee as soon as possible—

Dr. SHULKIN. Yeah.

Mr. HUELSKAMP [continued]. —evidence that an investigation occurred long before this comes up before the VA Committee.

Dr. SHULKIN. I think there—Congressman, I think there are two things. One is, I would be willing and absolutely at any time that you want to sit down in a closed hearing or—or privately, I just can't do this in a public forum, and share with you everything that I know right now, abs—and—and I have provided a letter with some of that, but I would be glad to share everything that I know to this date.

But as I said, my intention is to actually find out more and to do a thorough review of the details. So we could either sit down now or sit down later, but absolutely, I will share that with you.

The CHAIRMAN. Your time is expired, Mr. Huelskamp. Thank you.

And I will be happy to provide for any Member of the Committee the information that Dr. Shulkin has provided to us. We do want the IG to have an uninhibited opportunity to review this because this is extremely serious and this is one individual.

And I would be remiss in saying, you know, this is one of the good things that is happening now in what Dr. Shulkin is saying. Regardless of what has taken place in the past, the change in leadership throughout the agency is beginning to change the culture, some of the lax oversight that was done internally.

And this is the way it is supposed to work. We do our job as the oversight Committee, provide the information or ask the questions of the department. The department doesn't get defensive about it. They go about what needs to be done and we don't have a political football which, by the way, we try to keep it as bipartisan as we can in this Committee and bicameral as well.

So, you know, again, I think the line of questioning is appropriate. I think the answer is appropriate as well and we do want to say thank you.

Mr. Takano, you are recognized.

Mr. TAKANO. Thank you, Mr. Chairman.

Regarding the $40,000 price, I am a little bit confused as to why we know it is $40,000, because I recall asking Sloan Gibson the same question. I asked them, what is the price of this hep C drug?

And he says—he told me he couldn't—he would rather not answer the question.

So, is it that that question cannot be answered or he rather—or the VA would rather not? All of a sudden we are talking about the exact price or—

Dr. SHULKIN. Right.

Mr. TAKANO [continued]. —is this an estimated price?

Dr. SHULKIN. Right. That is an estimate price. We are prohibited from giving out confidential pricing information. That $40,000 figure, I think I have seen 41,000 also in the—in the public domain, in newspaper articles, but VA does not give out its exact pricing.

Mr. TAKANO. So, I am confused as to how we can sort of say it is $40,000. So, it is off by a few thousand, not off by tens of thousands?

Dr. SHULKIN. I—

Mr. TAKANO. Because, in California, I recall reading in—

Dr. SHULKIN. Yes.

Mr. TAKANO [continued]. —in the LA Times, this case of a doctor and a patient in a dispute with an insurer over when the insurer would approve the drug. The woman definitely had hepatitis C, but it was a matter of the timing. The doctor said we need to administer it sooner because it was going to impart damage to her body.

Dr. SHULKIN. Yes.

Mr. TAKANO. The insurer said, no, we have a different opinion, and so they were bending much higher numbers. And I was trying to get a handle on how much the VA pays.

Dr. SHULKIN. The list price of the drug is approximately—you know, it depends. The average course of treatment is somewhere between eight and twelve weeks, so it depends on the individual, so the price varies, so these are all estimates. But the average list price is $84,000.

VA's—the numbers that are in the public domain of approximately $40,000, again, we don't give out our pricing, but these aren't bad estimates.

Mr. TAKANO. Well, how are your budget estimates made, with respect to the hep C drug?

Dr. SHULKIN. We know exactly how much we pay—

Mr. TAKANO. You know internally?

Dr. SHULKIN. Yes.

Mr. TAKANO. My—you know, I just had a chat with somebody in the industry last night, the pharmaceutical industry, and he says that two-thirds of new drug discoveries happen in our country, and, really, we finance both, through basic research from the Federal Government and investment in private research, as well as the back end where consumers also pay these prices. And Americans are really not understanding why other countries can benefit from all of this. Countries like Australia, European countries, they pay far lower amounts, but it is because we—our market develops all of these drugs; is that right?

Dr. SHULKIN. Two-thirds of them, yes.

Mr. TAKANO. Two-thirds, I mean that is a huge share of the market.

Dr. SHULKIN. Yes.

Mr. TAKANO. And, of course, we don't want to see this innovation stop, but it doesn't seem quite fair that American consumers and taxpayers are the ones that are primarily funding these discoveries, and there is something amiss here.

How much research does the VA do? I wasn't aware—this technology transfer was—I was kind of scratching my head over this Technology Transfer Program. But you say that most of these researchers have a dual appointment.

Dr. SHULKIN. Yes, sir.

Mr. TAKANO. So, is—are there VA laboratories or is it mostly done at the universities?

Dr. SHULKIN. No, there are VA laboratories.

VA has about 2,000 researchers, but 95 percent are dually appointed, which means they share with an academic affiliate. Our—our research program for internal funding is 637 million. Our total funding is 1.8 billion, because we get external funds.

Mr. TAKANO. I realize I can't ask specific questions about Dr. Shinazi is it?

Dr. SHULKIN. Yes.

Mr. TAKANO. But, is it theoretically possible for an agreement to have been made where the researcher, a VA researcher with a dual appointment, could have full ownership without—full ownership of what they do? I mean can—could such an agreement have been crafted?

Dr. SHULKIN. Although—although, I am sure you appreciate I am not going to talk about—specifically talk about Dr. Shinazi—

Mr. TAKANO. You are not talking about—I am not asking—I am just asking hypothetically, could that happen?

Dr. SHULKIN. Yes, it could.

The way that—the way that this works is that we ask all researchers to disclose conflicts of interest and financial interests. We also look at whether any VA time or resources are involved.

If there is no VA time or resources involved and there is not a conflict of interest, it is possible that somebody could own something outside of VA.

Mr. TAKANO. Well, thank you.

Mr. Chairman, I really thank you for your letter. This is really, I think, a very important topic that you have raised, and I will be eagerly wanting to see that information that you got.

The CHAIRMAN. Absolutely. And we will make it available for all of the Committee Members as soon as we get it in.

Dr. Wenstrup, you are recognized.

Mr. WENSTRUP. Thank you, Mr. Chairman.

Thank you, Doctor, for being here. Thank you for leaving that pretty good job from the private sector to join us and try to do some good things.

And it is really a shame what has happened, because this is pretty much a stain on an, otherwise, very great moment for VA research.

Dr. SHULKIN. Uh-huh.

Mr. WENSTRUP. I think the first question I have is, what prompted the VA to take up this type of research? What was the stimulus for going in that direction? Was it a high number of patients with hepatitis C or where did that come from, do you know?

Dr. SHULKIN. Yeah. I think that—I think there—there are two things about this. If we are talking about the research primarily that Dr. Shinazi has been doing—and this is in the public domain that has been released through the Freedom of Information Act; that is why I am sharing this—almost all of his research has been done in antiviral medications and treatments, and mostly related to HIV. So that has—that has been where the focus of his advances in career have been.

The focus on hepatitis C, not necessarily research, has been related to the fact that so many veterans, unfortunately, have this disease. And prior to this particular new course of treatment, the old treatments were so toxic and were not curative, in fact, Dr. Chang, to my right, is actually—she is a researcher and a clinician in hepatology and has spent her career, 16 years at VA, dually working with the University of Pennsylvania, and this is exactly what she does in treating patients and studying this—this.

Mr. WENSTRUP. So, typically, for VA research, there is high evidence of a condition that drives the need for going in that direction?

Dr. SHULKIN. Our research program is dedicated to doing research to help veterans.

Mr. WENSTRUP. So, as we move forward and as we look at the current situation, what are the rules as you begin research, you know, as far as you mentioned disclosure and conflict of interest. Does VA have, like, an ethics committee that overlooks these types of things? Does the researcher sign something and say what is proprietary, what belongs to the VA and what doesn't? And what is going on and what do you envision it should look like, I guess?

Dr. SHULKIN. There—there are a number of things. We have VA handbooks on—one on intellectual property, and one on research oversight, as well as other VA handbooks. Every researcher that is funded has to sign off on the fact that they are following those handbooks and those policies, and that they acknowledge their responsibility.

There is no research that is done, unless it is approved by the associate chief of staff at the VA medical center. Our research is actually decentralized; it happens at the medical centers, these 100 medical centers.

We do have a research oversight committee who has to look at and approve all protocols to make sure the resources are used, and no researcher can begin research without the sign-offs on the Committee and by the associate chief of staff.

So we do have a number of controls. What I am not comfortable with to tell you today is that they are sufficient enough.

Mr. WENSTRUP. Okay. The intent is to have legal standing with—

Dr. SHULKIN. Absolutely.

Mr. WENSTRUP [continued]. —legal intent.

Dr. SHULKIN. Yes.

Mr. WENSTRUP. Okay. Well, thank you very much.

I appreciate it and yield back.

The CHAIRMAN. Mr. Costello?

Mr. COSTELLO. Thank you very much.

And, Dr. Shulkin, thank you for being here today and your testimony. And I am—part of me, obviously, wants to ask questions that I know that you can't answer, because I feel there is, at least, a possibility that we could all end up being outraged by what we find, and I respect the fact that you are constrained, so I don't want to probe you—

Dr. SHULKIN. Uh-huh.

Mr. COSTELLO [continued]. —to try and answer questions that you can't answer. And so, if you can't, I certainly can respect the fact that you are not trying to conceal information from us or are complicit in any way, it is just you need to respect the integrity of the review process.

The other part of me is actually somewhat optimistic that there can be, moving forward, after your review, a little bit more of an entrepreneurial approach to the way you go about research, mindful, though, that your research—and it says right here, I think in your testimony, your focus is on research areas most likely to benefit veterans and not necessarily what a normal entrepreneur would do, is to make money.

Dr. SHULKIN. Right.

Mr. COSTELLO. But I suspect that there might be some potential there, and I think that all of us are eager to see what your review yields.

You have used the word "review," and so I want to sort of disentangle various iterations of what the word "review" can mean.

Dr. SHULKIN. Uh-huh.

Mr. COSTELLO. Again, if you can answer this, has this been referred to the IG—and I am speaking specifically of Dr. Shinazi—or would you prefer not to answer that question?

Dr. SHULKIN. I would—I would prefer not to answer that.

Mr. COSTELLO. And I am not going to follow-up.

Dr. SHULKIN. I made—I made as much as I could, talk about that, I made that clear in the letter to the Chairman.

Mr. COSTELLO. Are you able to answer the question as to whether or not Dr. Shinazi completed a Federal conflict of interest form or would you prefer not to answer that question?

Dr. SHULKIN. I can't answer that specific question right now.

Mr. COSTELLO. Fair enough.

Dr. SHULKIN. Yeah. And in closed session, I would be glad to share that with you.

Mr. COSTELLO. Okay. And, obviously, you know, I would just say for the record that I think that a constituent of mine or any American, in learning some of this information, would say, there has to be—something is not right about that.

So if, in fact, Dr. Shinazi did not submit a completed Federal conflict of interest form, or did not do it properly, obviously that invokes a potential for criminal violations and the extent to which this should be a criminal probe, on that basis, I think, obviously, it should be.

The other piece of any use of the word "review" sort of invokes whether or not an audit should be done. And I do—you just were speaking a minute ago about you had some internal controls and the ability to know who is doing research and in what capacity and

for what reason, but, yet, no audit has been done, moving backwards.

You have been here seven months?

Dr. SHULKIN. Uh-huh. Yes.

Mr. COSTELLO. I have been here one year and one month, so I don't pretend to know it all.

But do you think an audit is appropriate for patent applications, issue patents, and royalties from co-owned inventions?

Dr. SHULKIN. From—from my—

Mr. COSTELLO. Going backward.

Dr. SHULKIN [continued]. —from my initial review, which has been two weeks long—

Mr. COSTELLO. Right. And initial.

Dr. SHULKIN [continued]. Yes. I do believe that we are going to want to strengthen this process. I think you have identified something that I have also identified, which is that we, the VA, have turned over much of the responsibility for patenting and licensing and monitoring to our academic affiliates, and I have to say I am not particularly comfortable leaving it there without either a robust audit provision in there or VA actually assuming some more of those responsibilities. So I think you have identified an area that I have concern about.

The second area that I have concern about is—and I have identified so far—is, I want to make sure the conflict of interest and financial disclosure forms are broader than what we are doing. We are doing them project by project now, and I think they should be blanket, across the board for researchers.

Mr. COSTELLO. And as part of your review, is it possible that you might be issuing recommendations to approve the process? I mean I think you just said that you probably will be doing that, but can you see even something broader, in terms of improving the TTP system, which may actually, I would also say, may actually be more welcoming to systems of higher-ed to be more involved in this.

Because I think that there is a real—I mean, from what I have reviewed, part of me really wants to ask a lot of questions about Dr. Shinazi. Part of me wants to say, what are the opportunities here to make this system and actually be a revenue-enhancement measure for purposes of VA funding down the line?

Dr. SHULKIN. Well, I—I think that you are looking at it exactly correct. I look at it both ways as well. One is, we have to assure that we are protecting the rights of the taxpayer in this. That is—that is one of the ways that this was set up.

But another reason why the TTP program was set up was actually to facilitate commercialization and access to technology to veterans.

One of the things also, that I see as an opportunity out of this is something Mr. O'Rourke said, which is that one of the reasons why clinicians like to work at the VA is because they actually have the opportunity to do both, clinical work and research. That is becoming much less common in academic centers, where you have to focus, you are either a researcher or a clinician.

So I do think this is one of our recruitment tools, to make it a place where you can come and both, see patients and do research

and do it easily. And so out of this process, I don't want it to be more bureaucratic, I just want to make sure it is fair, that we are not having the government taken advantage of, but it is actually a place you can do research and do it easily.

Mr. COSTELLO. That is an excellent point.

I see my time is expired. Thank you.

The CHAIRMAN. Mr. Coffman, you are recognized.

Mr. COFFMAN. Thank you, Mr. Chairman.

Dr. Shulkin, are you outraged by all of this?

Dr. SHULKIN. I don't know enough to be outraged. I will tell you, Congressman, I am taking this very seriously, and I reserve the potential to be outraged, but I don't know enough to be able to say that.

Mr. COFFMAN. Well, that is the pattern we get here from the VA; it is always somebody that they bring to testify that is just new and they can't be held accountable for anything that has occurred over any given issue.

So what you are doing is no different than the person before you and the person before you testifying before this Committee has been done. And it is interesting to me that the VA is so bureaucratically incompetent, that they can never figure out their own problems, that they have to come in from the outside.

So you are here, not because you identified the problem or because anybody in the VA identified the problem; it is because you were asked by this Committee to be here, who has recognized the problem. And how hard would it be to recognize a problem? Somebody on your team develops this vaccine and VA contracts for it at about $40,000 per patient and can't figure it out. Can't quite—you know, how hard is that to do?

And what is also extraordinary, because this fits in the same pattern that the person who is responsible always seems to retire just before the investigation starts. In Colorado, we have a billion-dollar cost overrun on a VA hospital, and just before the individual in charge was to be interviewed, he retired. He retired the day before.

So, I mean, this just fits this whole pattern. And, you know, I think at the end of the day, what I hope comes out of all of this is we give these research dollars to people that know how to do it. The NIH, just like in the situation in my town where that billion-dollar cost overrun of the VA hospital, we stripped the authority of the VA to manage the construction of another hospital, and it went to the Army Corps of Engineers who builds the same facilities for the Department of Defense, on budget, on schedule; they have taken that responsibility over from the VA. It is their day job.

I mean, who was in charge of this doctor? Who—can you identify who was in charge of him during this time that he developed this patentable vaccine?

Dr. SHULKIN. Yeah. As I said, VA research is decentralized, so it would be the Atlanta VA that actually oversees this research program.

Mr. COFFMAN. Who is the internal—who, can you tell me, was in charge of this person?

Dr. SHULKIN. The specific name of a person?

Mr. COFFMAN. Yeah.

Dr. SHULKIN. I don't—I don't have that information. I don't know whether my colleagues do.

Mr. COFFMAN. That is typical, because that is the question I ask always when there is a problem, who was in charge? And nobody can ever give me the name of anybody that was in charge.

Can you get me that name?

Dr. SHULKIN. Well, I can find that out for you, absolutely.

Mr. COFFMAN. Can you find that out for me? I mean I just think this is just a—just absolutely, I mean, extraordinary.

And the sad part about it, really about, you know, is it bureaucratic incompetence or is it corruption or is it a combination of the two that leads us to these massive problems? You know, this wasted resource is why this Nation is unable to take care of the men and women who have served this country in uniform.

And I just think that, you know, if I were you, I would be outraged.

And, Mr. Chairman, I yield back.

The CHAIRMAN. Thank you.

Dr. Benishek?

Mr. BENISHEK. Well, thank you, Mr. Chairman.

Well, Dr. Shulkin, welcome to your new job. Isn't this something, aye? You are learning a lot about it, I am sure.

You know, frankly, I tend to agree with Mr. Coffman with many of his thoughts, you know, and that once—you know, I agree, once again, we have a new guy who wasn't here and doesn't know the name of the person who is in charge.

Well, I don't want to dwell on the past too much. I am hopeful, you know, from knowing you a little bit, that you will continue to work on it. And you mentioned about this internal review of this procedure for sharing information or technology transfer.

Is there any consideration of an outside auditor of all this, rather than a VA person? Because we have had VA internal reviews before that—like wait times that turned out to be completely wrong. So, can you delve into that a little bit?

Dr. SHULKIN. This needs external review. That—that is going to—that is going to occur in this, and—

Mr. BENISHEK. I am glad to hear that.

Dr. SHULKIN. Yeah.

Mr. BENISHEK. The other question that always comes up in this sort of circumstance is the timeline. You know, we were going to do this, honest.

When will we have the report?

Dr. SHULKIN. There is going to be two levels of report here. One is the external review, and in my experience, the VA doesn't have the ability to set the timeline of the external review, so—so, I can't give you a specific answer to that.

The internal reviews, we are going to have done within 90 days.

Mr. BENISHEK. All right. Well, I am looking forward to seeing that.

I want to talk a little bit more about this academic partnership—

Dr. SHULKIN. Uh-huh.

Mr. BENISHEK [continued]. —and the review of the agreements and the accountability of what the academic partners are doing.

How do you monitor that?

Dr. SHULKIN. Right now, our system is set up—and this is one of the things that I want to take a look at—but our system is set up that we give the primary responsibility for the patenting and licensing to the academic affiliate. This was—our program was designed this way, saying that this is what academic centers do. They have the competency. This isn't what VA does well, so we have turned that over.

But I think, as we had mentioned before, my concern is without the proper auditing of that and without the proper oversight of that, that it is hard for VA to know that it is getting its proper ownership rights.

Mr. BENISHEK. Yeah, well, that is what occurs to me, as well, and I am sure to many people.

Dr. SHULKIN. Yes.

Mr. BENISHEK. So, are we going to kind of review that whole process? Is that a different review then?

Dr. SHULKIN. No. This is—

Mr. BENISHEK. Part of the whole scheme.

Dr. SHULKIN [continued]. —there is really—there is really several aspects of the review.

Looking at the overall circumstances and concerns that have been raised here, there is a review that we will use external people for, to take a look at, do we have the best practices for technology transfer that academic centers believe we should have, and we are going to be looking internally at our own policies and procedures.

Mr. BENISHEK. All right. Thank you.

I am going to maybe direct a couple of questions—I have got a minute left—for Dr. Chang.

And, you know, I am familiar with this class of drugs that treat hepatitis C a little bit and the dramatic effect they are having on the course of the disease and, really, maybe the eradication of the disease and, you know, a much lowering of costs in the long run because we are going to—liver transplantations and the long-term care, that is going to be dramatically reduced.

As far as the VA population of patients with hepatitis C, can you kind of review for me again, you know, how long is it going to take us to get this treatment to the patients that are there? Can you talk about that a little bit and, I mean, how long is it going to take to treat all of the patients?

Dr. CHANG. Right. So we have—first, I thank you for the opportunity to speak in this—in this forum, and I really appreciate all of your questions.

We have about 180,000, I believe, of veterans who have hepatitis C, plus, perhaps another 20 to 40,000 or so that might be uncounted for, as of yet.

I think in the past year, we have treated about 35,000 veterans already—I mean 35—yeah—thousand veterans already, so I think we are well on our way to treat.

And I think the key thing with the hepatitis C—you know, I started my career actually with hepatitis C as a major challenge in my clinical and research goal. And I am actually profoundly moved by the progress that we have seen, as all of you guys are saying, about the miracle drug that this is.

I spent the last 15 years of my life trying to treat these people with drugs that don't work—

Mr. BENISHEK. Right.

Dr. CHANG [continued]. —or drugs that we tried not to give to patients because they are suffering and they are actually damaged by it and so forth.

So I am very happy to have these opportunities to really cure people. And I want to emphasize the fact that we can cure them of the virus and the progression of liver disease; however, the disease that have already occurred over the 10 to 20, 30 years, that, we cannot actually cure.

So, in any case, I think we will—

Mr. BENISHEK. I appreciate your answer, but I am out of time. Thank you very much.

The CHAIRMAN. Dr. Roe?

Mr. ROE. Thank you, Chairman, and thanks to staff for bringing this up.

And I am not going to belabor all the points that have been made.

Dr. Shulkin, I too, gave up a pretty good job to get here and I appreciate the fact that you are here.

And, Dr. Chang, what you said, as a clinician and practitioner, it is nothing short of a miracle for patients. And as Mr. Walz said, we should be celebrating this, because it is a celebration of a real success.

And the NIH didn't bring this cure, the VA did. And I agree with decentralization of the research. As you well know, you put it all in one place, you will get one mindset, you will get tunnel vision.

You need a lot of different eyes looking at this from a lot of different directions, and so I would disagree with my friend, Mr. Coffman, about that. I think it is a big shout-out to the VA.

We will figure out what happened with the doctor that did this, but this is a miracle. And even at the cost, it is probably a savings. When you look at liver transplantation, just the emotional that it does to patients—I had a patient come up to me on Christmas Eve who had hepatitis C—her sister had just died of a liver—a complication of a liver transplant—and she was having problems with her private insurance getting the coverage, and fortunately that has occurred.

And as the Chairman brought up, and as Mr. Takano brought up, we have a real ethical problem in this country, as a physician going into the room, a real ethical problem of, I know I have a cure, but I can't pay for it.

And I—there is just one of the drug companies—I know this for a fact—that is grossing $4.5 billion a quarter—not a year, a quarter—with this drug.

Now, hopefully we can eradicate this disease, and I hope that that will happen.

And I have an ethical question for Dr. Chang or Dr. Shulkin, either one: What happens if a patient becomes reinfected due to behavior? I know we treat patients who smoke if they get lung cancer and then bladder cancer and cancer of the throat, cancer of whatever, directly related.

How, ethically—because it is an incredibly expensive—I started thinking about this, what if your behavior leads you to a second infection, what are we going to do? Have you all thought about that?

Dr. CHANG. Actually, we have thought about these things, but I have to say I am not an ethicist. I think what we typically see is patient in front of us, who we would like to take care of.

I think, typically, the issues that I have had in my clinical experience is not so much a reinfection, but a recurrence or relapse of viremia, because the drugs that we had were so inadequate.

I think, though, we may have to be ready for that consideration.

Mr. ROE. Well, I think you need to be thinking about it now, because it is not inexpensive.

And I, quite frankly, Mr. Takano, I might buy a—not a first-class ticket, as you helped provide us on the way back from Kuwait with your frequent flyer miles—but I might buy a cabin seat and go take the—and then have my viral tire checked and see if I was cured. If I didn't have the money, I might make that trip and do that. I think that is a—I think that is a huge issue that we have to think about.

And the other thing we have debated in this country for years are the costs—there is no question, a majority of drugs—new drugs brought to market are developed in the United States. The research is done here. It is brought here, and then other countries share in that wealth of knowledge that we get that we share with the world, and we should.

The question is, our people are paying the price for that, and when we look at a 42,000—it is 80,000 on the private side—to get this treatment, that all goes toward less money in your paycheck going home and all those things that other countries are not doing. So I think the Chairman and Mr. Takano make a great point; I don't know what the answer is. I don't want to shut it off, but I also don't want to see gouging either of—and make it impossible.

Dr. Chang?

Dr. CHANG. If I may also add, I think, certainly, the development of a drug is a great accomplishment, but I think it also is standing on the shoulders of all the researchers throughout the world who have actually furthered the cause of understanding a viral hepatitis and developing a system in which you can actually test these kinds of drugs, and without which, none of this would have actually happened.

So I think there is a particular group of people that may be benefitting, but I think this is really something that, internationally, people have banded together over the last 25 years to develop.

Mr. ROE. And, hopefully, this is just a start of instead of treating disease, curing disease. I mean just one of the things that has really—I have looked at how many diseases I have just treated over my career, boy it is remarkable you can walk into a patient's room and actually cure them.

And I was somewhat mixed up in reading the testimony where four percent of the veterans that you treat have hepatitis C, but then I heard 180—the number is 180,000 active patients that we have to treat?

Dr. SHULKIN. No. The—the actual numbers, as I understand them, today we have 116,000 patients with known hepatitis C in VA.

The amount of unscreened people—

Mr. ROE. I got it.

Dr. SHULKIN [continued]. —we think that that will add up to the 170, 180,000 patients. So that is what we think is out there, but documented, 116,000.

We also have 46,000 of those who have advanced liver disease; those are the ones that we really want to treat now.

Mr. ROE. Now. And the sooner you can—look, if you are a patient, why wait until—I know there are certain categories and Dr. Chang knows about who would qualify and all of that, but if I have the virus and I want to be cured, I don't want to wait until my liver is half-destroyed before I get the treatment.

So, Mr. Chairman, thank you for holding this hearing. I yield back.

The CHAIRMAN. Thank you.

Mr. Takano?

Mr. TAKANO. Mr. Chairman and Dr. Roe, that question you asked about we don't want to shut it off, we don't want to see price gouging either, can I suggest a roundtable or—and this is something that affects Energy and Commerce, as well, the jurisdiction—I would like to get some expertise from economists.

We don't want to see rent-seeking being incentivized by our laws, but we know that the American people pay for a lot of research and through the VA—I am learning something new—but if we could get a handle on your question, I would think a lot could come from that.

Mr. ROE. Would the gentleman yield?

Mr. TAKANO. Yes.

Mr. ROE. There is a fair ROI when you invest a billion and a half dollars from molecule to market. There is a reasonable expectation of a return on your investment.

But some of these, I think, are unreasonable returns on investment. And I think when you have patients out there that cannot get the treatment, a cure of a disease that is fatal because of a cost that is outrageous—and as the Chairman pointed out, perhaps as low as one percent of what they are charging here, in a foreign country—there is something wrong with that balance. So, I agree with you; we should do that.

Mr. TAKANO. Well, and then the Chairman mentioned to me in a side conversation about the issue of our patents being infringed upon in other countries—I mean there is also a trade element there going on, but it is hard to know whether that is really how valid those arguments are.

So I would love to see a far more in-depth—it is a big issue. I mean I have smaller insurance plans have come to me, labor unions, just one or two of their pool could blow up the whole plan, so it is enormously disruptive, this drug pricing. We have got to get to the root of it.

The CHAIRMAN. Thank you, Mr. Takano.

Thank you to the Members.

Also, let me throw another curve in the road to you. There actually are those that claim that Dr. Shinazi did not, in fact, discover this particular drug. So we have that to deal with, as well, as we go through the process.

I want to ask Dr. Shulkin just a couple real short questions. I think in your—not yours—but in the department's 2015 budget submission, VA stated that researchers collaborated with MIT and Brown University on the first powered ankle-foot prosthetic that is now commercially available for patients. But in your testimony today, I think you said that the device is not particularly commercially valuable.

And so my question is, does VA have ownership in the technology?

Dr. SHULKIN. I believe that that is one that we have asserted rights on.

I don't know if you know, Marisue?

Ms. CODY. Yeah, the—what we talked about in testimony is not that same ankle, so we will have to get back to you on exactly what our rights are on the ankle you are talking about.

The CHAIRMAN. Okay. Let me also ask you about, there is a disposable microchip that is being worked on right now that can diagnose a heart attack within minutes, and so what I want to know is, has this been disclosed to the VA? And if it has been, is the VA pursuing patent protection? And will it be a licensed product?

Dr. SHULKIN. We will get back to you on that.

I don't think you are aware of that either.

The CHAIRMAN. Okay. If you would.

And the other thing, Doctor—and I appreciate the questions that the Members have asked today and certainly your comments and answers. I appreciate your letter of February 1st, answering my request from back in December.

And I asked for the following—and I say this, because I am going to ask why two things were inserted into this letter—actually, three things—a list of all inventions disclosed to the VA between 2000 and 2015; I asked for a list of VA-funded research projects, same time frame; a list of all non-VA-funded research projects, same timeframe; and all determination of rights, issues—issued by VA.

I appreciate that. But in your response, you threw in you needed budget flexibility. Why did you throw that in your response to a very specific letter? In fact, you even talked about purchased health care streamlining and modernization.

I mean, I was pretty specific. Whether you need it or not is not a question. Why did you write this response?

Dr. SHULKIN. Right. Right.

I—I appreciate the fact that that is not directly related to your requests.

The CHAIRMAN. Not at all.

Dr. SHULKIN. Yes, I appreciate that. You are correct.

The CHAIRMAN. It is showing up in every single letter that comes to us and I am aware—I understand what the department would desire and we want to help in that way, any way we can.

I just—you know, the other thing is, why did you feel it necessary in the response to talk about all of the people that had been directors of the program over the last few years, by name?

Dr. SHULKIN. Yeah. It—it was felt since there was such a turnover of people and since Marisue is really in an acting role, that if we got questions related to going all the way back, that it was important to know that different people had served in those roles.

But it—but—but you did not directly ask for that, sir.

The CHAIRMAN. Okay. And I just—it was interesting that you specifically identified individuals.

I want to thank you again for being here. We have had a chance to hear about one specific opportunity, but we think there may be others where there had been lost opportunities in the technology and transfer program. It appears to have been misused, underutilized, and undersupported.

We appreciate, Dr. Shulkin, your response that it is going to be a much more robust oversight on your part. You know, we want to determine the extent of lost opportunities that VA has experienced, why they were experienced, and what VA is doing to ensure that they don't happen again, and to offer VA a chance to explain how it has let the program languish for so many years, and to establish the next steps to prevent these lost opportunities from continuing, so that veterans from the beneficiaries of the great inventions that come out of VA's research program.

And, again, I want to thank your candor today, and we look forward to the questions that you have taken for the record and their answers.

I would ask unanimous consent that all Members would have five legislative days, with which to revise and extend their remarks and add extraneous material.

Without objection, so ordered.

I want to thank, again, the witnesses and everybody for joining us today to discuss what we have, and this hearing is adjourned.

[Whereupon, at 12:04 p.m., the Committee was adjourned.]

A P P E N D I X

Prepared Statement of Jeff Miller, Chairman

I would like to welcome everyone to today's hearing titled, "Lost Opportunities for Veterans: An Examination of VA's Technology Transfer Program."

Let me begin by stating that the issues we will address today show how, despite VA's objections, it is critically important for this committee to look at both past and current failures of the department, in order to improve the future of Veterans' care. Without our investigative effort and our notice to conduct this hearing, VA would not have reviewed what we will talk about today. Moreover, VA would not be aware of the apparent exploitation of its technology transfer program from those inside the department. My concern is that the issues we will discuss today may not be limited to one researcher.

For those who are unaware, Federal agencies are authorized to assert ownership in inventions made by Federal employees using Federal resources. VA's technology transfer program was developed as the mechanism to determine ownership and then to transfer the benefits of VA owned technology to veterans and the public through patenting and licensing. Unfortunately, this program appears to be habitually underused, resulting in tremendous losses to Veterans and taxpayers.

A glaring example of where the technology transfer program perhaps should have been used is in connection with the Hepatitis C drug, Sofosbuvir, which is claimed to cure up to 99% of those infected with this ultimately fatal disease. This drug, reportedly developed by a VA employee, resulted in an $11 billion sale and $440 million personal profit to the employee. However, VA appears to have nothing to show for it, except a bill from the drug's current owner, Gilead Sciences, for VA's use to treat veterans.

More than two hundred thousand Veterans have been diagnosed with Hepatitis C, and VA pays upward of $40,000 for treatment for each Veteran infected with this virus. That is about $8 billion to treat veterans with a drug reportedly developed using VA resources. During last summer's financial crisis, VA had to ask Congress for additional funds just to pay for the treatment. So the question is, why is VA paying so much?

What we know is the drug's reported creator, Dr. Raymond Schinazi, was a 7/8th VA employee when the Hepatitis C drug was developed. He worked at VA for more than twenty five years and retired shortly after we requested he testify. Dr. Schinazi is listed as a senior career researcher and has received hundreds of thousands of dollars in VA research funding. Yet, in a letter to me, dated February 1, 2016, the day of his retirement, VA asserts that no money was given to Dr. Schinazi for his research on the drug.

But, questions remain whether earlier research on a different drug was used in the development of the hep-c treatment. Additionally Dr. Schinazi filed patents while he was a VA employee, but he never disclosed these inventions and patents to VA. So how is it that none of his claimed lifesaving inventions belong to VA and our Veterans? Interestingly, as I mentioned earlier, I asked Dr. Schinazi to appear at this hearing, but after being requested to testify, he retired from VA, effective February 1 - two days ago.

Secretary McDonald rightly promotes VA as having invented many cutting edge technologies like the nicotine patch, the cardiac stent and the CT-scan, but in actuality, VA reportedly receives no credit and no revenue from these inventions because it did not assert an ownership interest.

Although these inventions were developed prior to the inception of VA's technology transfer program, these lost opportunities should serve as lessons learned and, in the future, VA should be supporting and developing the program so that no other potential opportunities are lost. Our Veterans and taxpayers should be benefiting from these inventions. It is as simple as that.

VA oversees a $1.8 billion research program. Yet, in FY 2014, it only received 304 invention disclosures, filed only twenty five patents, issued only fifteen license

agreements and earned only $375,674 in royalties. To put that in perspective, the National Institutes of Health has a $3 billion intramural research budget and in FY 2014 received 370 invention disclosures, filed 153 patents, issued 222 license agreements and earned $137 million in royalty income, or about 360 times more than VA's reported royalties. Similarly, the USDA has a $1 billion research program and in FY 2014 received 117 invention disclosures, filed 119 patents, signed 412 license agreements and received $3.6 million in royalty income or about nine times more than v-a's reported royalties.

This begs the question, why has VA not seemed to capitalize on the many research successes it claims? We have already seen the results of one potential lost opportunity regarding the new Hepatitis C drug. But, how many more are there and how many more will there be? If VA wants to take credit for tremendous medical accomplishments, it should have something to show for it, certainly more than just talk. Veterans deserve the right to reap the benefits of these inventions given the fact that they were created by employees and with taxpayer resources specifically designated for their use.

Prepared Statement of Corrine Brown

- Thank you, Mr. Chairman.
- Since 1980, the federal government has worked to make taxpayer funded research more available to the private sector while making sure that taxpayers also gain from these research investments.
- This allows all of us the share in important research breakthroughs.
- University of Florida developed Gatorade and got a patent for it, so anybody who used it had to pay University of Florida royalties for its use. This concept of VA keeping its intellectual property rights for its employee's inventions can't be hard.
- But we need to strike the right balance here so academic institutions want to partner with VA to conduct research and get funding for research from royalties from inventions, and so research is available for businesses to develop products that help veterans and the public.
- This important program that should be overseeing this balance may not have received the leadership focus that it needs and employee turnover has been high.
- There are questions as to whether the process in place is sufficient to strike this balance, from the Veterans Health Administration to the Office of General Counsel.
- For this reason, I believe we should have an outside organization look at this program. I believe we should request the GAO to look into this program and provide us with the facts so that we can make sure the program strikes the proper balance.
- Finally, I believe that if this program is not working as it should, VA, and taxpayers, may end up holding the bag.
- Just last week the Chairman raised questions and concerns over the price paid by the VA for Hepatitis C drugs. He also pointed out that the drug was invented by a team led by a VA doctor.
- This doctor subsequently sold the company that developed the drug to Gilead (Jill-e-ad) Sciences.
- According to the Chairman, Gilead is charging the VA "upward of $40,000" while in Egypt the drug costs $900.
- Without the VA this drug would not exist.
- In the case of Gilead, we do not know if the process worked and whether the VA properly asserted its rights in this matter.
- That is why we requested that Gilead be invited to testify today.
- I believe that we should hold a hearing on drug pricing and how, moving forward, we can make sure that veterans are getting the drugs they need and VA is paying a fair price.
- In addition, according to a recent New York Times article, drug manufacturing issues have caused shortages and rationing. We need to make sure that we get to the bottom of this to make sure that veterans are not unduly affected. Let me repeat myself. We need to get to the bottom of this to make sure veterans are not unduly affected.
- Making sure that taxpayers are not ripped off, and that veterans get the medicines they need is vital.

- I look forward to us working together to explore these issues in the weeks ahead.
- One team one fight!
- Thank you, Mr. Chairman and I yield back the balance of my time.

Prepared Statement of David Shulkin, M.D.

Good morning, Chairman Miller, Ranking Member Brown, and Members of the Committee. Thank you for the opportunity to discuss the Technology Transfer Program at the Department of Veterans Affairs (VA). I am accompanied today by Dr. Kyong-Mi Chang, Acting Chief Research and Development Officer, and Dr. Marisue Cody, Director of Research Operations.

VA's Technology Transfer Program is housed within the Office of Research and Development, through which VA conducts a robust research program whose fundamental mission is to advance the healthcare of Veterans. VA research supports over 2,000 research projects at over 100 VA medical centers (VAMC) throughout the country, with an FY2016 direct appropriation of over $620 million. The VA research program is further enhanced by private and federal grants awarded to VA researchers, meaning total resources available for VA researchers will exceed $1.8 billion this year. VA research projects focus on VA-relevant biomedical laboratory, clinical, rehabilitation, and health services research through four research services, a Cooperative Studies Program for large clinical trials, and a quality improvement program that uses research evidence to improve clinical care. For over 90 years, VA research has worked to improve the lives of Veterans: performing the first successful liver transplants; developing high-performance prosthetic devices; establishing the value of aspirin therapy in improving heart health; showing the effectiveness of the Shingles vaccine; and developing the nicotine patch.

Established in 2000, VA's Technology Transfer Program reflects our research focus on the Veteran, ensuring that products and innovations created by VA researchers are accessible to all Veterans. Prior to the establishment of the Technology Transfer Program, VA had no policy on intellectual property rights, and generally waived ownership rights to inventions, tasking the inventor and usually the academic partner with patenting, marketing, and licensing responsibilities.

The Technology Transfer Program has three main areas of focus: 1) protecting and commercializing of intellectual property; 2) facilitating technology transfer and cooperative research and development activities among academic partners, local VAMCs, and industry; and 3) educating researchers within VA about their rights and obligations regarding intellectual property management and cooperative research activities. Technology Transfer within VA involves multiple integral individuals and entities nationwide, including researchers within VAMCs, the Office of General Counsel, academic affiliates, Nonprofit Corporations, and commercial partners.

Enabling greater cooperation with academic and private institutions is one fundamental goal of the Technology Transfer Program. To support this, the program executes over 1000 new Cooperative Research and Development Agreements per year, most are for clinical studies, and these agreements represent over $35 million in sponsored research dollars available to VA research centers.

The Technology Transfer Program's public mission requires aggressive dissemination of educational information to researchers, and of products to the market. It is also necessary that VA asserts an ownership interest in disclosed inventions whenever appropriate, so that discovery can be built upon. This ensures Veterans have access to these technologies. Often, as opposed to patenting inventions and delaying their availability in the public domain, the Technology Transfer Program works to ensure Veterans have immediate access to these technologies by releasing them publicly.

The Technology Transfer Program has had several recent successes, particularly in areas that are highly specialized. The program is crucial to the dissemination of products that are of limited commercial value to private institutions but can greatly improve Veterans' quality of life. This has included the development of several kinds of prosthetic feet, such as a foot that allows Veterans with lower leg amputation to easily change shoes without experiencing balance issues (allowing, for example, easier wearing of high heels or cowboy boots). This is an important quality of life issue for Veterans with lower limb amputation, but is not particularly commercially valuable, and would likely not be available to Veterans without the Technology Transfer Program. Other examples include products that make it easier for Veterans to use

wheelchairs, or prevent common injuries (pressure ulcer, carpal tunnel syndrome) related to use of wheelchairs.

Every year, VA researchers develop dozens of new health care-related technologies and other inventions that benefit VA's patients, other Veterans, and all Americans.

Unlike other Federal agencies, VA has no laboratories whose predominant function is research. VA includes research as part of the mission of each VAMC, although the primary mission of a VAMC is patient care for Veterans. In fact, the majority of VA researchers are active clinicians. This leads to a focus on research areas most likely to benefit Veterans. VA's research mission is entirely intramural. VA does not have authority to award grants to parties outside VA and all VA research funding is provided to VA-employed researchers.

Researchers work at more than 100 VAMCs conducting research. In addition, 124 VAMCs have formal affiliations with academic institutions and hospitals, and many full- and part-time VA employees also have academic appointments or are employed at an affiliated academic institution or hospital - they are dually appointed personnel. Many clinicians/researchers have laboratory access at both VA and the academic affiliate. Because of these arrangements, most VA inventions are jointly owned by VA and its academic affiliates, making technology transfer a collaborative effort. To better facilitate efficient technology transfer, the Technology Transfer Program has executed Cooperative Technology Administration Agreements on VA's behalf with many academic affiliates, allowing the affiliates to take the lead in the management of the co-owned inventions, while maintaining VA's joint ownership. This arrangement is particularly beneficial to VA, as affiliates are typically better positioned to manage these co-owned inventions, having greater flexibility with licensing terms and greater access to private sector partners.

VA research relies on researchers self-reporting invention disclosures, and this process is very similar to the one used by our academic partners. Without proper filing of invention disclosures, VA is unable to review and appropriately make a determination of rights. Any suspicion of wrongdoing or evidence of impropriety in this or any other VHA program has, and will be, referred to the Office of the Inspector General.

Thank you for the opportunity to testify today and we look forward to your questions.